

LAW OF GEORGIA ON TUBERCULOSIS CONTROL

Chapter I - General Provisions

Article 1 - Purpose of the Law

By effective control of tuberculosis, this Law intends to ensure the protection of health of natural persons and public health care, prevent the spreading of tuberculosis throughout Georgia, establish legal grounds for controlling cases of tuberculosis and provide proper aid for persons affected by tuberculosis.

Article 2 - Scope of the Law

This Law shall determine the basic legal, organisational and financial principles for arranging tuberculosis control measures in Georgia, shall regulate the issues related to tuberculosis control and the rights and duties of persons with tuberculosis.

Article 3 - Legislation of Georgia on tuberculosis

The legislation of Georgia on tuberculosis consists of the Constitution of Georgia, International Agreements of Georgia, this Law and other legislative and subordinate normative acts of Georgia.

Article 4 - Definition of terms used in the Law

For the purposes of this Law, the terms used herein shall have the following meanings:

- a) Tuberculosis - a contagious disease caused by the Mycobacterium of tuberculosis. It is spread/transmitted through the air;
- b) Pulmonary tuberculosis - a form of tuberculosis when Mycobacterium tuberculosis infects the lungs of a human;
- c) Extra-pulmonary tuberculosis - a form of tuberculosis when Mycobacterium tuberculosis damages human organs other than the lungs;
- d) Resistant tuberculosis - a form of tuberculosis when it is proven by a laboratory that the Mycobacterium tuberculosis that causes tuberculosis is resistant to anti-tuberculosis drugs;
- e) Regular tuberculosis - a form of tuberculosis when Mycobacterium tuberculosis that causes tuberculosis can be subject to treatment by first-line drugs for tuberculosis;
- f) Patient - a person (citizens of Georgia, foreigners - in the cases provided for by the Legislation of Georgia, stateless persons with the corresponding status in Georgia), whose condition was defined as a possible case of pulmonary tuberculosis or a confirmed case of pulmonary tuberculosis by a proper health care provider;
- g) Possible case of tuberculosis - condition in which a patient has symptoms of a damaged respiratory system and there is a high probability that these symptoms are caused by tuberculosis;
- h) Confirmed case of tuberculosis - condition in which a patient has been diagnosed with a confirmed case of pulmonary tuberculosis based on the criteria provided for by National Clinical Practice Recommendations;
- i) Contagious tuberculosis - pulmonary tuberculosis which is active because of emission of Mycobacteria tuberculosis into the air and is confirmed by laboratory testing of emission of bacterium provided for by The National Clinical Practice Recommendations;
- j) Screening - examination of persons without any signs or symptoms of disease in order to identify the presence of an unrecognised disease;
- k) Treatment of tuberculosis - a set of medical and other types of intervention provided in accordance with the requirements of The National Clinical Practice Recommendations and World Health Organisation recommendations in order to cure a person infected by tuberculosis;
- l) A health care provider - provider of health care services determined by the Law of Georgia on Public Health;
- m) Close contact - contact of a patient, who has a confirmed case of tuberculosis, with family members (parents, spouse, children, siblings, other persons living permanently with the patient) or contact with other persons in a closed space during the day for the period of time provided for by National Clinical Practice Recommendations and World Health Organisation recommendations;
- n) the Ministry - the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health, and Social Affairs of Georgia;
- o) the Minister - the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia;
- p) Local entity of public health care - non-entrepreneurial (noncommercial) legal person created by an appropriate municipality, in accordance with the Organic Law of Georgia on Local Self-Government, which operates in the field of Public Health within the framework of powers delegated to a municipality by the Law of Georgia on Public Health.

Law of Georgia No 3122 of 5 July 2018 - website, 11.07.2018

Chapter II - Tuberculosis Control

Article 5 - The essence of tuberculosis control

1. Tuberculosis control shall combine activities related to prevention of tuberculosis, diagnosis (examination) and management of a case of tuberculosis (which also includes diagnostics during the treatment).
2. Patients shall be entitled to benefit from the means and activities related to tuberculosis control.



3. Tuberculosis control shall be based on respect and protection of patients' general and social rights.
4. Within the scope of its authority, the Ministry shall plan, arrange, implement and coordinate activities for tuberculosis control.
5. Legal Entity of Public Law - L. Sakvarelidze National Centre for Disease Control and Public Health (hereinafter - the Centre) and local unit of public health care (hereinafter - local unit of public health) shall participate in organisation and implementation activities for tuberculosis control.
6. An administrative body, also a legal entity of private law that has material, technical and human resources and operates in accordance with the Legislation of Georgia, may participate in the process of tuberculosis control.

Article 6 - The Functions of the Ministry within the field of Tuberculosis Control

1. Within the field of tuberculosis control, the Ministry shall:
 - a) arrange, plan, implement and coordinate activities for tuberculosis control;
 - b) introduce the newest technologies and scientifically proven methods in order to improve the quality of prevention, diagnosis (examination) and management of tuberculosis cases;
 - c) ensure accessibility of the services (including palliative care of persons infected with tuberculosis) related to prevention, diagnostics (examination) and management of tuberculosis cases, also financial accessibility of anti-tuberculosis drugs for patients;
 - d) develop a long-term national strategy and action plan for tuberculosis control in compliance with international standards for tuberculosis control;
 - e) plan the activities of tuberculosis control and raise financial resources necessary for their implementation;
 - f) monitor and evaluate that the national strategy and action plan of tuberculosis control are implemented within the period determined by the legislation of Georgia;
 - g) prepare a report regarding the implementation of activities for tuberculosis control in accordance with the procedures established by the legislation of Georgia;
 - h) perform other functions provided for by this Law and other legislative and subordinate normative acts of Georgia.
2. While arranging and implementing the activities for tuberculosis control, the Centre shall exercise the authority granted to it by the legislation of Georgia.

Article 7 - The functions of a local unit of public health within the field of tuberculosis control

A local unit of public health, within the framework of powers delegated to it by the Law of Georgia on Public Health, shall:

- a) find persons who are in close contact with a patient and ensure that they timely visit an appropriate facility for a mandatory test for tuberculosis;
- b) find patients who have prematurely cancelled the treatment for tuberculosis and ensure that they will be re-engaged in the process of treatment;
- c) decide the expediency of involuntarily isolating a person in accordance with this Law;
- d) conduct educational work regarding tuberculosis with patients and the population;
- e) monitor the process of implementation of tuberculosis control activities in the municipality, within its competence;
- f) perform other functions provided for by this Law.

Article 8 - Tuberculosis control in a penitentiary facility

Legal relations regarding tuberculosis control in a penitentiary facility of the State Sub-agency within the Ministry of Justice of Georgia – Special Penitentiary Service shall be regulated by joint order of the Minister and the Minister of Justice of Georgia.

Law of Georgia No 3122 of 5 July 2018 – website, 11.07.2018

Chapter III - Prevention of Tuberculosis

Article 9 - The means and activities related to the prevention of tuberculosis

1. The means and activities related to the prevention of tuberculosis are:
 - a) preventive vaccination;
 - b) screening;
 - c) activities for identifying persons who are at risk for tuberculosis;
 - d) informational and educational activities about tuberculosis;
 - e) activities for infection control.
2. The means and activities related to the prevention of tuberculosis shall be arranged and coordinated by the Ministry. Local units for public health, also other legal entities of public and private law shall participate in the process of implementation of these means and activities.
3. The information about the means and activities related to the prevention is public.
4. A special program of preventive vaccination shall be conducted by health care providers.
5. The Ministry shall arrange screening programs for prevention of tuberculosis, while in penitentiary facilities it shall be done by the State Sub-agency within the Ministry of Justice of Georgia – Special Penitentiary Service.
6. Local units of public health care shall: find persons at risk of tuberculosis; find those persons who were in close contact with a patient and/or those persons who might have been in close contact with a patient; provide these persons with information about the fact that they are at risk for tuberculosis and ensure that they timely visit an appropriate facility for diagnosis (testing).
7. Informational and educational activities about tuberculosis shall be conducted for Georgian citizens, foreigners and



stateless persons with the corresponding status in Georgia in order to give them information about tuberculosis. The aim of informing these persons is to raise their awareness regarding tuberculosis and develop skills required to implement activities for prevention of tuberculosis. Local units of public health shall implement informational and educational activities about tuberculosis.

8. The Ministry shall ensure the implementation of the activities stipulated in the first paragraph of this article financed by the State Budget or by other possible financial resources.

Law of Georgia No 3122 of 5 July 2018 – website, 11.07.2018

Chapter IV - Diagnosis of Tuberculosis (examination)

Article 10 - Diagnosis of tuberculosis (examination)

1. Diagnosis (examination) of tuberculosis includes a set of specific laboratory, instrumental and general clinical testing.
2. Appropriate laboratory testing for diagnosis (examination) of tuberculosis shall only be conducted in accordance with the appropriate requirements of biosafety, in accordance with the National Clinical Practice Recommendations approved by the Minister's order.

Article 11 - Mandatory testing for tuberculosis

1. Mandatory testing for tuberculosis is an examination of emission of bacteria, which aims to identify *Mycobacterium tuberculosis* by sputum smear microscopy and sputum culture and/or by molecular examination.

2. Mandatory testing for tuberculosis must be taken by:

a) a person (Georgian citizen, foreigner, stateless persons with the corresponding status in Georgia), who visited a health care provider for medical assistance and who was advised by the health care provider to take a mandatory test for tuberculosis in accordance with the National Clinical Practice Recommendations;

b) a person (Georgian citizen, foreigner, stateless persons with the corresponding status in Georgia), who is in close contact with a patient with a confirmed case of tuberculosis;

Note: For the purposes of this sub-paragraph, a person who is considered to be in close contact with a patient with confirmed case of tuberculosis, shall be a person stipulated in the Article 4(m) of this Law;

c) a patient, who has a confirmed case of tuberculosis,- according to the periodicity defined by National Clinical Practice Recommendations;

d) a patient, who has a confirmed case of tuberculosis and was being treated but terminated the treatment of tuberculosis.

3. A proposal regarding mandatory testing for tuberculosis made by a health care provider to a person stipulated in paragraph 2(a) of this article, must be grounded and based on the symptoms/signs revealed during the process of giving medical assistance to this person.

4. In accordance with Article 4(m) of this Law, a local unit of public health shall find a person who is in close contact with a patient who has a confirmed case of tuberculosis, as stipulated in paragraph 2(b) of this article, based on an interrogation of this patient.

5. A health care provider shall identify and make a list of patients determined by paragraph 2(c) of this article.

6. The Centre shall find the patients determined by paragraph 2(d) of this article based on the information provided by the health care provider.

7. In accordance with the Article 11(3)(6), a health care provider shall propose the person/patient determined by the second paragraph of this article to take a mandatory test for tuberculosis within the period of 10 calendar days. The aim of this proposal is to receive consent from the person/patient in order to conduct a mandatory test for tuberculosis. This proposal shall be made in a special written form or via phone, e-mail or other technical tools, so that the persons'/patients' right to the confidentiality of their health information and principles of ethic are protected.

8. A special written form of the proposal regarding a mandatory test for tuberculosis described in paragraph 7 of this article and/or procedure for implementation of this proposal shall be approved by the Minister's order.

9. The person/patient, determined by the paragraph 2 of this article, is obliged to take a mandatory test for tuberculosis within the period of 7 calendar days after receiving a proposal as established by paragraph 7 of this article.

10. If a person/patient does not take a mandatory test for tuberculosis or refuses to take it within the period of time established in paragraph 9 of this article, within 24 hours after the deadline, a health care provider shall inform the local unit of public health according to the place of person's/patient's actual residence.

11. Within 4 calendar days after receiving the information mentioned in paragraph 10 of this article, in the manner prescribed in paragraph 7 of this article, the local unit of health care is obliged to make another proposal to the person/patient laid down in paragraph 2 of this article to take a mandatory test for tuberculosis.

12. Within 7 calendar days after receiving the second proposal from the local unit of health care, the person/patient laid down in the paragraph 2 of this article is obliged to appear at the health care provider in accordance with his/her place of actual residence and take a mandatory test for tuberculosis.

13. If the person/patient identified in paragraph 2 of this article is a minor, a health care provider and a local unit of public health shall perform the activities laid down in this article through the parents or legal guardians of the minor. Herewith, a minor's refusal to take a mandatory test for tuberculosis shall be taken into consideration if his/her parents or other legal guardians say so. Parents or other legal guardians of a minor are obliged to take him/her to a health care provider for a mandatory test for tuberculosis.

14. If the person/patient determined by paragraph 2 of this article could not appear at a health care provider for objective reasons, he/she is entitled to ask the local health care provider to ensure his/her transfer to the health care provider. In this case, the respective local unit of public health shall ensure the transfer of the person/patient to the appropriate health care provider.

15. After taking a mandatory test for tuberculosis, if it is confirmed that a person/patient has pulmonary tuberculosis,



he/she shall receive voluntary treatment provided for by this Law and other legislative acts of Georgia.

16. If the person defined in the Article 11(2)(a) or (b) does not take a mandatory test for tuberculosis within the period of time specified under paragraph 12 of this article, this shall be considered as a final refusal for a mandatory test for tuberculosis.

17. If a person defined in Article 11(2)(c) or (d) does not take a mandatory test for tuberculosis within the period of time specified under paragraph 12 of this article, this circumstance shall be considered as a final refusal for a mandatory test for tuberculosis, which is a basis to start taking measures of involuntary isolation.

Chapter V - Management of Tuberculosis Cases

Article 12 - Management of tuberculosis cases

1. Tuberculosis case means a possible or confirmed case of tuberculosis.
2. Management of a tuberculosis case is a combination of diagnostic, medical (including palliative care), long-term care and social support activities.
3. While managing a confirmed case of tuberculosis, involuntary isolation may be applied as an extreme measure.
4. A health care provider shall manage the case of tuberculosis. A local unit of public health shall participate in management of tuberculosis cases.
5. During the process of applying diagnostic, medical (including palliative care), long-term care and involuntary isolation measures, the authority of a health care provider shall be defined by the legislation of Georgia.

Article 13 - General principles of tuberculosis treatment

1. Treatment of tuberculosis shall be performed in accordance with the National Clinical Practice Recommendations and recommendations of the World Health Organisation.
2. In the presence of a tuberculosis case, a health care provider shall have the authority power to perform treatment of tuberculosis within its competence.

Chapter VI - Involuntary Isolation

Article 14 - The objective and general principles of involuntary isolation

1. The objective of involuntary isolation is to prevent the spread of tuberculosis and possible threat to public health.
2. Involuntary isolation is an extreme measure that shall be taken when all the other means, such as taking a mandatory test for tuberculosis by a patient and his/her voluntary engagement into the process of treatment, are exhausted and involuntary isolation is the only way to prevent the spread of infection.
3. Measures for involuntary isolation may be used:
 - a) on patients with confirmed case of tuberculosis, who have a contagious form of tuberculosis, but who refuse to take treatment for tuberculosis;
 - b) on a patient determined by the Article 11(2)(d) of this Law, who has made a final rejection to take a mandatory test for tuberculosis;
 - c) on patients with confirmed cases of tuberculosis, who were diseased with a contagious form of tuberculosis and were taking the treatment, but prematurely cancelled the treatment of tuberculosis and during the cancellation of the treatment were still diseased with a contagious form of tuberculosis.
4. Rights and freedoms of the person, who is subject to involuntary isolation, shall not be unjustifiably limited. The State is obliged to support this person's rights and freedoms.
5. Measures for involuntary isolation shall be financed by the State.

Article 15 - Procedures and terms for involuntary isolation

1. The basis to apply measures of involuntary isolation on the patient provided for by Article 14(3) of this Law, shall be the reasons stipulated in the same paragraph.
2. The necessity to enforce involuntary isolation shall be determined by a health care provider.
3. A health care provider shall perform involuntary isolation in a medical facility, which meets the requirements of inpatient service for tuberculosis disease provided for by the Legislation of Georgia.
4. After identifying the patient determined by Article 14(3) of this Law, a health care provider, within 48 hours, shall study the medical condition of this patient and determine the necessity to apply measures of involuntary isolation. The patient shall be considered as identified, if a health care provider receives confirmed information about this patient regarding existence of respective grounds determined by the Article 14(3) of this Law.
5. If a health care provider decides that it is necessary to involuntarily isolate the patient determined by the Article 14(3) of this law, it shall address the respective local unit of public health in writing with a motion for using involuntary isolation on this patient. The motion of using involuntary isolation on a patient shall be grounded and include compelling arguments to perform it.
6. The local unit of public health care, within 72 hours after receiving the motion determined by the paragraph 5 of this article, shall review the motion of the health care provider, decide expediency of applying involuntary isolation on the patient and apply to a court to use involuntary isolation.
7. The court, based on the application of the local unit of public health, within 48 hours after receiving the application, shall review it and make a decision regarding involuntary isolation of a patient in accordance with the rule established by the Administrative Procedure Code of Georgia. It is mandatory for the patient to participate in the hearing of the case of involuntary isolation, if it does not threaten other persons' health. When the court is reviewing the case of a juvenile patient, the interests of the juvenile patient shall be represented by his/her parents or other legal representatives. The



lawyer of the patient shall also participate in the hearing.

8. The ruling of the court regarding involuntary isolation of a patient shall be immediately enforced by the legal entity under public law within the governance of the Ministry of Justice of Georgia - the National Bureau of Enforcement, in accordance with the procedures established by the Legislation of Georgia. The patient shall be involuntarily isolated in the respective health care provider, which is provided with special security.

9. The ruling of the court regarding involuntary isolation of the patient is valid until the grounds for involuntary isolation are exhausted, but not longer than 6 months. This term may be continued for not longer than 2 months.

10. If the court does not make a decision to involuntarily isolate a patient, the respective local unit of public health shall cancel the proceedings for involuntary isolation of this patient.

11. After the measures of involuntary isolation are started and before the ruling of the court regarding the patient's involuntary isolation is issued, if the patient determined by Article 14(3)(a) or (c) of this Law agrees to start or resume the treatment for tuberculosis, or if the patient determined by Article 14(b) of this law agrees to take a mandatory test for tuberculosis after a final refusal, the patient shall receive a mandatory examination for tuberculosis and/or the treatment for tuberculosis in accordance with the procedures provided for by this Law and other legislative acts. Herewith, proceedings regarding involuntary isolation of this patient shall be cancelled.

12. During the period of patient's involuntary isolation, in order to inspect the expediency of the involuntary isolation, a medical commission shall be created, which will review the expediency of the involuntary isolation of a patient every 2 months after the ruling of the court regarding the patient's involuntary isolation is issued.

13. If the commission defined in the paragraph 12 of this article, after reviewing the respective question, concludes that it is no longer necessary to use involuntary isolation on the patient, it shall address the respective local unit of public health with a motion to terminate involuntary isolation of that person. If the respective local unit of public health decides that according to the conclusion of the medical commission the basis for involuntary isolation no longer exists, it shall make a decision to cancel the involuntary isolation and address the respective health care provider with a motion for discharging the patient from the medical facility.

14. The patient may appeal to a court with a motion to cancel the involuntary isolation, if he/she thinks that during the involuntary isolation the requirements established by this Law or other legislative acts of Georgia are breached or the basis of involuntary isolation no longer exists. The court shall cancel the involuntary isolation of the patient within 72 hours after receiving the motion. While making this decision, together with the other factors, the court shall take into consideration, the question of resuming voluntary treatment of tuberculosis by the patient under the circumstances of involuntary isolation. If the court decides to cancel the involuntary isolation of a patient, the patient shall continue the treatment of tuberculosis under the supervision of a health care provider.

15. The medical commission and its motion determined by Article 15(12) shall be established by the Minister's order.

16. If a health care provider, on its own initiative or based on the application of the medical commission determined by the Article 15(12), after the 6-month term defined in Article 15(9) expires, based on the patient's health condition, considers it necessary to continue the term of involuntary isolation of the patient, it shall address the respective local unit of public health with an appropriate motion, and the local unit of public health shall address the court.

17. A patient, in the case of a juvenile patient - his/her parents or other legal representatives, also the respective local unit of public health care shall have the right to appeal the ruling of the judge about involuntary isolation of the patient, resolution about refusing involuntary isolation of the patient, an order continuing the term of the court's decision regarding involuntary isolation of the patient or a resolution refusing continuation of the term of the court's decision regarding involuntary isolation of the patient in accordance with the rules established by the Administrative Procedure Code of Georgia.

Article 16 - A patient's rights during involuntary isolation

During involuntary isolation a patient shall have right to the following:

- a) to be provided with a place to live, food, products of personal hygiene, clothes and medical service;
- b) to meet family members and a lawyer, also any other person based on the agreement with a health care provider, by following the requirements of tuberculosis control, on the territory of the health care provider where the patient is involuntarily isolated.
- c) to address the court with a motion to cancel involuntary isolation in case of a case defined in Article 15(14) of this Law.
- d) to receive parcels and money orders;
- e) to receive information through mass media; to use books;
- f) to use a phone and internet, and have correspondence.

Chapter VII - Social Security Guarantees of Patients

Article 17 - Monetary incentives for patients

1. In order to support a patient, who is a citizen of Georgia, in following the regimen of tuberculosis treatment established by the Ministry, if the regimen of tuberculosis treatment is followed properly, the State shall provide the patient, throughout the course of outpatient treatment, with social assistance, which is issued in form of monetary incentives. The patient, infected with regular tuberculosis, shall receive the monetary incentives for no longer than 6 months, and patients, infected with resistant tuberculosis, shall receive the monetary incentives for no longer than 20 months.

2. The amount and procedure for issuing monetary incentives defined in the paragraph 1 of this article shall be determined by a resolution of the Government of Georgia.

Article 18 - Labour rights of patients

During involuntary isolation, issues related to a patient's labour rights shall be arranged by the Legislation of Georgia.



Chapter VIII - Liability

Article 19 - Grounds for liability

1. The liability for the violation of requirements established in the field of tuberculosis control shall be determined by the legislation of Georgia, including this Law. 2. An authorised person from the respective body of the Ministry shall have the right to draw up a protocol of an administrative offence provided for by this chapter, whereas the case shall be reviewed by court. 3. The form of a protocol for an administrative offence defined in this chapter, the procedure for drawing it up and submitting shall be determined by the Minister's order.

4. In cases when an administrative offence has been committed, the proceedings for the administrative offence shall be carried out in accordance with the Administrative Offences Code of Georgia.

Law of Georgia No 5578 of 24 June 2015 – website, 12.07.2016

Article 20 - The case when a health care provider, in accordance with Article 11(10) of this law, does not inform the respective local unit of public health regarding the fact that a patient refuses to take a mandatory test for tuberculosis

1. The case when a health care provider, in accordance with Article 11(10) of this law, does not inform the respective local unit of public health that a patient refuses to take a mandatory test for tuberculosis, shall result in imposing a monetary penalty in amount of 250 laris on the health care provider.

2. If the action defined in paragraph 1 of this article is repeated, - it shall result in imposing a monetary penalty in amount of 500 laris on the health care provider.

Chapter IX - Transitional Provisions

Article 21 - The terms for issuing/receiving the legal acts defined by this Law

1. The Minister before 1 January 2017 shall issue the following orders:

- a) on the National Clinical Practice Recommendation of tuberculosis;
- b) on the rules of procedure for implementing special written form of the proposal regarding mandatory testing for tuberculosis defined in the Article 11(8) of this Law and/or on the rules of procedure for making this proposal;
- c) on creating a medical commission and establishing its members defined in the Article 15 (12) of this Law;
- d) on the form of a protocol of an administrative offence defined in the Article 19(3) of this Law, the rules of procedure for drawing it up and submitting it.

2. Before 1 January 2017 the Ministry shall develop a long-term national strategy and action plan for tuberculosis control in accordance with international standards for tuberculosis control.

3. Before 1 January 2017, the Minister and the Minister of Corrections and Legal Assistance of Georgia shall issue a joint order regarding measures related to tuberculosis control in penitentiary facilities.

4. The Government of Georgia, according to the resolution until March 1 2016, shall determine the amount of monetary incentives defined in the Article 17(1) of this article and set rules of procedure for issuing them.

Chapter X - Final Provisions

Article 22 – Entry of the Law into force

1. This Law, except for Articles 1 - 20 of this Law, shall enter into force from 1 January 2016.

2. Articles 1 - 20 of this Law shall enter into force from 1 January 2017.

President of Georgia

Kutaisi

11 December 2015

No 4629-I b

Giorgi Margvelashvili

