

## **209: HEALTHCARE REGULATION IN THE UNITED STATES AND THE UNITED KINGDOM: LESSONS FOR QUALITY IMPROVEMENT**

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### **Objective:**

The regulation of healthcare organisations is increasingly used in many countries with the intention of bringing about performance and quality improvements, yet relatively little is known about the impact of regulation on these organisations' performance, or about the characteristics or determinants of effective regulatory strategies and approaches. This paper presents a framework for evaluating regulatory arrangements and sets out some characteristics of effective regulation.

### **Methods:**

An extensive review of the literature on healthcare regulation in the United States and the United Kingdom was undertaken, alongside a review of the wider literature on the theory and practice of regulation in other areas of the public and private sector. Interviews and meetings were undertaken with a wide range of stakeholders in healthcare regulation, including regulatory agencies, healthcare providers, healthcare purchasers, users/consumer groups. Examples are drawn from the regulation of hospitals, nursing homes, health plans, and other healthcare entities in both countries.

### **Results:**

In both the USA and the UK, healthcare regulation is undertaken by a host of different governmental and non-governmental agencies with varying statutory authority, scope and remit, approaches and results. As a result, healthcare organisations and healthcare users/consumers often encounter a complex, overlapping, duplicative and sometimes contradictory regulatory environment. Four key problems are highlighted: the degree of regulatory fragmentation and its effects on organisational performance and behaviour; the apparent lack of rigour and robustness in regulatory measurement and methodologies; the high costs of regulatory oversight; and the complex combination of positive and negative impacts which regulation can have on organisations' performance.

Empirical evidence from healthcare regulation and the wider theoretical literature on regulation suggest that a number of characteristics of effective regulation can be hypothesised, including that it should be explicitly directed at performance improvement; designed to be responsive to individual organisation's performance and behaviour; proportionate to the likely risks or opportunities for improvement; rigorous and robust in its measurements and assessments; capable of flexibility in application without creating inconsistency and unfairness; fully costed and designed to be parsimonious; open and transparent in its workings where that does not hamper improvement; able to use a wide range of enforcement measures including both incentives and sanctions; set up to be accountable for regulatory performance while preserving the regulator's operational autonomy from stakeholders in regulation; and committed to evaluation and review.

When existing systems of healthcare regulation are measured against these effectiveness criteria, they do not generally perform well, which suggests there is substantial scope to improve the effectiveness of healthcare regulation in bringing about quality and performance improvement.

### **Conclusions:**

Healthcare regulation is increasingly ubiquitous, and many healthcare systems (including, but not limited to, those in the USA and the UK) spend a large and growing amount on regulatory arrangements and securing regulatory compliance. This paper suggests that the return on that investment – in terms of the improvements in performance which it produces – could be much greater if the systems for regulation were designed and implemented with a better understanding of the characteristics of effective regulation.

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