Keynote Address, RAPS (Regulatory Affairs Professionals Society)
European Conference 2002, Budapest, 7 May 2002

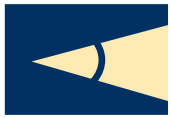
Balancing Regulation and Entrepreneurialism in Europe´s Health Care Sector

Reinhard Busse, Prof. Dr. med. MPH

Associate Research Director,
European Observatory on Health Care Systems

Professor and Director, Department Management in Health Care,
Technische Universität Berlin, Germany

European Observatory on Health Care Systems



Topics discussed

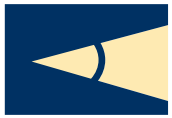
Why a study on regulation and entrepreneurialism?

- 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?

European Observatory on Health Care Systems



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 infra-structure, they have **no independent relationships with other actors** and no room for mergers or takeovers.

European Observatory on Health Care Systems

- 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

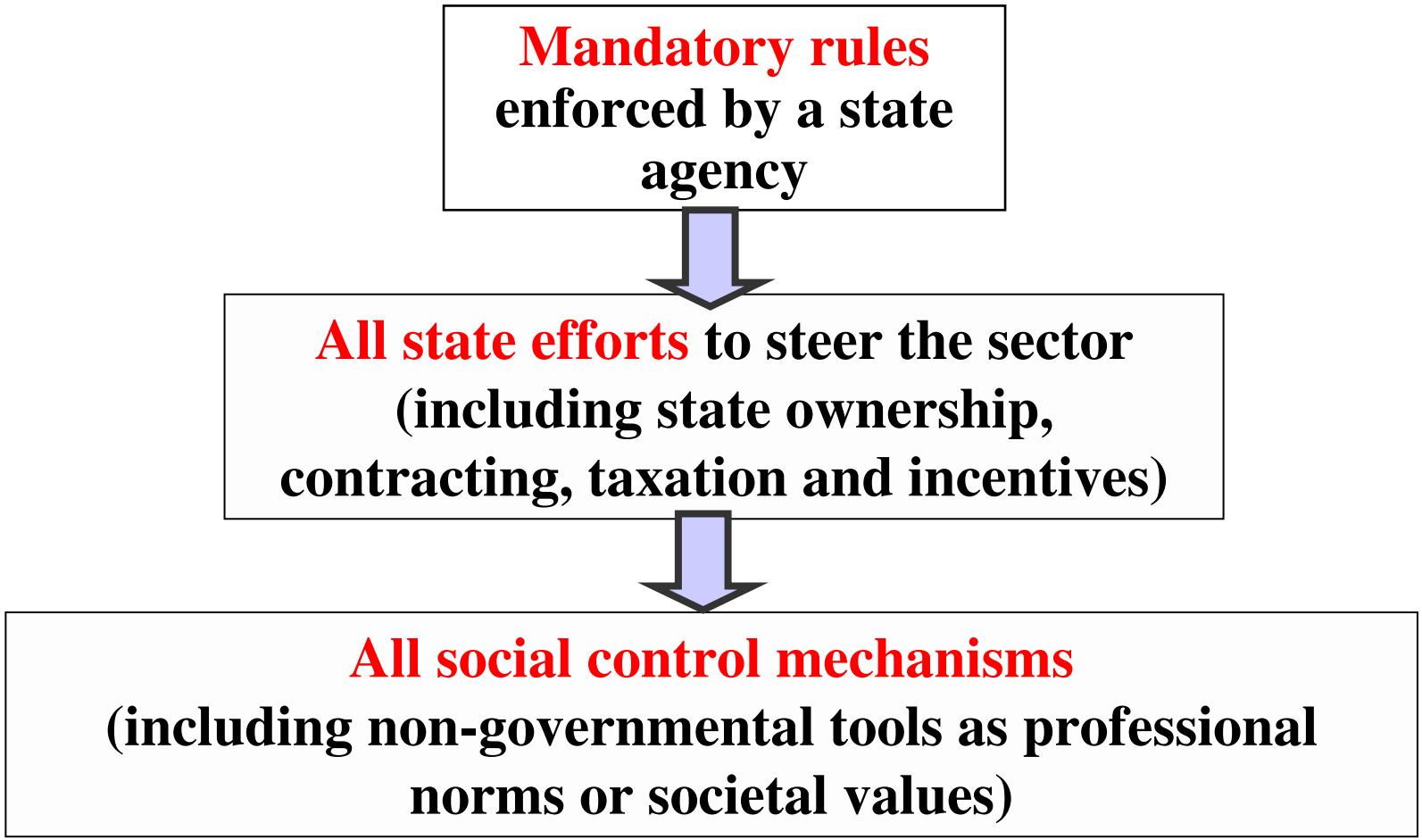
	Public	Not-for-profit	For profit
Austria	69%	26%	5%
Belgium	60%	40%	
France	65%	15%	20%
Germany	55%	38%	7%
Luxembourg	50%	50%	
Netherlands		100%	

European Observatory on Health Care Systems

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)

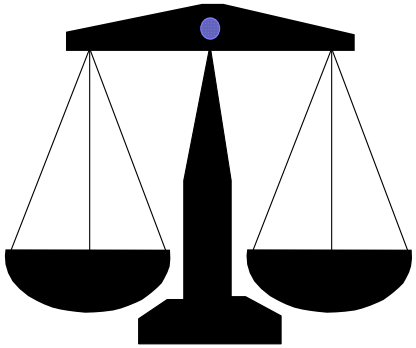
Regulation in the health sector can mean any of these things:



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

European Observatory on Health Care Systems

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/ negtive 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

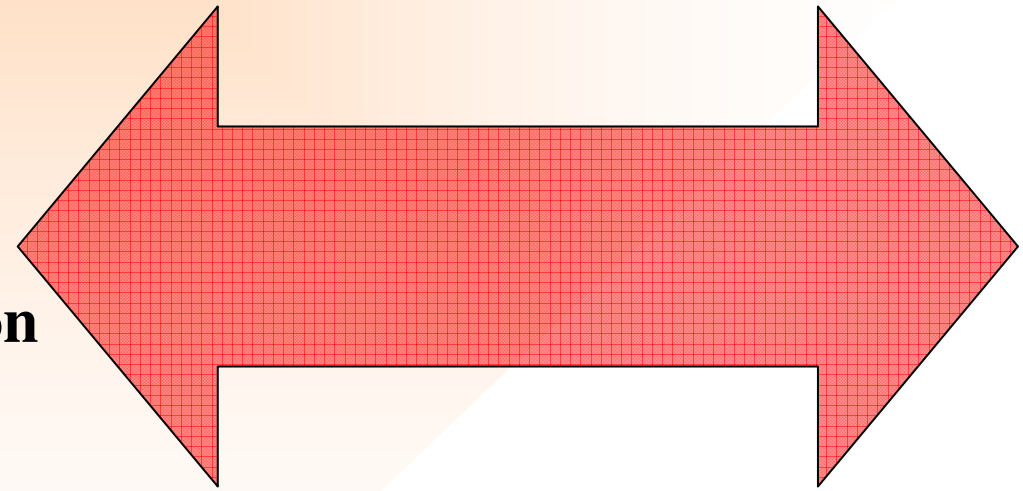
De facto more complicated:

- 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

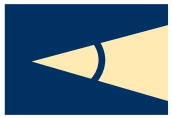
e.g. certification by professional associations, contracts between sickness funds and providers

European Observatory on Health Care Systems

Self-Regulation

Advantages and Disadvantages

Advantages	Disadvantages
• High commitment to own rules. • Low costs to government. • Enforcement and complaints procedures more effective.	• Professional self-interest. • Legal oversight may be problematic. • Inappropriate for areas as antitrust regulation.

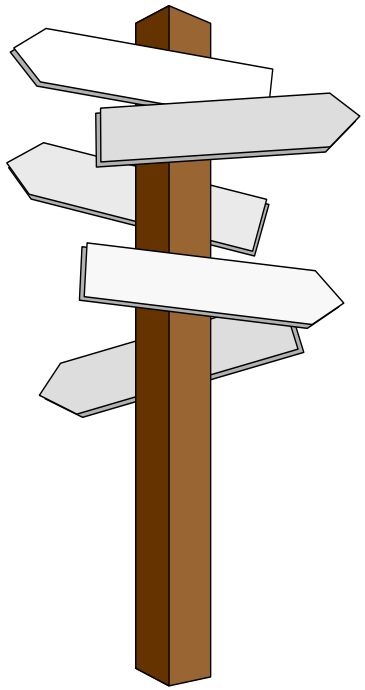


Who Regulates?

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.

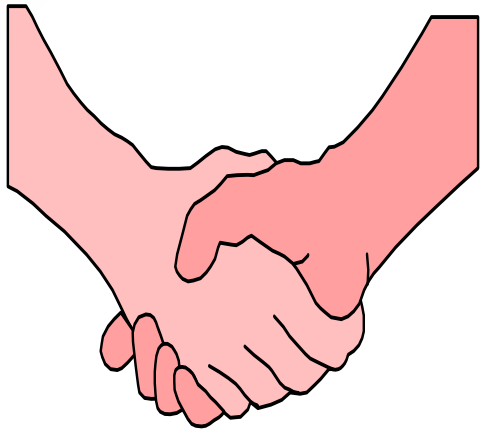


European Observatory on Health Care Systems

Government Versus Self-regulation

The International Experience

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



European Observatory on Health Care Systems

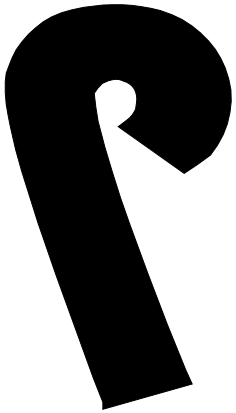
How to Regulate?

Overall Regulatory Strategies

Legal controls

"The stick"

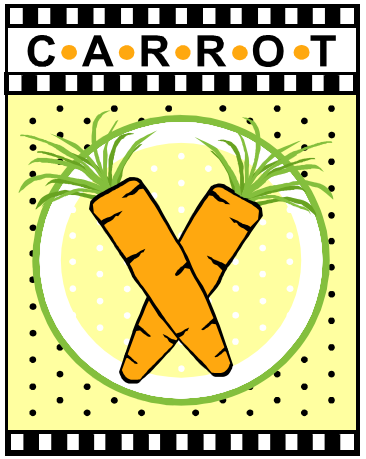
Providers must conform to legislative requirements and face punishment if they don't.



Incentive Schemes

"The carrot"

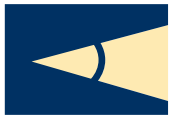
Providers modify their behavior in response to incentives.



European Observatory on Health Care Systems

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 reim-bursement 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

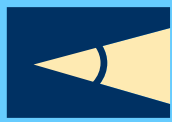
European Observatory on Health Care Systems

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.

Illustrations of this can be found in:

R.B. Saltman/ R. Busse/ E. Mossialos:

Regulating entrepeneurial behaviour in European health care systems

European Observatory on Health Care Systems series

Open University Press, February 2002

European Observatory on Health Care Systems

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.

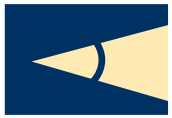
European Observatory on Health Care Systems

... founded on partnership

WHO Regional Office for Europe
Government of Greece
Government of Norway
Government of Spain
World Bank
Open Society Institute
European Investment Bank
London School of Economics and Political Science
London School of Hygiene & Tropical Medicine

Offices in:
Copenhagen/ Brussels
London
Madrid
Athens (SE Europe)
Berlin (Central Europe)

European Observatory 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“

European Observatory on Health Care Systems

Another „product line“ are the „HiT“ profiles, available for almost 40 countries at 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.

European Observatory on Health Care Systems

www.observatory.dk

European Observatory on Health Care Systems