

# THE CHALLENGE OF MANAGED CARE REGULATION

## Making Markets Work?



# Foreword

For some time, states have regulated managed care organizations to ensure their financial solvency, including their ability to cover the risk of enrollees. Over the past decade, the nature of states' regulation of the managed care industry has shifted to focus on preserving quality and patient and provider satisfaction. For example, states have passed legislation or established regulations to ensure that adequate provider networks are maintained and patients have adequate access to specialists through referrals.

More recently, the last three years have seen feverish debate in the Congress over a Patients' Bill of Rights, designed to give consumers recourse when care is denied by their health plan. Earlier this summer, the Senate passed S. 1052, sponsored by Senators John McCain (R-AZ), Edward Kennedy (D-MA), and John Edwards (D-NC). Under the bill, individuals could sue insurers in state court for medical decisions, or in federal court for administrative decisions. The House has now passed a companion bill, H.R. 526, with a more limited right for individuals to sue their health plan. If federal legislation is to finally become law, there must be House-Senate negotiations resulting in a bill President Bush is willing to sign.

There is little research or other empirical evidence, however, to support the implementation of these regulations or to provide information about their likely impact. The vast majority of the regulatory controls on the industry have come about on an ad hoc basis driven by regulators' and legislators' desires to improve the performance of managed care organizations and are based on their perceptions of what makes sense. Critics of the version of the Patients' Bill of Rights passed by the Senate, for example, argue that allowing consumers to sue health plans (and possibly employers) will drive up the costs of health care and result in businesses either dropping coverage or will cause those not currently offering health coverage to avoid providing it in the future. But proponents believe such regulations are needed to ensure

consumers' access to quality health care and to provide a legal remedy when the plan puts "profits above people."

The *Changes in Health Care Financing and Organization* (HCFO) program brought together researchers and regulators to discuss managed care regulations that have been proposed or implemented, and the research issues and questions that remain to be addressed in this area. Also at issue was the data available for addressing such questions and the lessons learned where such regulations have been implemented.

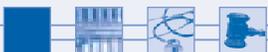
The purpose of this report is to provide a framework for thinking about the implications of managed care regulations and legislation under consideration in the states and in Congress. It highlights research projects that have helped fill information gaps about managed care regulation and policies and examines current projects that seek to further this cause. Finally, the report identifies questions for which policymakers seek answers, and guides researchers looking to provide evidence for the sound development and implementation of managed care regulation and legislation.



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# Introduction

By 2000, 92 percent of the population with employer-sponsored insurance was enrolled in some form of managed care (including point-of-service plans), up from 73 percent in 1996.<sup>1</sup> As of December 31, 2000, 57 percent of Medicaid recipients were enrolled in managed care plans.<sup>2</sup> In addition, the managed care industry has changed in many ways. Most managed care organizations now contract with a broad panel of physicians, share risk, and compete with each other for greater market share. Concerns about quality of care also have factored into the way managed care organizations market themselves and do business.

Despite the enormous growth and change, there is little understanding of the evolution of managed care organizations, including their structure, behavior, financing, and particularly, regulation. And although liberals and conservatives alike agree that regulation of the managed care industry is needed, they differ markedly about how much and what type of regulation is necessary. States have been the recent leaders in regulating the industry; from 1994 to 1999, more than 1,000 managed care laws were enacted by state legislatures. While some regulations, such as bans on gag clauses, direct access to OB/GYNs, and disclosure of plan information to consumers have been widely adopted, others have been adopted in only a few states. Lack of coordination among the states, coupled with the diversity of regulations, has created a complex regulatory scheme for managed care plans, especially those doing business in more than one state.

Gathering data on managed care regulations and developing appropriate models to analyze the data is quite difficult, however. The many simultaneous changes that have taken place in the health care market over the last several years — increasing managed care penetration, expanding health plan networks, and plan mergers — make it difficult to measure the impact of an individual factor, such as a specific new managed care regulation. Developing an understanding of the impact of regulations will help policymakers

determine where and when additional regulations are needed. To achieve this, researchers must study market behavior, including anticipated responses to a variety of changed incentives. Otherwise, administrative costs of implementation and unintended consequences could mitigate any benefit from a regulatory “fix.”

Policymakers must also consider the feasibility and affordability of implementing proposed regulations, and must be sure the regulation is understandable to consumers, providers, and health plans, as well as to those responsible for its enforcement. They must determine whether a proposed regulation has broad public support and is the best possible way to reconcile contradictory policy objectives and perceived market failures.

Given the speed with which managed care regulations have been adopted and their considerable variation across the states, it is important to identify, catalogue, and categorize them. It would then be helpful to talk to those who were key players in their development and implementation to determine why the regulation was put in place, if it has had the anticipated effect, and if there is a perception that it has had other impacts. This will help policymakers and researchers define a clear path for further evaluation and policy consideration.



# The Challenge of Managed Care Regulation

## Making Markets Work?

Over the last 30 years, managed care organizations have proliferated in the United States. There is little understanding, however, of their evolution, including their structure, behavior, financing, and regulation. While economists typically rely heavily on market theory to identify the need for market regulation and to predict its impact, regulation in the managed care industry has largely been implemented haphazardly. It is often based on anecdotal evidence, consumer and provider pressures, and political ambition, rather than on formal analysis of the problems in the managed care market or whether those problems arise from market failure. There also has been little exploration of whether various regulatory incentives will correct the identified problems. And, finally, to the extent that regulations have been implemented, there has been little formal analysis of their impact.

The purpose of this report is to provide a framework for thinking about the implications of managed care regulations and legislation under consideration in the states and in Congress. It synthesizes the experiences, to date, of regulating the managed care industry, and discusses how the theory of regulation might apply to the health care market. The report also identifies questions for which policymakers seek answers and serves as a guide to researchers looking to provide evidence for the sound development and implementation of managed care regulation and legislation.

### The Evolution of Managed Care Regulation

In large part, the growth of managed care organizations was spurred by the Health Maintenance Organization (HMO) Act of 1973.<sup>3</sup> The HMO Act mandated that employers with more than 25 employees, and required to pay minimum wage, offer an HMO option as part of their health benefits, if they provided health insurance. Employers

were prohibited from charging less for the HMO option than was charged for indemnity insurance (the dual-choice provision). Under the HMO Act, to become federally qualified, HMOs were required to provide a basic set of benefits. In addition, the Act provided capital, in the form of loans, for HMO development and pre-empted state laws that banned the corporate practice of medicine insofar as they would impede HMOs from operating in the state. In fact, the Act “prohibited all state laws or practices that served as barriers to the formation of HMOs, regardless of whether there was a direct conflict with federal legislation.”<sup>4,5</sup>

Throughout the late 1970s and the 1980s, the HMO Act was amended to limit the scope of supplementary benefits (e.g., podiatry) that HMOs had to provide and to allow for contracting with physicians in independent practices, paving the way for today’s point-of-service (POS) insurance options. By 1983, development loans were no longer provided to HMOs, and the dual-choice provision was relaxed and ultimately eliminated by 1995. Simultaneously, a variety of risk-sharing arrangements, including capitated or partially capitated payments, were developed between the managed care organizations and their providers.

There is some debate as to whether the federal legislation regulating HMOs evolved as a result of what was happening in the industry or whether the industry responded to the legislation, rendering many of its primary provisions moot over time. By the mid-1980s, few HMOs considered it a competitive advantage to become federally qualified, by meeting the provisions of the HMO Act. Many managed care organizations also began to experience solvency problems, prompting states to take on a larger role in terms of fiscal oversight. While the federal and state roles in regulating the managed care industry were changing, neither the states nor the federal government attempted to



directly regulate the quality of care provided by managed care organizations.<sup>6</sup>

Today's managed care organizations have, in many cases, changed dramatically from the staff-model, federally qualified HMOs of the 1970s and early 1980s. Most managed care organizations now contract with a broad panel of physicians, and many provide enrollees the option of seeking care outside of the network of providers with limited out-of-pocket expenditures. In addition, many managed care organizations share risk, often through some form of capitated payment, with their providers. HMOs now compete with each other for market share, as well as with the few remaining traditional insurance products.

Enrollment in managed care grew dramatically over the last decade. By 2000, 92 percent of the population with employer-sponsored insurance was enrolled in some form of managed care (including POS plans), up from 73 percent in 1996.<sup>7</sup> As of December 31, 2000, 57 percent of Medicaid recipients were enrolled in managed care plans.<sup>8</sup> In response to increased competition in the managed care industry, as well as to the realization that the majority of the nation's population is enrolled in some form of managed care, consumers and other industry watchers began raising concerns about the quality of care provided. In particular, due to the regulatory emphasis on fiscal solvency and the risk-sharing arrangements with plan physicians, concerns were raised about possible incentives for individual providers to make inappropriate cost/quality tradeoffs. These concerns about quality, often referred to as the "consumer backlash against managed care," have spawned a new type of regulation and legislation to improve the quality of care delivered by managed care organizations. Since quality of care was not addressed by the HMO Act, states were not precluded from regulating in this area.

Providers also have raised concerns about the constraints placed on the practice of medicine and their income potential by managed care plans. Therefore, recent regulations have also addressed issues of provider autonomy and competition. These newer regulations comprise such things as required lengths of stay for certain conditions or procedures, requirements for direct access to specialists without a referral from a gatekeeping primary care physician, and requirements for inclusiveness of the provider panel (any-willing-provider (AWP) laws).<sup>9</sup>

In recent years, state regulatory policies, rather than federal ones, have been the driving force behind managed care organization behavior.<sup>10</sup> While almost every state has enacted some type of managed care regulation and Congress has spent considerable time over the last four years debating a patients' bill of rights, there is little research that identifies systemic quality problems in managed care organizations. In addition, few evaluations have been conducted of regulations that have been enacted and implemented. Most regulations currently under discussion are being debated or enacted based on anecdotal evidence or political appeal, rather than scientific evidence of their impact on quality of care.

### Regulation vs. Competition

Economists have long debated the merits of "free" market price competition versus regulation. Economic theory holds that in a free enterprise economy, the two primary reasons for government intervention in the market are to ensure equity or to ensure efficiency.<sup>11</sup> In terms of equity, if a good, such as health care, is viewed as being so important that access must not be based on price alone, then

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regulation may be necessary. To ensure market efficiency, full information must be shared, with all participants fully understanding the good being sold or purchased, and they must have a real choice among competing products.

It is clear that most policymakers, and society as a whole, view health care as too important to have individual access dependent solely on ability to pay. While consumers increasingly have access to and understanding of medical information, providers still have a significant market advantage in that respect.<sup>12</sup> Finally, health care is not only important to individual welfare, but also serves to improve the public good. For these reasons, some regulation of health care markets generally is supported, although there is ongoing debate about how much and what type of regulation is necessary.

Policymakers have intervened to ensure access to those unable to compete in the free market. They have also acted to protect those able to participate in the market through measures that ensure financial solvency of health plans, contain costs, and, most recently, ensure quality and consumer and provider satisfaction.<sup>13</sup> Often, however, the policy debate occurs outside of a theoretical context, with policymakers failing to consider fully the market failures being addressed or the likely impact of the regulations under consideration. It is

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important to identify market failures and tailor regulations to directly address those failures. To do so, researchers must study market behavior, including anticipated responses to a variety of changed incentives. Otherwise, administrative costs of implementation and unintended consequences could mitigate any benefit from a regulatory “fix.” It is also important that regulations be understandable, enforceable, balance benefits and costs, and engender broad public and political support.<sup>14</sup>

### **Managed Care Regulation in the Current Era**

Recent managed care regulations fall into several categories. They include regulations to stabilize the insurance market, to protect providers from managed care policies, and patient protection regulations to improve access to and quality of care.<sup>15</sup> Insurance market regulations include requirements that plans disclose benefit information to consumers, requirements for the guaranteed issue and renewal of health insurance, and efforts to establish or encourage pooled purchasing of health insurance. Patient protection laws include regulations that: a) require direct access to specific kinds of care or providers; b) improve the quality of individual care through access to services; c) concern the provision of prescription drugs; and d) define a patient’s ability to file grievances against a

health plan. In addition, regulations have been adopted primarily to protect providers from managed care organization policies. These include AWP laws, freedom-of-choice (FOC) laws, bans on “gag rules” for patient-physician communications, and whistle-blower protections. Table 1 summarizes the types of managed care regulations that have been enacted.

### **Federal vs. State Regulation**

The locus of regulation of the managed care industry has floated between the federal and state governments over the last three decades. Traditionally, states have had responsibility for regulating insurance markets. The HMO Act, however, placed the federal government in the forefront of regulating managed care organizations, explicitly prohibiting states from enacting barriers to HMO formation, even where there was not a direct conflict with federal law.<sup>16</sup> In addition, states’ authority to regulate health plans is limited by the Employee Retirement Income Security Act of 1974 (ERISA).<sup>17</sup> ERISA preempts all state laws that “relate to” employee benefits plans, allowing states to continue to regulate insurance products but not employee benefits, including health insurance, provided by firms that self-insure.<sup>18</sup> Despite these limits, states have played a major role in enacting managed care regulation, particularly in terms of patient protection.

Indeed, states have been the recent leaders in regulating the managed care industry. Over the past several years, an increase in state regulation has been influenced both by the public managed care backlash and by increased legislative activity in other states. From 1994 to 1999, more than 1,000 managed care laws were enacted by state legislatures.<sup>19</sup> Because of the volume of legislation and the rapid time frame in which it was passed, these regulations have not been implemented or enforced in an organized manner. In addition, the numbers and types of provisions vary widely across the states, as depicted in Table 2. While some regulations, such as bans on gag clauses, direct access to OB/GYNs, and disclosure of plan information to consumers, have been widely adopted, others, such as access to clinical trials or “right-to-sue” provisions, have only been adopted in a few states.<sup>20</sup> Lack of coordination among the states, coupled with the diversity of regulations, has created a complex regulatory scheme for managed care plans. This situation is particularly difficult for the health



## TABLE 1: Definitions of Common Managed Care Regulations

### A) Regulations Requiring Access to Providers

**Direct Access to Non-primary Care Physicians** – Laws that require insurers to allow patients to visit a non-primary care physician without a referral from a “gatekeeper” primary care physician. Most states have passed direct access laws for OB/GYNs and some states have passed laws allowing patients with certain conditions to seek specialty care directly from other specialists.

**Standing Referral** – A variant of direct access laws mandating that patients be allowed to receive a “standing referral” to a specialty provider for treatment of a specific condition.

**Non-network Referrals** – Laws that require plans to cover referrals to out-of-network providers. These laws are intended to ensure that plan networks are adequately broad to meet patients’ needs and ensure that patients have access to specialists (specialties, not specific providers) that are not included in a plan’s network.

**Point-of-Service (POS) Requirements** – Laws that require insurers to offer a plan that allows consumers to choose providers outside of the plan’s network (usually at a higher cost-sharing rate determined by the plan).

### B) Regulations Requiring Access to Services

**ER “layperson standard”** – Laws to prevent limitation on coverage of emergency services by requiring that emergency services be covered if emergency care was warranted based on the determination of a “prudent layperson.”

**Length of Stay (LOS)** – Laws regulating the minimum length of a hospital stay for certain procedures. LOS laws apply primarily to hospitalizations for childbirth and mastectomy.

### C) Regulations Regarding the Provision of Prescription Drugs

**Off-label Uses** – Laws requiring plans to cover prescription drugs for uses that are not approved by the FDA (primarily cancer treatment).

**Off-formulary Procedures** – Laws requiring plans to have some procedure by which enrollees can obtain drugs that are not on the plan’s prescription drug formulary.

### D) Regulations Affecting a Patient’s Ability to File Grievances Against Health Plans

**External Review** – States have enacted a number of provisions regarding dispute resolution between health plans and patients. One of the most common statutes is a requirement that patients can appeal coverage denials to an independent external review organization. Although external review laws vary by state, the decision of the external reviewer is usually binding on the plan.

**Health Plan Liability** – Laws explicitly authorizing patients to sue their health plan for damages resulting from the plan’s involvement in denying or delaying coverage.

### E) Regulations Affecting Providers and Compensation

**Gag Clause Bans** – Laws banning clauses in health plan contracts with physicians that prevent physicians from discussing treatment options (including those not covered by the health plan) with their patients.

**Financial Incentive Limits** – Laws banning the provision of financial incentives that encourage physicians to limit access to “medically necessary care.” Financial incentive limits vary by state in defining what qualifies as a financial incentive. Laws generally do not apply to capitated payments to physicians.

**Provider Due Process** – Laws requiring that providers are able to apply to participate in a health plan’s network and that procedures exist to appeal contract terminations by the health plan.

**Any Willing Provider (AWP)** – Laws that require health plans to allow any provider willing to comply with contract terms to be included in the plan’s provider network. AWP laws apply most frequently to pharmacies, but have also been adopted less frequently for physicians, hospitals, and other providers.

**Source:** Butler, Patricia. *State Initiatives to Regulate Managed Care Health Plans*. Conference Draft, October 1999.

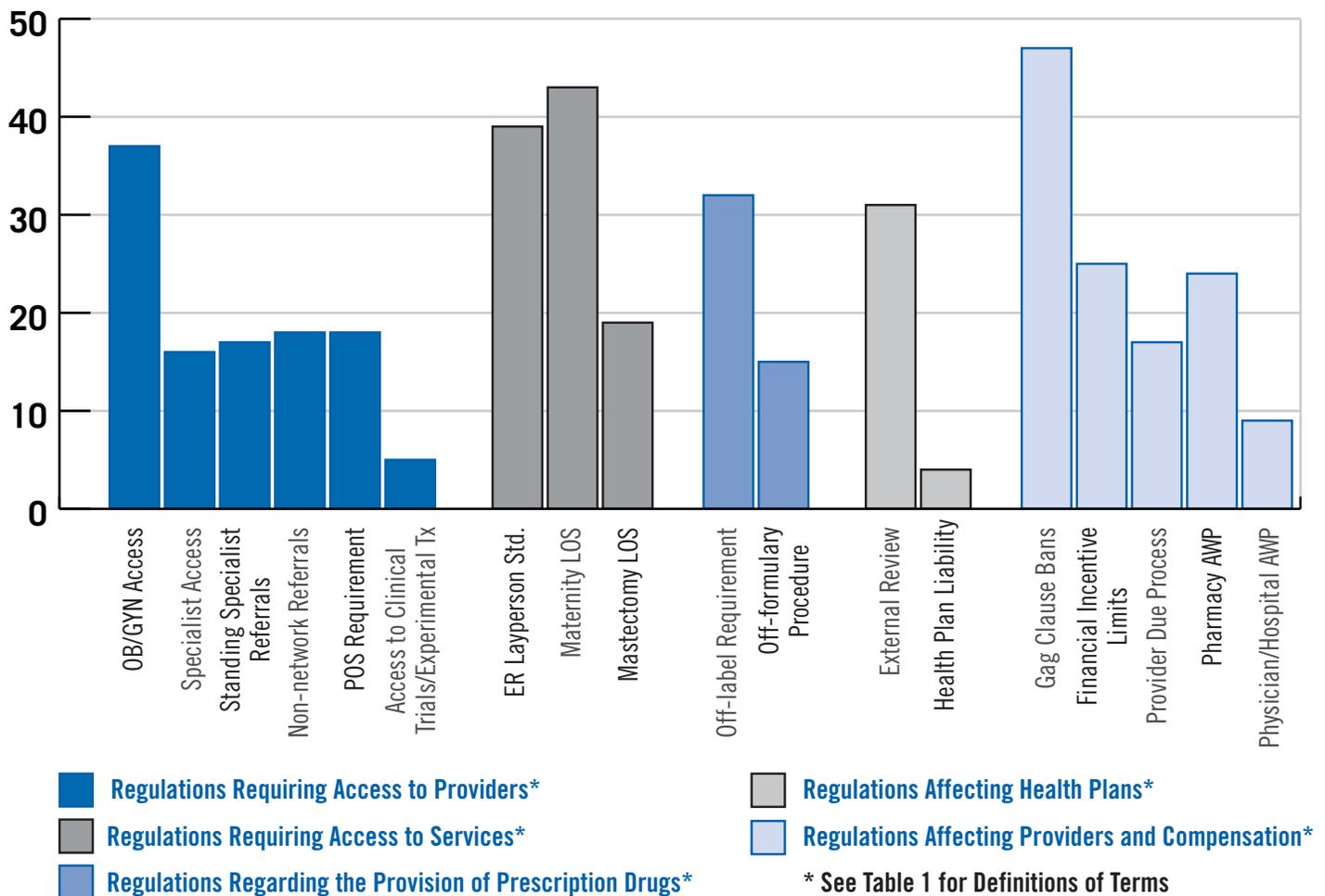
plans, as well as employers, with enrollees in more than one state, who must have multiple benefit structures and contracting arrangements to comply with the various state laws and regulations.

At the federal level, there has been very little managed care legislation enacted since the HMO Act was amended in the early 1980s. The one notable exception, the Health Insurance Portability and Accessibility Act (HIPAA) of 1996, created standards for pre-existing condition exclusions and required guaranteed issue and renewability by all health insurance plans.<sup>21</sup> In addition, like the states, the Medicare program over the last two decades has taken a variety of steps to ensure the delivery of quality care in various provider sites. The program monitors hospital care, including assessing medical necessity, through contracts with Peer Review Organizations (PROs). To obtain Medicare

certification, facilities and providers have to, at a minimum, meet state licensing requirements. The Medicare program also relies on some private and state initiatives to measure and improve quality, including the Health Plan (formerly HMO) Employer Data and Information Set (HEDIS), developed by the National Committee for Quality Assurance, and the Minnesota Reporting Standards for Health Care Utilization Data.<sup>22</sup>

For managed care plans, Medicare has adopted many of the same requirements as other purchasers in the areas of financial solvency, quality assurance, and enrollee rights. In addition, in 1976, the program implemented the 50/50 rule, stipulating that the combined enrollment of Medicare and Medicaid beneficiaries in a plan could not exceed half of a health plan's total membership. This rule was intended to control quality based on the assumption

**TABLE 2: Prevalence of Common Managed Care Regulations**



Source: Butler, Patricia. *State Initiatives to Regulate Managed Care Health Plans*. Conference Draft, October 1999.

that oversight by private purchasers would keep an HMO's quality of care high.<sup>23</sup> In 1981, the 50/50 rule was amended to a less restrictive 75/25 rule,<sup>24</sup> and the Balanced Budget Act of 1997 (BBA) stated that the rule did not apply to Medicare+Choice plans.<sup>25</sup>

Ultimately, the Quality Improvement System for Managed Care (QISMC) was developed as a tool for HCFA and states to implement the quality assurance provisions of the BBA, as amended by the Balanced Budget Refinement Act of 1999 (BBRA). The QISMC standards and guidelines are intended to improve upon and complement other HCFA quality initiatives, as well as those of certain public and private sector organizations. The QISMC standards and guidelines direct managed care organizations to: 1) operate an internal program of quality assessment and performance improvement that achieves demonstrable improvements in enrollee health, functional status, and satisfaction; 2) collect and report data reflecting their performance on standardized measures of health care quality; and 3) demonstrate compliance with basic requirements for administrative structures and operations that promote quality of care and beneficiary protection.<sup>26</sup>

During the past several years, Congress has debated various pieces of legislation referred to as a "Patients' Bill of Rights." At the close of the 106th Congress, none had become law, although two patient protection bills – S. 1344 and H.R. 2723 – were discussed by a House-Senate conference committee. The majority of the provisions in these bills were identical; however, key differences existed on the issues of a patient's right to sue his or her health plan and the scope of federal managed care regulation (all health plans vs. self-insured ERISA plans only).<sup>27,28</sup> Despite general support for managed care regulation in Congress and the executive branch, these sticking points were sufficient to stall debate over patient protection legislation during the 106th Congress.

The 107th Congress has taken up the patients' bill of rights debate again. The Senate passed S. 1052, sponsored by Senators John McCain (R-AZ), Edward Kennedy (D-MA), and John Edwards (D-NC). This bill would ensure that women can see OB/GYNs participating in the health plan without a referral or pre-authorization. In addition, if the bill becomes law, children would be able to select pediatricians as their primary care providers, as long as they participated in the health plan. The bill also would require health plans to cover emergency care,

regardless of whether the emergency room is in the patient's health plan network. S. 1052 would apply to all self-insured ERISA plans and health insurers in the group and individual markets, as well as to federal, state, and local government health insurance plans, including the Federal Employees Health Benefits Program, Medicare, and Medicaid. Under the bill, individuals could sue insurers in state court for medical decisions, or in federal court for adminis-

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trative decisions. There would be no limit on damage awards for economic losses or pain and suffering, and patients could recover up to \$5 million in "civil assessments" for violations of their rights in federal court. In state court, damages would be subject to the limits of state law.<sup>29</sup>

A companion bill to the McCain, Kennedy, and Edwards bill, H.R. 526, was sponsored by Representatives Greg Ganske (R-IA), John Dingell (D-MI), and Charles Norwood (R-GA), and passed by the House. However, prior to passage, an amendment negotiated by President Bush and Representative Norwood was adopted. The amendment would limit damages available to individuals suing their health plan to \$1.5 million in punitive damages, and \$1.5 million for pain and suffering. Damages for economic losses if medical decisions were made improperly would be unlimited. The House and Senate versions of the bill are once again likely to be discussed by a conference committee.<sup>30</sup>

President Bush has indicated his intention to veto the McCain, Kennedy, and Edwards bill, and many Republicans in the House and Senate continue to argue that it would create too large a burden for health plans.<sup>31</sup> The President now has indicated that he would sign a bill which limits lawsuits as the House version does. As of this writing, it remains unclear whether, and with what provisions, a federal patients' bill of rights will become law.

Assuming that the federal government will eventually succeed in passing comprehensive federal patient protection legislation, it is not clear

how it would interact with existing state regulation. An analysis by the Urban Institute begins to assess the likely impact of such legislation in 13 states.<sup>32</sup> The impact of federal law would depend not only on the similarity of the law to current state regulations, which vary widely, but also on the size of the targeted population and managed care penetration within the state.<sup>33</sup> In cases where federal legislation is similar to existing state legislation, it will have little impact, particularly if enforcement is left to the states. However, if a federal law applied to self-insured, as well as fully insured, employee benefit plans, then its impact would affect a broader population than existing state regulations, even if similar in substance. States with greater regulation than provided for in a federal law would still provide more protection for the fully insured population than for the self-insured.<sup>34</sup>

The other, largely unknown and unpredictable, factor that will affect the impact and authority of this mix of federal and state regulation of the managed care industry is the judicial system. There has been little consideration of the Constitutional issues that arise with respect to conflicting federal and state legislation, and it could take years for any lawsuits to make their way through the courts. The Supreme Court held in 1944 that interstate insurance firms operate in “interstate commerce,” over which Congress has exclusive jurisdiction. This effectively overturned a ruling from the 1800s in which the Court found that insurance regulation was within state jurisdiction.<sup>35</sup> In response, in 1945 Congress enacted the McCarran-Ferguson Act, delegating back to the states the power to regulate even those insurers operating across state lines.

While the constitutionality of federal *insurance* regulation is not in doubt, regulation of public health, perhaps including regulation of *providers*, has been interpreted as within state jurisdiction. That being said, it is plausible that the constitutionality of federal law in this area would be supported, were it challenged. So, in areas where federal and state regulation might conflict, the courts will need to determine whether states alone can adequately regulate the managed care industry or if protection of individuals, society, and interstate commerce are better served by standardized, federal regulation.

## Measuring the Impact of Managed Care Regulation

To understand the impact of managed care regulation enacted in the last several years, it is important to

evaluate its effect. This has relevance not only in locations where regulations have been implemented, but also in providing guidance for future regulatory and legislative efforts at both the state and federal levels. Policymakers are interested in understanding better whether patient-protection legislation currently under discussion will positively affect costs and quality of health care. Unfortunately, few formal evaluations have been undertaken, and they have produced mixed results.

Several questions must be asked in terms of evaluating the impact of managed care regulation and legislation to date, including: 1) What market failures were the regulatory efforts intended to “fix”? 2) What evidence was there that the problems existed? and 3) In whose interests was it to fix those problems? Some senior-level private, state, and federal policymakers, as well as health services researchers, posit that the vast majority of the recently enacted patient protection legislation resulted from political expediency,<sup>36</sup> and public debate around managed care regulation continues to be based on anecdotal evidence, without reliance on formal research.<sup>37</sup> Advocates for managed care regulation are responding to the widely publicized “managed care backlash,” while those opposed to it cite statistics indicating that most Americans remain satisfied with their managed care plans.<sup>38</sup>

Gathering data on managed care regulations, as well as developing appropriate models to analyze the data, is quite difficult. Given the multiplicity of health plan models and state regulations that existed prior to the implementation of patient protection legislation, it is difficult to identify and gather appropriate baseline data. Collection of baseline data is also more challenging in cases where regulations have been implemented quickly, as has been the case with much of the consumer protection legislation. In addition, the many simultaneous changes that have taken place in the health care market over the last several years, including increased managed care penetration, expanding health plan networks, and plan mergers, make it difficult to measure the impact of an individual factor, such as new managed care regulation. Furthermore, many of the new regulations were aimed at improving the quality of health care, and there is still much debate about how best to measure quality.



Finally, it is difficult to conduct analyses across states or to generalize lessons learned in one state to other states or the nation, since states vary significantly in the type and amount of regulation, have different levels of managed care market penetration, different models of managed care plans, and different demographics. That being said, there has been at least one comprehensive evaluation of AWP laws, one of the most widely implemented types of patient protection legislation at the state level. The study found that AWP laws have been enacted in 30 states, partially as a defensive strategy by providers attempting to protect themselves from managed care policies. However, while the laws have led to increases in HMO costs, they are not associated with significant changes in managed care market share or changes in premiums charged to employers or employees.<sup>39, 40, 41</sup>

In another study, researchers analyzed hospital discharge data for mothers and newborns in Illinois to examine the cost implications of a law requiring insurers to provide hospital coverage for at least 48 hours following vaginal deliveries and 96 hours following Caesarean deliveries. They found that most women in the sample remained in the hospital fewer days than the legislated minimum and that most newborns released from the hospital remained healthy, with approximately 2 percent being re-admitted during the first two weeks of life. Using these estimates, the researchers concluded that if 10 percent of women increased their stay to the legislated minimum, additional hospital charges would exceed savings unless 100 percent of re-admissions were avoided. As a percentage of total spending on birth-related admissions and re-admissions, the net effect of the law ranged from a savings of 0.1 percent to a cost of 20.2 percent.<sup>42</sup>

The cost implications of such regulations must, of course, be balanced against improvements in quality of care. No comprehensive evaluation of quality improvements resulting from minimum maternity requirements has been done, but researchers have begun to explore the influence of length of stay on patient satisfaction. Researchers surveyed a sample of women discharged after labor and delivery from 18 hospitals in a large metropolitan region from 1992 through 1994. There was no evidence that the satisfaction of patients with shorter stays was lower, with differences in satisfaction according to length of stay “small and of questionable practical significance.” The researchers

concluded that patients’ satisfaction with care may not depend on the absolute duration of the stay, but rather on whether they perceive the stay to be adequate.<sup>43</sup>

Researchers are currently examining the effects of state managed care patient protection laws on patients, providers, plans and networks, as well as on corporate and market structures. The researchers will: 1) develop an “index of regulatory intensity” of patient protection laws (among states and over time); 2) learn more about the complexities of implementing and enforcing states’ patient protection laws; and 3) determine whether patient protection laws have achieved their intended effects and avoided unintended consequences. They are studying primary legal sources and conducting a systematic national survey of state regulators and health care lawyers. In addition, they are



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conducting a combination of quantitative and qualitative studies, analyzing the Community Tracking Study of patients and physicians (1996-7 and 1999), and conducting in-depth case studies in six states. The objective of the study is to inform the national debate on the need for laws to protect patients enrolled in managed care organizations.<sup>44</sup>

Researchers are also studying the relationship between increased state and federal managed care insurance regulations and employers’ decisions to self-insure their managed care offerings. They will test the degree to which the decline in the percentage of employees who were offered self-insured managed care plans may be related to the passage of HIPAA and other federal mandates that could be applied to self-insured plans despite ERISA. The researchers hope to provide policymakers with better information about the interrelationships between self-insured employer plans, state and federal regulations, ERISA, and the health insurance market.<sup>45</sup>

## A Framework for Policymakers

Given the dearth of good information about problems in the managed care market, why is managed care regulation such a hot topic? What types of information do policymakers need to make better-informed policy decisions? At this point, it would be impossible to present policymakers with clear, objective, quantitative research to guide them regarding appropriate managed care legislation. State policymakers with experience implementing managed care regulation warn that effective regulation depends on clear identification of problems and a thorough, unbiased assessment of the proposed regulation's ability to address those problems. For example, prior to supporting maternity or mastectomy length-of-stay legislation, policymakers should be sure there is evidence of systemic decreases in quality as a result of shortened lengths of stay, not just one or two horror stories that make headlines. In short, policymakers must avoid knee-jerk reactions to anecdotes.

At the same time, policymakers need to consider whether the regulation is likely to have unintended consequences. For states, such consequences might include discouraging managed care plans to operate in the state or discouraging them from participating in the Medicaid program. In addition, providers might choose to locate in states where they are permitted more autonomy or perceive that they have the opportunity to generate more income. This is particularly true for state regulations, where the opportunity to operate or practice in a less regulated environment frequently exists. If plans or providers leave the market, this will lead to decreased competition and access to care, which, in turn, could lead to increased costs for those who are still able to afford it.

For federal legislation, since it affects the nation, policymakers must consider the implications of creating a regulated market where there might be no opportunity for consumers, providers, or plans to leave. The lack of such an opportunity could result in fewer plans and providers, since investors would support more lucrative businesses and individuals would choose careers other than medicine, thus leaving consumers with few options for gaining access to affordable, high-quality care. At both the state and federal levels, policymakers must also carefully consider the likely impact of consumer regulation on health plan solvency.

Policymakers need to consider the feasibility and affordability of implementing the proposed

regulation, and they must be sure the regulation is understandable to consumers, providers, and health plans, as well as to those responsible for its enforcement. Finally, policymakers should consider whether a proposed regulation has broad public support and is the best possible way to reconcile contradictory policy objectives and perceived market failures.

- Be sure there is evidence of systemic decreases in quality or other market failures, such as poor information or lack of plan and provider participation in the market.
- Consider the feasibility and affordability of implementing the proposed regulation.
- Consider whether the regulation is likely to have “unintended consequences” on the market.
- Be sure the regulation is understandable to consumers, providers, and health plans, as well as those responsible for its enforcement.
- Consider whether a proposed regulation has broad public support and is the best possible way to reconcile contradictory policy objectives and perceived market failures.

## Next Steps for Researchers

Carefully framed, unbiased research and evaluation of managed care regulations would be useful to policymakers. While there is currently little in the way of formal evaluation, we have outlined a framework in which policymakers can consider whether particular regulatory or legislative interventions are desirable. This alone will go a long way toward moving the market beyond politically salient responses to “managed care backlash.” However, there is more that researchers can do to increase and improve the information on which managed care regulations are developed, considered, and implemented.

Given the speed with which managed care regulations have been adopted and their variation across the states, it is first necessary to identify, catalogue, and categorize them. It would then be helpful to talk to those who were key players in their development and implementation to determine why



the regulation was put in place, if it has had the anticipated effect, and if there is a perception that it has had other impacts, whether expected or unexpected. This type of information might be collected through focus groups or in-depth interviews compiled into case studies. It is also important to catalogue other changes that affected the health care market over the same time period as the intervention being studied. While the study discussed above will be helpful,<sup>46</sup> it is clear that multiple efforts, using different methods, will be needed to grasp a true understanding of the need for regulation and its impact. Once qualitative data of the type described earlier is collected and analyzed, it might then be used as the basis for developing sophisticated econometric models to analyze more carefully the effects of specific types of legislation within and across states.

- Identify, catalogue, and categorize managed care regulations.
- Collect qualitative data through focus groups or in-depth interviews.
- Catalogue other changes that affected the health care market over the same time period as the intervention being studied.
- Develop sophisticated econometric models to analyze the effects of specific types of legislation within and across states.
- Reach consensus about how to measure quality within managed care plans.
- Consider outcome measures other than quality, for example, managed care market penetration, access, and cost, that might be considered important by policymakers, health plans, providers, and consumers.
- Analyze specifically the outcome that the regulation was intended to change.
- Account for differences in demographics, managed care penetration, consumer utilization, and the regulations themselves through evaluations of natural experiments, phased-in regulations, or demonstrations.
- Consider the implications of not being able to leave the regulated market when analyzing the impact of federal regulation.

Prior to conducting these types of quantitative analyses, however, there must be some consensus about how to measure quality within managed care plans. There must also be consideration given to other outcome measures, such as managed care market penetration, access, and cost, that policymakers, health plans, providers, and consumers might see as important. As mentioned earlier, it is important not only to evaluate a set of important outcomes, but to analyze specifically the outcome that the regulation was intended to change. Such analyses will allow policymakers in other settings to make better decisions about which types of regulations are most likely to address the particular market failures with which they are confronted.

Finally, if cross-state comparisons of the impact of managed care regulations are conducted, they must account for differences in demographics, managed care penetration, consumer utilization, and the regulations themselves. This will require that states with similar characteristics be compared, that variables be developed to control for differences other than the intervention or set of interventions being studied, or that within-state comparisons be made of populations subject to the regulation and those not subject to it. Such evaluations may be the result of existing “natural experiments” or of intentionally phased-in regulations or demonstrations designed to measure the likely impact of the intervention prior to widespread implementation.

Policymakers and the managed care industry have presented a challenge to health services researchers: to develop and disseminate the best possible information about managed care regulations and their impact in order for policymakers to be best able to consider the need for future regulation. It is always difficult to assess the impact of policy intervention in a dynamic environment, and all the more so when the intervention itself is dynamic. While it seems clear that the policy world cannot wait for formal evaluations of managed care regulation to be completed, the issues involved – health care quality and cost – will not soon disappear from the policy agenda. Therefore, to effectively inform the policy debate, researchers must begin to identify the best ways to evaluate managed care regulations – both those currently in place and those likely to be implemented soon.

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