

# EL2: Swedish legislation

## Laws and regulation

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The Swedish legislation will be discussed as an example. It will be examined through discussions in a later seminar (where you will have access to the information below). You are not required to memorize individual laws or specific legal provisions.

### Background of Swedish law

Optional reading

- **Fundamental laws** (“grundlagar”) decided by the parliament but stable over time
  - Not a “constitution”
- **Ordinary laws** (parliament)
  - New ones all the time
  - New laws to update existing laws
- Published in Svensk författningsamling, SFS
  - The “big blue book” is only a smaller collection of important laws
- **ordinances** (“förordning”) from the government to implement laws
- **regulations** (“föreskrifter”) from authorities to implement laws and ordinances



## **Two main branches of law**

- Civil and criminal law:
  - state what you can not do (everything else is “legal”)
  - Handled by ordinary courts
  - Ex: Brotsbalken kap 20 om tjänstefel m.m. (The Swedish Penal Code (Brotsbalken), Chapter 20 – Offences Relating to Public Office.)
- Public law: relationship between individuals and the state etc
  - state what the public authorities must and can do (everything else is “illegal”)
  - Handled by administrative courts
  - What we mostly care of here

## **Tryckfrihetsförordningen (TF)**

- World's oldest freedom of the press law (since 1766)
- Chapter 2: Public access to official documents
- Applies to public authorities and institutions
  - Including health care registers and medical records held by public authorities
- Everyone has the right to access official documents (TF 2.1)
- but there are exceptions (TF 2.2)
  - e.g., if disclosure would violate privacy or national security
  - if so, the government has the right to provide ordinary laws that restrict access (which they do ...)

## **Offentlighets- och sekretesslagen (OSL)**

- Law that regulates public access to official documents and secrecy
- Applies to public authorities and institutions
- Defines what information is considered secret and under what circumstances

## **OSL Chap 21**

Secrecy for private individuals' personal circumstances **no matter the context**

- E.g., health data, economic circumstances, family relations

OFS 21.1: Secrecy applies to information concerning an individual's health or sexual life, such as information about illnesses, substance abuse, sexual orientation, gender reassignment, sexual offences, or other similar information, **if it can be assumed** that disclosure of the information would **cause significant harm** to the individual or to someone closely related to them.

## **OSL Chap 24**

Secrecy for the protection of individuals in research and statistics.

- Special research databases etc
- Some regulations for research ethics boards

## **OSL Chapter 25**

Secrecy for the protection of individuals in activities relating to **health and medical care** etc.

OFS 25.1: Within the health and medical care services, secrecy applies to information concerning an individual's state of health or other personal circumstances, **unless it is clear** that the information may be disclosed **without causing harm** to the individual or to someone closely related to them. The same applies to other medical activities, such as forensic medical and forensic psychiatric examinations, insemination, in vitro fertilisation, abortion, sterilisation, circumcision, and measures to prevent communicable diseases.

- Exceptions exists,
  - for example to submit medical patient data to quality registers
  - to share data between public organisations for research purposes or statistics (OFS 25.11 p. 5).

## **OSL Chapter 10**

Provisions on disclosure overriding secrecy and provisions on exemptions from secrecy

OFS 10.28: Secrecy does not prevent information from being disclosed to another authority where a duty to provide information follows from an act or an ordinance.

- This would apply to data sharing for research purposes when there is a legal basis for that

## **Patientdatalagen (PDL)**

The Patient Data Act (PDL)

- regulates the processing of personal data within **health and medical care** in Sweden.
- Applies to **healthcare providers** (public and private).
- Main objectives:
  - Protect patient privacy
  - Ensure safe and effective healthcare
  - Enable **secondary use** of health data under strict conditions

## **Chapter 7 PDL**

National and regional quality registers

Opt-out for patients (every one is included by default until they opt out)

PDL 7.4: Personal data in national and regional quality registers may be processed for the purpose of systematically and continuously developing and ensuring the quality of healthcare.

PDL 7.5: Personal data processed for the purposes set out in Section 4 may also be processed for the purposes of

- the production of **statistics**,
- estimating numbers for the planning of clinical research,
- **research within health and medical care**,
- disclosure to a party that will use the data for purposes referred to in Sections 1 and 3 or in Section 4, and
- ...

### **Lag om hälsodataregister (SFS 1998:543)**

This law regulates health data registers outside the health and medical care system. A new law is being proposed to replace this one.

§ 3: Personal data in a health data register may be processed for the following purposes:

- the production of statistics,
- follow-up, evaluation and quality assurance of health and medical care, and
- research and epidemiological studies

### **Specific registers**

Register (Swedish)	Register (English)	Governing act / ordinance
Folkbokföringen	Population Register	Population Registration Act (1991:481); Population Registration Ordinance (1991:749)
Totalbefolkningsregistret (RTB)	Total Population Register	Official Statistics Act (2001:99); Official Statistics Ordinance (2001:100)
Nationella patientregistret	National Patient Register	Health Data Act (1998:543); Ordinance on the National Patient Register (2001:707)
Cancerregistret	Swedish Cancer Register	Health Data Act (1998:543); Cancer Register Ordinance (2001:709)
Dödsorsaksregistret	Cause of Death Register	Health Data Act (1998:543); Cause of Death Register Ordinance (2001:709)
Läkemedelsregistret	Prescribed Drug Register	Act on the Prescribed Drug Register (2005:258); Ordinance (2005:363)
Medicinska födelseregistret	Medical Birth Register	Health Data Act (1998:543); Medical Birth Register Ordinance (2001:708)
Tandhälsoregistret	Dental Health Register	Health Data Act (1998:543); Dental Health Register Ordinance (2008:194)

### **Arkivdatalagen (ADL)**

- Regulates the management of public records and archives

- Applies to public authorities and institutions
- Different authorities then have different rules for how long data must be kept
  - For example healthcare data is often required to be kept for at least 10 years

## **GDPR and Swedish law**

- GDPR is directly applicable in Sweden
- There are references to GDPR in Swedish laws such as PDL and OSL
- Swedish laws may provide additional regulations and requirements beyond GDPR
- Data protection authorities in Sweden: Integritetsskyddsmyndigheten (IMY)
- Should be easy to collaborate across EU borders due to GDPR, but more difficult with non-EU countries

## **Etikprövningsslagen (EPL)**

- Regulates ethical review of research involving humans (including their data!)
  - Had received some criticism and might be revised
- Applies to research projects conducted in Sweden
- Requires ethical review and approval by an ethics review board
- Aims to protect the rights, safety, and well-being of research participants
- Based on the Declaration of Helsinki and other international ethical guidelines
- One application for each new research project
  - Amendments for changes in already approved projects
- Application fees applies
- Swedish Ethical Review Authority

## **Bibliography**