

Statutory Order regarding Cosmetic Treatment

In pursuance of sections 18, 21, 22, subsection 3, section 71, subsection 2- 4, sections 72 and 91 of Act no. 451 of May 22nd 2006 regarding Authorization of Health Care Professionals and Professional Health Care Practice (hereafter Authorization Act) the following is hereby established:

Chapter 1

Definitions and age requirement

Article 1. Cosmetic treatment in this statutory order refers to any corrective procedure where cosmetic consideration is the main clinical indication, or any treatment which, as its chief aim, intends to change or improve the appearance, cf. the Authorization law section 71, subsection 1.

Article 2. The term surgery in this document is to be understood as operational procedures which break through skin or tissue, or procedures involving the introduction of apparatus into the natural apertures of the body.

Article 3. Cosmetic treatments must not be performed on patients younger than 18 years old.

Paragraph 2. Cosmetic orthodontics (treatment of irregular teeth) can however be performed on patients younger than 18 years of age.

Chapter 2

Cosmetic treatments

Article 4. The following treatments, when performed for cosmetic purposes, may only be carried out by doctors acknowledged as specialists in the named specialties:

- 1) Assessment of the patient before hair transplantation, cf. article 6, paragraph 1: Dermato-venerology (skin and venereal diseases) or plastic surgery.
- 2) Scalp flaps, or implant of tissue expanders on the scalp for the purpose of correction of baldness, however cf. article 6, paragraph 2: Plastic surgery.
- 3) Surgical lift of forehead: Plastic surgery.
- 4) Surgical lift of eyebrows: Ophthalmology (eye diseases) or plastic surgery.
- 5) Surgery on ears and nose: Oto-rhino-laryngology (ear-, nose- and throat diseases) or plastic surgery.
- 6) Surgical face- and neck lifts, including thread lifts: Plastic surgery.
- 7) Surgical operations in the eye region: Ophthalmology or plastic surgery.
- 8) Surgical insertion of implants in the face: Plastic surgery.
- 9) Surgical operations on breasts and removal of gynaecomastia (breast development in the male): Plastic surgery.
- 10) Surgical lift of the abdomen; abdominoplasty: Plastic surgery.
- 11) Liposuction: Plastic surgery.
- 12) Surgical insertion of implants in arms, legs, and buttocks: Plastic surgery.
- 13) Surgical lift of arms, legs, and buttocks: Plastic surgery.
- 14) Surgery on the male sexual organs: Plastic surgery or urology (Kidney and urinary tract diseases).
- 15) Treatment with autologous filler (the removal of fat for the purpose of injection into other places in the body) corresponding to over 100 ml: Plastic surgery.
- 16) Treatment with autologous filler corresponding to 100 ml or less: Dermato-venerology or

- plastic surgery.
- 17) Treatment with injection sclerotherapy in small blood vessels (the removal of small visible veins) and the injection thereof: Dermato-venerology, vascular surgery, or plastic surgery.
 - 18) Treatment with botulinum toxin and injection thereof: Dermato-venerology, neurology (diseases of the nerves and nervous system), ophthalmology, or plastic surgery.
 - 19) Treatment with permanent fillers: Dermato-venerology, or plastic surgery.
 - 20) Treatment with lipotherapy/injection lipolysis (the injection of materials for the purpose of dissolving fat): Dermato-venerology or plastic surgery.
 - 21) Treatment with laser lipolysis (the introduction of fine laser fiber for the purpose of dissolving fat): Dermato-venerology or plastic surgery.
 - 22) Dermabrasion (skin polishing): Dermato-venerology or plastic surgery.
 - 23) Treatment with lasers, in class 3B or 4, and with Intense Pulsed Light (IPL) and other methods, which can be equated with this, and the execution thereof: Dermato-venerology with documented, relevant qualifications.
 - 24) Chemical skin peel using trichloroacetic acid (TCA) and/or phenol: Dermato-venerology or plastic surgery.

Article 5. Doctors with permission to independently practice medicine and with documented, relevant qualifications can, after a specific assessment of their qualifications, receive permission from the National Board of Health to perform the cosmetic treatments named in article 4.

Article 6. The following treatments, when performed for cosmetic purposes, may only be carried out by doctors with permission to independently practice medicine and with documented, relevant qualifications:

- 1) Hair transplantation, however, cf. article 4, nos. 1).
- 2) Less invasive procedures in connection with scalp flaps or implant of tissue expanders which only call for stitching of the skin.
- 3) Treatment with non-permanent fillers.
- 4) Chemical skin peel using products with a pH value of 3 or less, however, cf. article 4, nos. 24).

Article 7. Surgical and non-operative composite resin and porcelain treatments for cosmetic purposes must only be carried out by dentists.

Paragraph 2. Tooth whitening for cosmetic purposes using bleaching agents which contain a hydrogen peroxide concentration that is higher than that allowed for in the Executive order on cosmetic products (Executive order no. 422 of May 4th 2006) must only be carried out by dentists or by dental hygienists with relevant qualifications.

Chapter 3

Admittance at the treatment facility

Article 8. In connection with larger and more complicated cosmetic procedures, including breast lifts, breast augmentation or reduction operations, surgical lifts of the abdomen (abdominoplasty), liposuction, as well as insertion of implants in the buttocks, the patient must be held for observation at the treatment facility, cf. article 9.

Paragraph 2. Following a chemical skin peel using phenol the patient must be held for observation at the treatment facility, cf. article 9.

Article 9. In connection with cosmetic procedures which call for admittance at the treatment facility, cf. article 8, the treatment facility must be equipped in such a way that surveillance and monitoring of admitted patients can be carried out responsibly.

Paragraph 2. During the patient's admittance at the treatment facility, observation is to be

conducted by a doctor with permission to independently practice medicine or a nurse with documented, relevant qualifications in observation of patients after surgery.

Paragraph 3. The doctor responsible for the cosmetic treatment or another doctor with the same qualifications must be able to be sent for within a reasonable time.

Chapter 4 *Use of assistants¹*

Article 10. For the named treatments and procedures in articles 4, 6 and 7, assistance cannot be used with the exception of the treatments mentioned in paragraphs 2 and 3.

Paragraph 2. In connection with the following cosmetic procedures, cf. chapter 2, the authorized health care professional may use assistance with documented, relevant qualifications except in connection with the pre-examination of the patient and during selection of treatment (determine indication):

- 1) Performing hair transplantation: Assistants must have documented relevant qualifications.
- 2) Treatment with injection sclerotherapy in small blood vessels (the removal of small visible veins): Doctors and nurses with documented, relevant qualifications.
- 3) Treatment with botulinum toxin: Doctors and nurses with documented, relevant qualifications.
- 4) Tooth whitening, cf. article 7, paragraph 2: Assistants must have relevant qualifications.
- 5) Surgical and non-operative composite resin and porcelain veneer treatments: Assistants must have relevant qualifications.

Paragraph 3. For treatment with non-permanent fillers, the removal of hairs and vessels as well as non-ablative (mild) wrinkle treatments with lasers, IPL, or other methods that can be equated with these, cf. chapter 2, the authorized health care professional may use doctors without permission to independently practice medicine and nurses with documented, relevant qualifications to assist, including in connection with the pre-examination of the patient and during selection of treatment (determine indication).

Article 11. Persons without professional health care authorization but with documented, relevant qualifications can, after a specific assessment of qualifications, get permission from the National Board of Health to assist in the treatments named in article 10, paragraph 2, nos.1).

Paragraph 2. Persons without professional health care authorization but with documented, relevant qualifications can, after a specific assessment of qualifications, get permission from the National Board of Health to assist in the treatments named in article 10, paragraph 3, but not in connection with the pre-examination of the patient and during selection of treatment (determine indication).

Article 12. In connection with use of assistants, cf. article 10 and 11, the authorized health care professional, cf. chapter 2, must be associated with the treatment facility in such a way that the health care professional can supervise that the work carried out on their behalf, is carried out in agreement with good professional practice and according to the legislation that the authorized health care professional is under an obligation to respect.

Chapter 5 *Registration of cosmetic treatment*

Article 13. Upon application, the National Board of Health will register authorized health care

¹ An authorized health care professional has to show care and conscientiousness in the use of assistants. The authorized health care professional must thoroughly instruct the assistant about the treatment delegated to the assistant and supervise the treatment the assistant does on behalf of the authorized health care professional. In the guideline connected to this statutory order the use of assistants is described in more detail.

professionals that, according to article 4-6, may perform cosmetic treatments, as well as individuals that, according to article 10 and 11, may be used as their assistants. The National Board of Health furthermore registers which cosmetic treatments the registered authorized health care professional and their assistants may perform, as well as at which treatment facility the cosmetic treatment takes place.

Paragraph 2. The National Board of Health will make an assessment of the qualifications of the persons named in articles 4-6 prior to their registration.

Paragraph 3. Registration can be refused to individuals who meet the criteria for removal from the National Board of Health's register for cosmetic treatment according to article 24 and 25.

Article 14. Performing the cosmetic treatments named in articles 4-6 respectively, as well as articles 10 and 11, assumes that the authorized health care professional involved, as well as their assistants, are registered with the National Board of Health, though cf. article 42.

Application for registration

Article 15. In order to be considered by the National Board of Health, the application for registration to perform cosmetic treatment must be made electronically via the board's homepage, www.sst.dk, and must include the following information:

- 1) authorization id, name, address, telephone number, and email,
- 2) the authorized health care professional's qualifications, including information about education and experience with the cosmetic treatment that is being applied for registration,
- 3) the cosmetic treatments that the authorized health care professional wishes to perform,
- 4) the names of any possible assistants to the authorized health care professional, including their personal identification numbers, and qualifications, including education and experience with the particular cosmetic treatment that the assistants are to perform,
- 5) The central business registration number (CVR nr.), production unit number (P nr.), name, address of the treatment facility, and the name of any doctor responsible for the health care practice at the treatment facility, where the authorized health care professionals and their assistants perform the cosmetic treatment, and
- 6) information regarding the medical presence, staffing, the provision for having a doctor on call, anaesthesia capabilities as well as admittance and surveillance capabilities.

Paragraph 2. Written documentation for information named in paragraph 1 must be attached to the application or be subsequently forwarded.

Article 16. Licensed health care professionals who apply for registration to perform cosmetic treatment are to pay a fee of DKK 14,600² in connection with the application to the National Board of Health to cover the administration expenses in connection with the registration provision and the extended supervision in the area.

Article 17. If the National Board of Health assesses that an applicant can be registered to perform cosmetic treatment, the applicant will receive written information regarding the registration from the board, and notice of the registration will be posted on the Internet homepage of the National Board of Health, cf. article 28.

Article 18. If the National Board of Health assesses that an applicant cannot be registered to carry out cosmetic treatment, the applicant will receive written correspondence from the board regarding this. Rejected applicants will be refunded the pre-paid fee according to article 16.

Maintenance of registration

² About 2,000 Euro

Article 19. In order for a registered authorized health care professional to maintain their registration with the National Board of Health they must

- 1) pay an annual fee of DKK 14,600 to cover the administration expenses in connection with the registration provision and the extended supervision of the area, and
- 2) forward documentation of any changes in the conditions which form the basis of the registration within the deadline named in paragraph 2.

Paragraph 2. The National Board of Health must receive documentation of any changes in the conditions which form the basis of the registration at the latest 2 weeks after the change has taken place.

Article 20. The payment of the fee named in article 19 comes due on the anniversary of the fee named in article 16.

Article 21. The National Board of Health can in special cases deviate from the collection of a complete annual fee.

Removal from the register for cosmetic treatment

Article 22. Removal from the register results in the authorized health care professional and their assistants no longer being allowed to perform the registered cosmetic treatment, cf. article 13.

Article 23. In cases where the basis, on which the authorized health care professional or their assistants were registered, is changed to the extent that the National Board of Health finds that the basis for the registration is no longer present, the health care professional concerned and their assistants are deleted from the register, and the authorized health care professional is deleted from the board's Internet homepage, cf. article 28.

Article 24. The National Board of Health can delete an authorized health care professional and their assistants from the register, and the authorized health care professional is deleted from the board's Internet homepage, cf. article 28, if the health care professional:

- 1) has received restrictions in the areas of their practice, cf. Authorization Act section 7, subsection 2, nos. 2),
- 2) has temporarily received restrictions in the areas of their practice, cf. Authorization Act section 8, paragraph 2, or
- 3) has had their authorization revoked, cf. Authorization Act section 8, subsection 1.

Paragraph 2. If the decision of the National Board of Health according to paragraph 1, nos. 2) and 3), is lifted by the Minister of the Interior and Health, the authorized health care professional and their assistants will be registered again.

Article 25. If the authorized health care professional has not complied with requirements made by the National Board of Health regarding the health care practice at the treatment facility, cf. article 39, the concerned and their assistants will be deleted from the register, and the authorized health care professional is deleted from the board's Internet homepage, cf. article 28.

Article 26. If the National Board of Health does not receive the designated fee named in articles 16 and 19 from the authorized health care professional by the fixed deadline named in articles 16 and 20, the concerned and their assistants will be deleted from the register, and the authorized health care professional is deleted from the board's Internet homepage, cf. article 28.

Article 27. Registered authorized health care professionals that are deleted from the National Board of Health's register for cosmetic treatment cannot demand a refund of previously paid fees.

Publication

Article 28. The National Board of Health continually publishes on its Internet homepage, www.sst.dk, which cosmetic treatments are performed by each registered authorized health care professional and their assistants and in which treatment facility the cosmetic treatments are performed.

Paragraph 2. The National Board of Health can publish on its Internet homepage, www.sst.dk, information on the results of the inspection of each health care professional and the treatment facility of each registered health care professional where cosmetic treatment is performed.

Chapter 6 Informed consent Information

Article 29. A patient must receive comprehensive information about the cosmetic treatment that they are contemplating having done.

Paragraph 2. The information is to be given by the authorized health care professional responsible for the cosmetic treatment.

Paragraph 3. The information is to be given both in writing and orally. The oral information is to be given subsequent to the written information and must be based on the written information and must take into consideration the individual patient's needs.

Paragraph 4. The information is to contain a comprehensible presentation of the cosmetic treatment without use of technical, professional, or bias expressions. The information is to be neutral and not promote or favour in a biased manner one treatment method over another.

Paragraph 5. The information is to be given in a considerate way and be adjusted according to the recipient's individual preconditions regarding age, maturity, experience, etc.

Article 30. Cosmetic treatment must not be performed on patients that have declined information about the treatment.

Contents of written information

Article 31. The written information must contain a comprehensive explanation of the contemplated cosmetic treatment, including what realistic expectations the patient can have regarding the result of the treatment. The information must be more extensive regarding more complex procedures, and when the treatment involves risk of serious complications and side effects.

Paragraph 2. The information must contain details regarding:

- 1) the expected result of the cosmetic treatment,
- 2) the type and the frequency of complications and side effects of the treatment and the possibilities for treating these, as well as
- 3) the possible delayed consequences and long-term complications and/or side effects of the cosmetic treatment.

Paragraph 3. If it is considered that the patient is ignorant of circumstances which are important for the patient's decision making process, the responsible authorized health care professional must specifically provide particular information regarding this.

Article 32. If the contemplated cosmetic treatment differs from the common method/methods professionally accepted in relation to the treatment, the responsible authorized health care professional must specifically provide particular information regarding this, including why any methods other than those common and professionally accepted are being offered.

Article 33. If the responsible authorized health care professional has limited experience regarding the particular cosmetic treatment, the patient is to be informed about this.

Paragraph 2 The responsible authorized health care professional must, where it becomes relevant, inform the patient regarding the results of their work, including any complications, etc. that have arisen.

Article 34. The written information must state that consent can first be given after the consideration time has passed, cf. article 35, and that the patient has the right to bring a supporter at the time of receiving the oral information.

Consideration time

Article 35. In connection with more complex cosmetic treatments, including surgical operation in breasts, surgical lifts of the abdomen (abdominoplasty), liposuction, the patient is to have a week's time for consideration from the time the oral information is received until consent is given.

Paragraph 2. In connection with less complex cosmetic treatments, including minor hair transplantations and skin peeling, the patient must have two days' time for consideration from the time the oral information is received until consent is given.

Consent

Article 36. A cosmetic treatment must not begin or be continued without the patient's informed consent.

Paragraph 2. Informed consent is to be understood in this statutory order as consent given on the basis of written and oral information, cf. article 31-34.

Paragraph 3. The consent is to be specific and is to be given as soon as possible after the granted consideration time, cf. article 35. The consent given must be for a specific cosmetic treatment in the near future (be current).

Paragraph 4. The consent is to be given to the authorized health care professional responsible for the cosmetic treatment.

Paragraph 5. The patient can revoke their consent at any time according to paragraph 1.

Keeping Patient Medical Records

Article 37. The patient medical record must describe which written and oral information the patient has received and what the patient has expressed based on this information.

Article 38. Before any cosmetic treatment is undertaken, a picture of the patient must be taken focusing on the area which is to be treated. The picture is to be included in the patient medical record and to be kept according to the regulation for storage of patient medical records.

Paragraph 2. If the patient attends a subsequent control, then another picture of the patient must be taken at an appropriate time after the cosmetic treatment and with the same focus and the same dimensional scale as the picture named in paragraph 1. The picture is to be included in the patient medical record and to be kept according to the regulation for storage of patient medical records.

Chapter 7 Supervision

Article 39. The National Board of Health may without court order inspect the treatment facilities where authorized health care professionals or their assistants perform cosmetic treatment, and can place requirements regarding the health care practice at the treatment facility, cf. Authorization Act

section 71, subsection 5.

Chapter 8
Complaints and penalties

Article 40. Complaints regarding decisions made by the National Board of Health in pursuance to chapter 5 can be brought before the Minister of the Interior and Health. The submission of complaints does not act as a stay of the proceedings, unless it is otherwise decided by the Minister of the Interior and Health.

Article 41. Violation of articles 3, 4, 6, 7, 10, 11 and 14 will be punishable by fine.

Chapter 9
Commencement and interim provisions

Article 42. This statutory order will take effect on December 1, 2007.

Paragraph 2. As long as an application for registration is submitted before February 1, 2008, then authorized health care professionals and their assistants who, already at the time of this statutory order's taking effect, are performing the cosmetic treatments named in chapter 2, can continue with this, until the National Board of Health has handled the registration application, but until no later than April 1, 2008.

Paragraph 3. In particular special cases the National Board of Health can give permission to individuals without professional health care authorization, who, already at the time of this executive order's taking effect, are performing cosmetic treatments named in article 10, paragraph 3, to continue with this until February 1, 2008.

The National Board of Health, October 24, 2007

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