REQUEST FOR EXPRESSIONS OF INTEREST
(Consultant Services – Individual Consultant)

Country: Republic of Kosovo
Project Name: Kosovo Comprehensive Approach to Health System Strengthening (KOMPAS)
Project ID: P179831
Loan No.: IDA 75410
Assignment Title: Legal Specialist – Digital Health Governance & IHIS Regulatory Framework
Reference No.: XK-MOH-A1.01-CS-INDV
Issued on: 18 November 2026

Background

The Government of Kosovo has received financing from the World Bank toward the cost of the Kosovo Comprehensive Approach to Health System Strengthening Project (KOMPAS) and intends to apply part of the proceeds for consulting services.

The consulting services ("the Services") include providing legal and regulatory expertise to develop a legally sound and actionable regulatory framework for the implementation of the Integrated Health Information System (IHIS) within the Ministry of Health, under Component 2 of the KOMPAS Project. The Consultant will determine the appropriate legal pathway for each required change; review the existing legal framework and draft the necessary laws, Administrative Instructions and Standard Operating Procedures (SOPs); propose legal provisions and mechanisms to mandate the use of IHIS by public and private health care providers and health professionals; map the rights, responsibilities, accountability and liability of all key actors in the IHIS ecosystem; and develop the legal framework for health data analytics at the National Institute of Public Health (NIPH).

The expected level of effort is up to 120 working days over a period of 12 months. The assignment is expected to commence in December 2026, with the exact start date to be confirmed upon contract signature.

The detailed Terms of Reference (TOR) for the assignment are attached to this Request for Expressions of Interest.

The Ministry of Health now invites eligible individual consultants ("Consultants") to indicate their interest in providing the Services. Interested candidates should submit:

- A Letter of Expression of Interest
- A detailed Curriculum Vitae (CV)
- Copies of diplomas and relevant certifications
- References for similar assignments (if available)

Selection Method

The Consultant will be selected in accordance with the Individual Consultants (IC) method set out in the World Bank Procurement Regulations for IPF Borrowers.

Qualifications and Experience Requirements

The Consultant shall meet the following minimum qualifications:

- Education: University Degree in Law; a Master's degree in Law is preferred.
- Minimum of 10 years of professional legal experience, with a strong focus on health legislation, labor law, or public administration in Kosovo.
- Proven experience in drafting administrative instructions, Standard Operating Procedures (SOPs), and regulatory frameworks within the public sector.
- Experience in data protection, digital health or ICT law, or alignment with the EU acquis is an asset.
- Experience in projects financed by international financial institutions or donors, preferably the World Bank, is an advantage.
- Fluency in Albanian and English is required. Working knowledge of Serbian is an asset.

The attention of interested Consultants is drawn to paragraphs 3.14, 3.16, and 3.17 of the World Bank Procurement Regulations for IPF Borrowers, setting forth the World Bank's policy on conflict of interest.

Further information can be obtained at the address below during office hours 09:00 to 16:00.

Expressions of Interest must be delivered electronically (by e-mail) to the address below no later than **December 3, 2026 at 4:00 PM local time**. Expressions of Interest received after the deadline will not be considered. Incomplete Expressions of Interest, which do not include all the documents requested above, may not be considered.

Ministry of Health
Project Coordination Unit Kosovo Comprehensive Approach to Health System Strengthening (KOMPAS)
Pristina, Kosovo

Attn: Fanol Duli, Project Coordinator
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TERMS OF REFERENCE

Country: Kosovo

World Bank Loan/Credit Name: Kosovo Comprehensive Approach to Health System Strengthening- KOMPAS

Project ID: P179831

Ref. No.: XK-MOH-A1.01-CS-INDV

Assignment name: Legal Specialist – Digital Health Governance & IHIS Regulatory Framework

1. Background

Referring to the Financing Agreement between the Republic of Kosovo and the International Development Association for the Kosovo Comprehensive Approach to Health System Strengthening Project (KOMPAS), the KOMPAS Project (P179831) was approved on 07 May, 2024. The Project Development Objective (PDO) is to strengthen institutional capacity and governance for quality of care in the Kosovo health system.

The Project has three components: Component 1 (strengthening key health system building blocks for Quality of Care), Component 2 (developing an Integrated Health Information System) and Component 3 (project management, monitoring and evaluation). The elements most relevant to this assignment are summarised below:

Component 1: Strengthening key health system building blocks for Quality of Care (QoC)

The objective of this component is to support aspects of public health/Pandemic Preparedness and Response (PPR), service delivery, and health financing (strategic purchasing), that will help unblock the bottlenecks in the structural and process of care. Of particular relevance to this assignment is Subcomponent 1.2:

Subcomponent 1.2 Developing and implementing strategic purchasing for quality. This subcomponent will support the development and implementation of key strategic purchasing elements which are not in place in Kosovo but are critical for both structural and process aspects of quality care. The IHIS is expected to supply the claims, reimbursement and performance data on which strategic purchasing by the Health Insurance Fund (HIF) will depend.

Component 2: Developing an Integrated Health Information System (IHIS): The objective of this component is to support the design, development, and implementation of an integrated digital health ecosystem that is critical for the functioning of the entire health system. The foundational

and key strategic IHIS building blocks will set the digitized health data environment to support health service delivery and decision-making.

This activity is informed by the "Kosovo eHealth Feasibility Study," which was completed under the Kosovo Emergency COVID-19 Project (P173819). The planned system will include Primary Health Care (PHC) facilities and hospitals, as well as laboratories and the National Institute of Public Health (NIPH), and will allow for the seamless transmission and sharing of health information among all authorized individuals. Based on globally recognized best practices and experience with previous health information systems development in Kosovo, the approach will be to not build one monolithic system but rather an ecosystem of cooperating information systems built on common governance, standardization, and technical foundational building blocks. Such a system will also require robust patient confidentiality and data privacy protocols to ensure that only authorized users can access patient data.

This component will include three sub-components, outlined below:

Subcomponent 2.1: Establishing foundational building blocks of IHIS. This subcomponent will support the establishment of critical elements of foundational environment (Enterprise Architecture) for digital health systems implementation, including: (i) the legal and regulatory framework for transformed health services delivery through digital systems utilization; (ii) the assessment and design of Master Data Management standards and systems, such as foundational registries and common coding and classification systems; (iii) design and implementation of the Health Information Exchange services; and (iv) upgrade of hardware platforms on central locations and in health facilities.

Subcomponent 2.2: Digital health support for improvement in QoC. Implementation of Component 1 will require finalization of the implementation and upgrade of the basic health information system (BHIS). Currently, the BHIS is not fully implemented in all Primary Health Care (PHC) facilities and with full functionality. This subcomponent will support: (i) rolling out the BHIS to all PHC facilities (including finalization of patient empanelment and zoning); (ii) upgrading the BHIS functions (automatic update of codes from key registries and allowing dashboard and smart reporting on facility level); and (iii) upgrading the integration with eReferrals system and introduction of eAppointments.

Subcomponent 2.3: Implementation of IHIS strategic systems. The eHealth Feasibility Study envisages full digitalization of the health sector in Kosovo to improve the effectiveness and efficiency of service delivery, clinical decision support, health financing, pandemic preparedness and public health functions, supply chain for pharmaceuticals and nutraceuticals, health workforce management, and health system management and policy making.

2. Objective of the Assignment

The primary objective of this assignment is to develop a legally sound and actionable regulatory framework to support the implementation of the Integrated Health Information System (IHIS)

within the Ministry of Health of the Republic of Kosovo, under the World Bank–financed KOMPAS Project.

In line with the Project Appraisal Document (PAD) and the Digital Health Blueprint, the Ministry is advancing the digital transformation of the health sector, with a particular focus on establishing an enabling legal and regulatory environment for the use of digital health systems. A key priority is ensuring that IHIS becomes an integral and mandatory component of healthcare service delivery.

The assignment will therefore include determining the appropriate legal pathway for each required change, and the drafting of legal provisions and mechanisms to mandate the use of IHIS by public and private health care providers and health professionals, as well as the development of the necessary legal texts and Standard Operating Procedures (SOPs) to support system implementation and enable health data analytics at the National Institute of Public Health (NIPH).

3. Scope of Work

The Legal Specialist will work closely with the Project Coordination Unit (NJKP/PCU), digital health working groups, and MoH legal departments to execute the following tasks:

The Legal Specialist is responsible for the legal and regulatory aspects of the tasks below. The design of technical governance arrangements, interoperability and data standards, system architecture and security controls remains the responsibility of the MoH, the IHIS technical teams and the SDHP. The Legal Specialist will work with these teams, and with the Agency for Information Society and the Information and Privacy Agency, to ensure that the technical arrangements have a sound legal basis and are reflected in the proposed legal and regulatory texts.

- **Legal Pathway and Instrument Mapping (first step):** As the first task of the assignment, determine for each required change whether it needs primary legislation (new law or amendment), an Administrative Instruction or other secondary act, SOPs, amendments to job descriptions or other employment-related instruments, contracts, or other acts. For each change, identify the responsible institution, the legal basis, the adoption procedure (including Government and Assembly procedures where primary legislation is needed), the sequencing and dependencies between instruments, and the likely timeline. The resulting map, once agreed with the MoH, will determine the form and sequencing of the drafts prepared under the other tasks.
- **IHIS Legal Framework Review (Activity A1.01):** Conduct a comprehensive review of the existing legal framework governing the IHIS. In line with the agreed legal pathway, draft and finalize the necessary legal and regulatory texts (e.g., laws, administrative instructions) to support the secure, interoperable rollout of digital health systems. The review and the draft texts shall address, at a minimum, the following areas:
    - **Governance and institutional mandates:** a clear legal definition of IHIS ownership and governance, including system ownership, the data controller and processor roles for each IHIS component, and the respective mandates of and relationships between the MoH, the NIPH, the HIF, the Agency for Information Society and the Information and Privacy Agency.

- **Health Insurance Fund and strategic purchasing:** the role of the HIF in the IHIS, its lawful access to data, and the legal link between IHIS records and claims, reimbursement and performance-based payment.
- **Patient identification and record linkage:** the legal basis for patient identification, unique patient identifiers, record linkage and the master patient index.
- **Patient rights:** consent models, patient access to their own records, rectification, audit trails of who has accessed a record, and complaint and redress channels, consistent with Law No. 06/L-082 and the EHDS.
- **Secondary use of health data:** the lawful basis and governance for the use of health data for research, planning and policy, including anonymisation and pseudonymisation standards and the body responsible for approving data access.
- **Commercial use of health data:** what private actors may and may not do with health data (for example marketing, insurance underwriting and the sale of data), and the terms on which health technology innovators may access data, to the extent this is not already covered by Law No. 06/L-082.
- **Digital instruments:** the legal validity of electronic signatures and electronic prescriptions in the health sector, the legal status of electronic records compared with paper records, and telemedicine, together with the regulatory provisions governing their mandatory use.
- **Cybersecurity and continuity:** security standards for the IHIS platform, incident notification and business continuity requirements, cross-checked against the national cybersecurity and critical infrastructure framework.
- **Hosting, cloud and cross-border exchange:** hosting location, use of cloud services, processing by foreign vendors, and cross-border exchange of health data with EU systems.

- **Private Sector Scope and Connection Obligations:** Working with the SDHP, prepare a mapping of the actors who must connect to the IHIS, who may connect and who are exempt, covering at least private clinics and hospitals, private laboratories, pharmacies, diagnostic centres, individual health professionals in private practice and private health insurers (if any). Because private providers are not bound by civil service instruments, propose the legal mechanisms that will apply to them, such as mandatory connection and reporting duties, conditions for licensing and accreditation, links to contracting with the HIF, and incentives for connection.
- **Technology Vendors, Procurement and Contracting:** Propose the legal and regulatory requirements for IHIS technology vendors and IT suppliers, including certification of vendors and software, initial and ongoing conformance testing against interoperability standards, data processing agreements, source code and data escrow, exit and data portability clauses, and liability for defects. Where the IHIS involves outsourced hosting,

managed services or public-private arrangements, assess the related public procurement and contract law implications.

- **Data Privacy & Security Compliance:** Ensure all drafted legal frameworks, AIs, and SOPs strictly adhere to Kosovo's Law No. 06/L-082 on Protection of Personal Data, establishing secure protocols for electronic patient records and the NIPH data warehouse.
- **NIPH Health Data Analytics & "One Health" Governance (Activity A3.08):** Review and draft specific legal and regulatory texts—including Administrative Instructions (AIs) and Standard Operating Procedures (SOPs)—required for redesigning and implementing NIPH health data analytics. This includes providing the legal frameworks for data warehouses, system interfaces, smart reporting mechanisms, and establishing data-sharing protocols to support **"One Health"** initiatives (ensuring legal interoperability with veterinary or environmental health data).
- **Legal Gap Analysis for Personnel:** Review the Law on Health, Law on Labor, Law on Civil Service, and current administrative instructions governing health professionals to identify legal and regulatory gaps related to the mandatory use of IHIS in healthcare service delivery. The review shall assess whether existing legal provisions adequately define the responsibilities of healthcare professionals for electronic data entry, digital record management, and compliance with IHIS-related requirements, and propose necessary amendments where required. The review shall also cover the professional licensing and regulatory framework that applies to health professionals in private practice.
- **Professional Duties and JD Provisions:** Propose legally appropriate provisions and mechanisms, including, where appropriate, amendments to job descriptions (JDs), employment-related instruments, administrative instructions or other relevant acts, explicitly defining "Digital Record Management" and real-time IHIS data entry as core professional responsibilities.
- **Mapping of Rights, Responsibilities, Accountability and Liability across the IHIS Ecosystem:** Map the legal rights, responsibilities, accountability and liability of all key actors in the IHIS ecosystem, including at least: the MoH, the NIPH, the HIF, public and private health care providers and health professionals, system administrators, non-clinical users, data controllers and data processors, technology vendors and service providers, and entities accessing health data for secondary use. For each actor, the mapping shall identify the applicable legal obligations, the accountability and liability for breaches or misuse, and any gaps in the current legal framework, and shall propose the provisions needed to address them.
- **Accountability & Compliance Framework:** Formulate a legal strategy defining compliance mechanisms and accountability measures for all IHIS actors identified in the mapping above, including the legal definition of "digital negligence" regarding patient registration, electronic prescribing, and clinical coding within the IHIS. The Consultant shall assess whether the proposed sanctions, disciplinary routes and incentives are proportionate and workable, and shall propose reciprocal obligations on the system

provider and the MoH (such as system availability and uptime, technical support and training) as conditions for enforcing user obligations.

- **Stakeholder Consultation:** Present the legal strategies, drafted texts, and SOPs to key stakeholders, including the NIPH, Chamber of Doctors, Chamber of Nurses, Chamber of Pharmacists, Chamber of Dentists, the HIF, the Agency for Information Society, the Information and Privacy Agency, representatives of private health care providers, and MoH leadership, incorporating feedback to ensure sector-wide alignment.
- **EU Alignment:** Review relevant EU digital health and health data governance requirements, including the European Health Data Space (EHDS), and ensure that the proposed legal and regulatory framework supports progressive alignment with applicable EU standards and interoperability requirements, including for patient rights, secondary use of data and cross-border exchange.

4. **Deliverables**

The Consultant is expected to deliver the following:

1. **Inception & Legal Gap Report:** Identifying current legal barriers for both IHIS utilization and NIPH data analytics, and including: (i) the legal pathway and instrument map (primary legislation, AIs, SOPs, employment-related instruments, contracts and other acts), with responsible institutions, adoption procedures, sequencing and an indicative timeline; and (ii) the private sector connection mapping (must connect, may connect, exempt); and (iii) the mapping of rights, responsibilities, accountability and liability of all key IHIS actors. Once approved by the MoH, this report will confirm the form and scope of Deliverables 2 to 5.
2. **Draft Regulatory Texts for IHIS (A1.01):** Comprehensive drafts of required legal/regulatory texts supporting the broader digital transformation of health services (Sub-component 2.1). The drafts shall cover the areas listed in Section 3, including governance and institutional mandates, patient rights, secondary and commercial use of data, private sector obligations and vendor requirements, in the form of instrument determined in Deliverable 1.
3. **NIPH Data Analytics Legal Framework (A3.08):** Drafted AIs and SOPs governing the data warehouse, interfaces, and smart reporting for the NIPH.
4. **IHIS Professional Obligations Package:** Proposed provisions making IHIS use mandatory, for integration, where appropriate, into the JDs, employment contracts and other employment-related instruments of public sector health professionals, together with the equivalent licensing, accreditation or contracting mechanisms for private providers.
5. **Draft Compliance Instrument(s):** Draft MoH Administrative Instruction(s) or other instrument(s), in the form determined in Deliverable 1, establishing the compliance and

accountability mechanisms, including the reciprocal obligations of the system provider and the MoH.

Language Requirement for Deliverables: All final, publication-ready legal texts (Laws, Administrative Instructions, SOPs) must be delivered in both official languages (Albanian and Serbian), alongside English versions for World Bank review and clearance. The MoH/PCU will arrange translation into Serbian; the Consultant shall support the legal validation of the Serbian versions.

5. **Qualifications and Experience Requirements**

- Education: University Degree (Preferred Master's) in Law.
- Professional Experience: Minimum of 10 years of professional legal experience, with a strong focus on health legislation, labor law, or public administration in Kosovo.
- Specific Expertise: Proven experience in drafting administrative instructions, Standard Operating Procedures (SOPs), and regulatory frameworks within the public sector. Experience in data protection, digital health or ICT law, or alignment with the EU acquis is an asset.
- Language: Fluency in Albanian and English is required. Working knowledge of Serbian is an asset.

6. **Reporting, Clearances, and Duration**

- **Reporting:** The Consultant will report directly to the KOMPAS Project Coordinator within the NJKP/PCU. The General Secretary of the MoH will provide strategic and technical oversight, including clearance of deliverables.
- **Duration:** The expected level of effort is up to 120 working days over a period of 12 months.
- The Consultant will submit monthly progress reports outlining activities undertaken, deliverables produced, and progress against the agreed work plan.
- The Consultant shall perform his/her duties in accordance with the terms and conditions of the contract, the applicable legislation of the Republic of Kosovo, and the World Bank Procurement Regulations and implementation procedures.

Client Contribution

Consultant will be based and work in the MoH premises in Pristina. The MoH will provide office space and equipment required.

Selection process

Experienced and qualified individuals will be selected in accordance with the World Bank's Procurement Regulations for Investment Project Financing (IPF) Borrowers ("the Regulations"), as updated in February 2025, based on an open call for Individual Consultants (IC) Selection.

The consultant will be selected based on:

- General qualifications (education, legal competencies, analytical and drafting skills) – 30%
- Specific professional experience relevant to the assignment (health legislation, regulatory and legal drafting, digital health governance, data protection, development of Administrative Instructions and SOPs) – 40%
- Experience in similar assignments/projects (public sector legal advisory roles, regulatory framework development, donor-funded projects, preferably World Bank–financed projects) – 30%