

Unofficial translation  
Ministry of Social Affairs and Health, Finland  
N.B. Legally valid only in Finnish and Swedish

## **Government Decree on Screenings (339/2011)**

Issued in Helsinki on 6 April 2011

In accordance with the Government decision made on the submission of the Ministry of Social Affairs and Health, the following is enacted by virtue of section 23 of the Health Care Act (1326/2010):

### Section 1

#### Definition of screening

(1) For the purposes of this Decree, "screening" means examination of the population or a certain part of the population, or sampling in order to discover a certain disease or its precursor or to identify a pathogen.

(2) Screening is part of preventive health care. Screening includes the definition of the target group, individual advice and guidance, performing and analysing the screening tests, delivery of feedback information, referral to further examinations and organization of the necessary health services.

### Section 2

#### National screenings

The following are screenings compliant with the national screening programme:

- 1) Breast cancer screening every 20–26 months for women aged between 50 and 69 who were born in 1947 or later;
- 2) Cervix cancer screening every five years for women aged between 30 and 60;
- 3) For pregnant women:
  - a) a general early pregnancy ultrasound scan during week 10+0 –13+6 of the pregnancy;
  - b) detection of chromosomal abnormalities primarily through early pregnancy combined screening (serum screen test in week 9+0 – 11+6 of the pregnancy and the measurement of neck oedema in connection with a general ultrasound scan in week 11+0 – 13+6 of the pregnancy) or, alternatively, through a second trimester serum screen test in week 15+0 – 16+6 of the pregnancy; and

c) an ultrasound scan for the detection of severe structural abnormalities in week 18+0 – 21+6 of the pregnancy or after week 24+0 of the pregnancy.

### Section 3

#### Other screenings

If the municipality provides screenings other than those included in the national screening programme, it shall assess, before starting any screening, the requirements and impacts imposed on the health care system and how screening affects it. The assessment shall include an examination of the disease to be screened, its incidence and treatment, screening methods, effectiveness, organization and total costs of screening, as well as the ethical aspects relating to screening.

### Section 4

#### Organization of screenings

(1) The screening shall be organized in accordance with a programme established by the municipality in advance, taking sufficient quality control and quality assurance procedures into account.

(2) In order to provide appropriate screening services, the municipality shall monitor and evaluate the quality of the entire screening process and the reliability of the screen tests on a regular basis.

### Section 5

#### Participation in the screening

(1) All of the municipality's inhabitants that belong to the screening group shall be entitled to participate in the screening on equal grounds. The participation in the screening is voluntary.

(2) The municipality shall ensure that its inhabitants have access to sufficient information on the objectives and effectiveness of the screening, the possible risks involved with the screening, and the organization of the screening.

(3) The health services shall be organized in such a way that there is no discrimination between the municipality's inhabitants who have participated or intend to participate and those who have not participated or do not intend to participate in the screening organized under the national screening programme or some other screening organized by the municipality.

### Section 6

#### Special conditions

(1) The health care unit participating in the collection, analysis, feedback delivery and further examination of the screening samples shall have sufficient expertise, as well as the necessary staff and equipment, at its disposal.

(2) The municipality shall appoint a supervisor for each screening.

## Section 7

### Direction and monitoring

The National Institute for Health and Welfare shall monitor and evaluate the ongoing screening programmes and their methods in collaboration with other operators in the sector.

## Section 8

### Entry into force

This Decree enters into force on 1 May 2011.