



Figure: Social security globe

Healthcare is both a service and an industry. As such it needs to be regulated so that the government's requirements are properly enforced.

Regulation is an important entity in healthcare and healthcare insurance. The role of regulatory bodies is to protect healthcare consumers from health risks, provide a safe working environment for healthcare professionals, and ensure that public health and welfare are served by health programs. Regulation works at all levels, and the regulatory standards are developed by government and private organizations as well. Regulations are necessary to standardize and supervise healthcare, ensuring that healthcare bodies and facilities comply with public health policies and that they provide safe care to all patients and visitors to the healthcare system.

Regulatory agencies thus monitor individual and corporate healthcare practitioners and facilities; inform the government about changes in the way the healthcare industry operates; ensure higher safety standards; and attempt to improve healthcare quality and follow local, state, and federal guidelines.

Functions of a regulator

A regulatory system helps keep track of how well the healthcare system is complying with its contractual obligations and other legal requirements, protecting the public interest. It also lays down the standards for technical operations, safety and quality

as required apart from the contracts themselves, and the penalties for non-compliance.

Cost-effectiveness, performance analyses, tariff evaluations, and regular reviews, as well as setting up mechanisms for settling disputes between parties, are all part of regulation. The regulatory body also advises the government on private-public partnerships in healthcare, helping to shape policies and other related matters.

Statutory vs. non-statutory bodies

Statutory bodies thus publish quality standards, offer accreditation, and offer continuing education and training for healthcare professionals. Regulatory bodies of this sort may regulate services or professionals.

In contrast to such governmental oversight, accreditation agencies offer another level of oversight which is voluntary but offers quality certification and rankings, incentivizing efforts to improve the quality of healthcare and promoting best practices. These are more indirect in their approach but intend to enhance patient care.

The pros and cons

Regulatory activities are aimed at building appropriate motives and attitudes, policies, and healthcare protocols, within facilities and systems. Some regulatory activities include regular inspections and measures to enhance good practice and a better clinical culture.

The flip side is that slavish imposition of regulations could fail to address real problems of attitude and a non-professional approach to healthcare, is not flexible enough to cope with challenges and changes in the industry and may promote a bureaucratic pattern of complying with rules mechanically rather than seeking the patient's welfare.

Some may perceive it as interference by an external authority that reduces the efficiency of work and intrudes on the smooth functioning of the clinical service, but regulatory oversight is designed to encompass a broader range of functions. This has led many individual and corporate observers to advocate for regulatory reform, leading to a simplified approach that clubs together regulations relating to similar services, and reduces the load on healthcare providers.

The main problems are multiple regulatory bodies that share the same aims; make for a complex and rapidly changing regulatory environment; and cause duplication of

work, increasing the workload and creating frustration and negative relationships with the regulatory bodies.

Not only so, but the uncoordinated nature of the interactions between the various organizations and agencies that are involved in regulation can also both create confusion within the regulated body, and cause resources to be diverted from where they could be best used, to produce a semblance of improvement for the sake of the regulator.

Both the time and the energy, apart from the money spent, in producing a portfolio of the evidence required to satisfy the regulatory bodies, are concerning issues, detracting from rather than enhancing the quality of healthcare.

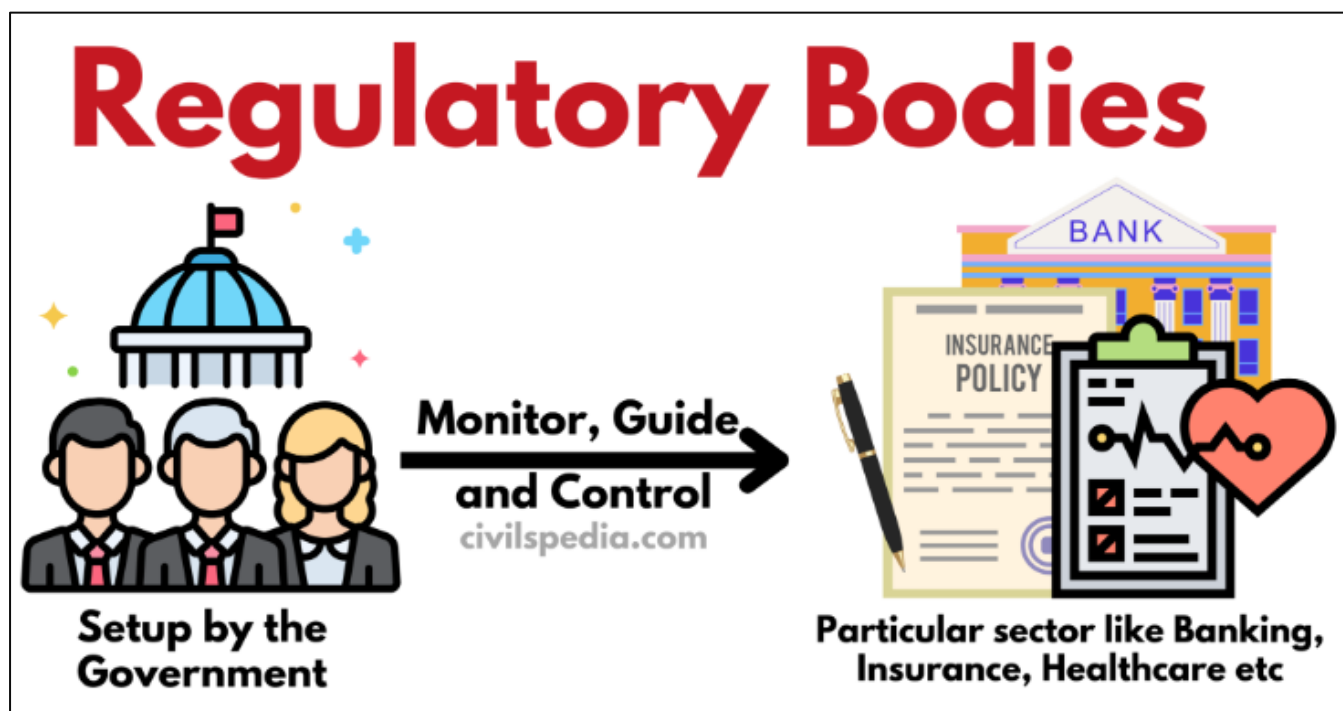


Figure: Regulatory Bodies (Source: civilspedia.com)

In the case of Natural Monopoly

A natural monopoly is a condition when an entire market is more efficiently served by one firm than by two or more firms.

In the case of a natural monopoly, regulation is necessary to protect consumer interests, control prices, and ensure the quality of service, as there is no competition in the market.

In India, the sectors such as transmission and distribution of electricity and railways are still natural monopolies.

Asymmetric Information

It is a situation when one party has more information than another. In India, asymmetric information is a significant reason for government intervention.

For example, In many sectors, like healthcare, insurance, and financial services, consumers may not possess the same expertise as service providers. Hence, regulation helps protect consumers by mandating disclosure requirements, ensuring transparency, and setting product quality and safety standards.

Presence of Externalities

Negative externalities refer to the costs or harms imposed on third parties not directly involved in a transaction or activity. When negative externalities exist,

market forces alone may not be adequate to address the issue. In India, regulation is often implemented to address negative externalities in various sectors.

For example, Industries or activities that generate pollution or degrade natural resources often impose negative externalities on the environment and surrounding communities. India has implemented regulations governing air and water pollution, waste management, and environmental impact assessments to mitigate these externalities.

Check Anti-Competitive practices

Detecting and preventing anti-competitive practices is a crucial reason for regulation in India. For example,

- ❖ The regulation targets cartels and collusive behaviour, where competitors engage in agreements to fix prices, allocate markets, or rig bids, aiming to restrict competition and maximize their profits.
- ❖ Regulatory bodies monitor and address cases where a dominant firm exploits its market power to restrict competition, drive competitors out of the market, or engage in predatory pricing.
- ❖ Regulations govern mergers, acquisitions, and combinations that have the potential to reduce competition significantly.

Compliance officer

The designated role of a corporate compliance officer (CCO) is gaining prominence in many businesses.

The CCO serves as the point person who champions corporate integrity, accountability, and ethics.

With the time-intensive oversight involved in implementing and monitoring a compliance program, the CCO's sole focus is to stay on top of the ever-evolving regulatory landscape and make the necessary compliance decisions.

Establish and maintain your policies and procedures

It isn't enough to simply have policies and procedures. They need to address the specific compliance areas identified in the audit listed above.

Plus, they need to be reviewed regularly to stay current with the always-changing regulatory landscape. Again, that's why it's helpful to designate a CCO.

In addition to having targeted policies and procedure tied to compliance, a key component of policy management involves the need to track when employees have read and signed your policies.

This plays a huge role in being able to prove compliance down the road, if necessary. If you can show the employee knew the policy, read and acknowledged it, and violated it anyway, then the company's liability significantly decreases.

This provides a much stronger position to take action against that employee.

A policy management software like PowerDMS can help you easily maintain records of all of these policy signatures.

Regulatory compliance training

Just like having your policies and procedures tied to compliance issues, you want to “train to your policies.”

If the policy is written to address specific compliance issues, then your training should reinforce that behavior and ensure employees comprehend what they are supposed to do.

Employees at every level need to adopt the philosophy that compliance is “everybody's business” – even if you have a designated CCO to oversee your corporate compliance program. (That's a key part of your training, as well.)

When your entire workforce understands the importance of compliance (and their role in making it happen), it distributes the knowledge broadly.

Compliance isn't about a handful of people who know the latest regulations and what that means for operations. Rather, everybody is up to speed on the latest changes and they've been trained on how it impacts them.

Continual improvement

Compliance is not a one-and-done program.

Your company needs to build in regular review periods and audits. Plus, your organization should seek input from subject-matter experts (ideally, the CCO) who can track regulatory changes and understand their impact on your business.

This allows you to continually assess the effectiveness of the program and be proactive in your actions.

It helps to automate this review process so nothing falls through the cracks. That's one of the powerful benefits of regulatory compliance software like PowerDMS.

It allows you to set workflows and reminders to route it to the appropriate people who need to review and make changes.

Now that you understand the critical importance of regulatory compliance (and the challenges you might face), you can use the above guidelines as your action plan.

These steps will help you create an effective regulatory compliance program in your business that protects your resources, your reputation, and your internal and external audiences.

Importance of Compliance with Regulatory Bodies

Compliance with regulatory bodies is crucial for businesses to operate legally and ethically. Regulatory bodies exist to ensure that businesses operate in a manner that is fair, safe, and in compliance with laws and regulations. These bodies set standards for industries, monitor compliance, and enforce penalties for non-compliance. In this section, we will explore the importance of compliance with regulatory bodies from different perspectives.

1. Customer Perspective

Customers rely on regulatory bodies to ensure that businesses provide safe and reliable products and services. Compliance with regulations helps to protect customers from harm and gives them confidence in the products they purchase. For example, the Food and Drug Administration (FDA) regulates food and drug safety in the United States. Compliance with FDA regulations ensures that products are safe for consumption and meet certain quality standards.

2. Business Perspective

Compliance with regulatory bodies is essential for businesses to avoid legal and financial penalties. Non-compliance can result in fines, legal fees, and damage to a company's reputation. Additionally, compliance can help businesses to gain a competitive advantage by demonstrating a commitment to ethical practices and high standards. For example, a company that complies with environmental regulations may be viewed more favorably by environmentally conscious consumers.

3. Societal Perspective

Compliance with regulatory bodies is important for the well-being of society as a whole. Regulations exist to protect the environment, public health, and safety. Compliance with these regulations helps to prevent harm to individuals and communities. For example, compliance with building codes and safety standards helps to prevent accidents and injuries.

4. Options for Compliance

There are several options for businesses to ensure compliance with regulatory bodies. One option is to hire compliance officers who are responsible for monitoring compliance with regulations. Another option is to outsource compliance to third-

party companies that specialize in regulatory compliance. Additionally, businesses can use compliance software to automate compliance processes and monitor regulatory changes.

5. Best Option for Compliance

The best option for compliance depends on the size and complexity of the business, as well as the industry in which it operates. Small businesses may find it more cost-effective to outsource compliance to third-party companies, while larger businesses may have the resources to hire in-house compliance officers. Compliance software can be a useful tool for any business to monitor regulatory changes and ensure compliance.

Compliance with regulatory bodies is essential for businesses to operate legally, ethically, and safely. Compliance benefits customers, businesses, and society as a whole. There are several options for ensuring compliance, and the best option depends on the size and complexity of the business.

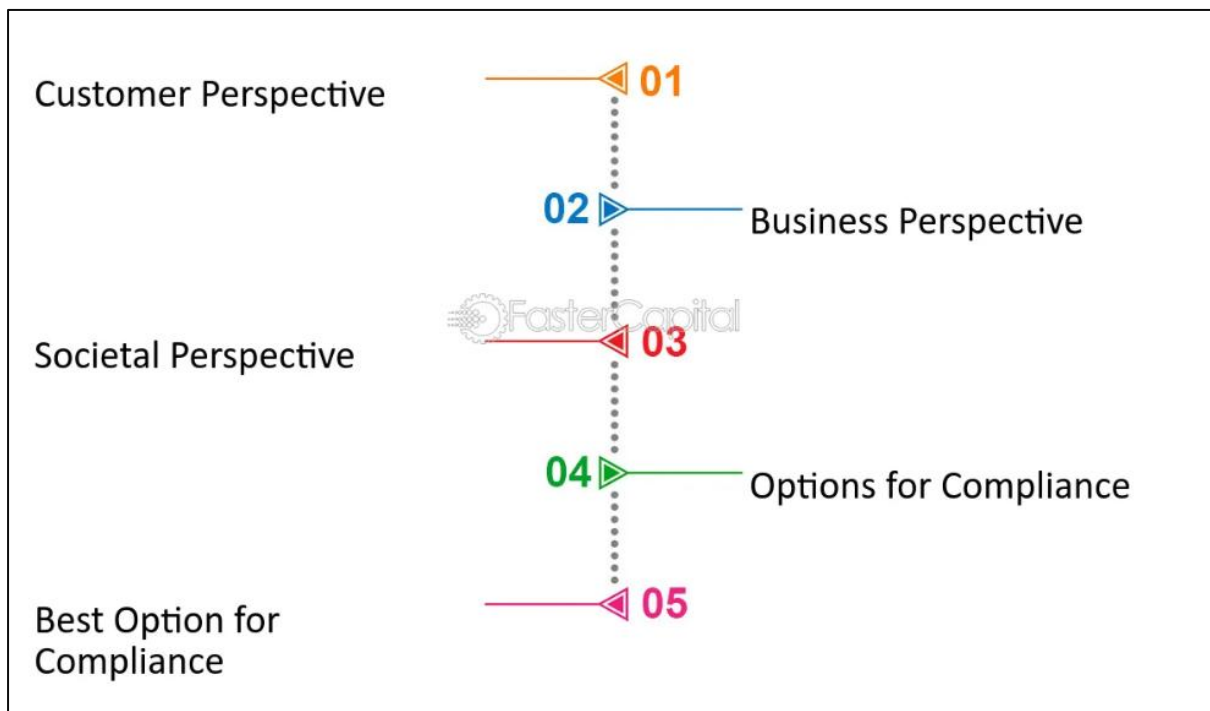


Figure: Perspectives of society in terms of regulatory bodies (Source: <https://fastercapital.com/content/Regulatory-bodies--Behind-the-Scenes--Regulatory-Bodies-and-their-Impact.html>)

Importance of Regulatory Bodies

Regulatory bodies play a vital role in ensuring that industries operate in a safe and ethical manner. Without these bodies, industries would be left to self-regulate, which could lead to disastrous consequences for both consumers and the environment. In this section, we will discuss the importance of regulatory bodies and the impact they have on society.

1. Ensuring Safety

One of the primary functions of regulatory bodies is to ensure the safety of consumers. For example, the Food and Drug Administration (FDA) regulates the safety and efficacy of drugs and medical devices before they can be marketed to the public. Similarly, the National Highway Traffic Safety Administration (NHTSA) sets safety standards for automobiles and regulates recalls when defects are discovered. Without these regulatory bodies, consumers would be at risk of using unsafe products or driving unsafe vehicles.

2. Protecting the Environment

Regulatory bodies also play a crucial role in protecting the environment. The Environmental Protection Agency (EPA) regulates emissions from industry and sets standards for air and water quality. Without the EPA, industries would be free to pollute the air and water without consequence, leading to serious health and environmental consequences.

3. Promoting Fair Competition

Regulatory bodies also promote fair competition in industries. For example, the Federal Trade Commission (FTC) regulates advertising and marketing practices to ensure that companies do not engage in false or deceptive practices that could harm consumers. Similarly, the Securities and Exchange Commission (SEC) regulates financial markets to prevent insider trading and other fraudulent practices. Without these regulatory bodies, companies could engage in unfair practices that would harm both consumers and other companies.

4. Balancing Industry Interests with Public Interests

Regulatory bodies also play a crucial role in balancing industry interests with public interests. For example, the Federal Communications Commission (FCC) regulates the telecommunications industry to ensure that consumers have access to affordable and reliable communication services. The FCC also regulates the use of the public airwaves to prevent interference and ensure that the airwaves are used in the public

interest. Without the FCC, telecommunications companies could prioritize their own interests over the public interest.

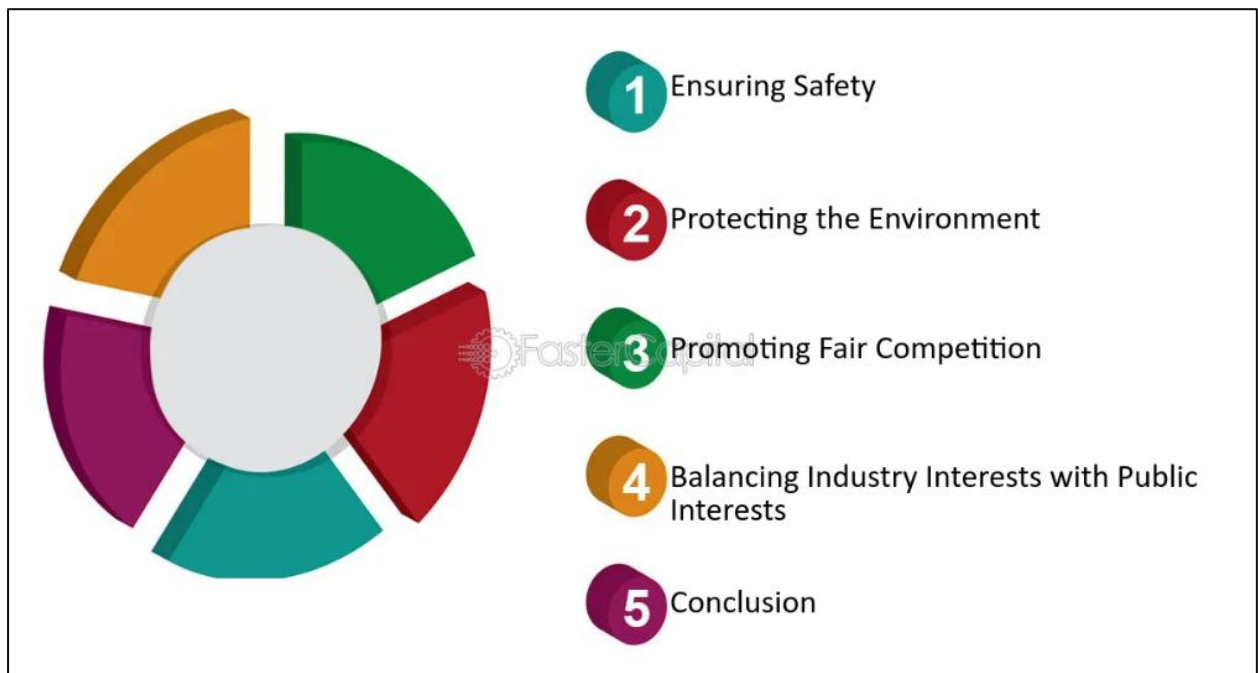


Figure: Industry interests with respect to Public interests (Source: <https://fastercapital.com/content/Regulatory-bodies--Behind-the-Scenes--Regulatory-Bodies-and-their-Impact.html>)

Practical solutions for real-world problems

ISO, the International Organization for Standardization, brings global experts together to agree on the best way of doing things – for anything from making a product to managing a process. As one of the oldest non-governmental international organizations, ISO has enabled trade and cooperation between people and companies the world over since 1946. The International Standards published by ISO serve to make lives easier, safer and better.

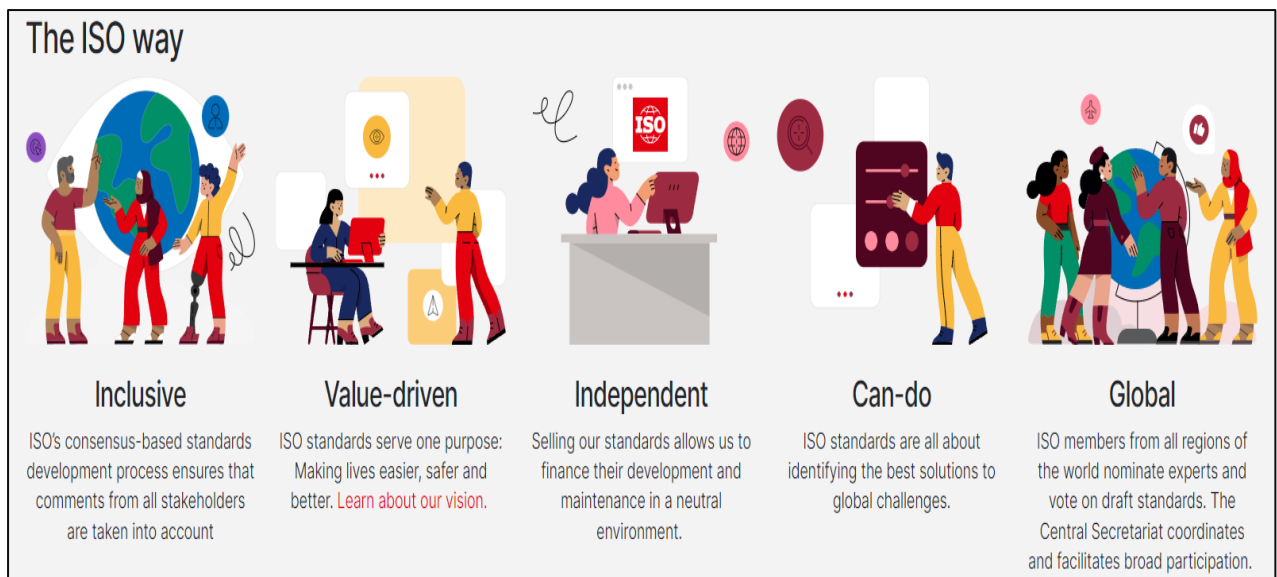


Figure: Role of ISO

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