PROJECT INFORMATION DOCUMENT (PID)
CONCEPT STAGE

Report No.: PIDC18096

Project Name	Health System Efficiency and Quality Improvement Project (P149752)
Region	EUROPE AND CENTRAL ASIA
Country	Montenegro
Sector(s)	Health (100%)
Theme(s)	Health system performance (90%), Other human development (10%)
Lending Instrument	Investment Project Financing
Project ID	P149752
Borrower(s)	Republic of Montenegro
Implementing Agency	Ministry of Health
Environmental Category	B-Partial Assessment
Date PID Prepared/ Updated	02-Jun-2015
Date PID Approved/ Disclosed	19-Jun-2015
Estimated Date of Appraisal Completion	21-Sep-2015
Estimated Date of Board Approval	08-Dec-2015
Concept Review Decision	Track II - The review did authorize the preparation to continue

I. Introduction and Context

Country Context

Montenegro is an upper middle income economy with a total population of 621,400 and a Gross National Income (GNI) per capita of US$7,260 in 2013. The country started accession negotiations with the European Union (EU) in June 2012 and is striving to accede to the EU by 2020.

After experiencing a double-dip recession due to the 2008 global financial and the 2012 Eurozone debt crisis, the Government has implemented a strong fiscal adjustment since 2010 entailing a freeze in public sector wages, staff rationalization, pension indexation freeze, expenditure restraints in the capital budget, which, supported by strengthened tax collection efforts, have helped the Government to reduce the fiscal deficit to below 3 percent of GDP in 2013

Poverty rates before the crisis had fallen more than 6 percentage points, from 11.2 in 2005 to 4.9 percent in 2008. However, the global crisis and growth deterioration led to significant increase in poverty rate to 8.6 percent in 2014, consequently counterpoising the earlier poverty reduction gains. The Gini increased from 24.3 in 2010 to 28.6 in 2013, indicating rise in inequality. The incidence of

poverty is in general about 10 percentage points higher in rural areas than in urban areas, but recently increase in poverty was recorded in urban areas resulting from troubling industries.

Sectoral and Institutional Context

Montenegrin health indicators have improved faster in the past decade than those of the most recent EU members (2004 - 2007), effectively closing the 5–10 percent gap in life expectancy and mortality that existed in the years 2000s. Life expectancy has increased 2.4 years between 2000 and 2013 (from 74.1 to 76.5). In the same period, infant mortality decreased by more than half, from 11.1 to 4.4 per 1,000 live births (which marked Montenegro as a country with the lowest level of infant mortality among South Eastern European –SEE – countries). Standardized mortality rate (all causes) was reduced from 953 to 846 per 100,000 inhabitants.

Total health spending accounts for about 7.6 percent of GDP, of which 60 percent comes from the public sector. This is in line with the level of public spending of comparable countries in the region. In addition, over 95 percent of the population is covered by social health insurance coverage - the highest in the Western Balkans.

Despite some efforts at cost control, the system continues to accumulate debts. Total debt of the Health Insurance Fund (HIF) and health care institutions at the end of 2013 was Euro 34.0 million (nearly 1 percent of GDP), a 36 percent increase from 2012. Expenditures for drugs, treatment abroad, and sick leave compensation are the main drivers of increased debts. Since 2010, the health budget has been disbursed by the Ministry of Finance (MoF), which has reduced the HIF's role as an active purchaser of health services. There is clear potential to introduce program planning and create a more advanced and flexible financing system to enhance efficiency and accountability in health care on all levels of decision making and management.

Many health services in Montenegro continue to deliver inefficiently. Hospitals continue to provide services that can be provided in the outpatient setting more cost – effectively. On the other hand, underdeveloped capacity to perform tertiary level of surgical treatment results in poorer treatment outcomes, increase in treatment abroad and higher patient dissatisfaction (HIF Surveys 2010, 2014). At the same time, primary care is not acting as an effective gate keeper, and its role in prevention needs to be strengthened.

The needs that the health system of Montenegro must address have changed as a consequence of the demographic and epidemiological transition in the country. The disease burden, earlier dominated by maternal and child health and communicable diseases, has now shifted to being dominated by chronic and non-communicable diseases (NCDs). In 2009, chronic NCDs accounted for 70 percent of causes of deaths in Montenegro. In 2012, cardiovascular diseases accounted for 51 percent of deaths (46% men, 54% women) while malignant diseases accounted for 20 percent of deaths (57% men, 43% women). The two combined are responsible for three of every four deaths. According to the Primary Health Care Information System, prevalence of cardiovascular diseases in the adult population of Montenegro was 30% in 2014, with predominantly primary hypertension (64%: 25% men, 38% women), while prevalence of diabetes in the total population was 4.5% with equal gender distribution.

Increasing the focus on prevention and better managing of NCDs would require placing more emphasis on primary care, and rewarding primary care physicians accordingly. The Ministry of Health (MoH) is considering the introduction of revised performance-based payments at a larger scale. The adjusted formula for provider payment in primary health care would, however, require changes in order to shift its focus from individual providers to institutions, and further towards prevention.

Hospitals have traditionally been paid based on historical, line-item budgets. Strict budget rules and slow, centralized governance over material and human resources limit hospitals' productive use of assets and obstruct effective service provision, resulting in inadequate management and planning,

and inefficient use of resources. Transition to activity-based financing for acute inpatient care using the Australian Diagnosis-Related Groups (DRGs) system has been initiated under the previous project. However, further efforts are needed to adapt the DRG system and build reporting and information systems and management capacity to implement DRGs for acute care at scale. Pharmaceutical spending is an area with high potential for efficiency gains. Public expenditure on pharmaceuticals in Montenegro increased by 60 percent between 2009 (Euro 25 million) and 2014 (Euro 40 million). This reflects inefficiencies driven by several factors: (i) lack of governance and resources to control the drug market and enforce the laws resulting in constantly increasing total costs of both multi-source and single-source drugs; (ii) delays in licensing of pharmaceuticals which limit competition on drug market; (iii) delays in tender procedures which result in shortages of pharmaceuticals in hospitals and out-patient sectors. Finally, (iv) there is no reference laboratory to perform analysis and detection of counterfeit drugs whereas global estimates for counterfeit drugs are as high as 10%.

The changes in demographics and epidemiological profile of the population call for a health system that is focused on prevention, management of non-communicable diseases and integrated care. The MoH has recognized the importance of improvement and standardization of quality of health care. Quality improvement, including development of clinical guidelines to cover greater number of conditions, as well as development of pharmacotherapeutic protocols, clinical pathways and institutionalization of accreditation and licensing are envisaged and strongly supported by the MoH.

Relationship to CAS

The proposed Project is closely aligned with the Country Partnership Strategy (CPS) for Montenegro 2011-14 (Report No. 57149-ME), discussed by the Executive Board of Directors on December 28, 2010, which was extended to FY15. The CPS seeks both to help the country recover from the 2009 recession and advance longer term goals. One of the two priorities of the CPS aims at supporting EU accession through strengthening institutions and competitiveness, and specifically targets the strengthening of the health system.

The World Bank remains the main source of support for policy and system reform in the Montenegro health sector. The proposed Project builds on the World Bank's involvement in the first Montenegro Health Improvement Project (P082223, LN39180, 2003 – 2009) which laid the foundation for most of the activities proposed in the current Project, including supporting the first phase health system reforms, increasing capacity for policy, planning and regulation, stabilizing health financing, and improving quality of health service. These reforms would be extended and consolidated under the proposed Project. The proposed Project would also contribute to the World Bank's Twin Goals by improving quality health care services, especially for the poorest segment of the population, and the health insurance system that supports a standard package of health service benefits and increase financial protection against catastrophic diseases.

II. Proposed Development Objective(s)

Proposed Development Objective(s) (From PCN)

The proposed Project Development Objective (PDO) is to support activities to increase efficiency of health expenditures and improve quality of care for priority NCDs

Key Results (From PCN)

The PDO indicators under consideration are as follows:

a) Percentage of adults over 40 registered with a primary care physician, who have been screened for high blood pressure in the previous year;

b) Number of healthcare institutions with quality indicators measured and ranked;

c) Share (%) of acute care inpatient payments for secondary hospitals based on DRGs in X period;
d) Percentage decrease in total cost of X (to be decided) most frequently dispensed prescription outpatient medicines;
e) Percentage decrease in the total combined cost of sick leave benefits, medical treatment abroad, and travel benefits in X period

III. Preliminary Description

Concept Description

The proposed Project would include the following four components:

Component 1: Strengthening Capacity for Improved Health System Management (Total cost: US $TBC; Loan financing: US$ 9.250 million)

This component seeks to build capacity to improve health system management by strengthening performance monitoring and active purchasing, improving pharmaceutical sector management and supporting complementary investments in information systems. It would include: (i) results-based financing for results achieved wherein Project funds are disbursed against the verified achievement of DLIs; and (ii) traditional investment project financing of technical assistance, training and goods.

Strengthening health sector management
Activities in this thematic area would support the transition from line-item budgets to program budgeting for health services, including greater flexibility for managers to reallocate funds within programs and build capacity for active purchasing and improved health sector management and oversight. To strengthen information systems, activities would (i) ensure the continuation of support to eHealth development in Montenegro; and (ii) ensure IT support to achieve Project objectives, including for the transition to program budgets, to implement pay for performance and to improve integration of PHC, hospitals, HIF and Drugs agency (CALIMS) information systems to optimize pharmaceutical spending.
The potential DLIs under consideration would target improved monitoring and management of health expenditures through active purchasing and implementing program budgeting. The institutional arrangements for the purchasing function are currently under discussion and are expected to be finalized during Project preparation.
The major investment activities to be financed would include: (i) Training and technical assistance (TA) on program budgeting for officials of the MoH, HIF and MoF; (ii) TA to support regulatory reforms, improved monitoring and accountability systems for financing of sick leave benefits, medical treatment abroad, and travel benefits and to better control costs; (iii) TA to build capacity and improve accountability for better management of health care institutions and (iv) Investments in Information Technology (IT) equipment and software as needed as well as complementary training and TA.

Improving pharmaceutical sector management
Activities under this thematic area would aim at improving the availability of pharmaceuticals, rationalizing the use of medicines and keeping pharmaceutical spending under control. It would include: (i) activities to improve pharmaceutical market regulation by enforcing existing rules and standards and supporting implementation of new regulations, and (ii) support to improve pharmaceutical procurement and distribution systems.

Pharmaceutical sector management activities would be entirely financed using DLIs mechanisms. The potential DLIs under consideration would target reductions in pharmaceuticals expenditures, improving availability and rational use of drugs, and increasing value-for-money from public spending on pharmaceuticals.

Component 2: Improving efficiency in health institutions (Total cost: US$TBC; Loan financing: US $37.050 million)

This component seeks to improve efficiency in health institutions by supporting the design and implementation of pay-for-performance in primary care and activity-based payments at hospitals, and investing in improvements in surgical and diagnostic capacities in the public sector, with a view to rationalizing expenditures on treatments abroad. It would include: (i) results-based financing for health financing reform results wherein Project funds are disbursed against the verified achievement of DLIs; and (ii) traditional investment project financing of technical assistance, training and goods.

Designing and implementing pay-for-performance
Activities in this area would support the design and implementation of primary care provider payments reforms and continue the transition to Diagnosis Related Group (DRG) payments in hospitals to improve the efficiency and quality of service delivery. Pay-for-performance at primary care would aim to strengthen incentives to expand coverage and improve the quality of prevention and Non Communicable Disease (NCD) management services. The design of revised primary care payments would be finalized during Project preparation, but key design elements may include: (i) pay-for-performance at the facility level linked to the delivery of specific preventive/ NCD management services; (ii) increased share of performance-linked payments in health workers' payments; and (iii) non-monetary incentives that can complement performance payments. Project activities would support phased implementation at both primary care and hospital levels to minimize possible disruptions to service delivery.
The major investment activities in this area would finance TA and training for the MoH, HIF and health institutions to build capacity for payment reforms, for the necessary modifications of legislation needed for effective implementation of efficient payment systems and to develop management tools for the revised payment system. The potential DLIs under consideration would target the implementation of changes to primary care and hospital payment systems.

Increasing Surgical and Diagnostic Capacities
Activities in this thematic area seek to: (i) increase efficiency of specialized (tertiary level) treatment and would support refurbishment towards modernization and increased capacity of surgery block within the Clinical Center in Podgorica and (ii) increase capacity for day surgeries. In doing so the Project aims to facilitate the provision of timely and cost-efficient treatment in Montenegro and reduce expenditures on treatments abroad. It would include traditional investment project financing of technical assistance, civil works, training and goods.

Component 3: Improving Quality of Health Care (Total cost: US$2.5 million; Loan financing: US $2.5 million)

This component would focus on improving quality of health care. It would include traditional investment financing for TA, training and goods.
Investment activities would focus on improving standards of quality and efficiency of health care by strengthening institutional capacity for: (i) monitoring of health parameters (National Health

Survey); (ii) further developing pharmacotherapeutic protocols, clinical practice guidelines and clinical pathways; (iii) strengthening and institutionalization of Continuous Medical Education (CME) and (iv) facilitating institutionalization of accreditation of health care institutions by the introduction and monitoring of appropriate indicators.
Investment activities under this component would also focus on systemic control, improving standards and quality of quality on drugs available on the market of Montenegro by provision of spectroscopes for the Montenegro Drug Agency (CAL IMS) which would serve as a regional center for detection of counterfeit drugs under the SEE Health Network.

Component 4: Project Implementation (Total costs: US$1.2 million; Loan financing: US$1.2 million)

This component would support the operational costs of implementing the proposed Project, including project coordination and supervision, monitoring and evaluation (M&E), fiduciary management (financial and procurement), audits of Project's accounts and technical audits for verification of DLIs. Monitoring the implementation of the proposed reforms, including potential unintended consequences, would be a key function that is supported under this component. The final institutional arrangements will be determined over the course of the preparation process. At this stage, however, it is envisaged that a Project Coordination Unit (PCU), headed by an externally-recruited Project Coordinator, would be established within the MoH to support day-to-day project management and implementation and liaise with the existing Technical Service Unit team (TSU) of the MoF, which would be responsible for providing fiduciary support for the proposed Project as it does for all other Bank-financed operations.

Financing Instrument and Approach.
The proposed operation would use an Investment Project Financing (IPF) instrument. It would follow: (a) a Results-based Financing approach supporting programs and the achievement of specific results (disbursement-linked indicators) under Component 1 and Component 2; and (b) a traditional investment approach for civil works, goods, technical assistance and training under all four components.
Disbursement-linked indicators would disburse against pre-defined Eligible Expenditure Program (EEP), which consists of salaries. The EEP is in compliance with OP 10.00 for IPF instrument that would be co-financed by the operation. A financing percentage would be agreed upon and would form the upper limit for the amount to be disbursed against the EEP expenditure, in opposite to a percentage of a transaction or contract as in traditional investment financing. Disbursements would be made against achievement of results through Disbursement-linked Indicators (DLIs) that should be challenging but realistic and support the achievement of the PDO. The potential eight DLIs identified at the PCN stage, and included in Annex 3, are indicative, and would be confirmed during preparation in discussion with the MoH, MoF, and HIF. In order to comply with the agreed percentage to be financed, the MoH would present, prior to the disbursements take place, a list of the selected recurrent expenditures. In addition, compliance with agreed DLIs, vetted by an independent verification agency, would have to be presented in order for disbursements to take place.
A DLI protocol table will provide a full explanation of the indicators, methods of measurement, periodicity and verification process and will be prepared for the PAD along with disbursement arrangements. For all components, traditional input-based financing and disbursements would also be used.
The use of a Programs-for-Results instrument (PforR) was considered, however, an IPF instrument

is deemed appropriate given the status of country system, overall project design and objectives entailing investment and results based priorities in parallel, while focusing on structural budgeting and payment reforms, pharmaceutical policy reforms, enhanced quality and performance of care and more rational spending in regards to treatment abroad, travel, and sick leave. Weak implementation and monitoring capacity in the sector, and the fiduciary and safeguards weaknesses of the country systems were also taken into account. The proposed operation would however strengthen technical and fiduciary (including safeguards) capacity of key stakeholders (MoH and HIF) in managing the health sector towards reaching the required capacity for a PforR in the future.

IV. Safeguard Policies that might apply

Safeguard Policies Triggered by the Project	Yes	No	TBD
Environmental Assessment OP/BP 4.01	x		
Natural Habitats OP/BP 4.04		x	
Forests OP/BP 4.36		x	
Pest Management OP 4.09		x	
Physical Cultural Resources OP/BP 4.11		x	
Indigenous Peoples OP/BP 4.10		x	
Involuntary Resettlement OP/BP 4.12		x	
Safety of Dams OP/BP 4.37		x	
Projects on International Waterways OP/BP 7.50		x	
Projects in Disputed Areas OP/BP 7.60		x	

V. Financing (in USD Million)

Total Project Cost:	50.00	Total Bank Financing:	50.00
Financing Gap:	0.00		

Financing Source	Amount
Borrower	0.00
International Bank for Reconstruction and Development	50.00
Total	50.00

VI. Contact point

World Bank

Contact: Ana Holt
Title: Health Specialist
Tel: 5265+3714
Email: aholt@worldbank.org

Borrower/Client/Recipient

Name: Republic of Montenegro
Contact:
Title:
Tel:
Email:

Implementing Agencies

Name: Ministry of Health
Contact: Mensud Grbovic
Title: Assistant Minister of Health
Tel: 38278113127
Email: mensud.grbovic@mzd.gov.me

VII. For more information contact:

The InfoShop
The World Bank
1818 H Street, NW
Washington, D.C. 20433
Telephone: (202) 458-4500
Fax: (202) 522-1500
Web: http://www.worldbank.org/infoshop