

Unfit to practise – the Swedish regulatory system and support from the Swedish Medical Association

Tomas Hedmark, legal advisor, The Swedish Medical Association

Patient Safety Act

- **Basic rules regarding responsibilities of health care providers and health professionals and about supervision of health care and health professionals**
- **Aim: Promote and enhance patient safety, in order to try to prevent adverse events/patient harm**
- **More proactive patient safety work**
- **Greater focus on systematic causes than individual mistakes made by health professionals**

Health care providers' legal responsibilities

- Provide high quality care
- Plan, organize and supervise its activities, to ensure the obligation to provide high quality care is fulfilled
- Have and implement the guidelines and routines necessary for high quality care
- Work proactively to try to prevent adverse events/patient harm
- Investigate adverse events that caused or could have caused patient harm
- Receive and answer complaints from patients and relatives of patients
- Report serious events and "risk individuals" to the Health and Social Care Inspectorate

Health care professionals' legal responsibilities

- **Contribute to upholding a high level of patient safety.**
For this purpose **Report to the health care provider risks and events that caused or could have caused patient harm**
- **Work according to good medical practice**
- **Individual professional responsibility**

Supervision and complaints – institutions

- Health care provider
- Patients Advisory Committee
- Health And Social Care Inspectorate
- Medical Responsibility Board
- Patient Insurance
- (Courts – damages and criminal prosecution)

Health and Social Care Inspectorate

Swedish supervisory authority - health care providers and health care personnel

Handles complaints/reports from patients/relatives, health care providers and pharmacies + can start investigations without any prior complaint/report

Complaints from patients/relatives:

- investigates provided the health care provider has had opportunity to answer and the complaint deals with a more serious issue that occurred within the last two years
- opportunity to answer the complaint proposed decision decision
- can criticize health care providers and health professionals
- not possible to appeal

Health and Social Care Inspectorate

Report from health care providers of serious events

- Report from health care provider of an *event* that caused or could have caused serious patient harm (serious adverse event)
- Inspectorate can choose to investigate further may criticize

Other Inspectorate investigations

- Report of "risk individual" from health care provider, report from pharmacy, investigation without any prior report/complaint
- Opportunity to answer in writing in-person meeting?
- Inspectorate may criticize or report licensed health professionals to the Medical Responsibility Board



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Den medicinska professionens organisation

Medical Responsibility Board

- Investigates licensed health professionals after report from the Health och Social Care Inspectorate
- Measures:
 - Probation/trial period (3 years)
 - Limit right to prescribe medication
 - Revoke license to practise
- Opportunity to answer in writing
- Appeal to administrative courts
- Apply for new license to practise or unlimited right to prescribe



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Swedish Medical Association support when a physician's fitness to practise is put into question

- In relation to the employer
 - employer responsible for patient safety (should help educate and rehabilitate)
 - "traditional union work"
- In relation to health care providers, authorities and courts
 - information booklet *If I am reported*
 - legal info and advice (discussion, in writing)
 - help with written comments and appeals
 - written opinion from expert physician
- Collegial advisors

Tomas Hedmark

+46 8 790 33 31

tomas.hedmark@slf.se