I. Introduction and Context

Country Context

1. Serbia continues to face major economic challenges following the 2008-09 financial crisis. The crisis led to a drop in real gross domestic product (GDP) of 3.5 percent in 2009. The timid recovery that followed was not sufficient to prevent the country from experiencing a double-dip recession. As a result, GDP growth in 2012 was, once again, negative. For the immediate future, the economic outlook remains cautious at best, with low projected growth of real GDP growth of 2 percent in 2013 and 2014, and a weak government fiscal position.

2. Impressive gains in poverty reduction during the 2000s were reversed by the crisis. Poverty fell from 13.4 percent in 2002 to 6.1 percent in 2008. However, poverty jumped back to 9.2 percent in 2010, with approximately 230,000 people falling back below the poverty line since the crisis. Unemployment rates rose from an already high base to above 20 percent in 2012. According to the Life in Transition Survey conducted in 2010, almost three-quarters of respondents answered that they had been hit significantly by the crisis, compared to about 50 percent, on average, for all of
3. Despite the tight fiscal space, the Serbian government has largely pushed ahead with reforms with a view to international integration. Serbia instituted a 15-month wage and pension freezes in 2009 to maintain fiscal discipline in the face of the crisis. In 2011, it secured IMF support for a new precautionary 18-month Stand-by Arrangement with potential support of €1.45 billion. Also in 2011, the European Commission (EC) recommended “candidate” status, an important milestone toward EU membership. At the same time, the Government pursued its opposition to Kosovo’s unilateral declaration of independence, which may delay full EU integration.

4. Further reforms will be needed to increase efficiency and quality to meet the rising demand for health and social services from an ageing population within the constrained fiscal environment. Serbia is facing a fairly advanced demographic transition. The growing share of population above 65 years (14 percent of total) and the old-age dependency ratio (21 percent of the working-age population) are roughly double the rates observed in other upper middle-income countries (MIC). Managing the escalating demand for health and social care will require a much stronger focus on efficiency and quality of service provision.

**Sectoral and Institutional Context**

5. Serbia spends almost twice as much per capita, on average, on health than comparable countries, yet has similar health outcomes indicating that health sector efficiency is a concern. Total health spending accounts for about 10.4 percent of GDP. While Serbia spends close to $1,200 per capita per year (PPP, constant 2005 international $) on health, upper MICs spend about $600 per capita per year on average and yet reach similar levels of life expectancy. Furthermore, public expenditure on health per capita has been increasing over time, with an increase of approximately 130 percent between 2001 and 2011. It is critical for Serbia to increase the productivity of its health spending, particularly given an environment of fiscal constraints and increasing demands for health care from an ageing population.

6. Serbia has started to transform provider payment systems to incentivize greater efficiency for acute care in hospitals. Hospitals in Serbia have traditionally been paid on the basis of historical, line-item budgets that do not encourage cost containment or efficient use of resources. In order to incentivize greater efficiency, Serbia has now begun the transition to activity-based financing for acute inpatient care using the Australian Diagnosis-Related Groups (DRGs) system. An initial pilot in 2008 was successful and further work has focused on adapting coding procedures for the Serbian context, capacity building and updating by-laws. 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.

7. Serbia has also introduced some performance incentives to providers’ payments at the primary care level. Serbia has already started to reform provider payment systems to promote incentives for greater efficiency at the primary care level. Since October 2012, a performance-linked component has been introduced in payments for health personnel at primary care level with the objective of creating stronger incentives for efficiency and quality. Under the new approach, health providers’ payments are divided into two parts: fixed (i.e., does not vary with performance) and variable. Providers’ salaries are determined based on national guidelines. 98 percent of their salary is ‘fixed’. Providers risk the remaining 2 percent of their salary subject to specific performance parameters and can earn an additional ‘bonus’ for good performance of up to 2 percent with the
result that the variable component of providers’ payments can range from 0 to 4 percent of their salary. Of this variable payment, approximately 40 percent is tied to patient enrollment adjusted for age (i.e., risk-adjusted capitation), 20 percent is tied to prescription patterns, 10 percent to average patient visits per working day and 30 percent to the share of preventive services in overall service delivery.

8. Much remains to be done, however, to strengthen incentives for efficiency and quality at the primary care level, both for individual providers and for primary care facilities. The current reforms indicate that important progress has been made, and these reforms have paved the way for greater progress in the future. However, at a maximum of 4 percent, the proportion of payment ‘at risk’ based on performance for individual primary care health workers is relatively low, which implies that the incentives introduced may not be powerful enough to improve efficiency or quality. Moreover, facility-level payments for primary care include no incentives to increase the efficiency with which resources are used, to improve quality of care or to expand preventive services that can effectively address the burden of Non Communicable Diseases in Serbia. In fact, the HIF contracts individual primary health care facilities on annually renewable contracts that are based on a yearly ‘workplan’ of services and purchases services using historically determined line item budgets. Individual primary care facilities submit invoices on services delivered and inputs used, and the HIF disburses approximately 1/12th of the agreed annual budget each month. There is, therefore, clear potential to create better incentives for primary care facilities to enhance efficiency and quality, and strengthen preventive care.

9. Clinical pathways have been introduced to strengthen quality of care, but the number of conditions covered needs to be expanded and pathways linked to payments to incentivize implementation. Clinical pathways are tools that specify patient care management for a defined group of patients during a period of time in order to improve efficiency and quality of care. The development and implementation of clinical pathways has been advanced through a national working group of clinicians that has produced 14 pathways covering some of the most common conditions treated in acute hospitals and primary health centers. An early evaluation found improved quality of care measured by several clinical indicators, a decrease in referrals from primary to secondary care, and a reduction in cost of care of up to 30 percent. Awareness and use of these pathways, however, is low amongst clinicians. Furthermore, the list of conditions covered by clinical pathways needs to be expanded to be more comprehensive. Although the working group developed a costing framework to reimburse providers based on use of specified clinical pathways, payments based on quality have not yet been introduced by HIF.

10. Health technology assessment is an effective tool to improve healthcare efficiency and contain costs, however the current system is not fulfilling its potential. Health technology assessment (HTA) is a systematic and transparent appraisal and deliberation process that uses criteria such as efficacy, cost-effectiveness, and overall fiscal space to make decisions on the public reimbursement of medical technologies, devices and procedures. HTA can aid the most efficient use of available resources when recommendations are the basis for inclusion into a health benefits package. Whilst a formal HTA committee was established in the Ministry of Health in 2003, it only assesses medical devices and procedures and is focused on service planning rather than formal HTA. A separate committee housed within HIF, the Central Drugs Committee, assesses new pharmaceuticals and all applications linked with requests for inclusion on the reimbursement list. Cost-effectiveness criteria, however, are not a routine part of these assessments. In general, there is suboptimal awareness of the role and benefits of HTA amongst policymakers.
11. Expenditures on pharmaceuticals are rapidly increasing, and largely reflect inefficiencies driven by decentralized procurement of most drugs and medical supplies. Spending on pharmaceuticals increased by 135 percent between 2004 and 2008. Expenditures on pharmaceuticals as a share of total health spending increased from 14.8 percent in 2004 to 17.9 percent in 2008. Approximately 80 percent of the HIF’s pharmaceuticals budget is procured by individual health facilities. The HIF allocates a budget to individual health care facilities to procure drugs and medical supplies. Each of these facilities then tenders competitively to procure drugs from wholesalers. The net result is a wide variability in prices, which clearly reflects the potential for increasing efficiencies in procurement. A second marker of potential inefficiencies in the procurement of drugs and medical supplies in Serbia is the large number of wholesalers: 332 for a population of 7.2 million. By contrast, Australia has 3 major wholesalers for a population of 22.6 million. There are also important inefficiencies in drug procurement at outpatient pharmacies, which account for between 60.4 percent of HIF funds allocated for drugs. The central pharmacy in each municipality procures drugs for the pharmacies in that municipality by tendering wholesalers or by direct negotiation. The reimbursement price offered by the HIF is fixed through reference pricing. In this situation, manufacturers compete for market share by offering rebates to wholesalers, rather than on price offered to the HIF, and the value of these rebates is lost to the HIF. Furthermore, a comparison of drug prices with Tuzla HIF in Bosnia, which has a cantonal population of approximately 400,000, shows that Tuzla is able to obtain better prices in many cases through competitive bidding than Serbia does through reference pricing. Given the larger population in Serbia, it is very likely that Serbia could lower prices further through pooled (i.e., centralized) procurement of outpatient drugs with prices determined competitively.

12. Serbia also needs to strengthen health sector legal and institutional frameworks to comply with European Union (EU) acquis requirements. A recent European Commission (EC) assessment identified a number of key priorities, including the need to strengthen the financial sustainability of the health sector, complete the alignment of tobacco control legislation and increase technical and administrative capacity in communicable diseases, mental health and others. The government’s 2013 EU pre-accession economic program recognizes many of these challenges facing the health sector and identifies three priorities for reform in the next four years: i) to increase the efficiency of the health care system, ii) to improve the health of the population and iii) to increase the quality of health care.

**Relationship to CAS**

13. ‘Improved efficiency and outcomes of social spending’ is one of the two core pillars of the Serbia Country Partnership Strategy (CPS) FY12-FY15, and this new health project is specifically mentioned in the CPS as an intervention to support this goal. This pillar was arrived at following close consultation with the Government and is consistent with ECA’s Regional Strategy, as well as the EC’s Europe 2020 Growth Strategy. The CPS highlights Serbia’s ageing population and its commitment to reduce budget deficits, to which this project responds. The EC has also asked the World Bank to support Serbia in strengthening its capacity to monitor and evaluate social spending, which will be aided by the capacity building activities encompassed by this project.

14. The proposed project builds on the World Bank’s involvement in the first Serbia Health project (2003 – 2009, extended with additional financing until March 2012). The first Serbia Health Project laid the foundation for many of the activities proposed in the current Project as it aimed to build capacity to develop a sustainable, performance oriented health care system where providers
are rewarded for quality and efficiency and where health insurance coverage ensures access to affordable and effective care. In particular, this project supported the technical work that led up to legislation enabling provider payments based on performance and efficiency, the DRG pilot started in 2008, the institutionalization of HTA, and the strengthening of health information systems.

15. The proposed Project also builds on the activities of the on-going Delivery of Improved Local Services (DILS) project that aimed to increase the capacity of institutional actors and beneficiaries in order to improve access to and the efficiency, equity and quality of local delivery of health, education and social protection services, in a decentralizing environment. The Ministry of Health in Serbia has shown a strong interest in initiating the reform agenda proposed under the Serbia Second Health Project. In order to expedite the implementation of centralized procurement reforms, the Ministry and the Bank are exploring the possibility of using some undisbursed funds from the DILS project to support Technical Assistance to expedite the design and implementation of centralized procurement which will be further supported by the proposed project.

II. Proposed Development Objective(s)

Proposed Development Objective(s) (From PCN)

16. The proposed PDO is to strengthen: (i) health financing systems in Serbia, and (ii) institutional arrangements governing the Serbian health sector in order to improve the efficiency and quality of the health system.

Key Results (From PCN)

17. The possible PDO indicators under consideration are as follows:
   a) Services from primary care facilities are purchased by the HIF using a capitation-based payments system with performance-linked payments
   b) HIF Payments for at least X conditions (to be decided) for acute inpatient care at secondary level hospitals are based on Diagnosis Related Groups (DRGs).
   c) Percent reduction in average unit price relative to baseline for a list [to be defined] of 10 most frequently dispensed multi-source pharmaceuticals
   d) HIF provider payments at the hospital level for at least X conditions (to be identified) is contingent on the use of nationally agreed clinical pathways
   e) Percentage of pharmaceuticals and health products newly approved for public financing in the preceding 12 month period recommended for inclusion on the basis of a Health Technology Assessment

Details on conditions that must be satisfied to meet proposed PDO indicator ‘a’ will be clearly outlined at a later stage.

III. Preliminary Description

Concept Description

18. Activities proposed under the Project seek to: (a) Strengthen health financing systems by improving incentives for efficiency and quality in provider payments and building management capacity to respond to these incentives; (b) Introduce and institutionalize centralized procurement of pharmaceuticals, medical supplies, diagnostic reagents and medical devices; and (c) Develop and support the implementation of clinical pathways for a comprehensive set of conditions in the Serbian health system, and the institutionalization of Health Technology Assessment.

19. The proposed Project will include the following four components:
Component 1: Health Financing (USD 15 million)
20. This component aims to strengthen the performance of the health financing system by introducing incentives to improve quality and efficiency at the primary care and hospital levels. The component will finance technical assistance, training, goods and equipment to support the design and implementation of incentives and oversee results. Implementation will be phased and monitored closely to avoid disruptions in service delivery, access or quality and minimize unintended adverse consequences.

Sub-component 1.1: Introducing DRGs for acute care at hospitals

21. Activities under this sub-component will focus on strengthening incentives for efficiency by supporting the design and subsequent phased implementation of DRGs for acute care at hospitals. This includes the improvement of information systems, reporting and management capacity at health facilities, in the Institute of Public Health and in the HIF to implement and oversee implementation of DRGs and make recommendations on governance arrangements to strengthen management autonomy and accountability of hospitals. TA under this component will also support necessary modifications to by-laws and regulations required to support the implementation of DRGs. Finally, this component will also explore the feasibility of adding a quality-linked performance bonus to DRG payments wherein an additional payment is linked to a quality audit that includes adherence to clinical protocols and pathways.

22. A DRG pilot started in 2008 under the World Bank supported First Serbia Health Project initiated the process of adapting the Australian DRG system to the Serbian context. This sub-component will support the additional work needed to adapt this DRG system to the Serbian context and to build supporting information and reporting systems, management capacity and governance arrangements for effective implementation. Given the complexities of implementing a DRG payments system, it is proposed that implementation should be phased. In the first phase of implementation, all acute hospitals will report based on DRGs and undertake parallel planning of hospital budgets by DRGs rather than inputs. Comprehensive reporting based on DRGs should facilitate accurate calculation of cost weights for the Serbian health sector. In the second phase of DRG implementation, contracts between the HIF and acute hospitals will be based on DRG groups, although historical budgets will still be in use. In the final phase of DRG implementation, payments for all acute care will be based on DRGs.

Sub-component 1.2: Performance incentives at the primary health care level

23. Activities under this sub-component will focus on strengthening incentives for efficiency and quality at the primary care level by introducing performance incentives in the contractual arrangements between the HIF and primary health care facilities, and strengthening performance incentives in payments to individual health care providers at primary health care facilities. Under the current approach, payments to primary health care facilities include few incentives to improve efficiency or quality. The HIF essentially purchases an annual workplan of services with a corresponding line-item budget determined using historical input costs. It is therefore proposed that the HIF should use performance-based contracting payment mechanisms to purchase services from primary health care facilities with facility payments linked to risk-adjusted enrollment plus a facility performance bonus linked to quality of care and preventive services delivered. It is also proposed that the performance component of health providers’ payments be strengthened by: (i) Expanding the variable proportion of payments and linking it with verified performance; and (ii)
Strengthening incentives for teamwork and collaboration through adjustments to the methods used to calculate performance bonuses. Under the currently implemented approach primary care teams comprised of a doctor and support staff are, in effect, ranked against other teams in that Primary Health Center when determining performance payments which disincentivizes cross-team collaboration within the PHC. The exact design of the payment incentives for primary health care facilities and health personnel will be developed during the preparation stage based on greater consultation and analytical work.

24. In addition, this sub-component will support the improvement of information systems, reporting and management capacity at health facilities, in the Institute of Public Health or IPH (which has a role in monitoring quality and developing annual workplans) and in the HIF to implement, administer and oversee the proposed provider payments. The sub-component will also support TA to make recommendations on governance arrangements to strengthen management autonomy and accountability. Issues of specific concern are autonomy over human resources and accountability for health facility finances. Furthermore, TA will support the necessary modifications to by-laws and regulation needed to support the implementation of this sub-component. It is currently proposed that performance incentives be introduced in a phased manner to iron out problems with design and implementation and minimize disruptions to service delivery, access or quality.

Component 2: Centralized procurement (USD 11 million)

25. This component aims to use framework agreements to centralize the procurement of pharmaceuticals, medical supplies, diagnostic reagents and medical devices in order to increase efficiency. It will finance goods, technical assistance and training.

26. Logistics systems to supply health facilities with the necessary drugs and supplies are currently private and function well with little evidence of stock-outs. The main policy concern here is to gain economies of scale and lower unit prices through greater negotiation power, and not necessarily to centralize ordering of products or to create a publicly managed supply chain. It is therefore proposed that centralized procurement should be implemented through a competitive tendering process for multi-source drugs and reference pricing for single source drugs with framework agreements (where individual facilities can place their own orders with wholesalers based on centrally negotiated agreements) with no current plans to create a publicly managed supply chain. Instead, under this approach, health facilities/pharmacies continue to purchase (under specific conditions), pharmaceuticals, medical supplies, diagnostic reagents and medical devices with renegotiated prices set out in the framework agreements. Framework agreements would also identify those suppliers whose products may be included in the medicines lists, together with relevant conditions governing their supply. At this stage, it is anticipated that centralized procurement would be managed by the HIF. Initial work on designing the procurement system is planned with undisbursed funds from the on-going DILS project. This component will build on the ongoing work on designing the procurement system under the DILS project to further refine the design and institutionalize the implementation of centralized procurement in Serbia. It is proposed that implementation of centralized procurement should be phased to minimize disruptions and unintended consequences and to ensure that lessons learned through monitoring can be incorporated.

27. In addition, this component will support the development and pilot testing of an e-procurement system to support centralized procurement, and the development of and training in a unified IT system that will enable the HIF to monitor the in-market availability and dispensing of...
pharmaceuticals. A pilot e-prescription system has been implemented in Kraljevo district. The Project will build on this by incorporating lessons learned from this pilot and international best practices. Investments in IT equipment will be included, if needed, after an assessment of existing capacity.

28. Finally, this component will support capacity building through TA and training tailored to the needs of the MoH, HIF, hospitals, primary health facilities, state outpatient pharmacies and the IPH in order to support the implementation of centralized procurement. In particular, capacity will be developed in managing the procurement process, demand forecasting, awarding and managing of framework agreements, monitoring safety and quality of pharmaceuticals and adherence to Good Distribution Practice. TA will also support modifications to legislation necessary to implement centralized procurement including existing laws and bylaws regulating centralized procurement of drugs and new legislation necessary to regulate centralized procurement of medical devices and supplies.

Component 3: Health Technology Assessment and Clinical Pathways (USD 10 million)

29. This component aims to improve standards of quality and efficiency of care in the Serbian health sector by strengthening institutional capacity for (i) health technology assessment of new pharmaceuticals, medical devices and procedures, and (ii) clinical pathway development and implementation. This component will finance goods, technical assistance and training.

Sub-component 3.1: Health technology assessment

30. This sub-component will finance the establishment of an independent unit for HTA that will evaluate existing health technology assessments for the Serbian context. The development of partnerships with international and regional HTA organizations is planned to provide technical oversight and support, as well as training activities in order to raise awareness of the role and benefits of HTA amongst stakeholders. Finally, this component will support legislative and regulatory changes needed to link HTA recommendations to public funding decisions on including technologies in health insurance benefits packages.

Sub-component 3.2: Clinical pathway development and implementation

31. This sub-component will fund the expansion in the number of clinical pathways to include the most common diseases and/or those where there are likely to be significant gains in efficiency and quality of care. In order to embed the use of clinical pathways within a culture of continuous quality improvement, activities under component 1 will seek to link performance bonuses for quality to adherence to clinical protocols and pathways. In addition, monitoring and evaluation activities will be funded to assess the impact of clinical pathways on improving efficiency and quality of care.

Component 4: Project management (USD 4 million)

32. This component will support the operational costs of implementing the project, including project coordination and supervision, M&E, fiduciary management (financial and procurement), including audits of project accounts. Monitoring the implementation of the proposed reforms, including potential unintended consequences, will be a key function that is supported under component 4. The final institutional arrangements will be determined during the preparation process. At this stage,
however, it is envisaged that a Project Implementation Unit (PIU) be set up within the MoH with overall responsibility for managing the proposed Project.

IV. Safeguard Policies that might apply

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V. Financing (in USD Million)

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