

Danish Act on the Right to Complain and Receive Compensation

Unofficial Consolidation Act with the amendments following the Danish Parliament's adoption of L 98 (extension of the patient compensation scheme, protection of unpaid compensation, etc.)

[...]

Chapter 3

Patient compensation

Area of application

Section 19: Compensation is given to patients or survivors of patients in accordance with the provisions of this Chapter when suffering injuries in Denmark in connection with examinations, treatment, etc., carried out in:

- 1) a hospital or on its behalf;
- 2) by health professionals and other personnel as part of prehospital care pursuant to the Danish Health Act;
- 3) a university school of dentistry; or
- 4) by the Danish Health Authority in connection with cases in accordance with the Danish Health Act, Chapter 21, provisions issued pursuant thereto or provisions issued pursuant to Chapter 5 (d) of the Danish Hospital Act, as upheld by the Danish Health Act, Section 277, Clause 12.

Clause 2: Irrespective of Clause 1, compensation is given to patients or survivors of patients in accordance with the provisions of this Chapter when suffering injuries in Denmark in connection with examinations, treatment, etc., carried out

by health professionals, cf. the Danish Health Act, Section 6.

Clause 3: Individuals who take part in health research, including clinical trials with drugs, that is not part of the diagnosis or treatment of the individual's disease or illness, are considered equal to patients. This also applies to patients from whom tissue and other biological material is taken.

Clause 4: This Chapter also applies to patients who receive free treatment or support for treatment in foreign hospitals, clinics, etc., in accordance with the Danish Health Act.

Clause 5: The Minister of Health determines additional provisions for areas that shall fall under Clauses 1, 3 and 4.

Clause 6: The Minister for Health may wholly or partly assign the processing of cases to private institutions in accordance with this Chapter. In such event, the Minister for Health must enter into the necessary agreements accordingly.

Clause 7: Should the Minister for Health assign the processing of cases to a private institution in accordance with this Chapter, the institution's undertaking will be subject to the Danish Public Administration Act .

Clause 8: Should the Minister for Health assign the Minister's powers in to a private institution in accordance with Clause 6, the Minister may determine rules for the appeals process.

Compensation for injuries

Section 20: Compensation is paid if the injury was most probably caused in one of the following situations:

1) When it can be assumed that an experienced specialist in the relevant field of expertise and under the given circumstances would have acted differently during the examination, treatment, etc., and the injury would have been avoided.

2) When the injury was caused by a fault or failure of technical equipment, tools or other equipment used in connection with or during an examination, treatment, etc.

3) When a subsequent assessment finds that the injury could have been avoided if a different available treatment technique or method had been used, which from a medical perspective, would have treated the patient's disease or illness just as effectively; or

4) When a patient contracts an infection or other complications of a more complex nature than what a patient is generally expected to tolerate due to an examination, including diagnostic interventions or treatment. The severity of the injury shall partly be considered, as well as the patient's illness or disease and state of health, the rarity of the injury and other possibilities for taking into account the risk of injury.

Clause 2: The Minister for Health can determine additional provisions on which injuries under Clause 1 are further covered by the Act. The Minister can also determine provisions on which injuries under Clause 1 (3) are exempted from this Chapter.

Section 21: Injuries resulting from an incorrect diagnosis of the patient's disease or illness are only compensated in the said cases in Section 20, Clause 1 (1) and (2).

Clause 2: Accidents not covered by Section 20, Clause 1 (2), are only compensated if the injured party is undergoing treatment, etc., at a hospital and the accident occurs on the hospital's premises in such a way that it can only be assumed that the hospital has incurred liability in accordance with general statutory compensation rules.

Clause 3: Compensation in accordance with this Chapter is not paid for injuries caused by the characteristics of pharmaceutical drugs used during examinations, treatment, etc.

Section 22: Compensation is paid to the subjects and donors that fall under Section 19, Clause 3, for any injury potentially caused by the trial or extraction of tissue, etc., unless it is most probable that the injury was caused by something else.

Clause 2: The rule in Clause 1 does not apply to injuries under Section 21, Clause 3.

Clause 3: Compensation is paid to blood donors that fall under Section 19, Clause 3, who suffer an injury through an accident in connection with transportation to an agreed or requested extraction of blood in a blood bank or mobile blood bank, unless the donor contributed to the injury through

gross negligence or with intent. However, compensation is not paid in accordance with the first sentence if the blood donor is entitled to compensation for the injury under other legislation.

Section 23: All authorised health personnel are responsible for informing the injured party if they become aware of injuries in their undertaking that will give entitlement to compensation and to the extent necessary assist the patient with reporting the matter to the Patient Compensation Association or private institutions assigned to process cases under this Chapter pursuant to Section 19, Clause 6.

Compensation sum, etc.

Section 24: Compensation and damages are determined in accordance with the provisions of the Danish Liability for Damages Act, cf. however Section 24 a.

Clause 2: Compensation, etc., in accordance with Clause 1 is paid after DKK 7,300 (2017 level) has been deducted from the main sum of compensation or damages. The Health Minister can determine provisions stating that compensation will only be paid for lost earnings and damages for pain and suffering if the injury results in incapacity for work or illness beyond a specified period, but no longer than three months.

Clause 3: Clause 2 and provisions determined in accordance with Clause 2 do not apply to injuries under Section 22, Clause 1 or Clause 3, cf. Section 19, Clause 3.

Clause 4: Compensation is not paid to cover recourse claims.

Clause 5: Compensation and damages in accordance with Clause 1 awarded by private institutions other than the Patient Compensation Association and for which the Minister of Health has entered into an agreement in accordance with Section 19, Clause 6, is paid for dental injuries if the total amount exceeds DKK 10,000. Compensation and damages are paid to the said prisoners and conscripts in Section 29, Clause 1 (9) and (10), if the total amount exceeds DKK 1,000.

Clause 6: The amounts determined in Clause 2 are adjusted on 1 January each year by 2.0 per cent with the adjustment rate for the applicable financial year added, cf. the Danish Rate Adjustment Percentage Act.

Section 24 a Those or the person who has parental custody of a child, who dies before the age of 18 due to an injury that falls under this Chapter is entitled to damages to the sum of DKK 162,000.

Clause 2: A child under Clause 1 shall be understood as a living newborn child and a stillborn child if the pregnancy lasted for at least 22 full weeks.

Clause 3: Damages in accordance with Clause 1 is only paid as a lump sum. When parents have joint parental custody damages are paid in accordance with Clause 1 with half each.

Clause 4: The amount determined in Clause 1 for damages is adjusted on 1 January each year by 2.0 per cent with the adjustment rate for the applicable financial year added, cf. the Danish Rate Adjustment Percentage Act. The deducted amount is then rounded off to the nearest amount of Danish kroner divisible by 500.

Adjustments are carried out based on the applicable amount for rounding off on the adjustment date.

Clause 5: Damages are set based on the amount, which according to Clause 4, applied on the date payment for damages could have been demanded in accordance with Clause 6.

Clause 6: A demand for payment of the total damages determined in Clause 1, cf. Clause 4, can be put forward in accordance with the provision of the Danish Liability for Damages Act, Section 16, Clause 1, first sentence.

Clause 7: The payment for damages accrues interest from the date when payment can be demanded in accordance with Clause 6 with an annual interest rate corresponding to the interest in the Danish Interest Act, Section 5.

Section 25: Compensation to the patient or the patient's survivor can be reduced or in some circumstances revoked if the patient contributed to the injury through gross negligence or with intent.

Section 26: To the extent that the patient or the patient's survivor has received or is entitled to compensation in accordance with Section 24, the compensation claim cannot be filed against anyone, who has incurred liability for the injury.

Section 27: If the person who, in accordance with general compensation rules, has incurred liability for the patient or the patient's survivor, falls under Clause 19, payments can, in accordance with Clause 24, only form the basis for recourse claims if the injury was caused by gross negligence or with intent.

Section 28: The provisions of Section 26 and 27 will not apply if liability applies in accordance with the provisions of the Danish Product Liability Act.

Organisation of the compensation scheme

Duty to pay compensation

Section 29: The following have the duty to pay compensation in accordance with this Chapter:

- 1) Operations managers at public hospitals and prehospital care in accordance with the Danish Health Act.
- 2) The patient's region of residence and, if the patient does not have a residence in Denmark, the region where the patient is staying in connection with treatment for injuries for which a foreign hospital, etc., is responsible in accordance with Section 19, Clause 4.
- 3) Operations managers for regional dental care, odontological district and knowledge centre offices, and the municipal health services in accordance with Chapters 36-41.
- 4) The operations manager of a university school of dentistry.
- 5) The region in which a private practising authorised health professional has his/her practice or where a non-private practising doctor works as a doctor on call or where a non-private practising doctor administers vaccinations in accordance with the Danish Health Act, Section 158, cf. however clause 3, first sentence, which is not applied to practising specialists, who are not specialists in general medication, unless it concerns an examination by a specialist in connection with the case

processing of public authorities, insurance companies, etc., and does not constitute a patient service.

6) The region in which a private hospital, clinic or other specialist practice is located when the treatment is given as part of the region's planned treatment capacity cf. the Danish Health Act, Section 64, Clauses 1-3, Section 75, Clause 2, Section 79, Clause 2 and Section 89, Clause 2.

7) Private hospitals, clinics and specialist medical practices for injuries after treatment, examinations, etc., that are carried out in accordance with the Danish Health Act, Section 87, or not paid by the public health service.

8) The State in terms of damages under Section 19, Clause 1 (4).

9) The State in terms of injuries suffered by conscripts or contractual staff as a result of health treatment in the armed forces or emergency rescue services.

10) The State in terms of injuries suffered by prisoners as a result of health treatment in the correctional service's prisons and detention centres. However, for dental injuries only if the prisoner is entitled to treatment.

11) The region in charge of operations or the municipality of an institution, a residence, a nursing home, etc., within a social environment in which an authorised health professional is employed.

12) The region where an undertaking, organisation, etc., that employs health professionals has its address. However, this does not apply to private hospitals, clinics

and specialist medical practices mentioned in point 7.

13) The region in which the a health professional causes an injury during an examination, treatment, etc., that is not carried out as part of the employment contract or part of the employee's work in a private clinic.

14) The State in terms of injuries caused by medical treatment performed by detention centre doctors and doctors who take blood samples for the police, Clinic of Forensic Psychiatry under the Ministry of Justice, the State Serum Institute or Radio Medical.

Clause 2: The duty to pay compensation under this Chapter also includes specialist medical practices specialising in general medicine, who do not comply with the agreement, cf. the Danish Health Act, Section 227, Clause 1, cf. Section 60, Clause 1, for injuries after treatment, examination, etc., that are not paid by the public health service. However, the region in which the specialist medical practice is located, has a duty to pay compensation for injuries after treatment, examinations, etc., that are carried out in accordance with the other provisions of the Danish Health Act.

Clause 3: Should the processing of cases under this Chapter be assigned to a private institution in accordance with Section 19, Clause 6, the Minister for Health can decide that the duty to pay compensation under this Chapter rests with the applicable institution or the applicable private practising authorised health professionals that the institution represents.

Clause 4: If, in accordance with Clause 1 (1) , 5 and 6, a regional council is liable to

pay compensation to a sum higher than the average under these provisions, the regional council shall inform the Danish Patient Safety Authority, so it can investigate the matter in accordance with the Danish Health Act.

Clause 5: If, in accordance with Clause 1 (7) or Clause 2, first sentence, a private hospital, clinic or specialist medical practice is liable to pay compensation to a sum higher than the average under these provisions, the aforesaid insurance company shall inform the Danish Patient Safety Authority, so it can investigate the matter in accordance with the Danish Health Act.

Clause 6: The Minister for Health can determine additional provisions for the duty to inform in accordance with Clauses 4 and 5, including counting the number of compensation payments and limitation of cases.

Duty to insure

Section 30: Compensation claims under this Chapter shall be covered by insurance from an insurance company, cf. however Section 31, Clause 1.

Clause 2: The insurance company in which an insurance policy has been taken under this Chapter shall inform the Danish Patient Safety Authority of the insurance. Insurance companies affected by the first sentence shall notify the Danish Patient Safety Authority and Patient Compensation Association should the insurance coverage be withdrawn.

Clause 3: The Minister for Health determines the annual coverage for the said insurance in Clause 1.

Clause 4: The coverage amounts determined in accordance with Clause 3 are adjusted according to the provisions of the Danish Liability for Damages Act, Section 15.

Clause 5: The Minister for Health determines provisions for the execution of the duty to insure, including minimum conditions for insurance companies when taking out insurance that falls under this Chapter. The Minister also determines the following provisions:

1) That the region in which the liable person, cf. Section 29, has his/her residence or homestead shall pay compensation in cases when the liable person has not taken out insurance in accordance with Clause 1, as the region can file a recourse case against the liable person.

2) That the region in which the liable person, cf. Section 29, has his/her residence or homestead shall pay compensation in cases when the liable person has not taken out insurance in accordance with Clause 2, as the region can file a recourse case against the liable person.

3) That insurance companies who have taken out insurance that falls under this Chapter shall jointly pay compensation in cases when the operations manager's liability exceeds the insurance coverage determined in accordance with Clause 3.

4) That insurance companies, that have taken out insurance that falls under this Chapter, and self-insuring authorities jointly pay compensation in accordance with Section 24, when it is not possible in all

fairness to point out the person liable in accordance with Section 29.

Clause 6: The Minister of Health determines provisions on maximisation of joint liability in accordance with Clause 5 (3) and (4).

Clause 7: The Minister for Health can determine the rules for recording and inspecting insurance coverage in accordance with Clause 1.

Section 31: The State, regional council and municipal councils are exempted from the duty to insure in accordance with Section 30.

Clause 2: By agreement, the Minister for Health can authorise regional councils and municipal councils to take over the duty to insure in accordance with Section 30, Clause 1, for private operations managers, cf. Section 29. This can only be done for private operations managers who carry out work within the boundaries of the region or municipality.

Clause 3: Regional and municipal councils can demand coverage from the private operations managers for the cost of the said insurance arrangements in Clause 2 when affected by the arrangements.

Clause 4: The Minister for Health determines the annual coverage for the said insurance in Clause 2.

Clause 5: The coverage amounts determined in accordance with Clause 4 are adjusted according to the provisions of the Danish Liability for Damages Act, Section 15.

Clause 6, Section 30, Clause 5 (3) and Clause 6 do not apply if a regional or

municipal council has taken over the duty to insure in accordance with Clause 2.

Clause 7: The right of distraint applies to the said costs in Clause 3.

Patient compensation

Section 32: Insurance companies that have taken out insurance that fall under this Chapter, and self-insuring regional and municipal councils shall jointly establish an association with the name Patient Compensation and select a board of directors for the association. The Minister for Health can set rules to determine that the State can be a member of the board.

Clause 2: The Minister for Health can determine the articles of association for the association's board of directors and the undertaking. The operational expenses of the association and costs that are otherwise imposed on the association under this Chapter are paid by the insurance companies and self-insuring authorities according to shared distribution set out in the articles of association.

Clause 3: The Patient Compensation Association submits an annual report to the Minister of Health on its activities.

Case processing

Section 33: The Patient Compensation Association receives, discloses and decides all compensation cases in accordance with this Chapter. In accordance with more specific provisions in the Articles of Association, the association can authorise individual insurance companies and self-insuring authorities to disclose and decide more specific case types.

Clause 2: The said potentially liable persons in Section 29, Clause 1, shall inform the Patient Compensation Association of the rules in the Danish Health Act that have been applied when examining, treating, etc., the patient or whether the examination, treatment, etc., was not paid by the public health service. The information must be sent to the Patient Compensation Association within 30 days after receiving the request. If it is not possible to meet the deadline, the Patient Compensation Association must be informed of the reason for not meeting the deadline prior to expiration, and when it can be expected that the request will be fully processed.

Clause 3: The Patient Compensation Association can allow witnesses to be heard by the city court in their homestead.

Clause 4: The decision of the Patient Compensation Association is sent to the person's insurance company, the State or the self-insured regional or municipal council, who shall thereafter pay the determined sum immediately after the complaint deadline, stated in Section 58 (b), Clause 2, first sentence, expires. However, this will not apply if the decision is appealed.

Section 33 a A refund for compensation and damages paid in accordance with Section 33, Clause 4, cannot be claimed or offset against other compensation claims or damages, cf. however Clauses 2 and 3.

Clause 2: If, against their better judgement, the patient or survivor of the patient refrains from giving information or gives incorrect information and the missing information or incorrect information leads

to a different decision than the Patient Compensation Association or its Appeals Board would have passed, if the information had been given or incorrect information had not been given, the Patient Compensation Association or its Appeals Board will pass a new decision. Based on the Patient Compensation Association's or its Appeals Board's new decision, the liable person can demand repayment of compensation and damages paid in accordance with Clause 33, Section 4. The demand for repayment only applies to decisions when the applicable information was significantly important to the outcome of the decision.

Clause 3: Clauses 1 and 2 do not apply to compensation and damages for dental injuries that are awarded by private institutions other than the Danish Compensation Association with whom the Minister for Health has entered into an agreement in accordance with Section 19, Clause 6.

Section 34: (Repealed)

Section 35: (Repealed)

Section 36: (Repealed)

Section 37: In accordance with Section 30, Clause 1, etc., the Patient Compensation Association can demand that regional and municipal councils, customs and tax authorities and others, including hospitals, institutions, treating doctors and other health professionals, the Danish Health Authority, Labour Market Insurance, insurers and the injured party disclose all information, including hospital medical records, record entries, police reports, autopsy reports, information from insurance and pension companies, etc., that the

Association deems important for processing cases in accordance with this Chapter. The information must be sent to the Patient Compensation Association within 30 days after receiving the request. If it is not possible to meet the deadline, the Patient Compensation Association must be informed of the reason for not meeting the deadline prior to expiration, and when it can be expected that the request will be fully processed. The information can be collected electronically. The Patient Compensation Association and the Danish Health Authority can gain access to the terminal for information in the income register.

Clause 2: The Patient Compensation Association shall submit the information to its Appeals Board and the Ministry of Health, which is necessary in order for these authorities to carry out tasks in accordance with this Chapter.

Chapter 4

Compensation for pharmaceutical injuries

Scope of application

Section 38: Compensation is paid to patients who sustain an injury due to the characteristics of pharmaceutical drugs used during an examination, treatment, etc., (pharmaceutical injuries) in accordance with the rules set out in this Chapter. This also applies to the survivors of such patients.

Clause 2: Individuals who take part in clinical trials with drugs (scientific health studies), that is not part of the diagnosis or treatment of the individual's disease or illness, are considered equal to patients. This also applies to patients from whom

tissue and other biological material is taken.

Clause 3: With pharmaceutical injuries, no distinction is made between a personal injury caused by a pharmaceutical drug used for personal care or to treat the person and for whom the drug is prescribed. Compensation is only paid if the injury is not covered by the Danish Workers Compensation Act.

Clause 4: The Minister for Health can determine additional rules on which injuries under Clauses 1-3 are covered by this Chapter.

Section 39: Compensation is only paid if the pharmaceutical drug is commercially dispensed in Denmark for consumption or clinical trials with pharmaceutical drugs. The drug shall be dispensed through a pharmacy, hospital, doctor, dentist or approved non-pharmacy sales outlet for over the counter pharmaceutical drugs in accordance with the Danish Medicines Act.

Section 40: By a pharmaceutical drug it is meant a product that is presented as a suitable agent to treat or prevent human diseases/illnesses or one that can be used or administered to humans to either restore, change or affect physiological functions with a pharmacological, immunological or metabolic effect or to set a medical diagnosis.

Clause 2: The pharmaceutical drug must be approved for marketing in Denmark in accordance with the regulations. However, this does not apply to pharmaceuticals used in clinical trials, cf. Section 38, Clause 2.

Clause 3: Compounded pharmaceuticals and drugs that are imported for certain

individuals with prior permission from the Danish Medicines Agency fall under the rules of this Chapter.

Clause 4: Herbal medicines, homeopathic medicines, vitamin and mineral supplements do not fall under this Chapter. However, this does not apply if these products are used in clinical trials (scientific health studies) with the objective of obtaining marketing permission as a pharmaceutical drug, cf. Clause 2, first sentence.

Clause 5: The Minister for Health can determine additional rules on which pharmaceutical drugs, etc., in accordance with Clauses 1-4, fall under this Chapter.

Section 41: A pharmaceutical injury caused by a prescription drug is only compensated if the drug was prescribed for the injured party.

Section 42: A pharmaceutical injury is not considered a disease or other injury:

- 1) caused by the drug not having the intended effect on the patient concerned; or
- 2) one that is caused by a mistake or negligence in connection with the prescription or dispensing of the drug to the patient.

Section 43: A pharmaceutical injury that is caused by the side effects of a pharmaceutical drug is only compensated if the nature or scope of the side effects affect the injured party in a way that is in all fairness acceptable. The provision includes both known and unknown side effects, as well as those that are expected and unexpected.

Clause 2: When making a decision in relation to Clause 1, emphasis should be placed on the following:

- 1) The nature and severity of the disease/illness for which the treatment was intended.
- 2) The injured party's state of health.
- 3) The scope of the injury; and
- 4) Other possibilities for taking into account the risk of injury.

Clause 3: The Minister for Health can determine additional rules on which injuries, in accordance with Clauses 41-43, fall under this Chapter.

Section 44: Compensation is only paid if the injury was most probably caused by taking or using the pharmaceutical drug.

Section 45: All authorised health personnel are responsible for informing the injured party if they become aware of injuries in their undertaking that will give entitlement to compensation under this Chapter and to the extent necessary assist the patient with reporting the matter to the Patient Compensation Association.

Compensation sum, etc.

Section 46: Compensation and damages are determined in accordance with the provisions of the Danish Liability for Damages Act, cf. however this Chapter.

Clause 2: Compensation is paid after DKK 7,300 has been deducted from the main sum of compensation or damages.

Clause 3: The Health Minister can determine provisions stating that compensation will only be paid for lost

earnings and damages for pain and suffering if the injury results in incapacity for work or illness beyond a specified period, but no longer than three months.

Clause 4: Clauses 2 and 3 do not apply to pharmaceutical injuries that fall under Section 38, Clause 2.

Clause 5: The amount determined in Clause 2 is adjusted on 1 January each year by 2.0 per cent with the adjustment rate for the applicable financial year added, cf. the Danish Rate Adjustment Percentage Act.

Section 46 a: Section 24 a shows a similar application to cases that fall under this Chapter.

Section 47: Compensation is not paid to cover derivative recourse claims, cf. the Danish Liability for Damages Act, Section 17.

Section 48: Compensation to the patient or the patient's survivor can be reduced or in some circumstances revoked if the patient contributed to the injury through gross negligence or with intent.

Section 49: Serial injuries are understood to be pharmaceutical injuries suffered by several individuals caused by the same characteristics of the same substance in one or multiple pharmaceutical drugs; and:

1) concern side effects that were not specified by the Danish Medicines Agency approved summary of the drug's characteristics or registered drug catalogue on the date the drug was dispensed and the subsequent injury was of such a nature that a professional should have predicted

the injury at the time the drug was dispensed; or

2) were caused by a defect in the drug as result of an error(s) in instructions, manufacturing or distribution.

Clause 2: A serial injury is attributed to the year in which the first compensation claim was submitted to the Minister for Health or Patient Compensation Association, cf. Section 55, regardless of when later injuries are reported.

Section 50: The compensation sum for injuries in accordance with the law are limited to DKK 150 million per calendar year.

Clause 2: However, the compensation sum for each serial injury, cf. Section 49, is limited to DKK 100 million.

Clause 3: The compensation sum for pharmaceutical injuries in connection with clinical trials on drugs (scientific health studies) is limited to DKK 25 million per trial.

Clause 4: Compensation cannot exceed DKK 5 million per injured party.

Section 51: If the specified sums in Section 50 are not sufficient to cover all the claims of the injured parties, each claim will be proportionally reduced, however this will only apply to compensation that has not yet been paid. If it is found that such a reduction is necessary after an injury has been sustained, a decision might be made to only temporarily pay a portion of the recognised claim.

Section 52: To the extent that the patient or the patient's survivor has received or is entitled to compensation in accordance

with this Chapter, the compensation claim cannot be filed against anyone, who has incurred liability for the injury.

Clause 2: The provisions of Section 1 will not apply if liability applies in accordance with the provisions of the Danish Product Liability Act.

Section 53: Should the State pay compensation in accordance with this Chapter, the Ministry of Health will become a party to the patient's claim against the manufacturer of the pharmaceutical drug and middlemen in accordance with the Danish Product Liability Act.

Clause 2: The State may pay legal fees, case costs, etc., to obtain compensation from pharmaceutical drug manufacturers and middlemen in accordance with the Danish Product Liability Act, Clause 1. The obtained compensation in connection with this is assigned to the State.

Financing of the compensation scheme

Section 54: The State pays compensation costs and other expenses connected to the compensation scheme.

Clause 2: The Minister for Health calculates and pays compensation. The Minister for Health can authorise others, including private entities, to carry out calculations and pay compensation, etc., in accordance with this provision.

Case processing

Section 55: The Minister for Health processes, discloses and passes decisions on cases in accordance with this Chapter.

Clause 2: The Minister of Health can authorise the Patient Compensation

Association, cf. Chapter 3, to process, disclose and pass decisions on cases in accordance with Clause 1. The expenses of the Patient Compensation Association are hereby paid by the State, cf. Section 54, Clause 1.

Clause 3: The Danish Public Administration will be applied accordingly in cases when the Minister for Health has authorised entities other than public authorities to carry out tasks in accordance with this Chapter.

Clause 4: The Minister for Health or authorised entity thereof can allow witnesses to be heard by the city court in their homestead.

Clause 5: The State pays the determined sum immediately the complaint deadline, stated in Section 58 b, Clause 2, first sentence, expires. However, this does not apply if the decision is appealed.

Section 55 a A refund for compensation and damages paid in accordance with Section 55, Clause 1, cannot be claimed or offset against other compensation claims or damages, cf. however Clauses 2 and 2.

Clause 2: If, against their better judgement, the patient or survivor of the patient refrains from giving information or gives incorrect information and the missing information or incorrect information leads to a different decision than the Patient Compensation Association with the authorisation of the Minister for Health or the Patient Compensation Appeals Board would have passed, if the information had been given or incorrect information had not been given, the Patient Compensation Association or its Appeals Board will pass a new decision. Based on the Patient

Compensation Association's or its Appeals Board's new decision, the Minister for Health or authorised entity thereof can demand repayment of compensation and damages paid in accordance with Clause 55, Sections 1 and 2. The demand for repayment only applies to decisions when the applicable information was significantly important to the outcome of the decision.

Section 56: (Repealed)

Section 57: (Repealed)

Section 58: In accordance with Section 30, Clause 1, etc., the Minister for Health or authorised entity thereof can demand that regional and municipal councils, customs and tax authorities and others, including hospitals, pharmacies, institutions, treating doctors and other health professionals, the Danish Health Authority, Labour Market Insurance, insurers and the injured party and relevant pharmaceutical company disclose all information, including hospital medical records, record entries, police reports, autopsy reports, information from insurance and pension companies, etc., that is deemed important for processing cases in accordance with this Chapter. The information must be sent to the Patient Compensation Association within 30 days after receiving the request. If it is not possible to meet the deadline, the Patient Compensation Association must be informed of the reason for not meeting the deadline prior to expiration, and when it can be expected that the request will be fully processed. The information can be collected electronically. The Patient Compensation Association and the Danish Health Authority can gain access to the terminal for information in the income register.

Clause 2: The Minister for Health, or entity the Minister authorises to carry out tasks in accordance with this Chapter, shall submit information to the Patient Compensation Appeals Board that will enable the Board to maintain its tasks in accordance with this chapter.

Chapter 4 a:

Patient Compensation Appeals Board

Section 58 a The Minister for Health shall establish an appeals board for the Patient Compensation Association consisting of a Chair and one of the Minister's determined number of Deputy Chairs and appointed members.

Clause 2: The Minister for Health appoints the Chair and Deputy Chairs. The Chair and at least three Deputy Chairs must be high court judges. The other Deputy Chairs must be judges. The other members are appointed by the Danish Health Authority, the Association's regional councils, the National Association of Local Authorities in Denmark (KL), Insurance & Pension Denmark, the Danish Bar and Law Society, the Danish Consumer Council, Disabled People's Organisations Denmark and Danish Patients.

Clause 3: The Danish Health Authority appoints a number of professionally qualified expert members in the areas of expertise necessary to process the cases.

Clause 4: When deciding individual cases, the appeals board shall consist of:

- 1) the Chair or one Deputy Chair;
- 2) two expert members appointed by the Danish Health Authority in accordance with Clause 3;

- 3) one member appointed by the Association's regional councils;
- 4) one member appointed by the National Association of Local Authorities in Denmark (KL);
- 5) one member appointed by Insurance and Pension;
- 6) one member appointed by the Danish Bar and Law Society;
- 7) one member appointed by the Danish Consumer Council;
- 8) one member appointed by the Disabled People's Organisations Denmark; and
- 9) one member appointed by Danish Patients.

Clause 5: The Chair or applicable Deputy Chair decides which expert members shall take part in deciding each case based on the area of expertise concerned or area in which they shall take part in accordance with Clause 4 (2).

Clause 6: The appeals board is quorate when a case is decided and the board consists of a Chair or one Deputy Chair and at least four members, of which at least one member falls under Clause 4 (2) and (6,) respectively, one member under Clause 4 (3), (4) or (5), and one member under Clause 4 (7), (8) or (9).

Clause 7: The Minister of Health can authorise the board's Chair or one Deputy Chair to pass a decision on a case when no doubt is deemed to exist.

Clause 8: The members of the board are appointed for four years. If an appointment is made during a term, it will only apply until the end of the term.

Clause 9: The Minister of Health determines the board's rules of procedure after negotiating with the board.

Clause 10: The Patient Safety Authority provides secretariat assistance for the disposal of the appeals board.

Clause 11: Section 18 also applies to payment of the appeals board's operational expenses.

Section 58 b: The decisions passed in accordance with Sections 33 and 55 can be appealed before the Patient Compensation Appeals Board, which will pass the final administrative decision. The Appeals Board can reaffirm, repeal or change the decision.

Clause 2: Complaints to the Patient Compensation Appeals Board must be submitted within one month after the complainant is informed of the decision. The complaint has a suspensive effect.

Clause 3: The Patient Compensation Appeals Board can ignore breach of the complaint deadline if there is special reason to do so.

Clause 4: The second sentence of Clause 2 does not apply to compensation and damages for dental injuries that are awarded by private institutions other than the Danish Compensation Association with whom the Minister for Health has entered into an agreement in accordance with Section 19, Clause 6.

Section 58 c: Patient complaints that fall under Section 58 b shall be submitted to the Patient Compensation Association through the digital solution provided by the Patient Safety Authority (digital self-

service). Complaints that are not submitted through digital self-service will be rejected by the Patient Safety Authority, cf. however Clauses 2 and 3.

Clause 2: If the Patient Safety Authority finds that special circumstances prevent the citizen from using digital self-service and cannot therefore be expected, the Patient Safety Authority shall offer the complainant an alternative method to submission via digital self-service in accordance with Clause 1. The Patient Safety Authority decides how a complaint affected by the first sentence is to be submitted, including whether it shall be submitted orally or in writing.

Clause 3: In extraordinary situations, beyond those mentioned in Clause 2, the Patient Safety Authority can decide not to reject a complaint that has not been submitted via digital self-service if it benefits the Patient Safety Authority to receive the complaint in an alternative way based on an overall financial assessment.

Clause 4: A digital complaint is considered received as soon as it is made available to the Patient Safety Authority.

Clause 5: Decisions passed by the Patient Safety Authority in accordance with Clauses 1-3 cannot be brought before any other administrative authority.

Section 58 d: Decisions passed by the Patient Compensation Appeals Board can be brought before a court of law, which can reaffirm, revoke or change a decision.

Clause 2: The decision must be brought to a court of law within six months after the decision has been announced.

Chapter 5

Statute of limitation and penalty provisions

Section 59: Compensation claims under Chapter 3 must be reported to the Patient Compensation Association within three years after the person entitled to compensation has been notified or should have been notified of the injury.

Clause 2: However, the statute of limitation for compensation claims will be effectuated within 10 years after the date on which the injury was sustained.

Section 60: Compensation claims under Clause 4 must be reported to the Minister of Health, or entity the Minister authorises to carry out tasks in accordance with this Chapter, within three years after the person entitled to compensation has been notified or should have been notified of the injury.

Clause 2: However, the statute of limitation for compensation claims in accordance with this Chapter will be effectuated within 10 years after the date on which the pharmaceutical drug was dispensed to the injured party.

Section 60 a: Notification of a compensation claim submitted to the Patient Safety Authority in accordance with Chapters 3 and 4, are considered submitted to the correct authority once they have been received by the Patient Safety Authority, cf. Sections 59 and 60. Notifications are immediately forwarded to the correct authority.

Section 60 b: Should a binding decision be passed regarding recognition of an injury that falls under Chapter 3 or 4, or measurement of compensation for such an

injury, a limitation deadline of three years from the decision date will be applied to claim compensation for the injury.

Clause 2: However, if the person entitled to compensation was unaware of the compensation claim, the limitation deadline under Clause 1 will apply from the date on which the person was notified or should have been notified of the claim.

Clause 3: The statute of limitation is effectuated within 10 years after the said decision in Clause 1, but within 30 years after the date on which the injury was sustained or the pharmaceutical drug was dispensed to the injured party.

Section 61: If a health professional does not comply with an obligation in accordance with Section 12, Clause 2, Section 16, Clause 1, Section 33, Clause 2, Section 37, Clause 1 or Section 58, Clause 1, the person will be punished with a fine.

Section 62: Violation of Section 30, Clause 1, is punished with a fine. Companies, etc., (legal persons) can be imposed criminal liability in accordance with the provisions of the Danish Criminal Code, Chapter 5.

Chapter 6

Entry into force, etc.

Section 63: The Act enters into force on 1 January 2007, cf. however Clauses 3 and 4.

Clause 2: At the same time, the following provisions of law will be repealed:

1) Chapter 3 and Section 27, Clauses 2 and 3 of the Danish Central Administration of the Health Service, etc., cf. Consolidation Act, No. 790 of 10

September 2002, as last amended by Section 20 of Act No. 69 of 4 February 2004.

2) Danish Patient Insurance Act, cf. Consolidation Act, No. 228 of 24 March 1997. The Act will continue to be applied to injuries sustained before the entry into force of the Act herein.

3) Danish Act on Damages for Pharmaceutical Injuries of 20 December 1995, No. 1120. The Act will continue to be applied if the pharmaceutical drug that caused the injury was dispensed to the injured party before entry into force of the Act herein.

Clause 3: (Omitted)

Clause 4: (Omitted)

Clause 5: Rules determined pursuant to the Danish Central Administration of the Health Service Act, Chapter 3, and others, the Patient Insurance Act and Act on Damages for Pharmaceutical Injuries will remain in force until they are repealed or replaced by rules determined in accordance with the Act herein.

Section 64: The Act does not apply to the Faeroe Islands and Greenland. In the case of Greenland, however, it can enter into force through a Royal Decree with the deviations the special Faroese conditions imply.