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# **Balancing Regulation and Entrepreneurialism in Europe's Health Care Sector**

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on Health Care Systems

# Topics discussed

Why a study on regulation and entrepreneurialism?

- What is regulation?
  - Why regulate?
  - Who regulates?
  - How to regulate?
  - What to regulate?

– using the example of hospitals

Who is the Observatory and what does it?



# Scenario 1



In an **entrepreneur's ideal world**, one could set up a hospital, determine how to run it and be responsible for all losses and profit,

including the freedom to choose a **location**, determine the **size**, decide on the **range of technology and services** offered, set **price levels** and **refuse to accept certain patients**,

the right to decide on **staffing numbers** and **qualification mix**, the working conditions of the employees and their **salaries**.

There would be **no restrictions on business relationships** with suppliers and other hospitals, including the right for **mergers** and horizontal and vertical **takeovers**.



# Scenario 2



The **national government** - or a subordinated public body such as a Health Authority – establishes hospitals where and at what size deemed necessary according to a **public plan**.

The **authorities determine** the technology installed and the range of services offered. Services are delivered free to all citizens at the point of service, hence **no prices** need to be set.

Staffing and working conditions are decided by the public authorities and standard **public salaries** apply.

As the hospitals are part of the public health services infrastructure, they have **no independent relationships with other actors** and no room for mergers or takeovers.



- **Both hospitals are not regulated,** either **intentionally not to restrict the market** behaviour of the hospital owners/ managers, or due to public sector **”command-and-control”**.
- There has been a visible move towards more autonomy and market-style mechanisms to providers and other actors and to re-direct politics to **“steer-and-channel”**, requiring regulation.
- Hospitals in most European countries now fall somewhere in between the two extremes and require a carefully calibrated set of regulation.



# Public-private ownership of hospital beds in Bismarckian countries

	Public	Not-for-profit	For profit
Austria	69%	26%	5%
Belgium	60%	40%	
France	65%	15%	20%
Germany	55%	38%	7%
Luxembourg	50%	50%	
Netherlands		100%	



# How do countries autonomize?

- purchaser-hospital (provider) split
- introduction of contractual relationships between purchasers and hospitals (like in Bismarckian systems)
- increase decision-latitude of hospital about services, staffing etc.
- increase financial autonomy (“residual claimant” status)



# Regulation in the health sector can mean any of these things:

**Mandatory rules**  
enforced by a state  
agency



**All state efforts** to steer the sector  
(including state ownership,  
contracting, taxation and incentives)



**All social control mechanisms**  
(including non-governmental tools as professional  
norms or societal values)

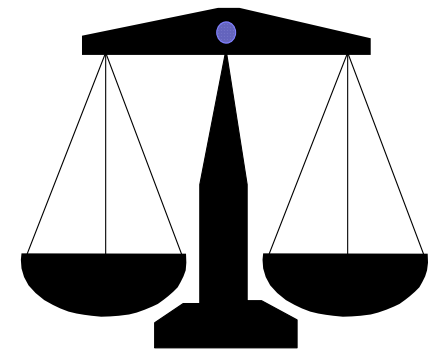


# Why Regulate?

## Rationale for Health Sector Regulation

To achieve **social objectives**, e.g.:

- **Equity and justice**: Ensuring needs-based access to health care for the whole population including elderly, poor, rural etc.
- **Social cohesion** through NHS or SHI
- Individual **choice** of provider and/or insurer.
- **Health and safety**: worker protection, public health, health service effectiveness
- Economic **efficiency**



# Why Regulate?

## Rationale for Health Sector Regulation

To address the question “**How are we going to make it work better?**”, e.g. by:

- **effectiveness** and **quality** of services: assessing cost-effectiveness and deciding upon benefits basket (incl. positive/negative lists), training health professionals, accrediting providers,
- **patient access**: gate-keeping, co-payments, rules for subscriber choice among third-party payers, GP location planning,
- **provider behaviour**: transforming hospitals into public firms, capital borrowing,
- rules for **contracting** between payers and providers



# Who Regulates?

## “Governmental” Regulation

De facto more complicated:

- Parliament/ legislative branch: laws
- Cabinet/ executive branch: decrees
- Courts/ juridicial branch: rulings
- Devolution to regional/ local authorities
- Independent Regulatory Authorities/ Agencies



# Who Regulates?

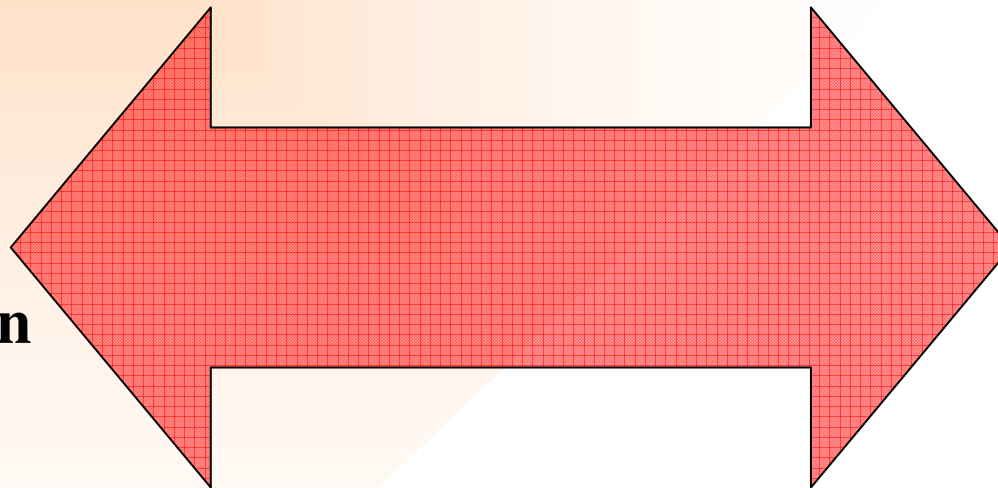
## (Enforced) Self-Regulation

**Low**

*Degree of government enforcement*

**High**

**Purely  
private  
self-regulation**



**State-mandated  
self-regulation**

*e.g. certification  
by professional  
associations,  
contracts between  
sickness funds and  
providers*



# Self-Regulation

## Advantages and Disadvantages

### Advantages

- High commitment to own rules.
- Low costs to government.
- Enforcement and complaints procedures more effective.

### Disadvantages

- Professional self-interest.
- Legal oversight may be problematic.
- Inappropriate for areas as antitrust regulation.

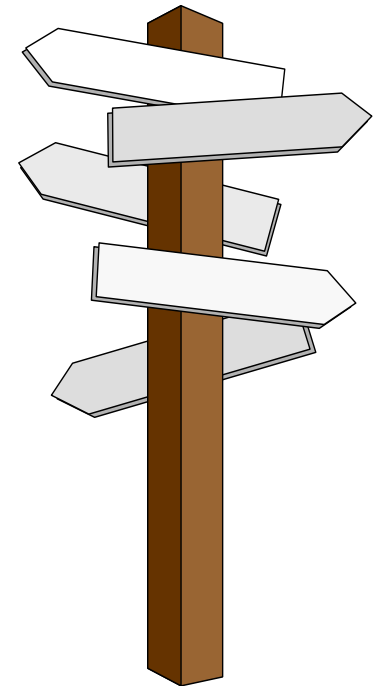


# Who Regulates?

## Government versus Self-regulation

**Who** regulates **what** depends upon:

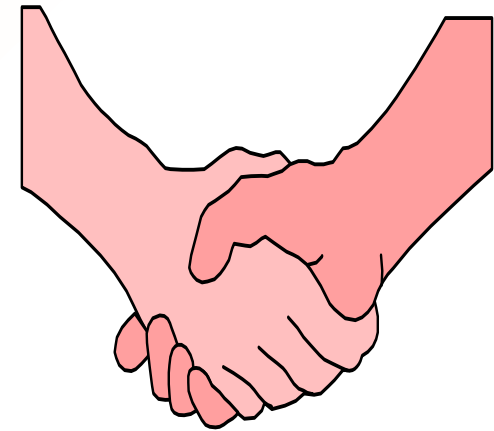
- The type of **activity** being regulated.
- The **segment** of the health system being regulated (hospitals, physicians, insurers).
- The **capacity** of various regulators.
- A variety of **national factors** including institutional structure and cultural traditions.



# Government Versus Self-regulation

## The International Experience

- **Efficiency** (e.g. capacity, antitrust) regulation is mainly *governmental*.
- **Quality** issues are good candidates for *self-regulation*.



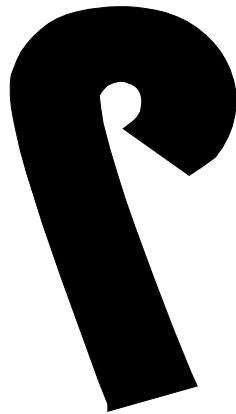
# How to Regulate?

## Overall Regulatory Strategies

### Legal controls

*“The stick”*

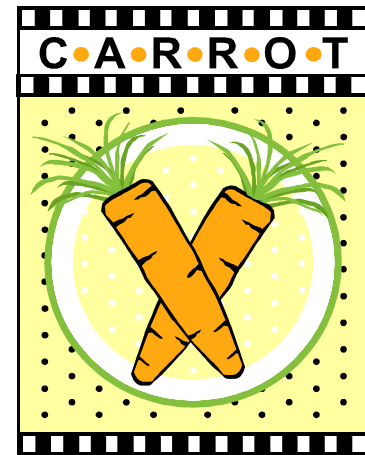
*Providers must conform to legislative requirements and face punishment if they don't.*



### Incentive Schemes

*“The carrot”*

*Providers modify their behavior in response to incentives.*





# Types of regulation by intention and impact

- **Pro-competitive** regulation that **stimulates** market opportunities
- **Pro-competitive** regulation that **restricts individual** market-driven behaviour
- Regulation restricting hospitals to achieve **social objectives** as access, social cohesion, public health/ safety, quality, and sustainable financing
- Regulation **without good reasons**



# Pro-competitive regulation that stimulates market opportunities

- Replace input-oriented budgets with contract-based performance-related reimbursements
- Allow retention of surplus/ profit
- Allow patients to choose the hospital for treatment (with or without GP guidance)
- Let money follow patient choice of hospital
- European Union regulations on free movement of services



# Pro-competitive regulation that restricts individual market-driven behaviour

- Include case-mix adjusters into flexible reimbursement system (i.e. restrict adverse selection)
- Restrict (horizontal) mergers and acquisitions of other hospitals
- Restrict (vertical) mergers, acquiring and operating other healthcare institutions



# Regulation restricting hospitals to achieve social objectives

- Regulate minimum service hours
- Mandate delivery of services to everybody
- Make accreditation/ quality assurance/ health technology assessment mandatory
- Mandate the public disclosure of performance (“league tables”)
- Set uniform or maximum price/ reimbursement or regulate that it is done by self-governing actors



# What areas need to be regulated?

- To **enable hospital care**: establishment of hospitals, capacity and technology
- To **specify and reward hospital services**: access, types, quality and prices
- To **protect hospital employees**
- To **steer the business behaviour** of hospitals: e.g. mergers, financial reserves, advertisements



# Enabling hospital care



- Planning of capacities, ex-ante (= before hospitals are built) or ex-post (= contracts for existing hospitals)
- Combining planning with money for investments
- “Certificate of need“ for high technology



# Specifying and rewarding hospital services

- **Access:** disallow patient selection, mandate non-scheduled admissions, require physician staffing around the clock, allow patient choice
- **Types of services:** There may be a case to restrict certain ambulatory services if they can be delivered more efficiently outside hospitals.
- **Quality:** require accreditation, QA programmes
- **Prices:** transparency and administrative ease are advantages of uniformly regulated prices but ...



# Protecting hospital employees

- equal treatment, opportunities and pay for men and women (76/207/EEC and 75/117/EEC)
- right to part-time work (97/81/EC; 98/23/EC)
- safeguarding of employees' rights in the event of transfers of undertaking, businesses or parts of businesses (77/187/EEC; 98/50/EC)
- working times (93/104/EC)





Finally, remember that regulation is an inherently **political** and **cultural** process. There is no universally appropriate model.

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Illustrations of this can be found in:  
R.B. Saltman/ R. Busse/ E. Mossialos:  
**Regulating entrepreneurial behaviour  
in European health care systems**

European Observatory on Health Care Systems series  
Open University Press, February 2002



# The European Observatory on Health Care Systems

- supports and promotes **evidence-based health policy-making**
- by bridging the gap between scientific evidence and policy-makers' needs
- through comprehensive and rigorous analysis of the dynamics of health care systems in Europe.



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on Health Care Systems

# „Regulating Entrepreneurial Behaviour in European Health Systems“

is part of a new book series published with Open University Press. Other volumes include:

- **The appropriate role for hospitals**
- **Funding health care – options for Europe**
- **Health Care in Central Asia**

In progress: „Social Health Insurance countries in western Europe“, „Successful purchasing for health gain“, „Health and accession“ and „Putting primary care in the driver’s seat“



Another „product line“ are the „HiT“ profiles, available for almost 40 countries at [www.observatory.dk](http://www.observatory.dk)



# Basic philosophy of “HiT” profiles

- HiTs are based on a common set of questions and follow the same structure.
- This enables comparisons between countries and within countries over time.
- The HiTs will be updated every 2-3 years.
- Production is based on co-operation: In-country authors provide inside knowledge, external reviewers add a broad range of views and editors guarantee a similar standard across all countries.



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