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# Efficiencies in Health Care Regulation: Observations Near and Far

*John D. Blum, J.D., M.H.S.\**

## I. INTRODUCTION

Multiple layers of regulation scatter the landscape of American health care as virtually every aspect of health delivery is in some fashion affected by regulation. From very basic entrance requirements, such as those dictated by licensure, to more esoteric and complex directives like those found in Medicare fraud and abuse areas, government regulations impact and increasingly define the enterprise of health care delivery.<sup>1</sup> Capturing the essence of health regulation proves difficult, as the area serves various purposes: from protecting the public's health, to providing the operative details of a given program, to addressing the broader concerns of cost, quality, and access.

Health regulation constitutes an enterprise, which proliferates with the problem of the day, and existing regulatory schemes are rarely reevaluated or abolished prior to issuance of new requirements. From the standpoint of the regulated, dealing with a myriad of mandates churned out at all levels of government, as well as in the private sector, constitutes an expansive and ever-present operational challenge. Curiously, although the health sector is so profoundly impacted by regulation, evaluation of regulatory interventions tends to be rather narrow and typically spurred on by cost considerations and politics.<sup>2</sup> Broad-based evaluation of health regulations'

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1. See generally HEALTH LAW HANDBOOK, 2003 EDITION (Alice Gosfeld ed., WestGroup 2003) (1989) (covering a wide range of health law topics, which generally provides readers with a sense of the scope of the regulatory area in health care).

2. Countless reports, emanating from Congressional oversight committees to the work of the General Accountability Office, analyze virtually every legislated health program. While

impacts on fundamental health policy concerns, such as the overall quality of population health, occurs infrequently and tends to be highly speculative. In fairness, the challenges of ascertaining the short and long term effects of any regulatory scheme are complex, and when that undertaking is geared toward measuring effectiveness of regulations on health, such enterprise is clouded with ambiguity, lacks clear bench marks, and is highly susceptible to the biases of evaluators.<sup>3</sup>

This essay explores the broad question of the effectiveness of health care regulation while the collective body of public and private regulation impacts the quality of health care generally. This article analyzes regulation in its broadest sense as a combination of administrative rules and program directives based on legislation, rule making, contractual obligations, and voluntary acquiescence. In turn, the concept of quality is cast in a global fashion, beyond traditional concepts of structure, process and outcome, to broad considerations of our entire health delivery system's effectiveness to support individual and population health needs. Inherent in this global notion of quality is the promotion, via regulatory intervention, of the core goals of health policy – namely, clinical quality, cost effectiveness, and individual access to services. This essay presents a modest attempt to make observations about the highly complex and eclectic arena of health care regulatory evaluation, and in no way purports to do more than point out directions of inquiry and posit several general considerations that may be useful in sparking future analyses. The general inquiry of the effectiveness of health regulations on quality considers whether the overall expenditures required by our extensive regulatory system enhance the overall stature of American health care. In approaching the question of value for money, this essay will consider the current nature of health regulations, the question of what those regulations cost, and conclude with an examination of comparative national expenditures on health. The three areas noted will serve as a springboard for several concluding observations about the need for future analyses of American health care regulatory policies.

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such reports are highly detailed, they tend to be rather narrowly cast. In addition, the executive branch issues countless reports each year exploring particular government programs.

3. For an excellent example of an analytical document that attempts to look at the sum total of health care regulation, see generally AMERICAN HOSPITAL ASSOCIATION, TASK FORCE ON REGULATORY RELIEF AND REFORM: FINAL REPORT (Oct. 2002), [http://www.aha.org/aha/key\\_issues/reg\\_relief/content/boardregrefrep0210.doc](http://www.aha.org/aha/key_issues/reg_relief/content/boardregrefrep0210.doc). This Report presents a detailed discussion of regulation in the hospital sector and makes a number of suggestions for reform which may be noteworthy, but must be viewed in the context of self-interest.

## II. HEALTH REGULATIONS: FORMATS, MEASUREMENTS, AND COMPARISONS

All three branches of government heavily scrutinize health regulations, but they typically restrict such examination to the details of a given regulatory initiative; or, in the case of the judiciary, examinations are restricted to the viability of a given legal challenge concerning aspects of a particular regulatory scheme.<sup>4</sup> However, what is collectively known about regulations in health care tends to be speculative and often reflects strong commentator biases, usually in the case of the regulated.<sup>5</sup> Achieving a collective vision of health regulation is complicated by the fact that regulatory initiatives are triggered for a variety of reasons from broad, fundamental public health protections, to providing programmatic operational details, to addressing varying types of problems in the delivery system.

Further complicating the ability to achieve a comprehensive portrait of regulation is the fact that governments at all levels (federal, state, and local) frequently mount new regulatory initiatives and alter and expand existing programs; the same can be said for private sector regulators such as the Joint Commission on Accreditation of Health Organizations (JCAHO).<sup>6</sup> Even the most fundamental regulations, such as licensure and core program operating directives like those encountered in Medicare, tend to be fluid as new problems or developments in the health delivery system change the rules. The development of problem-oriented regulations present a common pattern in regulation, centering on addressing individual issues of the day and issue-oriented regulation is often poorly integrated with existing mandates. Politics drive issue-oriented regulation, which frequently results in both the federal and state levels regulating the same set of problems in ways that are often poorly harmonized.<sup>7</sup> Broadly speaking, it seems

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4. Medicare is an excellent example of a regulatory program that undergoes constant evaluation at the legislative and executive levels of government, and is often an area subjected to a myriad of legal challenges. See generally COMMERCE CLEARING HOUSE, MASTER MEDICARE GUIDE (2006), available at <http://hr.cch.com/primesrc/bin/highwire.dll>. Interestingly enough, a House Appropriations Committee Report has sparked an ongoing examination of the whole process of health regulation at the federal level. See generally H.R. REP. NO. 108-636 (2004), available at <http://thomas.loc.gov/cgi-bin/cpquery/T?&report=hr636&dbname=108&> [hereinafter HAC Report].

5. See generally AMERICAN HOSPITAL ASSOCIATION, *supra* note 3.

6. Joint Commission on Accreditation of Health Care Organizations, <http://www.jcaho.org> (last visited April 1, 2006).

7. A good recent example of regulatory duplication can be seen in the area of patient safety, where many states have enacted regulatory schemes, on the heels of which quickly followed a new regulatory program. See generally JILL ROSENTHAL & MAUREEN BOOTH, NATIONAL ACADEMY FOR STATE HEALTH POLICY, DEFINING REPORTABLE ADVERSE EVENTS: A GUIDE FOR STATES TRACKING MEDICAL ERRORS, (2003), <http://www.premierine.net/all/>

reasonable to argue that health regulations are extensive, layered, and disjointed.

### *A. Regulatory Formats*

A general lack of consensus about the most appropriate mechanisms of health care regulation further confounds the challenge of achieving regulatory effectiveness. Even the most ardent critic of government health care regulation would concede that some types of interventions are needed to promote basic public health goals in access, cost effectiveness, and quality. However, even occasional agreement on the need for regulation does not translate into consensus about the appropriate manner of regulation.

Typically regulatory goals are actualized through established legal requirements, such as administrative rulemaking, that dictate the processes and structure of given mandates. On the other hand, many would point out the practical and theoretical undesirability of such interventions.<sup>8</sup> In fact, a fundamental tension exists between those who favor a bureaucratic, governmentally directed regulatory process and those who see the market as the most effective lever of control. Beyond the extremes of the free market approach and traditional administrative rulemaking lay several other regulatory pathways that have emerged, including private or voluntary regulation, which are all geared toward implementing some manner of oversight and control on the health sector.<sup>9</sup>

In 2003, the American Hospital Association convened a Task Force on Regulatory Relief and Reform (“AHA Task Force”) which identified seven primary forms of regulation encountered in the hospital sector, including: command and control (rulemaking), public utility regulation, inspection, reporting and disclosure, performance based regulation, delegated

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advocacy/trustees/docs/nashp-reporting-adverse-events.pdf; *see also* Patient Safety and Quality Act of 2005, Pub.L.No.109-41,119 Stat.424 (codified as amended in scattered sections of 42 U.S.C § 299).

8. Honorable Jon Kyl, Heritage Lecture: What is True Medicare Reform? 4, 10-11 (Oct. 23, 2003), *available at* <http://www.heritage.org/Research/HealthCare?HL805.cfm?renderforprint=1>; *see generally* AMERICAN HEALTH CARE: GOVERNMENT, MARKET PROCESSES, AND THE PUBLIC INTEREST (Roger D. Feldman ed., Transaction Publishers 2000) (discussing the benefits of free markets in health care); *see generally* FEDERAL TRADE COMMISSION & DEPARTMENT OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (July 2004), *available at* <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

9. *See generally* BETTY LEYERLE, THE PRIVATE REGULATION OF AMERICAN HEALTH CARE (M.E. Sharpe Inc. 1994). A growing academic movement has embraced the concept of new governance, which promotes alternatives to traditional regulation. For an example of this, *see* Louise G. Trubek & Maya Das, *Achieving Equality: Healthcare Governance in Transition*, 29 Am. J.L. & Med. 395, 410-15 (2003).

regulation, and market regulation.<sup>10</sup> While the AHA Task Force found that command and control regulation was by far the most dominant model in the hospital arena, it concluded that none of the identified regulatory formats were satisfactory.<sup>11</sup> In fact, the AHA called for the development of new regulatory models, which can better balance the needs for public controls with the realities of meeting such mandates on the part of the regulated.<sup>12</sup> It seems reasonable to conclude that from the health care industry side in particular, a general dissatisfaction with how health care is currently regulated is a common sentiment, and from the legislative and bureaucratic perspectives, it would be unlikely that a consensus over how best to regulate health care can be achieved.

### *B. Measuring the Costs*

Yet another complicating factor in trying to develop a collective sense of the effectiveness of health care regulation is the surprising lack of accurate information on the cost of regulation. Detailed information available about regulatory costs only exists in the context of given programs, stemming largely from budget and appropriation processes and agency analyses, but such oversights rarely capture a sense of overall costs, particularly those involving compliance. An accurate sense of the costs of developing, implementing, and complying with health regulations is lacking, and further meaningful cost/benefit analyses of regulatory programs rarely exist.

Dr. Christopher Conover, a Duke University health economist and a leading authority on health care economics, writes about the notion of “top-down” cost analysis, referring to the development of a general sense of health care regulatory costs garnered via comparisons between health and other industries.<sup>13</sup> According to Conover, a “top-down” analysis on health care costs would be based on consideration of the percentages of gross economic activity in health care, in comparison with other industries such as aviation or telecommunications where regulatory costs are better known.<sup>14</sup> While this “top-down” approach to costs is rudimentary and flawed, it is more meaningful than the current intuitive manner of concluding that health care regulatory costs are high, springing from a logical, but speculative, conclusion of costs based on volume of activity. On the other hand, the case for high regulatory costs, which rests on the

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10. AMERICAN HOSPITAL ASSOCIATION, *supra* note 3 at 4.

11. *Id.* at app. E/Hospital Regulation/1: A New Blueprint for the Future.

12. *Id.* at 1.

13. Christopher J. Conover, *Health Care Regulation A \$169 Billion Hidden Tax*, 527 *Cato Inst. Pol’y Analysis* 3 (2004).

14. *Id.*

sheer volume of regulation, is often buttressed by a more acute sense of expenditures on the part of the regulated, which results from the escalating costs of compliance that continues to expand with new and changing mandates.<sup>15</sup>

The Cato Institute published a detailed study of health care costs conducted by Conover in 2004 which examined costs from a range of state and federal health care regulatory programs. The study included regulation of health facilities, health professionals, health insurance, drugs, and the costs of medical liability.<sup>16</sup> The Conover study classified costs in four ways: government regulatory costs, compliance costs, indirect costs, and social welfare costs. The study concluded that the annual cost of health services regulation exceeds \$339.2 billion.<sup>17</sup> The study attempted to balance the total costs against benefits and based on this analysis concluded that the expense of health regulation outweighed the benefits two-to-one, costing the average American household \$1500 per year.<sup>18</sup> The details of the Conover study are beyond the scope of this essay, but the effort, while laudable, is very much an initial foray into a highly complex and unsettled arena. Clearly, more research on health regulatory costs, and on the even more elusive area of deciphering the benefits of regulation, needs to be conducted. However, the overall point that regulatory costs are excessive and appear to outweigh the benefits is a most compelling observation, calling into question the effectiveness of the health care regulatory enterprise.

### C. Comparisons

Weighing the effects of our regulatory system as a whole against other nations presents another way to measure the effectiveness of U.S. health care regulations collectively. Undoubtedly, there are some who would question the value of a comparative approach to the question of regulatory effectiveness, arguing that such an endeavor is fatally flawed because there are too many differences across the spectrum of national health systems to make such an exercise worthwhile. Perhaps the greatest difficulty in developing comparisons is the dearth of measurements about health care system indices in other countries in contrast to the United States, which is heavily engaged in generating system measurements of every sort.

Beyond the lack of comparative data, major differences make

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15. PriceWaterhouseCoopers, *Cost of Caring: Key Drivers of Growth in Spending in Hospital Care*, 17-18 (2003), available at <http://pwchealth.com/pdf/caring.pdf>.

16. Conover, *supra* note 13.

17. *Id.* at 4-6, 18.

18. *Id.* at 1.

comparisons of regulatory intervention problematic, from the overall public nature of many health systems to wide variations in population characteristics. Even in countries that have strong similarities to the U.S., such as Canada, there are marked differences in the structure and financing of their health systems. Key Canadian health policy issues, such as user fees and waiting lists, lack comparable weight south of the border.<sup>19</sup> Still, in the developed nation context, there are strong similarities in the nature of challenges faced by government regulators, such as devising effective cost controls, improving quality outcomes, increasing efficiency of delivery systems, moving health care into a more information based mode, controlling administrative costs, and limiting the growth of resources attributed to the sector. Such challenges are coupled with parallel interests on the part of regulators in developed countries, including promotion of information technology, adoption of patient safety measures, evaluation of the effectiveness of medical care, development of clinical practice guidelines, etc. Thus, the noted challenges and the resultant interests serve as a compelling basis for consideration of how other nations approach health care regulation, with particular focus on expenditures and outcomes in light of major gaps in comparative data and system disparities.

For purposes of this essay, the gross domestic product (GDP), which entails aggregate spending on health generally, will serve as a frame of reference for comparison. There should be a correlation between health GDPs and the amount a nation spends on health care regulation, although such a correlation must be carefully examined on an individual country basis. The GDP, when correlated with key health outcome measures, becomes a barometer against which to probe the effectiveness of a national health system. It may also serve as a gauge to examine whether a given nation is pursuing optimal regulatory strategies.

The U.S. GDP devoted to health is now over 15% totaling \$1.9 trillion. This far exceeds Germany, which has the second highest health GDP of 11.5%, followed by Switzerland at 11%.<sup>20</sup> The U.S. health GDP stands in stark contrast to other industrialized nations.<sup>21</sup> The average American family spends \$5267 on health care every year, compared with a median

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19. Nadeem Esmail & Michael Walker, *How Good is Canadian Health Care? 2005 Report*, FRASER INST. 2005 CRITICAL ISSUES BULL. 8 (2005), available at <http://www.fraserinstitute.ca/admin/books/files/HowGoodIsCanHealthCare2005.pdf>.

20. Organisation for Economic Co-operation and Development, *OECD Health Data 2005: How Does the United States Compare*, available at <http://www.oecd.org/dataoecd/15/23/34970246.pdf> [hereinafter OECD]; see also Gerald F. Anderson et al., *Health Spending in the United States and the Rest of the Industrialized World*, 24 HEALTH AFFAIRS, 903-14 (2005).

21. See OECD, *supra* note 20.

expenditure of \$2193 in the developed world.<sup>22</sup> When the American health GDP is considered against standard public health system outcome measures, such as life expectancy, childhood immunization, and medical service utilization patterns (i.e. doctor visits, hospital admissions, use of prescription drug), the U.S. does not always fare so well.<sup>23</sup> Serious questions must be raised about the costly American health system, which ranks 19th in infant mortality globally and achieves life expectancies lower than many other industrialized nations.<sup>24</sup> A sea of international public health statistics could be quoted to make the case that there is something fundamentally amiss in the way in which money is spent in the American health system, with special concerns for very high expenditures in areas such as paperwork and bureaucracy.<sup>25</sup>

In relation to regulation, raw GDP numbers do not indicate what amount is attributable to government regulatory efforts. However, it does seem reasonable to speculate that the percentage of the American health care GDP that is devoted to health care regulation is likely much higher than other developed countries. One element of international comparison, which comes the closest to regulatory expense, is the amount nations devote to expenditures on health care bureaucracy and paperwork. The Organisation for Economic Co-operation and Development (OECD) estimates that the U.S. spends four hundred billion dollars annually on health care bureaucracies and paperwork and a major portion of that expense is likely due to regulatory compliance.<sup>26</sup> In contrast to the United States, Canada, which outperforms the U.S. in many public health quality measures, spends 70% less on paperwork and bureaucracy and likely spends far less on regulation even though the Canadian system is primarily public.<sup>27</sup>

Beyond broad comparisons of public health measures contrasted with total national health expenditures, other types of comparative analyses look at other health care indicators. For example, the Commonwealth Fund sponsored a research project which entails a comparison of twenty-one health care quality indicators in five countries broken into two broad areas:

22. *See id.*

23. A myriad of comparative statistics on health care systems is reported by OECD and the World Health Organization, *see* <http://www.who.int/healthinfo/statistics/whstatsdownloads/en/index.html> (last visited March 1, 2006).

24. *Id.*

25. *See* Rep. Tim Murphy, Rx Health Care FYI #17, Paper Costs and Kills, *available at* [http://murphy.house.gov/UploadFiles/HealthCareFYI\\_17.pdf](http://murphy.house.gov/UploadFiles/HealthCareFYI_17.pdf) (last visited Mar. 1, 2006).

26. David U. Himmelstein, Statement on the Administrative Waste in the U.S. Health Care System in 2003, Public Citizen, Health Services research group, *at* <http://www.citizen.org/hrg/healthcare/articles.cfm?ID=10299> (last visited Mar. 1, 2006).

27. *Id.*; *see also* Steffie Woolhandler et al., *Costs of Health Care Administration in the United States and Canada*, 349 *NEW ENG. J. MED.* 768-775 (2003).

first, outcome indicators, including survival rates for various cancers and avoidable health events, and secondly, process indicators that focus on the application of appropriate public health measures, such as disease screening.<sup>28</sup> An article summarizing results of the Commonwealth Fund project noted that the United States may achieve better quality scores in some areas, but in light of the huge difference in expenditures with other study nations, “the extra spending is probably not buying better experiences . . . with the exception of shorter waits for nonurgent surgery.”<sup>29</sup>

<sup>29</sup> While the Commonwealth Fund comparative study does not deal with regulatory costs, its results demonstrate that our high health care expenditures do not translate into higher quality and must call into question all the elements factored into the total expenditure, including regulatory cost.

In the future, another potentially helpful base of comparative analysis concerns a growing international interest in consumer satisfaction with health systems. In the U.S., there has been an ongoing analysis of patient satisfaction with health care services, which is best illustrated in the area of health plans through the Consumer Assessment of Healthcare Providers and Systems (CAHPS).<sup>30</sup> Europeans are beginning to look at consumer satisfaction and a research group based in Sweden, the Health Consumer Powerhouse, has developed the Euro Health Consumer Index that compares basic consumer satisfaction measures across twelve countries.<sup>31</sup> Interestingly, the European countries that spend a considerable amount on health, such as Switzerland and Sweden, do not necessarily rate higher on consumer satisfaction scales than those who spend less.<sup>32</sup> Using similar measures to the Euro Health Consumer Index, it would be interesting to measure whether our costly health system results in greater consumer satisfaction than what is found in other countries. Just as the quality comparisons noted earlier do not directly correlate with regulatory costs, so too would be the case of consumer satisfaction measures. Here as well, low satisfaction scores and high system costs would call all aspects of health expenditures into doubt, including regulation.

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28. Peter S. Hussey et al., *How Does the Quality of Healthcare Compare in Five Countries?* HEALTH AFFAIRS, May/June 2004.

29. *Id.*

30. See generally The National CAHPS Benchmarking Database (NCBD), available at <http://www.cahps.ahrq.gov> (last visited Mar. 1, 2006).

31. Health Consumer Powerhouse, *2005 EuroHealth Consumer Index*, available at [http://www.healthpowerhouse.com/media/EHC12005\\_EN.pdf](http://www.healthpowerhouse.com/media/EHC12005_EN.pdf) (last visited Mar. 1, 2006).

32. *Id.* at 8.

### III. CONCLUSION

Perhaps the most apparent observation that can be drawn from the preceding discussion is that far too little is known about the costs and benefits of health regulation in America. The most basic points, such as a good general measurement of the individual and collective costs of health care regulations and the relationship between regulations and individual/population health, largely remain matters of speculation. In some instances, we may be able to track the costs of individual program regulations, but a broader view of costs, which entails compliance and balance with benefits, is not currently available in the health sector.<sup>33</sup> Undoubtedly, addressing the question of value for money in the health care regulatory sector is an evaluation laced with complexities. Measuring the sum total of health regulatory costs requires value judgments about what to include in cost calculations and becomes highly subjective when raw costs are judged against a list of benefits that allegedly flow from given regulatory initiatives. Still, there is a need to better understand all aspects of our expensive health care delivery system, particularly in light of the growing awareness that other developed countries spend less, but achieve better population health results. Broad concerns about improving the quality of our health system in all facets, including regulation, make assessments of health care expenditures and their ultimate correlation vital to quality. Comparisons with other nations concerning expenditures on health and outcomes should not be dismissed on the bases of differences in populations and delivery mechanisms. Comparative analyses should be pursued with particular attention to both deciphering how to enhance quality and reduce expenditures, or at least to contain them.

The role of regulation should not be marginalized as a secondary consideration in the health care quality and cost debates. Instead, it needs to be seen as a focal point reflective of the priorities and strategies in this sector. All aspects of health regulation should be reconsidered – not only costs, but also broad, fundamental approaches to regulation, as well as, particular regulatory processes, old and new.

A key aspect of reform will entail proposals to harmonize regulatory efforts between the states, federal government, and private entities to reduce costly duplication. Ultimately creating needed efficiencies in health regulation is contingent on a national vision of what health care in America should be, but achieving that consensus remains an elusive goal. For the

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33. *Supra* note 4, HAC Report (the House Appropriations Committee has charged the HHS Assistant Secretary for Planning and Evaluation and the Office of Management and Budget (OMB) with examining the impacts of health care regulation and devising recommendations for streamlining this area).

present, the lesser goal of extracting better value for money in health regulations through various large and small alterations must not be delayed, as efficiencies in health care are in short supply. In the long term, the systematic study and reform of health care regulation addresses more than operational efficiencies, but can be seen as the catalyst for achieving meaningful progress in improving the quality of the delivery system. In the extreme, regulatory reform could play a central role in forging a comprehensive vision for the future of American health care.