## Ethiopia's Health Sector Legal Framework

## **Description**

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#### Introduction

The Ethiopian health sector is one of the areas that has shown good progress in the recent past. Following the change of government in 1991, the new Government of Ethiopia put in place many political and socio-economic transformation measures. Among these, it developed a first national health policy, which was followed by the formulation of four consecutive phases of comprehensive Health Sector Development Plans (HSDPs), starting from 1996/97. The policy and the first HSDP were based on critical reviews of prevailing national health problems and a broader awareness of newly emerging health problems in the country. At the core of the health policy are democratization and decentralization of the health care system; developing preventive, promotive and curative components of health care; assurance of accessibility of health care for all parts of the Population; and encouraging private and NGO participation in the health sector. During the past fifteen years, the Federal Ministry of Health has

built an impressive framework for improving the health for all, including maternal and neonatal health.

Providing an effective and adequate legal framework for the health sector plays a crucial role in enhancing the development of the health sector by advancing the quality of service and its coverage.

There are only a few scattered laws and regulations enacted to govern and regulate the health sector.

#### **Legal Framework of Health Sector**

#### **FDRE Constitution 1995**

The legal framework plays an important role in promoting, developing, and regulating the health sector. The health sector deals with the life of a human being; it's all about the protection of the health of citizens; hence, strict and effective regulation is very important. The purpose of laws is not only regulation; they also play a significant role in promoting the development of the health sector by encouraging the participation of the private sector and all other stakeholders in the health sector. The EFDRE Constitution provides a general framework for the state structure, rights, and duties of citizens and government. The 1995 FDRE Constitution also provides a general framework with regard to public health and the right to a clean and healthy environment. The Constitution, under Article 41(4), imposes an obligation on the state to allocate ever-increasing resources to provide public health, education, and other social services. States play an important role in providing good public health in developing countries like Ethiopia, where the private sector is not strong enough to provide effective health services to the public. The health sector also deals with citizen's health rights. The EFDRE Constitution, also under Article 44, recognizes citizen's right to a clean environment, and it provides that all persons have the right to a clean and healthy environment. This right is also among the rights that obtain international recognition through different treaties and conventions. Ethiopia also enacted a proclamation that regulates environmental issues. The Constitution also imposes an obligation on the state to establish and implement basic policies for public health, which is provided under Article 51 of the Constitution. The government also has a duty to protect and promote the health, welfare, and living standards of the working population of the countries. Ensuring access to public health and a clean environment are also among the duties of government provided under the constitution. This general framework provided in the constitution is implemented by proclamations, regulations, and directives issued by the representatives of the House of Representatives, the Council of Ministers, and Health Minister, respectively.

#### Proclamations governing the health sector

In order to encourage the expansion of health services, the government enacted Social Health Insurance Proclamation No. 690/2010. Social health insurance is one of the sustainable health care financing mechanisms that enhance equitable access to improved health services through cross-subsidization. The main objective of this proclamation is to ensure the expansion of health service coverage, which plays a significant role in the accelerated socio-economic development of the country. The other objective of social health insurance is to provide quality and sustainable universal health care coverage to the beneficiary through the pooling of risks and reducing financial barriers at the point of service delivery. This social health insurance ensures the expansion of health services through cost sharing between beneficiaries and the government in the health sector. This social health insurance is playing a crucial role in ensuring health service coverage, especially in rural areas. The health service package given to beneficiaries of this social health insurance includes all essential health services and other critical curative services, which are determined by regulations.

The health sector is one of the areas that needs strict and effective regulation. Unless regulated, unsafe, inefficacious, and of poor quality modern and traditional medicines can cause serious health problems in the society. To prevent such risk Food, Medicine and Health Care Administration and Control Proclamation, PROCLAMATION NO. 661/2009 is issued. Primary objective of this proclamation are:

- To protect the public health from unsafe, inefficacious and poor quality modern and traditional medicines:
- To protect the public from health risks emerging out of unsafe and poor quality food;
- To avert health problems due to substandard health institutions, incompetent and unethical health professionals, poor environmental health and communicable disease;
- To control and deter illicit production, trafficking and use of narcotic drugs, psychotropic substances, and precursor chemicals;
- To make the fragmented and poor quality administrative and regulatory system in the health sector efficient and effective, it is found necessary to establish a new and coordinated food, medicines and health care regulatory system.

Unlike Proclamation No. 690/2010, which focuses on encouraging the expansion of health services, Proclamation No. 661/2009 is concerned with the regulation of the health sector, especially with regard to medicine, food quality, drugs, and chemicals, and providing an effective and efficient legal framework W Firm LLP for the health sector.

#### **Entry Regulation**

Health professionals to engage in this activity of providing health services, first of all, they have to obtain a license or certificate issued for a health professional to provide medical or other health-related services. Proclamation No. 661/2009, under Article 33, provides that no person shall practice as a health professional without having obtained a professional practice license issued by the appropriate organ.

Proclamation No. 661/2009 has regulatory purpose. Hence executive organs play significant role in this regulatory activity by:

- prepare and submit to appropriate organ health regulatory standards for safety and quality of food, safety, efficacy, quality and proper use of medicines, competence and practice of health professionals, hygiene and environmental health, competence of health and controllable health related institutions:
- Issue, renew, suspend and revoke certificate of competence for specialized health institutions, food and medicine processing plants, quality control laboratories, bioequivalence centers, importers, exporters, storages and distributors and trans-regional health service institutions. The other power and duties of the executive are provided under Article 4 of Proclamation No. 661/2009

#### Regulation after entry

The law regulates not only at the point of entry or license, but even after health professionals obtain a license to provide health services, they are subject to regulation and inspection. The executive organ appoints inspectors to implement the provisions of the Proclamation and other laws and directives related with food, medicine and healthcare administration and control.

The other proclamation is Drug Fund and Pharmaceuticals Supply Agency Establishment Proclamation, PROCLAMATION NO.553/2007.Primary objective of this proclamation are:

- to supply quality assured essential pharmaceuticals at affordable prices in a sustainable manner to the public;
- to design a system of mobilizing funds from different sources to ensure uninterrupted and sustainable supply of pharmaceuticals to all public health facilities and thereby serve the public in an equitable manner

This proclamation establishes the Pharmaceutical Supply Agency (hereinafter referred to as "the Agencyâ€) as an autonomous federal organ having its own legal personality. The objectives of the agency include:

- to enable public health institutions to supply quality assured essential pharmaceuticals at affordable prices in a sustainable manner to the public;
- to play a complementary role in developmental efforts for health service expansion and strengthening by ensuring enhanced and sustainable supply of pharmaceuticals
- to create enabling conditions for enhancing the accumulation of the Fund in its revolving and cost recovery process

The other legal framework is the Proclamation on Public Health, Proclamation No. 200/2000. This proclamation is issued to promote the health of society and the creation of a healthy environment for future generations by enhancing the active participation of society in the health sector. This Proclamation imposes a duty on the Public Health Authority to appoint qualified inspectors to implement the provisions of Proclamation No. 200/2000 and other laws and directives related to public health. Public health proclamations regulate food quality, food standard, water quality, waste handling and disposal, the availability of toilet facilities, the disposal of dead bodies, control at entry and exit ports, communicable diseases, etc. The primary concern of this proclamation is to protect public health by regulating and setting standards in order to protect society from any health issues. This Proclamation is also one way by which the government implements its constitutional duty to protect public health as stated under Article 90 of the EFDRE Constitution.

#### Conclusion

The health sector is one area that is showing good progress in terms of quality of services and coverage. Legal frameworks also play an important role in regulating and promoting the health sector. In this short brief on the legal framework of the Ethiopian health sector, we try to discuss constitutional frameworks and different proclamations enacted by the House of Representatives to govern the health sector and promote the development of this area. The legal framework governing the health sector in Ethiopia is more scattered and disorganized, and the number of articles and commentary written on this area is also very few. We recommend that an effective, efficient, and organized legal framework is very essential to the development of the health sector and protecting public health.

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