COUNCIL OF MINISTERS REGULATION No. 299/2013

COUNCIL OF MINISTERS REGULATIONS TO PROVIDE FOR FOOD, MEDICINE AND HEALTH CARE ADMINISTRATION AND CONTROL

This Regulation is issued by the Council of Ministers pursuant to Article 5 of the Definition of Powers and Duties of the Executive Organs of the Federal Democratic Republic of Ethiopia Proclamation No. 691/2010 and Article 55(1) of the Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009.

PART ONE

GENERAL

1. Short Title

This Regulation may be cited as the “Food, Medicine and Health Care Administration and Control Council of Ministers Regulation No. 299/2013”.

2. Definitions

In this Regulation unless the context otherwise requires:

1/ “Proclamation” means the Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009;

2/ “food” means, without prejudice to the definition provided under Article 2 (1) of the Proclamation, a product that is produced by food manufacturer for more than one regional state or foreign markets.

3/ “food manufacturer” means a manufacturer producing food intended to sale for more than one regional state or foreign markets, excluding micro and small enterprises engaged in the preparation of traditional foods;
4/ "food safety" means the proof and control of food that is safe for use in the process of delivering food to the consumer through proper manufacturing, preparation, handling, storage and transportation;

5/ "food irradiation" means the process of exposing food to radiation energy to kill harmful bacteria and other organisms to extend shelf-life;

6/ "potentially hazardous food" means food exposed to or capable of supporting the growth of disease-causing microorganisms or the production of toxins;

7/ "pre-packed food" means food that was already packed by the manufacturer before reaching the seller;

8/ "food supplement" means a type of food that supplement the normal diet and which is a concentrated source of vitamin, mineral or other substance with a nutritional or physiological effect, alone or in combination, designed to be taken in measured small quantities and is prepared in capsule, pill, powder, liquid, drops or any other similar forms;

9/ "infant formula" means milk or milk-like product of animal or vegetable origin formulated industrially in accordance with the appropriate standard for infant formula and intended to satisfy the nutritional requirements of infants starting from birth and during the first six months;

10/ "follow-up formula" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with the appropriate standard for follow-up formula and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age;

11/ "complementary food" means any food processed industrially, suitable as a complement to breast milk, infant formula or follow-up formula when it become insufficient to satisfy the nutritional requirement of the infant;

12/ "genetically modified food" means meat and edible plants modified through genetic engineering;
alcoholic beverage” means any beverage containing alcohol, whatever its strength;

“sell” means to offer, advertise, keep, store, display, or deliver for sale or to exchange food, medicine or tobacco product in any manner for consideration;

“certificate of pharmaceutical product” means a document issued by the Authority or the manufacturer country regulatory body confirming that the medicine is manufactured by a licensed manufacturer;

“good manufacturing practice” means the basic principles which any food or medicine manufacturer should consistently comply with in manufacturing safe and quality food or safe, efficacious and quality medicine;

“complimentary or alternative medicine” means a raw or partially or fully processed product which is neither indigenous traditional medicine nor associated with modern medicine;

“dangerous chemical” means a chemical that can cause severe injury to human health if not cautiously kept or utilized and categorized as dangerous by the Authority;

“hazardous waste” means any waste deleterious to human health and that cannot be recycled;

“recyclable waste” means liquid waste that could be treated to avoid injury to human health or waste that could be transformed into usable thing through various mechanisms;

“frontier port” means international airport, controlling station at border or dry port designated by the competent body;

“communicable disease” means disease that can cause major epidemics by spreading rapidly;

“quarantine” means separation of persons who are suspected to be exposed or infected with emergent communicable disease until the infection is confirmed;
24/ "isolation" means separation of a person who is infected with communicable disease for certain period so that he may not transmit the disease to other persons;

25/ "conveyance operator" means airplane or train captain or the driver of any other operator of conveyance;

26/ "health professional" means a person registered as a health professional by the appropriate organ to protect human health or provide health services and includes complementary or alternative medicine practitioner;

27/ "health service" means a service provided by a health professional as per the type and scope of practice permitted by law;

28/ "insufficiently available health professionals" means health professionals regarded as insufficiently available by the Ministry of Health where the national demand remains unfulfilled;

29/ "impairment" means a mental or physical condition which reduces the competence or judgment of a health professional in performing his professional duties;

30/ "mental disorder" means a disorder of thought, perception, feeling or behaviour that seriously impairs a person's judgment, capacity to recognise reality, ability to associate with others or ability to meet the ordinary demands of life, in respect of which treatment is advisable;

31/ "unprofessional conduct" means the conduct of a health professional contrary to professional ethics or obligations stipulated in the Proclamation, this Regulation or other relevant law or standards;

32/ "client" means a patient or user who establishes contractual or otherwise relationship with a health professional to obtain health service for himself or for a third party;

33/ "institution" means health or complementary or alternative medicine service institution or food establishment;

34/ "food establishment" means an establishment undertaking food trade in accordance with Article 2(2) of the Proclamation, but does not include food retail trade;
42. "Artificial reproduction service" means the introduction of semen into a female vagina or ovule for the purpose of fertilization by a person other than the natural father.

43. "Transplantation" means the surgical transfer of cells, tissues, or organs from one body to another, either within the same person or between different people.

44. "Emergency medical treatment" means medical treatment provided in a timely manner to prevent the deterioration of a patient's health or the exacerbation of an illness or injury.

38. "Life-sustaining emergency treatment" means a medical treatment that is necessary to sustain or improve the life of a patient who has encountered imminent life-threatening disease or injury, until the patient has access to regular health care services.

37. "Health" means a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.

36. "Food handler" means any person involved in the food manufacture, import, export trade activity or fortification of food, or in any activity that affects the food chain.
44/ "Authority" means the Ethiopian Food, Medicine and Health Care Administration and Control Authority;

45/ other definitions provided under Article 2 of the Proclamation shall be applicable.

PART TWO

FOOD AND MEDICINE ADMINISTRATION AND CONTROL

CHAPTER ONE

FOOD SAFETY AND QUALITY

3. General
No food unfit for human consumption or not complying with appropriate safety and quality standards may be manufactured, imported, exported, stored, distributed, transported or made available for sale or use to the public.

4. Food Manufacturing
1/ No food manufacturer may, without registration and permit from the Authority, sell food product intended for distribution in more than one regional state or for export market, or change the type and production process of the food.

2/ The Authority shall register or issue a permit in accordance with sub-article (1) of this Article upon ascertaining the fulfilment of good manufacturing practices, food safety and quality laboratory test and other necessary requirements.

3/ Without prejudice to the provision of sub-article (1) of this Article the Authority shall adopt directive determining the kinds of foods that shall be registered.

5. Food Adulteration and Counterfeiting
1/ It shall be prohibited to add or mix any substance to any food so as to increase its bulk or weight, or make it appear better or for any other similar purpose.

2/ It shall be prohibited to partially or completely embed in any food anything harmful to human health or that can affect the safety and quality of the food.

3/ It shall be prohibited to present any food as if it is produced by the real manufacturer or affecting quality and safety by imitating its package, identification, trade mark, trade name or any mark.
6. Food Storage, Transportation and Display

1/ Any food manufacturer, exporter, importer or distributor shall store, display, pack or transport perishable food at appropriate temperature or cold chain.

2/ Any food manufacturer, exporter, importer or distributor transporting food on or in any part of a vehicle may only be possible where that part has been cleaned to such an extent that chemical, physical or microbiological contamination of the food is prevented.

3/ It shall be prohibited to store, load or transport any food together with contaminated food, waste food, poison, any harmful substance, animal or any other contaminant.

7. Food Fortification

1/ For the purpose of protection of public health the Authority may order any food manufacturer to fortify food with different minerals and vitamin.

2/ Any food establishment may only manufacture, import, distribute or sale any food identified for fortification in accordance with sub-article (1) of this Article where such food is enriched in accordance with requirements adopted by the Authority.

3/ The labelling of fortified food shall contain the phrase stipulating with what mineral or vitamin the food is fortified.

8. Food Irradiation

1/ A food irradiation establishment shall be designed to meet the requirements of safety and good hygienic practices.

2/ The radio nuclei remain in any food may not exceed the acceptable limit.

9. Food Import and Export

1/ Any person may only import food for public consumption upon obtaining permit issued by the Authority after ascertaining the safety and quality of the food.
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10. Food Supplement and Genetically Modified Foods

1/ Any person may only sell food supplements upon the registration and permit of the Authority.

2/ No person may sell a food supplement unless in pre-packed form and its labelling contains the phrase “food supplement”.

3/ No labelling, presentation or advertisement of a food supplement may describe that a balanced and varied diet cannot provide appropriate quantities of nutrients or attribute to the food supplement the property of preventing or treating a human disease.

4/ Special permit of the Authority shall be required to manufacture, import, export or distribute genetically modified foods.

5/ No person may sell genetically modified food unless in pre-packed form and its labelling contains the phrase “genetically modified food”.

11. Infant and Follow up Formula and Complementary Food

1/ Special permit of the Authority shall be required to manufacture, import, export or distribute any infant and follow up formula or complementary food.

2/ The Authority shall adopt specific requirements regarding the marketing of breast-milk substitute.

12. Trans-Regional Water Supply

Any person may only carry out trans-regional water supply services upon the approval of safety and quality of water by the Authority.

13. Sale of Alcohol

1/ Any alcoholic beverage produced at industry level for distribution in more than one region or for export market or imported for local consumption shall comply with the standards prescribed by the competent organ.
2/ Alcoholic beverage supplied to market pursuant to sub-article (1) of this Article having less than ten per cent of alcoholic content shall state its expiry date on its label.

3/ The Authority shall issue directive regarding regulation of alcoholic beverage.

CHAPTER TWO
MEDICINE ADMINISTRATION AND CONTROL

14. General
No medicine the quality, safety and efficacy of which is not ascertained may be manufactured, imported, exported, stored, distributed, transported or made available for sale or use to the public.

15. Manufacturing and Certificate of Registration of Medicine

1/ Any medicine manufacturer or an agent may only manufacture or import a medicine that is included under the national drug list.

2/ Notwithstanding sub-article (1) of this Article, domestic medicine producer may produce medicine not included in the national drug list and have it registered in a special circumstance to sell it to foreign market.

3/ No medicine that is not included in the national drug list and not having certificate of registration may be supplied to market.

4/ The Authority shall issue a certificate of registration of medicine market authorization after:

a) assuring the medicine manufacturer’s compliance to good manufacturing practice;

b) the medicine dossier is evaluated and found to fulfill safety, quality and efficacy requirements; and

(c) the medicine fulfill laboratory quality test requirements.

5/ Any medicine manufacturer may change any information submitted during application for certificate of registration of a medicine after issuance of the certificate only upon written notification to and approval of the Authority.
6/ Any manufacturer who has got registered medicine shall submit an application to the Authority for the renewal of the certificate of registration of the medicine six months before the expiry of the period stipulated under Article 13(3) of the Proclamation.

16. Storage, Transportation and Distribution of Medicine

1/ Any medicine manufacturer, exporter, importer or distributor shall store, transport or distribute medicine at appropriate temperature or cold chain.

2/ Any medicine manufacturer, exporter, importer or distributor may transport medicine by any conveyance only where the compartment of the conveyance that has link with the medicine has been cleaned to the extent that chemical, physical or microbiological contamination of the medicine is prevented.

17. Medicine Adulteration and Counterfeiting

1/ It shall be prohibited to add or mix any foreign substance to any medicine so as to change its amount, content or weight, or to make it appear better or for any other similar purpose.

2/ It shall be prohibited to partially or completely embed in any medicine anything harmful to human health or that can affect the quality, safety and efficacy of the medicine.

3/ It shall be prohibited to present any medicine as if it is produced by the real manufacturer by imitating its package, identification, trade mark, trade name or any special mark or present it by altering its content and nature.

18. Importation of Medicine

1/ Any person may import medicine upon obtaining pre-import permit and a permit of entry from the Authority at a port of entry.

2/ The Authority shall cause the disposal or the return to the country of origin of imported medicine, as may be appropriate, when its safety, quality or efficacy are not up to the standard.
3/ The Authority shall issue appropriate evidence for the disposed medicine when requested by medicine importer.

19. Raw Material and Packing of Medicine

1/ Any person may only produce, import, export, distribute or store raw materials and packaging of medicine after obtaining permit from the Authority.

2/ The Authority shall issue detailed directive regarding raw material and packaging of medicine.

20. Import of Medicine Not Registered

The Authority may, on any one of the following grounds, grant a special permit for the import of medicine not registered:

1/ for clinical trials or any other scientific investigations;

2/ for personal use of a patient, when prescribed by physician;

3/ for conducting laboratory quality test for registration purpose;

4/ for natural or man-made disaster or similar emergency aid;

5/ for use of diplomatic missions; or

6/ for medicine lacking motivation of importers or for medicine used for the treatment of diseases not given adequate attention.

21. Poisons and Radioactive Pharmaceuticals

No person may manufacture, import, export, distribute, store or possess poisons or radioactive pharmaceuticals without obtaining a certificate of competence from the Authority.

22. Clinical Trial

1/ Clinical trial on human subjects may be authorized by the Authority after the research proposal is being evaluated and accepted from scientific, legal and ethical perspectives.

2/ Any researcher applying for authorization in accordance with sub-article (1) of this Article shall submit to the Authority the research proposal, relevant information about himself and his associates, the medicine for the trial, permit from Clinical Trial Ethics Committee and other necessary documents.
3. The Authority shall regulate the progress of an authorized clinical trial regularly in accordance with good medical procedure, suspend or stop the clinical trial where necessary, evaluate the results and authorize the use of the result in such a way that it benefits the public.

23. Clinical Trial Ethics Committee Supervisory Body

1. The Authority shall establish a Clinical Trial Ethics Committees Supervisory Body.

2. The Clinical Trial Ethics Committees Supervisory Body shall be responsible for recognizing and monitoring clinical trial ethics committees established at different levels and, where necessary, for establishing them.

3. The Director General of the Authority shall be the Chairperson of the Clinical Trial Ethics Committee Supervisory Body.

4. The Clinical Trial Ethics Committee Supervisory Body shall issue directive necessary for discharging its responsibilities.

24. Obligations of the Researcher

1. The researcher of the clinical trial may not disseminate the result of the research without notifying to and getting approval from the Authority.

2. The researcher of the clinical trial shall have the duty to allow access to and cooperate with the Authority in inspecting the place of the trial and the trial documents.

3. Except covering reasonable costs incurred in the clinical trial, the researcher of clinical trial may not make any payment, in cash or in kind, to the person subject to the clinical trial.

25. Clinical Trials on Pregnant Women, Nursing Mothers, Minors or Foetus

Clinical trial on pregnant women, nursing mothers, minors or foetus may only be carried out in accordance with Article 15(4) of the Proclamation upon ascertaining the fulfillment of the following conditions:
3/ the informed consent of the person with mental disorder is obtained if he is capable to give his consent or, where he is not capable to give his consent, the consent of his guardian is obtained after being briefed about the clinical trial.

27. Clinical Trial on Prisoners

1/ Clinical trial on prisoners may only be carried out in accordance with Article 15(4) of the Proclamation upon ascertaining the fulfilment of the following conditions:

a) the clinical trial is to diagnose, prevent or treat a disease that may particularly affect prisoners; and

b) the prisoner participating in the clinical trial can make decision whether to participate in the trial free of any undue influence.

2/ The concerned prison administration shall have the right to be made aware of, and have the responsibility to provide the necessary cooperation for, the conducting of clinical trial on a prisoner pursuant to sub-article (1) of this Article.

28. Withdrawal from Clinical Trial

Any person, who has given his consent for a clinical trial to be conducted on him, may withdraw from the clinical trial at any time.

CHAPTER THREE
TRADITIONAL AND COMPLEMENTARY OR ALTERNATIVE MEDICINE ADMINISTRATION AND CONTROL

29. Registration of Traditional Medicine

1/ Any person may apply to the Authority for the registration of traditional medicine by submitting information with regard to the source and use of the medicine and other necessary information.

2/ The Authority shall issue certificate of registration upon ascertaining the efficacy, safety and quality of the traditional medicine.

3/ The Authority shall ensure the confidentiality of the information obtained in accordance with sub-article (1) of this Article.

30. Registration of Complementary or Alternative Medicine

The provisions of Article 15(2) of this Regulation stipulating on the registration of medicines shall, mutatis mutandis, be applicable for registration of complementary or alternative medicine.
7/ Any health professional shall immediately inform the Authority any adverse drug effect as well as problems that he encounters with respect to the efficacy or quality of medicine.

32. Food or Medicine Seizure and Disposal

1/ The appropriate organ may seize food or medicine and order disposal or sending back to the country of its origin where the food or medicine:
   a) does not have market authorisation;
   b) is counterfeit;
   c) has expired;
   d) is of deteriorated quality;
   e) is stored, distributed, offered for dispensing or dispensed by a person without certificate of competence issued in accordance with this Regulation; or
   f) used in unauthorised clinical trial.

2/ The appropriate organ shall issue a certificate to the owner or possessor of the food or medicine disposed in accordance with sub-article (1) of this Article upon request.

PART THREE

CONTROL OF TOBACCO PRODUCTS

33. Requisite of Permit

No person may import, distribute or sell a tobacco product except with the permit of the Authority upon confirmation of the product's compliance with requirements.

34. Protection of Minors from Tobacco Product

No person may directly or indirectly sell to or create temptation upon a minor to use tobacco products.

35. Packaging and Labelling of Tobacco Product

1/ The labelling of any tobacco product shall describe the characteristics of the product and the health problem and hazard it causes, and may not directly or indirectly create the impression that it is less harmful than any other tobacco products.

2/ The label of any unit packet, package and outside packaging of tobacco products shall:
a) bear health warning describing the harmful effects of tobacco use which shall constitute 30 % or more of the principal display areas;

b) describe the health warnings in words or picture that smoking causes cancer, cardiac or bronchitis diseases or immature death or serious health problems caused as a result of tobacco use;

c) be written in Amharic or English in large, visible, legible and irremovable manner; and

d) contain information on the major constituents and main hazardous constituents found in the emissions of the tobacco products.

3/ For the purposes of this Article, the term "outside packaging " in relation to tobacco products applies to any packaging used in the retail of the product.

36. Places Prohibited for Smoking

1/ No person may smoke tobacco in a place for public gathering or use.

2/ Places for public gathering or use shall include the following:

a) rooms of health institution;

b) class rooms of educational institution;

c) public conveyances;

d) dining places like hotels and restaurants; and

e) such other places prohibited for smoking, as may be determined by the appropriate organ.

3/ Notwithstanding the provisions of sub-article (1) of this Article, smoking in places for public gathering or use identified by the Authority may be allowed at a designated smoking areas.

PART FOUR

HYGIENE, ENVIRONMENTAL HEALTH AND COMMUNICABLE DISEASES CONTROL

37. Dangerous Chemical

1/ The production, import, storage, transportation, distribution, sale or use of any dangerous chemical shall comply with the requirements set by the Authority to prevent any hazard to public health.
2/ In case of violation of the requirements prescribed pursuant to sub-article (1) of this Article, the appropriate organ may seize or recall from market and order the disposal of the dangerous chemical or sending it back to its country of origin and take other necessary measures.

38. Transportation and Disposal of Dead Bodies

1/ It shall be prohibited to bring into the country or send abroad a dead body or human remains unless otherwise permitted in accordance with the requirements set by the Authority.

2/ No dead body may be exhumed before seven years from the date of burial except by the order of a court or where burial place is required for public purpose in accordance with the relevant law.

3/ The provisions of sub-article (1) of this Article may not be applicable with respect to the transportation of human remains for archaeological or tourism purpose.

39. Waste Handling and Disposal

1/ It shall be prohibited to burn or dispose by any other means a poisonous or contagious waste without obtaining permit from the appropriate organ.

2/ No person may engage in recycling or disposal of poisonous or contagious wastes without obtaining permit from the appropriate organ upon fulfilling requirements set by the Authority.

3/ The appropriate organ shall, prior to the designation of a place for disposal or recycling of waste, confirm that the disposal or recycling of waste at such place may not cause damage to public health.

4/ No person may discharge liquid waste to the environment unless treated in accordance with the standards to be issued by the appropriate organ.

40. Institutions Subject to Health Related Control

The appropriate organ shall ensure that institutional health related control satisfy the necessary hygienic and environmental health protection requirements and take necessary measures thereof.
41. **Sound and Air Pollution**

Any person shall comply with the requirements for the prevention of sound and air pollution set by the Authority for the protection of public health.

42. **Toilet of Public Facility**

Any toilet of a public facility shall fulfill the requirements set by the Authority.

43. **Vaccination of International Passengers**

1/ Vaccination of international passengers shall be given at health institutions designated by the Authority.

2/ Any conveyance operator who has brought a person not allowed to enter into the country in accordance with Article 26(2) of the Proclamation shall be obliged to return the person to the country of his departure covering the expenses of his stay.

44. **Conveyance and Consignments Control at Frontier Port**

1/ Any conveyance entering into or transiting the country may not bring or dump any waste or remains of waste in Ethiopian territory except in accordance with accepted manner.

2/ Notwithstanding the provision of sub-article (1) of this Article, any person may import recyclable waste or by-product upon the permission of the Authority.

3/ If any conveyance or consignment entering or leaving the country is suspected of transmitting communicable disease, it shall enter or leave the country after undergoing the necessary sanitization including spraying and permit from the Authority.

4/ Importing or exporting blood, blood products, human tissue or organ, urine or stool may only be allowed by obtaining permit from the Authority.

5/ Any conveyance operator who has brought a consignment not allowed to enter the country or waste shall be obliged to return same to the country of shipment at his own and the owner's cost.

45. **Individuals Crossing Boarder on Foot**

Any person entering or leaving the country on foot at the time of epidemic and public health emergency may not enter or leave the country without undergoing health inspection and obtaining permission at a frontier port.
46. Suspected Person and Duty to Report

1/ Any international entry passenger shall be obliged to respond to quarantine inspection through verbal or written request for protection of public health.

2/ In the course of travel, if any passenger is suspected to be infected with any communicable disease, the conveyance operator shall inform the head of the nearest or destination frontier port about the type of the disease, principal symptoms and any other relevant information.

3/ The head of the frontier port receiving information in accordance with sub article (2) of this Article shall immediately report the information to the inspector at the port.

4/ For the purpose of this Article “head of frontier port” means the head of the frontier port aviation or Revenue and Customs Authority station.

47. Quarantine and Isolation

1/ Suspected person shall be quarantined immediately. The Authority shall immediately send the suspected person to the public health emergency management body for quarantine.

2/ The Authority shall ensure that any suspected person upon confirmation of his infection be transferred to an isolation room in a health institution and provided with the necessary curative and rehabilitative treatment.

3/ The public health emergency management body shall organize quarantine centres in the main frontier ports or designate the nearest health institutions as isolation centres.

48. Measures taken to Control Communicable Diseases

1/ The Authority may take the following measures to control communicable disease:

   a) ordering the closure of schools and other public places for a certain period;

   b) establishing temporary controlling posts in any part of the country; and

   c) taking any other necessary measures.
2/ The relevant bodies shall cooperate with the Authority at frontier ports to effectively undertake control of communicable diseases.

PART FIVE

HEALTH CARE

CHAPTER ONE

HEALTH CARE SERVICE

49. Vaccination Obligation and HIV/AIDS Counselling Service

1/ Any health institution and health professional employed by the institution shall, based on the medical standard and the service provided, have the obligation to give vaccination and access to HIV/AIDS counselling service to maternal and pregnant women.

2/ Parents or guardians shall have the obligation to vaccinate children in accordance with the directive to be issued for the implementation of the Proclamation and this Regulation.

50. Health Education

Any health institution shall, based on the services provided by it, have the obligation to provide health education and current information to clients.

51. Curative and Rehabilitative Medical Service

1/ governmental health institution shall provide medical service in accordance with the referral system and its capacity.

2/ Medical service may be provided at a health institution, at a work place, at the patient’s home, at the place of accident, in an ambulance or at any other similar place according to the standards to be issued by the appropriate organ.

52. Patient’s Informed Consent

1/ Medical service may not be provided without obtaining the patient’s informed consent.

2/ Notwithstanding the provision of sub-article (1) of this Article, medical service may be provided to a patient without obtaining his consent when:
a) the patient is unable to give his consent and such consent is given by:

(1) a person authorized by the patient in writing to give consent on his behalf;

(2) in the absence of a person authorized to give such consent, the spouse, child, parent, brother or sister of the patient; or

(3) a person authorized to give such consent in accordance with the law or a court order;

b) failure to treat the patient, may result in a serious risk to public health;

c) the patient has not expressly or in any other way refused to get the medical service and any delay in the provision of medical service could result in irreversible damage on his health.

3/ Any health professional shall make reasonable effort to obtain the patient’s informed consent.

4/ The health professional shall explain to the patient who refused to get medical service, the possible risks of his refusal on his health and shall record same in writing.

5/ A consent given under this Article shall be valid when it is obtained from the patient or any other third party in writing, unless it is permitted by directives to be expressed orally or through conduct with respect to specific types of medical services.

53. Emergency Medical Service

1/ Any health institution shall have the obligation to provide life saving emergency treatment.

2/ Any health institution shall have the obligation to provide emergency medical treatment in accordance with applicable standards of health institutions.

3/ Emergency medical treatment may be provided in all emergency and epidemic cities in collaboration with the relevant organs.
54. Referral System

1/ Any health institution shall have the obligation to provide medical services in accordance with health service standard to be issued by the appropriate organ.

2/ Where any health institution is unable to provide the proper examination or treatment to a patient, it shall refer the patient to the appropriate health institution where he can get the proper service in accordance with the referral system.

3/ Any health institution shall have the obligation to admit a patient sent to it in accordance with the referral system and give feed back to the sending health institution.

4/ The referring health institution shall, before referring a patient for emergency treatment, have the obligation to make sure that the receiving health institution can admit the patient.

5/ Any person shall have the obligation to observe the directive on the implementation of referral system.

55. Death and Post-Mortem Examination

1/ Death shall be ascertained when there is no sign of life as approved by a competent health professional based on examination of functions of brain, heart and breathing organs.

2/ Post-mortem examination may be conducted only where the spouse, child, who attains majority age, parent or guardian of the deceased or the appropriate organ requests to know the cause of death.

3/ Examination to determine cause of death may be carried out by a competent health institution.

4/ Notwithstanding the provisions of sub-article (2) of this Article post mortem examination for education or research purposes may be carried out where the deceased has given his written consent during his lifetime or where the deceased has not prohibited such donation during his lifetime and the consent of his family has been obtained.

56. Medical Certificate

Every health institution shall issue medical certificate to a patient containing the following information:

1/ name, age and address of the patient;
2/ examination result and medical treatment provided to the patient and, as the case may be, sick leave and board decision;
CHAPTER TWO

DONATION OF BLOOD AND BLOOD PRODUCTS AND DONATION AND TRANSPLANTATION OF ORGANS AND TISSUES

59. Organ and Tissue Donation and Transplantation

Principles

1. Transplantation of organs or tissues may only be conducted with the consent of the potential recipient. The consent of the donor must be obtained before the removal of the organ or tissue.
2. Blood and blood products may only be given to recipients after their safety and quality are tested. Blood and blood products used for the purpose of saving life or scientific research may not benefit the donor and recipient financially.
3. A person may at any time revoke the act by which he has promised to donate his organs or tissues, or may donate his organs or tissues in any other way while alive or after his death.

58. Donation of Blood and Blood Products

1. Blood and blood products donated, collection and distribution shall be done based on principles of humanity.
2. Artifical Reproduction

57. Artifical Reproduction

1. Artificial reproduction services may be provided by a health institution and licensed personnel.
2. The patient’s current situation and other necessary information

3. A woman shall not be sterilized before or after childbirth without her consent.

4. A woman’s right to bear children is protected.
5/ The following acts shall be prohibited:
   a) trading in human organ or tissue;
   b) receiving, giving or promising to give monetary or non-monetary benefit for organ or tissue donation;
   c) advertising demand or supply of organ or tissues;
   d) using animal organ or tissue for the purpose of transplanting it to human.

60. Organs and Tissues Collection from Deceased Person

1/ Where a person has consented to donate his organs or tissues upon his death, the organs and tissues that can be used for transplantation may be collected upon his death.

2/ No health institution may collect organs and tissues pursuant to sub-article (1) of this Article without obtaining special license from the Authority.

3/ Where there is no written evidence showing express prohibition of donation made by the deceased, while alive, and where the spouse, children or parents or siblings of the deceased, in the order of their list, agree with the donation, organs and tissues that can be used for transplantation may be collected from the deceased.

4/ Where the individuals listed under sub-article (3) of this Article are suspected of crime for the death of the deceased, they may not have the right to give consent with respect to donation of organs and tissues of the deceased for transplantation.

5/ Unless the donor ordered a particular recipient as beneficiary in accordance with provisions of transplantation, selection of organs and tissues recipients shall be based on compelling medical reasons and the principles of justice and equity.

6/ Health professionals who declare the fact of death of the donor may not be less than two; and be different from, and have no monetary relationship with, those who conduct the transplantation.
61. Organs or Tissues Collection from Living Persons

1/ Collection of organ or tissue from a living person may be carried out where competent health professionals believe removal of organ or tissue from the donor does not pose any serious and permanent danger to his health or life and where:

a) the donor has capacity to give consent and enter in to juridical acts, and agrees in writing, based on informed consent, in the presence of two witnesses; and

b) it is established by the National Transplantation Committee referred to in Article 62 of this Regulation that:

(1) there is spousal bondage or relation by consanguinity or affinity between the donor and the recipient; or

(2) in the absence of spousal bondage or relation by consanguinity or affinity, there is no monetary relationship between the donor and the recipient.

2/ Notwithstanding paragraph (a) of sub-article (1) of this Article, bone marrow tissue may be collected from a minor upon the consent of his guardian.

2/ No health institution may collect organs and tissues pursuant to this Article without obtaining special license from the Authority.

62. Transplantation

1/ No health institution may transplant organs and tissues without obtaining special license from the Authority.

2/ The Authority shall establish National Transplantation Committee with a view to ensuring that organ or tissue collection and transplantation is being carried out in accordance with professional ethics.

3/ Any transplantation may not be performed unless the National Transplantation Committee approved the transplantation request; provided however, that the National Committee may, where necessary, give delegation of power to transplantation committee established at regional level.
PART SIX
HEALTH PROFESSIONALS
CHAPTER ONE
PROFESSIONAL LICENSING AND REGULATION

63. Designation of Health Professions and Requisite of Professional License

1/ The Authority shall designate, register and license health professionals and set their scope of practice.

2/ No health professional with professional license may provide health services beyond the scope of practice of his profession unless with special decision of the appropriate organ in exceptional compelling circumstances.

3/ Any person qualified with more than one health profession shall be entitled to a professional license to practice all of his health professions so far as he satisfies the necessary requirements.

64. Health Professionals Register

1/ The Authority shall have a register for registering every health professional practicing in Ethiopia comprising his name, nationality, principal residence and place of business and such other necessary particulars.

2/ Any higher education institution shall send its graduate lists in health profession to the Authority and appropriate organ.

3/ The register to be kept in accordance with sub-article (1) of this Article shall be open to the public as may be necessary.

65. Issuance of Professional License

1/ Any health professional shall be granted with health professional license upon fulfilling the requirements set by the Authority for health professionals.

2/ The appropriate organ may issue restricted professional license, as may be appropriate, for impaired health professional.

3/ No health professional may in any manner transfer or rent his professional license to third party.
66. Renewal of Professional License

1/ In applying for renewal of professional license in accordance with Article 33(2) of the Proclamation any health professional shall present:

a) certificate of completion of the required continuing professional development in his profession; and

b) medical certificate proving his fitness to practice the profession.

2/ For the purpose of this Article "continuing professional development" means a training periodically attended by a health professional during his practice to maintain his professional knowledge and skills and enhance his professional competence in accordance with the directive to be issued by the Authority.

67. Inactive Status

1/ Any health professional who did not practice his profession for more than two years for any reason shall notify the appropriate organ prior to resumption of practicing his profession.

2/ The appropriate organ may authorize the professional referred to in sub-article (1) of this Article to practice his profession upon requiring him to produce evidence of completion of continuing professional development or causing him to attend training, or to work under the supervision of a competent health professional working in a health institution chosen by the Authority.

3/ If a health professional who did not practice his profession for more than two years engages in practicing without notifying the appropriate organ, he shall be deemed as practicing without professional license.

68. Health Professional Trained in Foreign Country

1/ Without prejudice to the provisions of Article 65(1) of this Regulation, any person with a duly recognized foreign educational background applying for professional license shall:

a) produce evidence of equivalence of qualification issued by the competent body;

b) complete from six months to a yearlong internship program at assigned health institution by the appropriate organ where he did not practice his profession in any foreign country for more than two years.
2/ Notwithstanding the provisions of sub-article (1) of this Article, a health professional with more than two years of professional practice in any foreign country shall complete internship program as determined by the Authority if the disease pattern of the country of his training or practice is incompatible with Ethiopia’s disease pattern.

3/ Notwithstanding the provisions of sub-article (1) and (2) of this Article, the Authority may issue temporary professional license for a health professional with foreign educational background, where the professional intends to provide health services in short term charitable activity, emergency humanitarian crisis or other health services to be determined by the Authority.

4/ The institution which brought the health professional on temporary basis shall:

   a) upon the completion of the professional’s mission, notify the Authority and ensure the surrender of the temporary professional license;

   b) bear civil responsibility for any damages caused by the health service provided by the professional.

69. Surrender of Professional License

Any health professional shall have the obligation to surrender his professional license where his license is suspended or revoked or he completes his mission or relinquishes practicing his profession.

CHAPTER TWO

HEALTH PROFESSIONAL CODE OF CONDUCT

70. General Principles

Any health professional:

1/ may not practice his profession in any manner that violate the Proclamation, this Regulation or any other relevant law;

2/ shall provide health services to the client without any discrimination;

3/ shall give the utmost consideration for the health and need of the client.

71. Health Professional Ethics Committee

1/ A Health Professional Ethics Committee (hereinafter the “Committee”) is hereby established.

2/ Members of the Committee shall be professionals drawn from the relevant institutions and be designated by the Minister, and their number shall be determined as necessary.
72. Powers and Duties of the Committee

The Committee:

1/ shall examine, investigate and propose appropriate administrative measure to the Authority on complaints made with respect to substandard health services and incompetent and unethical health professionals;

2/ shall, where it proves availability of sufficient evidence to support the complaint, send summon to the health professional or institution against whom a complaint is lodged with the notification to respond within 30 days;

3/ may, where appropriate, assign an independent researcher in consultation with the Authority to investigate the complaint;

4/ may propose suspension of license or certificate of competence to the Authority until the appropriate decision is passed on the complaint;

5/ shall, upon identifying the root causes of frequently lodged complaints and grievances, propose policy directions intended to provide sustainable solutions to the problems;

6/ shall perform such other duties that may be assigned to it by the Authority.

73. Meetings of the Committee

1/ The Committee shall meet as frequently as its functions requires.

2/ The presence of more than half of the members at any meeting of the Committee shall constitute a quorum.

3/ Decisions of the Committee shall be passed by majority votes; in case of a tie, the Chairperson shall have a casting vote.

4/ Without prejudice to the provisions of this Article, the Committee may adopt its own rules of procedure.

74. Main Responsibilities of Health Professionals

Any health professional shall:

1/ be accountable for the health services he provides and for his decisions as per his assigned duty;

2/ obtain informed consent from a patient, in accordance with the relevant law, before rendering a service;
3/ provide genuine and adequate information during professional communication with colleagues and clients;

4/ respect patient confidentiality, privacy, choices and dignity;

5/ maintain the highest standards of personal conduct and integrity;

6/ discharge his professional duty in a team work respecting the contribution of other health professional;

7/ provide appropriate counselling service to the client;

8/ update his professional knowledge and skills to new medical technologies and innovations;

9/ maintain proper and effective communication with his patients and other health professionals;

10/ register and keep accurate client records;

11/ avail himself and provide professional service in his working place during assigned duty hours;

12/ ensure public participation and acceptance in designing and implementing public health programs;

13/ comply with any lawful instructions and procedures of the appropriate organ with respect to his profession.

75. Fees and Commission

Any health professional may not:

1/ accept commission or any benefit apart from service charge from a person or another health professional or institution in return for the services he renders;

2/ pay commission or offer benefits to any person for recommending patients;

3/ offer or accept any payment or benefit which is intended to induce to act or not to act in a particular way not professionally indicated or to over-charge patients;
4. charge or receive fees for services not rendered personally or by his employee or partner or substitute;

5. receive payment or any benefit for recommending or referring patients to another health professional, for treatment or for participation in clinical trials or other research;

6. provide health service, for his benefit, that does not serve the needs of his patient.

76. Practicing with other Health Professionals

1. A health professional shall employ a health professional who is licensed by the appropriate organ.

2. Unless for training purposes, a health professional may not work with or give any kind of professional support to another health professional not licensed by the appropriate organ.

77. Professional Confidentiality

1. A health professional may not disclose, verbally or in writing, information regarding a patient unless the appropriate organ believed that there is a prominent health risk to the public demanding to do so, it is ordered by a court, he gets written consent from the patient or the patient’s guardian or it is permitted by law.

2. A health professional may release or transfer information regarding patients for the purpose of conducting scientific research or studies where the information released is in such a manner that it does not identify directly or indirectly any individual patient.

3. A health professional shall encourage a patient with communicable diseases to disclose his status to individuals with potential exposure to the infection.

78. Preferential Treatment and Referral of Clients

1. Any health professional shall render the same level of care to his clients in itinerant and resident practice.

2. Any health professional may not provide any preferential treatment to a client by considering the relationship established with him in another health institution where the same professional works.
| 3/ | A health professional may not refer a patient to another health institution where he works unless for services unavailable and necessitating referral upon declaring the vested interest of the professional in the referred health institution. |
| 4/ | For the purpose of sub-article (1) of this Article, “resident practice” means a practice which a health professional conducts on full time basis regularly while “itinerant practice” means a practice which a health professional conducts other than the resident practice. |

### Prohibition of Secret Remedies

1/ No health professional may use secret remedies.

2/ Every health professional shall, in the conduct of his practice, use only an apparatus or health technology or intervention which is proved upon investigation to be capable of fulfilling the claims made in regard to it.

3/ For the purpose of this Article “secret remedy” means a medication or treatment that cures a disease or disorder or relieves its symptoms that is known by only a few people or professionals and intentionally withheld from general knowledge.

### Advertisement of Profession and Service

1/ Any health professional may not advertise:

   a) his services if the advertisement is unprofessional, untruthful or misleading;

   b) his services unless otherwise he is authorized by the appropriate government organ;

   c) in a manner that directly or indirectly encourages the unnecessary use of health services;

   d) his services in a manner that affects or undermines the services of other health professionals;

   e) his services by drawing attention to his personal qualities and superior knowledge;
f) his services in a manner that promises a gift, discount or other inducement to attract a person to use the service.

2/ Any health professional shall ensure the advertisement of a health institution whose certificate of competence is issued in his name respect the provisions of sub-article (1) of this Article.

81. Medicine and Medical Instrument Advertisement

1/ A health professional may not advertise medicine or medical instrument unless he is a direct employee of the manufacturer or distributor and authorized to do so by the appropriate government organ.

2/ A health professional may not, in consideration of the benefit he may derive, advocate the preferential use of any medicine or medical instrument that would not be clinically appropriate or cost-effective to the client.

82. Research Participation

A health professional may only participate in research performed on human subject if the research has written approval after appropriate ethical evaluation and is being performed in accordance with the approved research protocol.

83. Requesting and Providing Professional Support or Consultation

1/ In case of any doubt or difficulty and need of supplementary or higher level of care, a health professional shall request support or consultation from any other professional colleague for the benefit of the client.

2/ A health professional consulted by a colleague shall provide the required professional advice and service as per the standard of his profession.

84. Obligation to Serve Despite Belief

A health professional may not refuse on grounds of personal belief to provide services such as contraceptive, legal abortion and blood transfusion.

85. Issuance of Official Documents

1/ A health professional shall sign official documents relating to patient care such as laboratory and other diagnostic requests and results, prescriptions, certificates, patient records, hospital and other reports after writing his full name.
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2/ A health professional shall issue genuine and complete sick leave or certificate of illness.

86. Prescriptions and Medicine Dispensing

1/ No health professional may prescribe medicine or formulations about which he has no knowledge about its composition and pharmacological action.

2/ A prescription on which a health professional prescribe shall be standardized and prepared in accordance with the standard of the institution and type of the profession.

3/ Any health professional shall prescribe medicine registered in the national drug list unless for compelling reason.

4/ Any professional dispenser of medicine may not dispense or keep any medicine obtained through illegal channel.

87. Waste Disposal and Disease Prevention

1/ Any health professional shall dispose of disposable healthcare wastes in an appropriate manner for the sake of himself, the client and the public health.

2/ Any health professional shall respect safety provisions that ensure the non transmission of diseases from himself to client, from client to client or from client to health professional.

88. Disclosing Prognosis

1/ A health professional shall explain the nature and possible outcome of the terminal or severe illness to the patient or, in case of a minor or mentally ill person, to the guardian.

2/ Notwithstanding the provisions of sub-article (1) of this Article, a health professional may only communicate the nature and possible outcome of the terminal or severe illness to family members of the patient where he believes that the patient may harm himself due to emotional instability.

89. Reporting of Impairment and Unprofessional Conduct

Any health professional shall report the following to the appropriate organ:
1/ an impairment in another health professional if he is convinced that such professional is impaired;
2/ his own impairment if he is aware of it or has been publicly informed, or he has been advised by colleagues to obtain help in view of an alleged impairment;
3/ the provision of health service by a person without professional license or whose professional license has been suspended or revoked; and
4/ any unprofessional conduct of another health professional.

PART SEVEN
INSTITUTIONS

90. Certificate of Competence

1/ No person may establish and run institution without obtaining a certificate of competence from the appropriate organ.
2/ A certificate of competence issued to any institution shall be renewed annually.
3/ Any institution shall undertake its business in accordance with the requirements on the basis of which its certificate of competence issued.
4/ The appropriate organ may issue or renew a certificate of competence subject to restrictions on the type of the product or service, means of production, processing, storing and any other necessary conditions relating to the quality and safety of the product or service.
5/ It is prohibited to transfer in any manner a certificate of competence to a third party without the permission of the appropriate organ.

91. Surrender of Certificate of Competence

Any institution whose certificate of competence is revoked, cancelled or denied renewal or which has ceased operation shall surrender its certificate of competence to the appropriate organ.

92. Professionals Health Examination

1/ Any institution shall make health professional or food handler who has contact with clients to undertake pre-employment and annual medical examination, except for HIV/AIDS.
2/ No health professional may undertake medical examination for himself in accordance with sub-article (1) of this Article.

3/ Any food handler shall notify the institution where he is infected by food borne communicable disease. Any food establishment shall screen a food handler infected by food borne communicable disease.

4/ Any food establishment shall remove any food handler who is infected by food borne communicable disease from activities involving contact with food until the disease becomes non communicable.

5/ The Authority shall issue directive on the type of medical examinations that a health professional or food handler who has contact with clients shall undertake.

93. **Institution Requirements and Prohibitions**

1/ Any institution shall develop internal waste management system to manage its hazardous substances and wastes.

2/ An exporter institution shall obtain special permit from the Authority for transiting medicine or food from foreign country to another country.

3/ No institution may import, keep or distribute prohibited or expired food or medicine.

4/ No wholesale or import institution may distribute food or medicine for a person with no certificate of competence.

5/ Any health institution which permits a student on practical training to provide health service shall be responsible for any damage the student may cause to a patient.

**PART SEVEN**

**MISCELLANEOUS PROVISIONS**

94. **Duty to Furnish Information**

1/ Any health professional shall cooperate with the appropriate organ whenever requested to show his professional license or provide information about his professional performance or that of others.
2/ The appropriate organ shall keep the confidentiality of information obtained in accordance with sub-article (1) of this Article unless otherwise permitted by law.

95. Duty to Report

1/ Any person who believes that a health professional is unfit to practice or commits unprofessional conduct shall notify the appropriate organ.

2/ Any person who in good faith notifies the appropriate organ in accordance with sub-article (1) of this Article may not be legally liable.

96. Service Fees

Every person shall pay service fees to the appropriate organ at the rate approved by government for obtaining or renewing professional license or certificate of competence, registering medicine or receiving other certificates and services.

97. Repealed and Inapplicable Laws

1/ The following are hereby repealed:

a) the Licensing and Supervision of Health Service Institutions Council of Ministers Regulation No.174/1994; and

b) the Ethiopian Health Professionals Council Establishment Council of Ministers Regulation No.76/2002.

2/ No regulation, directive or customary practice shall, in so far as it is inconsistent with this Regulation, be applicable with respect to matters provided for by this Regulation.

98. Power to Issue Directives

The Authority may issue directives necessary for the implementation of this Regulation.

99. Effective Date

This Regulation shall enter into force on the date of publication in the Federal Negarit Gazette.

Done at Addis Ababa, this 24th day of January, 2014.

HAILEMARIAM DESSALEGN
PRIME MINISTER OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA.