A Comprehensive Analysis of Regulatory Policies in the U.S. Healthcare System

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2. Executive Summary

Economic regulation in the healthcare industry has long been a subject of debate, balancing the need for affordability, competition, and innovation. From antitrust laws designed to prevent monopolies to government-imposed price controls on essential medications, regulatory policies shape the accessibility and cost of healthcare for millions of Americans. The U.S. healthcare system operates within a complex framework of public and private entities, where economic regulations influence insurance coverage, hospital pricing, and pharmaceutical costs. Understanding these regulations is essential, as they directly impact both current and future generations.

Economic regulation within the healthcare industry is a topic of great importance to SPRING. As an organization composed of students who are young adults, we have experienced first-hand the impacts of fluctuating prices and regulations. Especially as the next generation of global citizens who will be most impacted by various healthcare policies, it is critical that we raise awareness about issues that matter so much to us.

As part of our continued goal to highlight youth viewpoints on issues of concern to them, SPRING seeks to bring the unique perspectives of students into global policies to implement more sources of renewable energy. This paper analyzes the economic implications of regulation within the U.S. Healthcare industry, pulling from specific historical scenarios to analyze the benefits and harms of various viewpoints. This includes FTC antitrust laws, market-based price controls, and more.

3. Introduction

3.1 Context

The United States healthcare system is a mixed system that is financed by both the government and private healthcare plans[1]. The two big government health coverages are Medicaid and Medicare. Private insurance ranges from employer contributions to private health care.[2]

Hospitals are financed by Diagnostic-Related Groups (DRG) which are payments based on certain specific conditions and treatments. Medicaid and Medicare use in-patient DRGs where they pay the hospital a fixed amount based on DRGs which covers accommodation costs but not physician costs. Private insurance companies pay based on DRGs, care rates, per diems, and fee-for-service.

3.2 Health Insurance Plans and Programs

Private insurance has two sectors: first individuals are given insurance through their employers where employers contribute to private insurance premiums (group insurance); second, individuals can purchase private health insurance (nongroup insurance). Based on certain insurance plans insurers then pay providers (hospitals and clinics). Most of the time these insurance plans don't cover the entire cost and individuals may have to pay a certain amount before their insurance may apply.

The two main public insurance programs Medicaid and Medicare are publicly financed by the federal government.[3] Medicare is a national health insurance for the aged and disabled that consists of Part A and Part B. It is the largest insurance plan as 13% of the population is on Medicare. Medicare is financed by payroll taxes and federal revenue. Part A is payments made by 1.4% payroll taxes of both employer and employee that are given during an individual's working year. Part A covers inpatient hospital care, some nursing home services, and home health services. Part B is payments made through premiums when an individual is eligible (Retriment) and is financed through enrollees and federal revenue. Part B covers physician costs, ambulatory services, and medical equipment (wheelchair).

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[1] ISPOR, 2022
[2] De Lew et. al., 1992
[3] ISPOR, 2022

Medicare is a national health insurance plan for individuals who are under the poverty line or who cannot afford it. It covers preventative, acute, and long-term care for 10% of the population. To finance the program the federal government marches state Medicaid, state amount varies depending on state income levels. The program funds long-term nursing homes whereas 43% of expenses are spent on skilled nursing facilities and intermediate care facilities.[4]

Individuals also may choose not to have insurance or individually finance their healthcare. They may pay through co-payments or out-of-pocket. Individuals without health insurance are responsible for paying the full amount.[5]Because of the rate of inflation and the health care costs increasing there has been an increase in out-of-pocket payments.[6] Affordable healthcare is a serious issue in America as 1 in 4 adults report that they have delayed or not gotten healthcare due to the cost.[7]

3.3 Affordability

Rising inflation caused an increase in the cost of supplies, operations, facilities, and administration which directly impacts health care costs.[8] Health insurance does not guarantee that medical care is affordable as half of Americans struggle to afford healthcare and prescription services.61% of uninsured adults report not getting healthcare due to the costs and 21% of insured individuals report not getting health care due to the cost.

In 2022 healthcare affordability dropped by 61% and overage rose by 7% in 2023. Health care has been unaffordable for many workers at small employers as 41% of Americans have medical bills they cannot afford. Most commonly dental care is the most put off due to health care costs; 25% for vision services; 24% for doctor visits; 18% for mental health care; 14% for hospital services; and 10% for hearing services.[9]

3.4 Economics and Policy

[4] De Lew et. al., 1992
[5] ISPOR, 2022
[6] Sobotko, 2024
[7] Rakshit et. al., 2024
[8] New City Insurance, 2024
[9] Lopez et. al., 2024

The United States is the third most populated country and has spent 16% of its GDP in 2018.[10] In 2022, the U.S. spent $4,464.4 billion on health care; 30% went to hospital care; 14.5% on physician services; 5.3% on clinical services; 3% on home healthcare; 4.3% on nursing care facilities; 9.1% on prescription drugs; 16.5% on other personal health care; 1.2% on government administration; 6.3% on net cost of health insurance; 4.7% on government public health activities; 4.9% on investments. With so much money being allocated to different sectors of healthcare physician care spending grows the slowest as between 2012 and 2022 the annual growth rate was 4.2% in comparison to hospitals which was 4.4% and prescription drugs which was 4.7%.

For healthcare reforms, Congress is responsible for federal healthcare laws. The Department of Health and Human Services is responsible for the provision of medicine, public health services, and social services. There are several oversight agencies to manage different sectors of the field: Federal Drug Administration (FDA), Centers for Medicaid and Medicare (CMS), National Institute of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and Centers for Disease Control and Prevention (CDC).[11]

In February of 2024, Health and Human Services issued a final rule. Regulations and requirements such as healthcare providers may use consent and information breach notifications. The Final rule also extends healthcare privacy by prohibiting covered entities from using and disclosing health information for certain purposes and requiring covered entities to update their notice of privacy. Covered entities are also to obtain a signed attestation stating certain requests for protected health information.[12]

New marketing rules were introduced for the Centers for Medicare and Medicaid Services. Regulations such as individuals cannot send representatives to your home uninvited, cannot send representatives to your home uninvited, cannot market their plan or enroll new people during an educational event, cannot permit agents to steer enrollees into plans that don't meet their health and or financial need, cannot use misleading language or official medicare logos to market private plans, cannot suggest their contact number hotline, and cannot imply that consumers are missing out on benefits they are entitled to receive. Also established was the CMS interoperability and prior authorization final rule (CMS-0057-F) which sets requirements for medicare advantage organizations to improve electronic exchange of health information and prior authorization processes. Such regulations are implemented to reduce the burden on patients, providers, and payers. Also starting in 2024 CMS requires all entities to use

[10] AMA, 2024
[11] ISPOR, 2022
[12] Williams et. al., 2024

standardized CMS templates to ensure that price estimates are in the same format across hospital websites, this allows documents to be easier to read and compare. Furthermore, starting January 1st states must provide 12 months of continuous coverage for Medicaid and CHIP enrollees under 19 regardless of income changes; uninterrupted coverage translates to better health outcomes.[13]

[13] George, 2024

4. Price Controls on the Pharmaceutical Industry

4.1 History of Price Controls

The pharmaceutical industry has seen various methods of price control coming from Washington itself, aiming to protect consumers from the harsh prices of Big Pharma. There has been a historical lack of government intervention regarding pharmaceutical prices, resorting to a more “laissez-faire” policy style when dealing with that industry. Only in recent times has the US Government enacted laws that place hard caps on prices for life-saving drugs such as insulin. However, government actions in the late 1900s really shaped the pharmaceutical world as we know it today.

One of the first of many policies that the Federal Drug Administration (FDA) would implement was the Durham-Humphrey Amendment in 1951, separating prescription and over-the-counter drugs. This would impact drug pricing in a key way, by forcing companies to think about different drugs in different ways and selling to the consumer in different manners. For example, following the Durham-Humphrey Amendment, corporations would focus more on selling over-the-counter drugs as prescription drugs had to be regulated by a licensed practitioner.[14] Another landmark policy was the Medicare Modernization Act of 2003, specifically Medicare Part D, which covered prescription drugs for those applicable.[15] Furthermore, Medicare was not allowed to negotiate prices for prescription drugs covered by Part D.[16] This was removed in the Inflation Reduction Act (IRA) in 2022 which also introduced much lower costs for life-saving drugs like insulin, vaccines, and an increased cap for prescription drug costs.[17]

These policies have largely served to better the lives of citizens and reduce the amount of money it costs for people to buy life-saving medicine. One of the most needed drugs - insulin - was largely set at ridiculously high prices by pharmaceutical corporations, but due to the high need for the drug by diabetics, the government has intervened to cap the price at now 35$ for those with Medicare.[18] These policies have also shown that Big

[14] FDA, n.d.
[15] Cubanski, 2024
[16] CMS, 2025
[17] ibid
[18] Cubanski et. al., 2023

Pharma corporations are able to lower their prices to better help consumers and that the US government is willing to enforce policies to better the health of their citizens.

4.2 Benefits

Price controls in the pharmaceutical industry serve one main goal - to benefit the consumer. This comes in the era where health care costs have been at one of the highest in US history and consumers are the ones suffering, without the ability to buy life-saving medicines. The US government has therefore recently focused on maintaining low prices for pharmaceutical drugs for the consumer, especially as the lack of government intervention resulted in a huge rise in prices since the 1900s. Consumer sentiment also leans towards government intervention, with 25% of Americans stating that they cannot afford life-saving medication.[19] This is also largely due to the inflated market, with insulin rising by 900% in just two decades.[20] Compared to other countries, the US has some of the highest prices for medication, with about 150% higher than countries in Europe and 2 to 4 times the price in Canada and Australia.[21]

The US government's price control policies also tend to allow pharmaceutical companies to take their share of money for research and development (R&D) but mainly focus on driving down prices. For example, the federal government provides pharmaceutical companies five to seven years of market exclusivity, helping companies to make a profit to cover their R&D on the product.[22] Following these years, generic brands can enter the market and their introduction can immediately lower prices for every consumer. The US also implements policies that directly benefit the consumer. These policies can be organized into two categories - the hard cap and varying price reduction.

The US introduced a hard cap for insulin in 2023, establishing a $35 price tag on insulin. Insulin is a life-saving medication necessary for all diabetics, about 38 million Americans or 11% of the population.[23] Despite so much demand for insulin, prices have only managed to go up until the US government set a hard price ceiling on insulin. This was a huge step in limiting prices for insulin, as previously, individuals were paying upwards of $400 to $900 in previous years.[24] With the new $35 limit, individuals with

[19] Houser, 2022
[20] ibid
[21] Waldrop, 2021
[22] ibid
[23] American Diabetes Association, n.d.
[24] Putterman, 2024

diabetes are much better off financially and have long-term healthcare benefits, particularly those with Medicare. This policy was also able to curb yearly prices by $500 for diabetics and the increased access to insulin has saved over 30 thousand years for diabetics.[25]

The US also incorporates various types of varying price controls, most notably the Inflation Reduction Act of 2022. This act allowed the US government to negotiate prices with pharmaceutical companies for certain drugs and medications. The US government is also limited to a maximum reduction of 75% for certain drugs and medications.[26] This limit is meant to ensure a "maximum fair price" that is supposed to maintain a net profit for pharmaceutical corporations.

4.3 Harms

Government-instilled price controls can be a double-edged sword of sorts. Despite the ability of a consumer to buy drugs and medications at low prices, it also limits profits for pharmaceutical corporations. These profits directly lead to less money for them to perform R&D and innovate more drugs and medications. Although the US government's price control policies try to largely account for that loss of money, it is still very significant to R&D research, which then plays a direct role on consumers. These price controls not only harm corporations but also the overall innovation market.

Pharmaceutical corporations are commonly criticized for manipulating the prices of drugs and raising them as time goes on, however, they raise the prices in order to raise funds for research and development of new and innovative drugs. Furthermore, they are incentivized to make some profit on their medication. On average, a pre-tax cost of a new drug costs $800 million with a $400 million post-tax.[27] The average gross return of a drug is about $500 million and corporations take about $50 million as profits for each new drug they create. Price controls have an almost detrimental impact on revenue, with a 40-50% price cut by the government reducing pharmaceutical development and innovation on new drugs by 30-60%. Many drugs have already been canceled in the early R&D stages due to recent price controls. The Inflation Reduction Act of 2022 led to various cancellations, including Eli Lilly's drug to counter blood cancer.[28] This act is projected to lead to cancellations of 78% of projects in the innovation market. This huge reduction in R&D post-price control also has a detrimental impact on the innovation industry as a whole. Since most pharmaceutical companies work alongside other

[25] Shao et. al., 2022
[26] Cubanski et. al., 2023
[27] NBER, n.d.
[28] York, 2023

research institutions like colleges, by cutting back on R&D, corporations terminate partnerships with these research institutions, limiting them and restricting their growth. This is incredibly harmful as potentially successful firms are restricted and hindered from developing into large research companies. This carries over to the employees of such institutions. With over 300 thousand workers in the pharmaceutical R&D industry, a cut by over half of the R&D would be detrimental to the workforce.[29]

[29] Crane, 2023

6. FTC Antitrust Laws

6.1 Context

The Federal Trade Commission (FTC) is crucial to keeping competitive markets in the United States healthcare sector. By strictly applying antitrust laws, the FTC aims to preempt monopolistic practices and advance consumer welfare.[30] The antitrust regulations of the FTC are analyzed in detail in this particular section, together with their development as well as implications for the healthcare business.

6.2 Key Policies

The FTC is accountable for enforcing several basic antitrust laws, including the Sherman Act, Clayton Act along with Federal Trade Commission Act. The Sherman Act functions as a foundation of antitrust law, prohibiting agreements that unduly restrain trade and proscribing behavior that results in monopolization.[31] The Clayton Act addresses particular anticompetitive practices, especially those involving mergers as well as acquisitions which might considerably decrease competition, in addition to this.[32] The Federal Trade Commission Act strengthens the regulatory framework created to safeguard market integrity by preventing unfair competition and misleading practices.

In the healthcare industry, the FTC has published policy statements to elucidate its enforcement approach. For example, the 1996 "Statements of Antitrust Enforcement Policy in Health Care" provided guidance on different collaborative arrangements amongst healthcare providers, such as hospital mergers and joint ventures, striking a sense of balance between the efficiencies obtained through cooperation and also the imperative to maintain strong competition. The FTC acknowledged the changing dynamics of healthcare markets and withdrew these policy statements by 2023, deeming them to be outdated and not relevant to present market conditions.[33] The Commission pointed out that its extensive record of enforcement actions and advocacy initiatives would serve as more pertinent guidance moving forward.

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[30] USA Gov, 2024
[31] National Archives, 2022
[32] Cornell Law Institute, 2022
[33] K&L Gates, 2023

6.3 Stakeholders

The FTC's antitrust maneuvers exert profound implications across various stakeholders. Impact on consumers is the most crucial of these. The FTC aims to keep affordability and enhance the quality of healthcare by challenging anticompetitive and negative mergers and practices. [34] A notable illustration of this commitment is the FTC's successful challenge to the 2011 merger between Phoebe Putney Memorial Hospital and Palmyra Medical Center in Georgia. The Commission asserted the transaction would engender a monopolistic market structure, triggering elevated costs for acute care hospital services.[35] In 2013 the FTC won a decision from the Supreme Court that upheld the benefits of competition within the medical market.[36]

Healthcare providers also encounter considerable scrutiny when thinking about mergers or collaborative ventures. The FTC meticulously evaluates whether such transactions diminish competition to the detriment of consumers.[37] In 2010 the FTC challenged ProMedica Health

System's acquisition of St. Luke's Hospital in Ohio worried it would result in increased healthcare costs - a case which can serve as an excellent illustration of this particular scrutiny.[38] The Commission directed St. Luke's to be divested - a decision upheld in 2011 by an administrative judge. [39]

Furthermore, within the pharmaceutical sector, the FTC has actively intervened against anticompetitive practices that promote high prices of drugs. The Commission filed a legal action in 2024 against the 3 largest pharmacy benefit managers - Caremark of CVS Health, Express Scripts of Cigna, and OptumRx of UnitedHealth Group - alleging they altered the drugstore supply chain to artificially increase insulin rates. The lawsuit contended that these entities strategically favored higher-priced insulin products to secure bigger rebates, ultimately raising costs for diabetic patients. [40]

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[34] KFF, 2023
[35] Federal Trade Commission, 2011
[36] Lexology, 2013
[37] Federal Trade Commission, 2003
[38] Southwest Virginia Health Authority, 2016
[39] United States Court of Appeals, 2014
[40] National Law Review, 2012

6.4 Benefits

The enforcement of antitrust laws within the healthcare market yields several crucial benefits. Foremost, it promotes enhanced competition. By curbing monopolistic practices, the FTC ensures that multiple providers keep market access, thereby stimulating competition which produces enhanced services and technological innovation. Furthermore, antitrust enforcement can be a safeguard for consumer protection. The FTC aims to stop price increases which would ordinarily happen because of market consolidation by stopping anticompetitive transactions by preventing them before they happen.[41] Its proactive stance against hospital mergers has played a crucial part in stopping unjustified rises in healthcare expenses.

Furthermore, the FTC's interventions engender heightened market transparency. [42]The Commission's oversight of intricate pharmaceutical pricing methods, especially those involving pharmacy benefit managers, aims to illuminate opaque drug pricing structures, ultimately encouraging conditions favorable to cost reductions for customers.

6.5 Harms

Even with its admirable work, the FTC's antitrust enforcement inside the healthcare industry encounters formidable challenges. The changing dynamics of the market dynamics is among the greatest hurdles.[43] The accelerated consolidation inside the healthcare industry, exemplified by vertical integrations and the burgeoning role of private equity ownership, presents novel issues for antitrust oversight. [44] The FTC has acknowledged that its prior guidelines might no longer suffice, requiring the withdrawal of outdated policy statements and the development of new enforcement methods.[45]

Furthermore, legal hurdles complicate the FTC's enforcement mandate. The nature of antitrust cases is complex and often long-running and often requires substantial evidentiary evidence to support allegations of anti-competitive damage. An example is the FTC's challenge to ProMedica's purchase of St. Luke's Hospital, which entailed extensive litigation before obtaining a resolution.[46]

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[41] Federal Trade Commission, 2021
[42] Investopedia, 2022
[43] Federal Trade Commission, 1995
[44] American Antitrust Institute, 2023
[45] Mullen, 2023
[46] Federal Trade Commission, 2017

The balance of innovation and competition is yet another crucial issue. Although collaborations among healthcare providers frequently catalyze medical advancements and enhance patient care, the FTC should exercise judicious oversight to ensure that such partnerships don't overly limit competition.[47] Striking this equilibrium is imperative to stop regulatory interventions from inadvertently stifling advantageous innovations within the sector.

[47] Stanford Report, 2023

7. Conclusion

The healthcare industry is financed through both the federal and state governments. Policy changes in the healthcare industry are based on the cost of producing and implementing the drug. Nevertheless, reducing healthcare costs will make life-saving medicine more affordable and ultimately see better health results. The pricing of healthcare drugs is set by large pharmaceutical corporations that hold the power to reduce prices. Reducing healthcare costs, however, poses a decrease in profits for healthcare corporations. Cutting prices can limit research and growth in innovations as price cuts interfere with general revenue.

Healthcare in the United States is funded through taxes and federal revenue. Healthcare costs are high but insurance companies can reduce the financial burden for recipients. Insulin, a drug for diabetes has increased its costs for consumers with insulin increasing by 900% in two decades. However, the United States introduced a hard cap for insulin in 2023, a $35 dollar price tag. This is an example of how healthcare policies can shape access to healthcare. The reduction of costs of healthcare increased access to insulin.

The FTC's role in enforcing antitrust regulations in the U.S. healthcare industry is essential to keeping competitive marketplaces and preserving consumer rights. The Commission aims to stop anti-competitive behavior that may result in higher costs and diminished quality of care through strict oversight. The dynamic and quickly changing dynamics of the healthcare sector call for constant rebalancing of enforcement methods. The FTC has to continuously upgrade its regulatory framework to meet new industry challenges to make sure that antitrust policies work in promoting competition as well as consumer welfare.