Defining the Regulatory Role -- *How* Hospitals are Regulated

This research helps define the regulatory role.
Prepared in February 2007 by the Muskie School.

The purpose of this document is to develop some common vocabulary for talking about different types of regulatory strategies and the role of a state regulatory agency.

The "Regulators"

For the purposes of this discussion, a "regulator" is defined very broadly to include a wide range of entities that "regulate," or influence the behavior of a hospital with respect to quality. In broad categories, these regulators would include:

- The state agency or entity responsible for monitoring and promoting compliance with government promulgated rules and standards.
- The hospital or hospital industry itself.
- Those who purchase health care, to the degree that their purchasing power influences the behavior of hospitals. This category would include large employers, large government purchasers, managed care entities, individual consumers, etc.

Regulatory Strategies

For the purposes of this discussion, potential regulatory strategies are grouped in four broad categories:

Market Mechanisms: The market can regulate quality by defining expectations for quality, selecting based on quality, paying for performance, and otherwise using purchasing power to influence the behavior of hospitals. For example, the Medicare program, the Medicaid program, and large employers are influential market "regulators" to the degree they use their purchasing power to define expectations for quality. A consumer able to make informed choices between alternative providers could also be a market force that selected hospitals based on quality. The market is an imperfect mechanism for regulating quality, given the lack of information and agreement about what constitutes quality care.

Voluntary and Self Regulation: Voluntary and self-regulation are the traditionally dominant forms of quality regulation in the health care industry. Health care professionals and organizations have voluntarily regulated their own quality through professional norms, professional standards, and peer review. Hospitals also set performance targets, implement a continuous quality improvement cycle, or use other internal mechanisms for improving quality. The health care industry has regulated itself through professional organizations imposing sanctions for poor quality or accrediting bodies setting accreditation standards. Voluntary and self-regulation is an important mechanism for regulating quality because health care professionals and organizations have the most direct control over and information about quality. However, voluntary and self-regulation falls short when doctors or hospitals can choose not to adhere to best practice.

External Regulation of Self-Regulation: This regulatory approach incorporates state agency enforcement of self-regulating mechanisms. A state regulatory agency can regulate quality indirectly by defining expectation for self-regulation and then monitoring compliance with those standards. For example, a state regulatory agency can define expectations for key elements of a quality improvement program and then monitor the capacity and performance of the quality improvement program. Or the regulatory agency could require a hospital to obtain Joint Commission accreditation. Under this approach the focus is on the hospital's internal mechanisms for assuring or improving quality rather than its adherence to minimum standards for quality. The advantage of this approach is that hospitals have flexibility in how to comply, tailoring their internal systems to their own needs. At the same time, this approach does not adequately address those situations where there are defined minimum standards of quality.

Command & Control Regulation: Command and control is another traditional approach to quality regulation. A state agency applies a command and control regulatory approach when it defines and enforces a minimum standard of quality. For example, command and control is used to set minimum requirements for obtaining a license, prescribing what is considered a standard of quality and how a hospital is expected to comply. Command and control is an appropriate form of regulation where there is agreement about the minimum standards for quality. However, command and control is not as effective for improving quality. It is difficult to set standards higher than the industry average. In addition, where a command and control focuses only on rules-based compliance with minimum standards, a hospital might be diverted from cultivating its own internal and flexible mechanisms for monitoring and improving quality.

The pyramid on the next page orders the different regulatory strategies by the degree of formal constraints imposed on a hospital.

Networked Governance and Responsive Regulation

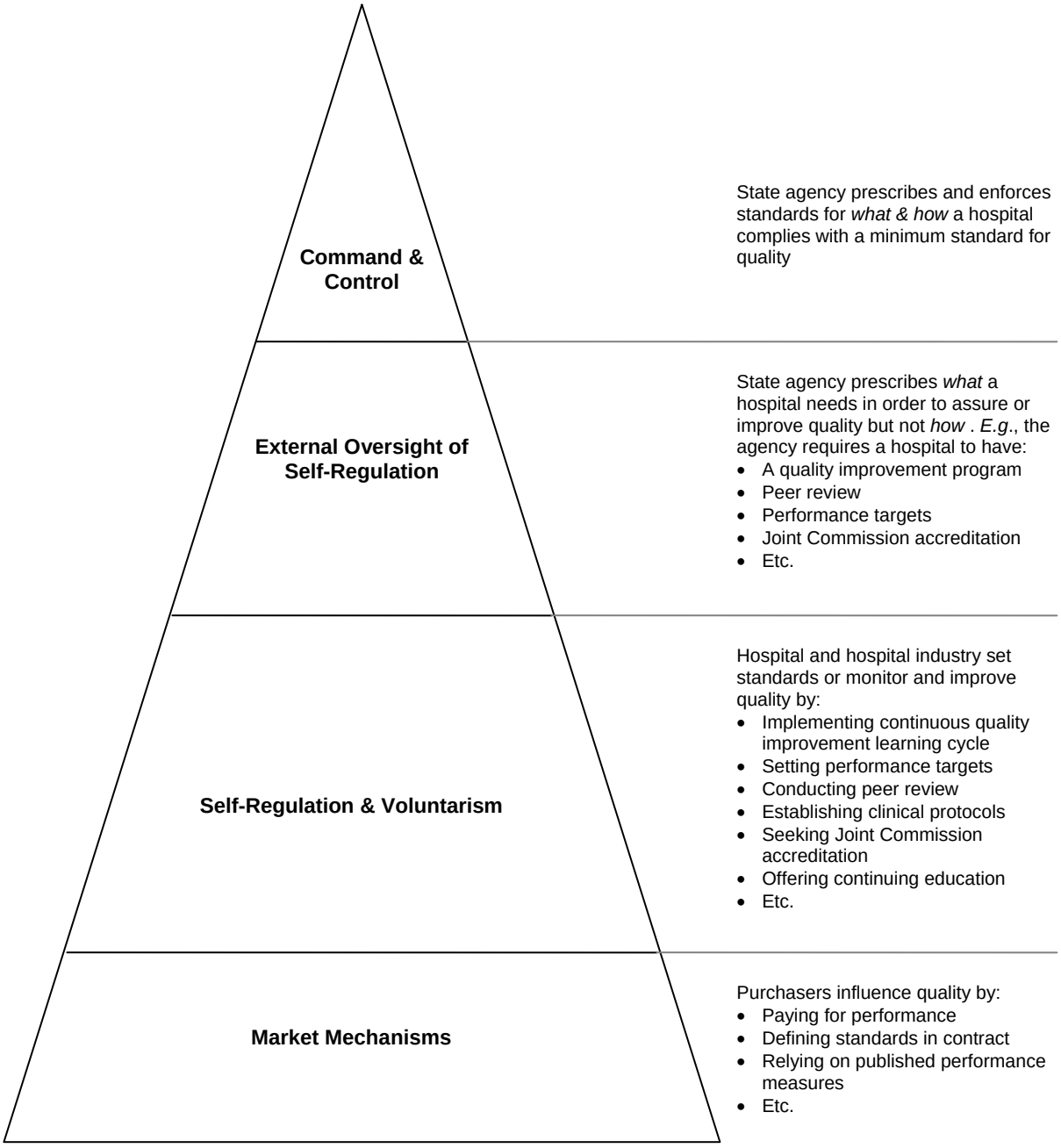
The range of entities playing a role in regulating hospital quality suggests the danger of potentially duplicative, inconsistent and unnecessarily burdensome regulation. Regulating quality will be more effective through "networked governance," where the roles of public and private stakeholders are coordinated and organized. (Braithwraite 2005).

Through networked governance, a range of levers and regulatory strategies can be used to govern hospital quality, depending on the context. Called a "responsive" approach to regulation, this approach acknowledges no one regulatory strategy is effective in all situations.

In the context of defining a regulatory role for a state agency, "responsive regulation" is a helpful way to look at sharing the regulatory role across different types of "regulators." For example, a state regulatory agency might decide that major purchasers adequately monitor certain quality measures and there is no need for formal regulatory requirements in that area. At the same time, the regulatory agency might decide that the market and the hospital industry do not adequately regulate other critical areas and decides to take on a command and control approach or to oversee the hospital's self-regulation.

"Responsive regulation" is also a useful way to look at regulation in the context of a specific situation. For example, a state agency could tailor regulatory oversight of a hospital to

performance and other data related to that hospital. Where quality indicators and complaint data indicate are fine, the regulatory agency could continue to monitor a hospital's self-monitoring.



Regulatory pyramid and health care safety and quality mechanisms. Adapted from Braithwraite et al. (2001).

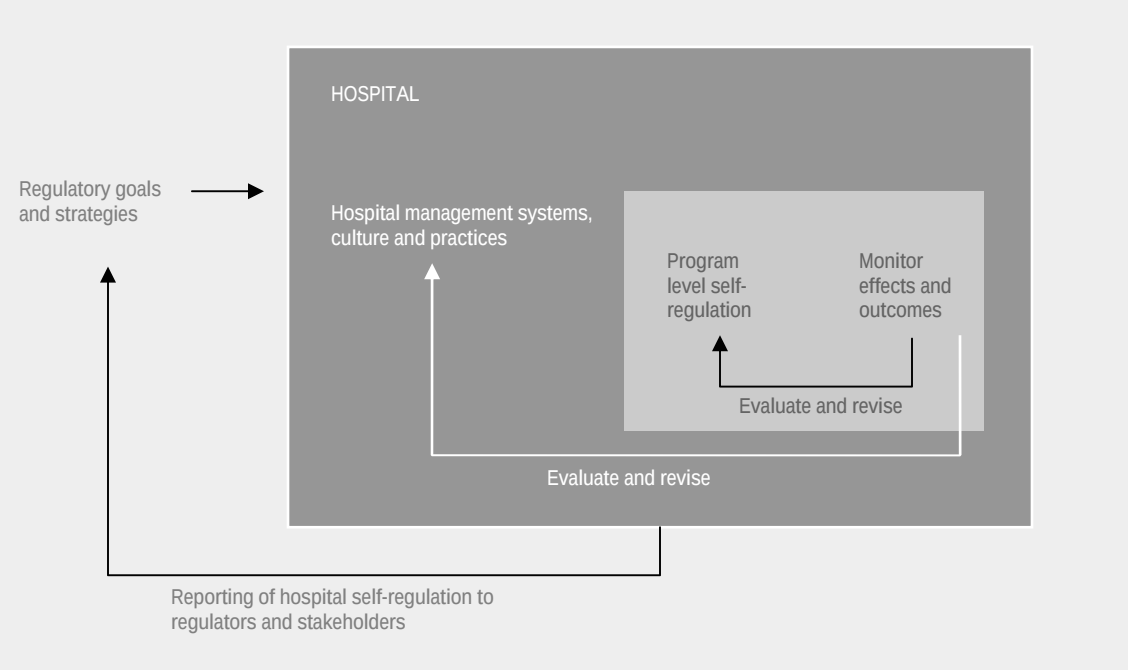
However, where both indicate a certain problem, the regulatory agency might conduct a targeted survey or impose a prescriptive plan of correction.

Responsive regulation is also a useful way of looking at regulatory sanctions. Traditionally, regulatory agencies have defined in advance which regulatory response applies to which problem. Using a responsive approach, a regulatory agency could tailor the regulatory response to the individual circumstances of the hospital. For example, when appropriate, the regulatory agency could seek voluntary compliance before escalating to a warning letter, a penalty or actions to suspend or revoke a license.

While one of the strengths of responsive regulation is the ability of the regulatory agency to be flexible and tailor its response to the current context, some would criticize this approach as inconsistent.

Triple Learning Loop

In a triple loop learning model, a state regulatory agency's regulatory strategy can be informed by the learning of the hospital's it regulates. In this model, the first loop is the internal learning cycle in which a hospital innovator monitors his or her effectiveness at improving an outcome. The second loop is at the hospital level, where senior managers learn about the innovation and its effectiveness and change the hospital's management systems, culture and practices in response to the learning. The third loop occurs when the government learns from monitoring the hospital's double loop learning, and revises its regulatory goals and strategies for the whole field. (Braithwraite 2005, citing Parker)



Triple-loop learning. Adapted from Braithwraite (2005).

Discussion Questions

1. Is this vocabulary a useful or adequate way of describing regulators or regulatory strategies? Is there anything missing or confusing?

2. In thinking about the regulatory pyramid, what criteria might be useful for deciding when one regulatory strategy should be used rather than another, when establishing the regulatory role for the department?

3. Does it make sense to think about having escalating regulatory strategies, depending on a specific circumstance or situation? For example, could the regulatory role of the Department be to set standards for self-regulation, but be ready with a more prescriptive, command and control approach when certain criteria are met?

4. Is there a role for triple-loop learning in Maine? What mechanisms should the Department explore for incorporating triple-loop learning into its regulatory role?