Act on Patient Safety in the Danish Health Care System

ACT No. 429 of 10/06/2003 (Current)

Subsequent changes to the instructions

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Act on Patient Safety in the Danish Health Care System

WE MARGRETHE THE SECOND, by the grace of God Queen of Denmark, hereby make known: Folketinget has passed and We have by Our Consent confirmed the following Act:

Part 1

Objective, applicability, definitions etc.

1. – (1) The objective of the Act is to improve patient safety within the Danish health care system. The Act shall apply to the reporting of adverse events occurring in connection with the treatment of patients within the health care system, however, cf. subsection (2) below.

(2) The Minister for the Interior and Health may lay down rules as regards the applicability of the Act to the primary health care sector including health care professionals in private practice. The Minister may specify deviations from the provisions of the Act which may be justified by special circumstances within the primary health care sector.

(3) The National Board of Health may lay down rules on which hospitals and other institutions of treatment are subject to the duty to report, and the Board may also lay down special rules for the reporting system of private hospitals.

(4) The provisions of this Act concerning counties shall also apply to the Copenhagen Hospital Corporation, the municipalities of Copenhagen and Frederiksberg and the municipality of Bornholm as well as private hospitals.

(5) The provisions of this Act shall not apply to other statutory reporting systems regarding adverse events or errors occurring during treatment. The National Board of Health may in cooperation with the authorities concerned lay down rules specifying and perhaps coordinating reporting circumstances, cf. the first sentence.

2. – (1) An adverse event shall mean an event resulting from treatment by or stay in a hospital and not from the illness of the patient, if such event is at the same time either harmful, or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons. Adverse events shall comprise events and errors known and unknown.

(2) For the purposes of this Act health care professionals shall mean people who are authorised under special legislation to carry out specialist health care tasks and people acting on their responsibility.

(3) For the purposes of this Act treatment shall mean examination, diagnosis, clinical treatment, rehabilitation, specialist health care and prophylactic health care measures in relation to the individual patient.

Part 2

Patient safety systems

3. – (1) County councils shall receive, record and analyse reports on adverse events for use in the improvement of patient safety and treatment and for the reporting of information to the National Board of Health, cf. section 4 below.

(2) A health care professional, who becomes aware of an adverse event in connection with a patient's treatment or stay in a hospital, shall report such event according to subsection (1) above.

4. – (1) The National Board of Health shall receive reports on adverse events from the county councils and shall establish a national register for such events. On the basis of the information received the National Board of Health shall advise the health care system on patient safety.

(2) The National Board of Health shall lay down rules on which adverse events shall be reported by the county councils to the National Board of Health, when and in which format such reporting shall take place as well as its contents. Similarly, the National Board of Health shall lay down rules on the cases in which health care personnel shall report adverse events to the county council, when and in which format such reporting shall take place as well as its contents.

(3) The National Board of Health may from county councils obtain additional information about reported events for use in the Board's advisory work, cf. subsection (1) above.

(4) The National Board of Health may from county councils obtain information from patient registers and other registers as well as information from accounts and budgets for use in the Board's advisory work, cf. subsection (1) above.

(5) In the reports of adverse events from county councils' to the National Board of Health pursuant to subsections (1) and (3) above both patient and health care professional shall be anonymous.

(6) The National Board of Health shall issue an annual report on its activities pursuant to this Act.

Part 3

Disclosure of information etc.

5. – (1) Reports on adverse events, which may be attributed to specific individuals, may without the consent of the patient or the involved health care personnel be exchanged within the group of people who locally, within the county council, handle tasks pursuant to section 3(1) above, and may be passed on to clinical databases and other registers where health information is recorded with a view to documentation and quality development within the patient safety area.

(2) County councils shall not disclose information about the reporting health care professional's identity to anybody except the people carrying out tasks pursuant to section 3(1) above.

6. A health care professional reporting an adverse event shall not as a result of such reporting be subjected to disciplinary investigations or measures by the employing authority, supervisory reactions by the National Board of Health or criminal sanctions by the courts.

Part 4

Commencement and transitional provisions etc.

7. – (1) This Act shall come into force on 1 January 2004, however, cf. subsection (2) below. The Act shall apply to all adverse events occurring after its commencement.
(2) Section 8 shall come into force on 1 July 2003.

8. The following amendments shall be made to the Act on the Danish Health Care System, cf. Consolidated Act No. 687 of 16 August 1995 as amended, most recently by Act No. 145 of 25 March 2002:

1. The heading of Part 3 shall be phrased as follows:

»Speciality planning and recording of clinical data etc.«

2. The following shall be inserted in Part 3 after section 15:
» 15 a. – (1) The Minister for the Interior and Health may lay down rules specifying that county councils, town councils, private individuals and institutions running hospitals as well as practicing health care professionals shall report information to clinical quality databases for which a public authority is responsible and where health information etc. is recorded with a view to monitoring and developing treatment results for limited patient groups.
(2) The Minister for Internal Affairs and Health may determine that a registered person shall on request be entitled to have access to the information recorded about that person in the clinical quality databases mentioned in subsection (1) above.
(3) Information reported pursuant to subsection (1) above, which may be attributed to specific individuals, may be reported without the consent of the individual in question.«

9. The Act shall not extend to the Faroe Islands or Greenland, but may by Royal decree be extended to the Faroe Islands with the variations dictated by special Faeroese conditions.

Given at Christiansborg Castle, 10th June 2003

Under Our Royal Hand and Seal

MARGRETHE R.

/Lars Løkke Rasmussen