Consumer Protection and Quality Oversight in Managed Care: How are States Meeting the Challenge?

E. Mitchell
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JULY 1998

Funded by
The David and Lucile Packard Foundation
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How Are States Meeting the Challenge?

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July
1998

NATIONAL ACADEMY
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Any errors or omissions in this report are solely the responsibility of the authors.
Consumer Protection and Quality Oversight in Managed Care:
How Are States Meeting the Challenge?

Executive Summary

States play numerous, complex roles in assuring the quality of health care provided to their citizens. They license and regulate commercial, or private, managed care plans (which now serve 40 million Americans), operate and oversee Medicaid managed care programs, and administer managed health benefits for state employees and retirees. As consumer and provider concerns over managed care receive wide-spread attention, as Congress debates patient protection, and as the federal government prepares to hand states additional responsibilities for Medicaid, both states and the federal government are struggling to establish their respective, appropriate roles in the oversight of the evolving managed care system.

While there appears to be general agreement that quality oversight warrants a closer look and that consumer anecdotes may reflect real trouble in the system, there is little data that supports those concerns and considerable lack of agreement on the best mechanisms to address the problems. Nevertheless, states and the federal government are acting quickly to introduce new proposals aimed at reforming the current system.

This paper examines the challenges faced by states as they attempt to ensure quality and provide effective consumer protection to those enrolled in managed care. It also evaluates legislative activity in states and at the federal level and considers the potential impact of these legislative proposals on the quality of care.

Challenges: States face numerous, complex challenges as they seek to create an effective quality oversight system for managed care. Those challenges include, but are not limited to: a lack of reliable information on current quality performance, a limited understanding of how reforms will affect health care costs (both in the short and long term), and the lack of sophisticated information systems to assess managed care organizations’ performance and adherence to contract specifications.

Current federal law, specifically The Employee Retirement Income Security Act (ERISA) has further frustrated state efforts to establish meaningful oversight provisions. Established in 1974, ERISA was designed, in part, to encourage interstate employers to provide employee welfare benefit plans by eliminating the need for employers to administer their plans differently in each state. To that end, ERISA excludes self-insured employee plans from any state oversight. This preemption has stymied both incremental and more comprehensive state regulation of health plans. Approximately 40 percent of Americans (125 million people) working in the private sector are covered under ERISA self-insured plans.

State Initiatives: In spite of ERISA, state lawmakers have considered and, in many instances,
passed legislation designed to improve consumer protection and quality oversight in managed care. Until recently, many state initiatives were focused on incremental change and were designed to address the very specific concerns of consumers, providers, and others. Recently, however, states have turned to more comprehensive proposals. Typically referred to as Consumer Bills of Rights, these initiatives are designed to effect more substantial change in the health care system. In 1997, 17 states passed some form of omnibus bill of rights legislation, bringing to 28 the total number of states with such laws.

**Federal Initiatives:** Four major consumer protection and quality oversight bills were introduced in Congress in 1997 and 1998, all are designed to amend ERISA and would permit the imposition of certain consumer protections and quality mandates on virtually all managed care plans in the country. Many of the Congressional bills contain provisions already passed by numerous state legislatures around such issues as direct access to specialists and specific types of grievance procedures. States may find that their efforts are either reinforced or preempted by federal action in the next year. Some states that chose not to pursue managed care regulation may find new controls on their markets.

**What’s a Policy Maker To Do?** Perhaps the most complicated, but possibly the most promising, approach to ensuring quality is through the development of an oversight system, with minimal duplication and appropriate division of labor. Each state regulatory agency plays a role in this system, as do private sector entities, independent accrediting bodies, and of course consumers and policy makers. The goal is to strike the appropriate balance between oversight and market innovation, with the incorporation of the best data available. As data becomes available, it must be shared through adequate information systems and incorporated into regulation and statute as well as accrediting standards. A successful system may be based on:

- clear standards for all MCOs;
- independent monitoring;
- consumer education and grievance procedures to enhance accountability and provide feedback for system improvement;
- enforceable actions/sanctions to address problems in the system;
- good data shared on good information systems; and
- coordination of actions by private accrediting bodies, governments & purchasers.
### Consumer Protection and Quality Oversight in Managed Care:
How Are States Meeting the Challenge?

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Section 1: MANAGED CARE QUALITY OVERSIGHT: THE CURRENT PICTURE

As the number of Americans enrolled in some form of managed care continues to grow\(^1\), so, too, does public interest in safeguarding the quality of care. With over 40 million Americans (including approximately 85 percent of U.S. employees) enrolled in managed care, public concern has grown over the perception that managed care limits patient choice and access. Providers, who under managed care must accept new controls on the services they provide and reductions in their salaries\(^2\), have further fueled concern and debate. In response, the vast majority of states have proposed some type of “quality” health care legislation ranging from benefit mandates to comprehensive consumer bills of rights. A Presidential commission to study the quality of the U.S. health care system and to present recommendations for improvement has recently finished its work. And the U.S. Congress is considering a range of bills designed to improve the quality of health care. Most of these bills and proposals are aimed at health plans and managed care practices.

States play numerous, complex roles in assuring the quality of care provided to their citizens. In addition to licensing and regulating commercial, or private, managed care plans, states are increasingly involved in the operation and oversight of Medicaid managed care programs as well as the administration of managed health benefits for state employees and retirees. At a time when state responsibility is set to increase further under Congress’ Medicaid and Medicare reform legislation, there seems to be growing

\(^1\)According to the most recent annual Mercer/Foster Higgins National Survey of Employer-Sponsored Health Plans, approximately 85 percent of U.S. employees are now enrolled in managed care, up from 77 percent in 1996 and 70 percent in 1995. The Health Care Financing Administration data demonstrate that a rapidly increasing percentage of Medicaid and Medicare beneficiaries are enrolling in managed care as well. Source: Managed Care Outlook, 1/23/98.

\(^2\)The 1996 Annual Report of the Physician Payment Review Commission showed that real median income across all specialties (including primary care) averaged a $10,000 decline between 1993 and 1994, with ranges in some specialties decreasing by as much as $100,000. According to the Commission’s 1997 report, incomes rebounded by 3.8 percent on average, but remained 2.5 percent below median incomes in 1993. The 1997 study also found that the decline in physician earnings was directly related to the increase in managed care penetration. Because of the growth of managed care, there has been a modest shift in demand and an increase in salary for generalists, whose incomes have declined less than those of specialists.
consensus that the role of state government in evaluating and improving managed care quality is "due for a checkup.""

At the same time, health plans argue that they are being unfairly blamed for systemic problems in the health care system and that they are, in fact, responsible for improvements in both quality and accountability. They also point to managed care's lowered health care costs and increased access to coverage, important—much desired—accomplishments that will be undermined, they claim, by new regulations. Health plans argue that sufficient private sector quality controls, such as accreditation by independent organizations, already exist, making further governmental regulation unnecessary.

Nevertheless, the intense debate surrounding quality oversight and the amount of current legislative activity indicate that state and federal policy makers are unsatisfied with existing quality oversight methods. While there appears to be general agreement that quality oversight may warrant a closer look and that consumer anecdotes may reflect real trouble in the system, there is a lack of agreement on the best mechanisms to address the problems. This paper examines the different options for quality oversight along with their strengths and weaknesses. It also evaluates legislative activity in states and considers the potential impact of these legislative proposals on the quality of care.

**How is Quality Defined?**

As defined by the Institute of Medicine, quality "is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and is consistent with current professional knowledge."  

Regardless of health care service or arrangement, experts have long recognized several approaches to measuring the quality of care. The three standard approaches to quality measurement focus on:

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the structure of care systems, to measure the attributes of the health care system or provider;

the process of care, to measure the activities and actual process used to address patient care needs;

the effectiveness of care, to establish measurable and enforceable performance outcome standards as a test of quality.

Recently, consumer satisfaction has been introduced as a fourth criteria.

Changing definitions and regulatory concern
In recent years the term quality has been used to mean very different things. Traditionally, quality was a term used by the health care industry and by medical professionals in reference to clinical quality. Quality legislation or regulatory action typically dealt with medical records, procedures, and the development and use of outcome measures. The technical field of quality measurement tended to be narrow and isolated, creating mechanisms for detailed tracking of clinical performance and methods of regulating provider practice using these performance measures. Traditional quality efforts were rarely incorporated into statute, but more often found in regulations and practice guidelines.

More recently, the term quality has been used to refer to a more publicly oriented evaluation, often in legislation, addressing provider access and coverage of services. In the past four years there has been relatively little legislative activity on clinical quality, but there has been a significant increase in both regulatory activity and the number of incremental and comprehensive consumer rights bills in state legislatures, in Congress, and from the Clinton Administration. These bills are presented as ways to ensure "quality" health care for consumers but have much less to do with clinical quality standards than with regulating the process of care delivery. Almost without exception, recent efforts target the practices of health plans and managed care organizations that have altered care delivery substantially in the past few years.

The process of care delivery impacts patient health in a number of ways. Timely access to appropriate

5Structural aspects might include the credentialing and training of staff, the use of equipment that is up-to-date and in good working order, and the presence of clinically appropriate and routinely reviewed standing orders for dealing with commonly occurring patient care situations.
services can be as much a factor in maintaining patient health as up-to-date provider knowledge. The current quality efforts aimed at managed care generally seek to regulate the non-clinical aspects of care rather than the practice of medicine. Some efforts, such as the President’s Commission on Consumer Protection and Quality in the Health Care Industry, address both areas, but public attention currently seems focused on process: on access to and choice of providers and on coverage of particular services. Narrow bills have emerged in state legislatures that focus on process by mandating coverage of certain services, banning gag clauses on providers, and/or requiring specific types of grievance procedures. Other popular quality efforts in states are comprehensive consumer rights bills. Consumer rights bills sometimes include more traditional requirements for disclosure and reporting but, in general, target the managed care practices of limiting access and choice.

Quality Managed Care vs. Quality Fee-for-Service: What’s the Difference?

The different structures of the managed care system and the fee-for-service system result in different quality oversight concerns. Because fee-for-service providers bill and are usually reimbursed for each service they provide patients, the system can result in more care being provided than may be appropriate, leading to significant increases in medical costs and occasional over-service. Over-service occurs when a health service is provided that poses substantially greater risks than potential benefits to the patient. Examples of over-service are well-documented and seem to be more likely in a fee-for-service system. A 1994 study reported in the Journal of the American Medical Association, found that 23 percent of requests to insert tympanostomy tubes in children with chronic ear infections were clinically inappropriate and an additional 36 percent were of questionable clinical utility. A 1988 study, also from JAMA, of appropriate use of coronary artery bypass graft (CABG) surgery among the Medicare population in the early 1980s found that about 14 percent of procedures were inappropriate and an additional 30 percent were of questionable clinical value. A more recent study in New York, a state

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6 However, laws such as those that mandate the time a patient must remain in the hospital after a particular procedure are seen by some as regulating clinical practice.


with high managed care penetration, shows that just 2 percent of CABG procedures were inappropriate and about 7 percent of uncertain value, a notable decrease which may indicate the influence of managed care on service delivery.  

Indemnity/fee-for-service systems (with the possible exception of Primary Care Case Management plans) have no single point of accountability. Providers in these systems may address a patient’s greater health needs but are not necessarily expected (or paid) to coordinate care and be responsible for the patient’s overall health. Fee-for-service systems also lack provider organization and coordination which may limit a provider’s capacity to coordinate and monitor care. Regulators of indemnity/fee-for-service systems typically respond to service complaints about specific providers or practices. For this reason, perhaps, quality efforts in fee-for-service have historically focused more specifically on clinical practice standards.

In contrast, managed care providers are asked to provide more than a specified set of services. They are expected to manage the health of beneficiaries based on their needs, both acute and long-term. In other words, a managed care organization (MCO) is paid to protect and improve the health and functional status of its enrolled beneficiaries. The system both creates the potential for improved care and heightens the need for accountability. By coordinating service delivery, managed care plans also assume responsibility for more aspects of patients’ health. For this reason, consumers and regulators have come to expect more from MCOs and to hold them accountable when the system fails.

Managed care was developed for cost-containment, as a response to double-digit medical inflation, and as a way to improve access to care and prevention, in order to improve the overall quality of members’ health. By managing service delivery, cost controls, coordination, and oversight can be built in to health maintenance. Managed care holds the promise of improved patient health by coordinating and managing all services and creating improved oversight and accountability. Managed care’s cost containment goals are reached essentially by emphasizing preventive care to avoid more costly illnesses and managing care

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so that only "medically necessary" care is delivered in the appropriate setting. However, for consumers, this change in delivery is often perceived as limiting needed services.

Unfortunately, neither system contains the perfect mix of incentives to achieve the goal of health care that is both high-quality and low-cost. While managed care has demonstrated initial success in keeping costs down, balance—perhaps in the form of governmental intervention—may be needed to assure that service limits are appropriate and do not jeopardize quality.

Criticisms of Managed Care

Changes in Benefits

Whether or not a health service is covered by insurance has been demonstrated to affect the frequency of its use. For example, a recent study showed that 64 percent of women who were insured received a pap test compared to 48 percent of the uninsured. That same study showed that while 64 percent of insured women received mammography screens, only 31 percent of the uninsured received them.10 The extent to which a service is covered also influences use, with high out-of-pocket expenditures creating significant deterrents to access.

There is some evidence that the perceived reduction in access to care in MCOs is based on an actual reduction of covered benefits. Knowing that coverage is closely related to access, a recent study entitled, "Health Care Plan Design and Cost Trends: 1988 through 1997," looked at plan benefit design in MCOs. Among its findings, the study found that behavioral health care has been increasingly subjected to different limits, caps, and deductibles. The number of plans with limits on out-patient behavioral health visits increased from 26 percent in 1988 to 48 percent in 1997. The number of plans imposing a limit on in-patient psychiatric care increased from 63 percent in 1990 to 86 percent in 1997.11

Health plan representatives insist that outcomes for people needing mental health services have not declined and that measurement of the effectiveness of care is needed. Managed care proponents also argue that costs can be reduced without negatively impacting health outcomes by eliminating

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unnecessary care and coordinating care for maximum benefit. In addition, the managed care industry asserts that patients are not adversely affected by these coverage reductions, claiming that what is needed is more effective care rather than more care.

Changes in outcomes?
The perception that care received by patients is affected by their type of insurance coverage is fueling much of the current debate. Some consumers insists that HMO coverage limits access to care and jeopardizes patient health.\textsuperscript{12} While there may be merit to some claims about new limits on services, current research does not find any clear correlation between managed care and negative health outcomes. In fact, many recent studies show that satisfaction with benefits is actually higher in managed care, in part because out-of-pocket expenses are minimized and access enhanced.\textsuperscript{13}

A recent analysis by the Congressional Research Service found that primary care doctors did not provide reduced levels of care to clients in managed care plans. In fact, the study found that in certain circumstances doctors treating only HMO patients gave higher levels of care. The study found that diagnostic and screening services were performed more often during visits to HMO physicians’ offices than to physicians accepting multiple kinds of insurance. (The same was true of doctors taking only fee-for-service patients. They, too, provided a greater number of diagnostic and screening services than those accepting a mixture of plans.) Therapeutic and preventive services were also performed more frequently during office visits to HMO-only physicians. Other recent data from the National Committee for Quality Assurance shows that managed care plan enrollees obtained screening services at higher rates than the national average.\textsuperscript{14}

\textsuperscript{12}Surveys of “popular opinion” demonstrate apparently conflicted consumer perspectives on managed care. Results of separate Democratic and Republican polls conducted in May 1998 found that between 86 percent and 90 percent of Americans support the federal consumer protection legislation, PARCA. However, a November 1997 survey by The Henry J. Kaiser Foundation found that 66 percent of Americans would give their own managed care plans “a grade of A or B.”

\textsuperscript{13}Elizabeth A. McGlynn, “The Effect of Managed Care on Primary Care Services for Women”, \textit{Women’s Health Issues}, 8(1):1-14, Jan-Feb 1998.

\textsuperscript{14}National Committee for Quality Assurance, \textit{The State of Managed Care Quality} (Washington, DC, 1997).
Robert Miller's and Harold Luft's rigorous survey of 35 studies comparing managed care plan performance to that of fee-for-service, found insufficient evidence to support either the "fears" that HMOs would lead to poor quality of care or the "hopes" that it would necessarily lead to uniform quality improvement. They found equal numbers of statistically significant positive and negative results for HMO performance, compared with non-HMO plans. "Because the evidence is mixed," Miller and Luft write, "HMO proponents and opponents can find support for their positions on quality of care." They caution policy makers and others against generalizing the results of particular studies given design and data limitations and attribute the difficulty in comparing the two systems, at least in part, to inadequate quality measurement and reporting. Until the science of quality measurement and reporting comparability improves, no easy or conclusive comparisons can be drawn, they assert.\(^{15}\)

What's behind all the criticism?

If the impact of managed care on outcomes is, at worst, neutral and managed care has limited the growth of medical inflation, why has it attracted such negative attention? A recent study shows that there may be a slight media bias against managed care, but that "based on...findings, it would be difficult to argue that media coverage is by itself creating whatever backlash currently exists."\(^{16}\) Legislators and Congress are clearly relying on consumer anecdotes, but are the anecdotes representative of the entire system? What is generating the intense debate and flurry of regulatory efforts at every level of government from all parts of the country? Are the identified shortcomings in health care quality worsened in a managed care system?

A significant portion of the current "assault" on the managed care industry is driven by consumer charges and fears that the rush to lower costs will reduce access to care, quality of care, choice of providers, and basic consumer protections.\(^{17}\) In the political arena, managed care was identified as "the most emotional issue in the country this year." Members of Congress have recounted HMO "horror stories" on the floor of both chambers. Candidates in governors' races are also identifying managed care as an election issue.

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\(^{15}\)Robert H. Miller and Harold S. Luft, "Does Managed Care Lead to Better or Worse Quality of Care?" *Health Affairs*, Sept/Oct 1997.

\(^{16}\)Mollyann Brody, Lee Ann Brady, and Drew E. Altman, "Media Coverage of Managed Care: Is There a Negative Bias?" *Health Affairs*, Jan/Feb 1998, Vol 17, No.1.

A recent slogan in one race asked: "If you can pick the person to fix your car, you should be able to pick who’ll deliver your baby".\textsuperscript{18}

At the heart of the problem may be consumers’ perception that medicine has become just another business with its eye on corporate profits. This perceived focus on the bottom line signifies a fundamental shift in health care practice that many Americans distrust. Consumer concerns over managed care tend to focus on a central goal of managed care: to reduce costs, largely by doing less.\textsuperscript{19} In a 1996 survey, Americans said that, in choosing a health plan, quality of care was their biggest concern (42 percent) over low cost (17 percent).\textsuperscript{20} It may be that, as costs have come under control, the pressure for cost containment has eased among consumers and the concern for quality emerged. Or it may be that while Americans are willing to make some sacrifices for reduced costs, they were unprepared for the sacrifices they perceive to be required by managed care in terms of access, choice, and quality.

Whatever the reason, popular opinion seems to be that the managed care industry has gone too far and that Americans are willing to ask government to step in and remedy perceived problems. In fact, the same 1996 survey shows that 88 percent of Americans believe there is a role for government in assuring the quality of health care.

Doctors and other health professionals have also voiced strong concerns about managed care. The Medical Association of Georgia, for instance, has issued a resolution outlining its stand on "the new marketplace of medicine" in which it claims that financial incentives reward inappropriate care. The Association argues that such incentives should be banned and that profit motives and cost-containment strategies threaten to seriously undermine the relationship between doctors and patients, threaten to turn such relationships into "a mere business contract."\textsuperscript{21} The Medical Association of Georgia is not alone in taking this stand. Doctors and health care providers have, in fact, played a central role in questioning the

\textsuperscript{18}American Health Line, May 7, 1998.


\textsuperscript{20}Americans as Health Care Consumers: The Role of Quality Information, a nationally representative telephone survey of 2006 adults designed by The Henry J. Kaiser Family Foundation, the Agency for Health Care Policy Research, and Princeton Survey Research Associates.

benefits of managed care. In the fee-for-service system, doctors maintained almost complete control of care decisions. Their reasons for fighting managed care, both philosophical and financial, are many.

While traditionally supporters of managed care, some employers are also starting to join the chorus of managed care opponents. There concerns seem based primarily on mounting evidence that HMOs may not be able to maintain cost reductions. In recent months, HMOs nationwide have been proposing significant premium increases that are drawing strong objections from purchasers. According to the May 19, 1998, Wall Street Journal: "Corporate America is disillusioned by the failure of HMOs to keep a lid on medical costs." Some industry observers point to the resurgence of large annual cost increases as evidence of the failure of managed care to effectively manage service delivery in a sustainable way. Others, however, conclude that the same forces behind many of the consumer driven regulatory reforms (freedom of choice and expanded coverage) have undermined managed care's ability to keep costs down.

The Industry's Defense

Health plan officials acknowledge that they need to do a better job explaining their mission to the American public and proving their effectiveness. Karen Ignagni, CEO of the American Association of Health Plans, insists that public misconception of managed care is the heart of the problem, based in large part on the confusing vernacular used by the industry and a negative bias in the media. She also notes that health plans must show their support for quality improvement by providing data that demonstrates their effective treatment of patients, evidence that will become clear as the results of longitudinal outcome studies materialize.\textsuperscript{22} Ignagni argues that assertions that quality is suffering because of managed health plans "ignores the quality problems that have always existed in fee-for-service care." In fact, managed health plans claim that they, in fact, are responsible for building the structures, such as quality assessment and improvement programs, that will bring a focus to evidence-based medicine and help produce better medical care.\textsuperscript{23}

Opponents of recent regulatory efforts argue that the various proposals impose too many rules and represent government intrusion into what should be autonomous business decisions. They also argue that

\textsuperscript{22} Managed Care Outlook, January 16, 1998.

\textsuperscript{23} The Managed Care Debate: Correcting the Errors and Omissions", American Association of Health Plans, April 1998.
increased regulation means increased costs for consumers, and, ultimately, more uninsured individuals. Health plans insist that they have made health coverage more affordable for workers and families, and as a result, more Americans can afford health insurance. According to a 1997 study commissioned by AAHP, between 3 and 5 million Americans who would have lost their employer-sponsored health insurance were able to keep it because "health plans brought out-of-control health care costs under control". Finally, they point to the fact that managed care organizations have adopted their own mechanisms to assure quality, such as accreditation by independent organizations, making government regulation unnecessary.  

Fact and Fiction
For the moment, the research seems to support the claims of health plans. An analysis of the 1960-1996 nationwide spending on health care demonstrates that health care inflation in 1996 was at its lowest point in years. Between 1966 (when Medicare and Medicaid began) and 1993, health spending growth averaged 11.7 percent annually. From 1993-1996 (years of managed care growth), the average growth rates in health care spending fell to 3.3 percent in 1994, 2.2 percent in 1995, and 1.9 percent in 1996. The trend appears to have continued.

HMO doctors are providing the equivalent, if not more, of many health services to patients. Problems of over service seem to be declining. And existing outcomes research shows no negative correlation


26 K.R. Levit, H.C. Lazenby, B.R. Braden, and the National Health Accounts Team, “National Health Spending Trends in 1996,” Health Affairs, Vol. 17, No.1, January/February 1998. The authors attribute the slowdown to payment incentives in managed care and public programs that have acted to slow increases in health care consumption, among other factors.

27 No health spending analysis of this assertion is available for 1997 and 1998, but the slower health spending growth rates appear to have persisted to date. KPMG Surveys of Employer-Sponsored Health Benefits, however, do demonstrate one healthy market indicator: health insurance premiums increased only 3.3 percent in 1998 amid predictions of 5 percent or more.
between service in health plans and health outcomes. Yet the level of public dissatisfaction is high. Regulatory activity is proliferating and the public is demanding action to increase oversight of managed care. The current reexamination of managed care has the capacity to seriously undermine the ability of managed care to do what it does best: lower health care costs. It will be important for policy makers to understand the impact of their proposed reforms and to weigh the cost and consequences of bills that may change the system but may also increase costs without improving quality.

**The Challenges for Policy Makers**

According to Janet Corrigan, Executive Director of The President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry, outcomes research indicates that people’s overall health fares equally well in managed care and fee-for-service systems. While there is a slight difference, favoring managed care for preventive services and fee-for-service for chronic care, research indicates that the "very serious quality failings in the health care industry” are systemic.

The President’s Commission found that while most Americans receive high-quality health care, too many receive substandard care. Real quality problems have been identified, including: 1) avoidable errors; 2) under-use of health care services; 3) overuse of services, and 4) variation in services. These shortcomings endanger the health and lives of all patients, add costs to the health care system, and reduce productivity.

What is the goal and likely outcome of current quality efforts? If Americans want better quality health care, there must be a thoughtful and coherent strategy to achieve that goal. Clearly, many consumers and regulators are wary of managed care practices. Judging from the multitude of bills filed in legislatures and Congress, it appears that some individuals are being denied care and some individuals are experiencing negative health impacts. But while most Americans recognize the need for reform (and recognize that 40 million Americans are uninsured), President Clinton’s major health reform initiatives of 1994 were rejected. The move to managed care represents both a popular and Congressional decision to let the market place address the problems of the health care system. Despite growing awareness of the

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28 Although this is generally true among most health consumers, poor seniors and people with disabilities have been shown to experience some negative health consequences in managed care.

problems, consensus has yet to be reached on what needs to be fixed within the U.S. heath care system and how.

While considering the multitude of bills at the state and federal levels directed at managed care, policy makers will want to weigh whether the problems they hope to address are the result of managed care delivery changes or something more systemic. Does current legislation targeting managed care practices hold the potential to address these problems? Some problems, such as the overutilization of services, may actually be improved by managed care. The remaining question for policy makers is how to strengthen consumer protection without undermining the real and potential gains that managed care may offer.
Section 2: SOMETHING OLD, SOMETHING NEW: STATE, FEDERAL, PRIVATE ACTIVITY

Managed care has provided a tremendous oversight challenge for states, making it difficult for their oversight agencies to meet the additional responsibilities posed by the new systems. In blurring the once-clear distinction between insurance coverage and medical practice and in introducing new practices that have no counterpart under the existing fee-for-service system, managed care has required states to regulate new entities and practices using old tools. Increasingly, states have turned to legislation to craft new quality oversight and regulatory mechanisms.

State Managed Care Oversight, Pre-1997
The oversight of managed care at the state level has traditionally been governed more by state regulation than legislation and has typically been the responsibility of a state's Departments of Insurance, Medicaid, and/or Health, depending on the nature of the activity. The following sections, based on NASHP's 1996 survey of state regulation of prepaid managed care entities, describes how and what states have monitored under their traditional regulatory frameworks.

The Regulatory Framework: Traditional Architecture of State MCO Oversight
While authority for the regulation, monitoring, and enforcement of standards for MCO's varies by state, some general statements can be made about what states have traditionally monitored and in what administrative agency the authority to monitor has rested.

Functions that have typically been regulated by insurance departments include financially related items for plans that serve either a commercial or Medicaid population, items such as capital reserves, timely claims payment, premiums/charges/rate setting, and solvency. Many insurance departments indicated they regulated some consumer protection items other than health plan financials including the nature of the benefit package, marketing/outreach activities, grievance procedures, membership/enrollment

29Jane Horvath and Kimberly Snow, Emerging Challenges in State Regulation of Managed Care, Report on a Survey of Agency Regulation of Prepaid Managed Care Entities, National Academy for State Health Policy, August 1996.
reporting, and enrollee rights. Few insurance agencies reported monitoring quality standards such as those for disenrollment, network composition, medical records, or peer review requirements. The oversight of grievances has generally been the purview of insurance departments, however, consistent with their traditional functions of collecting and arbitrating insurance complaints.

Public Health departments historically have had significant roles in the regulation of quality or consumer protection functions for commercial plans, such as access standards, provider credentialing grievance procedures, internal quality assurance program standards, medical record standards and/or audits, quality assurance committee standards, and utilization review program standards.

Medicaid agencies have traditionally been more consistently responsible for both quality and financial monitoring of their managed care contractors than either public health or insurance departments have for commercial plans. Among Medicaid agencies generally, there has been a greater emphasis placed on consumer protection and quality than was found among public Health or Insurance Departments.

All states license and regulate MCEs, such as HMOs, that contractually bear risk and provide a comprehensive set of services to enrollees, or those plans which provide managed health services to Medicaid populations, but few agencies have separate and unique standards for entities such as Provider Sponsored Networks and Physician Hospital Organizations.

Regulatory Overlap and Gaps
In the 1996 survey, many states reported that at least two agencies were involved in monitoring quality assurance, and seventeen states reported that at least two agencies monitored compliance with financial standards. In both instances, one of the agencies was Medicaid. Until recently, Medicaid managed care entities have been under greater quality and price scrutiny than have those plans operating in the private sector. All three agencies in the NASHP survey tended to require data and reporting from health plans, and each agency tended to have its own—sometimes overlapping—reporting format.

In general, state oversight of private sector plans has tended to focus on financial operations rather than quality standards. Specific examples of quality oversight gaps were cited in the 1993 Aspen Systems publication: “Report to the Governor on State Regulation of Health Maintenance Organizations.” Among
the gaps: 1) 24 states did not require specific MCO license renewal, so a license was considered valid until revoked, 2) only six states required on-site surveys of quality assurance, 3) 38 states did not require audits of medical records or medical record reviews either by law or regulation.

In 1998, definitions of quality, quality assurance, and quality improvement are evolving concepts. The health care industry, the public, and government have yet to reach a clear consensus on how best to measure, monitor, or assure quality. States differ on whether health plan quality assurance and monitoring are proper tasks for the public sector. While some have increased the level of state public health plan scrutiny, others have left it to plans to demonstrate quality and compete for customers by receiving private accreditation from bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA).

The Role of Private Accreditation
Health plans argue that these private sector accreditation organizations can more effectively manage quality oversight than states or the federal government. After consumers and legislators rejected the Clinton plan, a move that paved the way for a more devolved, market-based system, reliance on such independent entities as NCQA and JCAHO increased. Many employers now rely on the evaluations of these organizations when making purchasing decisions, and more and more states are writing these entities into statute as appropriate arbiters of quality. Currently, fifty-five percent of HMOs participate in the voluntary NCQA accreditation process, accounting for 75 percent of HMO enrollees.

Who are these private accreditation bodies and what does accreditation mean?

The National Committee for Quality Assurance (NCQA) describes itself as an independent, nonprofit organization made up of health care quality experts, employers, labor union officials, and consumer representatives. Most of NCQA's standards assess the MCOs' quality improvement structures and processes. Health plans must produce a documented plan for assessing the quality of care provided to members. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the oldest of the accrediting networks, founded in 1951 by the American College of Surgeons. Many of the JCAHO network accreditation standards are similar to the NCQA standards in their assessment of quality improvement, but JCAHO also includes standards for assessing ethical business and medical practices.
The American Accreditation Healthcare Commission/Utilization Review and Accreditation Commission (URAC) has, as its first aim, to introduce more consistency into utilization review (UR) processes as well as improve the quality and efficiency of the interaction between the UR industry and health care providers, payers, and purchasers. URAC offers utilization review entities and preferred-provider organizations (PPOs) a means to evaluate, accredit and upgrade their performance. Though each of these entities has a distinct focus, all three require networks to have some form of a quality management program in place, a documented protocol for provider credentialing, specific patient education and communication requirements, and a mechanism for members to communicate and resolve grievances.

Although private accrediting bodies address many of the areas of quality that are of concern to consumers and policy makers, some question the wisdom of relying too heavily on these organizations. Policy makers are now seeking regulatory changes that go beyond the scope of the accrediting bodies. Many smaller health care organizations and providers find the cost of accreditation prohibitive and have expressed concern about passing on cost increases to consumers. Critics of accreditation also say that it does not guarantee a high quality health plan, only that the plan provides adequate care. Many also acknowledge overlap and duplication in existing public and private sector oversight activities. But they also see opportunity to reduce overlap and redundancy by forging stronger partnerships between private accreditation and state efforts.

JCAHO has recently announced the “Oryx Initiative” which will permit health plans to choose from a selection of outcome measures and add them to JCAHO’s traditional “capability” survey criteria. NCQA’s draft 1999 Managed Care Organization Accreditation Standards will merge its accreditation structure with its Health Plan Employer Data Information Set (HEDIS), the standard tool for measuring health plan performance. The inclusion of consumer satisfaction measures in the 1997 upgraded HEDIS 3.0 was considered a benchmark event in quality-based competition in health care. Satisfaction measurement is now one of HEDIS’s eight domains and a necessary data element and formatting requirement for submitting data to the HEDIS national, centralized database. NCQA says that consumer

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31 HEDIS results will initially count for 25 percent of a plan’s accreditation score; the remaining 75% will be based on a plan’s degree of compliance with NCQA’s standards. New standards will commence July 1, 1999. NCQA Quality Matters, Volume V. No.1, Spring 1998.
satisfaction measures help focus competition on areas of importance to purchasers and consumers. The process will include effectiveness of care measures and satisfaction survey results, as well as outcomes by products and populations, including HMOs, point-of-service, Medicaid and Medicare. One of the goals of the new measurement standard is to make the information more user-friendly and to encourage plans to improve their information management systems. Ninety percent of health plans report on HEDIS data in some form. NCQA hopes that future managed care legislation or regulation, whether federal or state, will "highlight the work of existing accreditors, encourage broader participation in oversight programs, and build on NCQA's considerable successes to date. Such a coordinated public-private approach would likely do far more to promote quality and protect consumers than independent efforts."

The two new quality panels envisioned by the President's Commission on Consumer Protection and Quality in the Health Care Industry would require unprecedented cooperation among accrediting organizations that develop their own performance measures and standards. While the managed care industry fears duplication of efforts, most accrediting bodies acknowledge the need to develop uniform standards and increase the success of the public-private partnership. The Kaiser/Harvard "National Survey of Americans' Views on Consumer Protections in Managed Care" indicates that a majority of the 2,000 adults surveyed (57 percent) believed that non-government, independent organizations should be primarily responsible for protecting consumers.

On May 19, 1998, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), The American Medical Accreditation Program, and NCQA announced that they will collaborate to form a 15-member Performance Measurement Coordinating Council to "evaluate doctors, hospitals and managed care organizations." The project is designed to ease the burden of collecting quality data; produce more relevant comparisons between plans; ensure that all the "links in the health care chain focus on improving their records on well-established measures;" and raise the level of care.

State Legislative Efforts to Improve Quality

Political Overview

Increasingly, in states across the country, lawmakers have sought to reconcile what have come to be

viewed as the competing issues of managed care: health care quality vs. cost. For while managed care has improved cost savings and budget predictability for large and expensive state funded programs such as Medicaid and state employees’ benefits, it has also resulted in constituent concerns over quality and access. Frequently, legislators cite these concerns when explaining their support for regulatory change. Richard N. Gottfried, Chair of the Health Committee in the New York Assembly supported four consumer protection bills this year in an effort to "protect consumers from decisions based on health plan profit rather than medical necessity." Patricia Blevins, State Senator from Delaware says that, "Managed care has helped reduce health care costs, but at a price." Like many state legislators, she supports action to improve regulation and accountability. 33

As legislators grapple with the very complex substance of what does and should constitute high quality managed care, they must also attempt to reconcile through legislation the apparently competing interests of health plans, consumers, and the entire range of medical professionals. Lawmakers have responded to provider and consumer concerns by enacting a number of single-issue and then more comprehensive pieces of managed care legislation. These laws are designed to remedy problems by defining and protecting consumer rights (including the right to sue a health plan), proscribing specific aspects of plan conduct, or mandating specific MCO requirements not heretofore considered in state law. More legislation than ever before now exists for the purpose of guaranteeing quality in managed care. Whether any state’s consumer protection legislation will do in whole or in part what it is designed to do remains to be seen because so much of the legislation must first overcome the hurdles posed by ERISA.

ERISA: Why State Legislation is Only Part of the Picture

States’ many legislative oversight efforts have frequently been frustrated by current federal law. ERISA, or The Employee Retirement Income Security Act, was signed into federal law in 1974. Its purpose was to protect beneficiaries of pension and employee benefit plans from abuses by individuals who managed and invest the assets of these plans, and to encourage interstate employers to provide employee welfare benefit plans by eliminating the need for employers to administer their plans differently in each state. 34


34 There is considerable confusion about the term "health plan" in the discussions of ERISA. Managed care organizations call themselves "health plans" but they are not "plans" under ERISA. States cannot regulate ERISA plans (regardless of whether they are insured or self insured) but they can regulate all MCOs or "health plans."

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ERISA has had a broad impact on employee benefits and has been the subject of much litigation. In practice, ERISA excludes self-insured employee plans from any state oversight, although states can regulate insurers and MCOs even if they deliver services to ERISA-covered plans. This preemption—in which federal ERISA law, not state law, takes precedence—has stymied both incremental and more comprehensive state regulation of health plans. Approximately 40 percent of Americans (125 million people) working in the private sector are covered under ERISA self-insured plans.

Because of the ERISA preemption, achieving a coherent state-law based strategy to regulate the conduct of all plans has been virtually impossible.\textsuperscript{35} Even if a state passes a law governing some aspect of these health plans’ activity, if federal preemption is applicable, and there are no governing federal rules about such a plan’s conduct, then the state law in question is invalid, and that aspect of the health plan’s conduct is left essentially unregulated for those enrollees whose group coverage is provided under a self-insured ERISA plan. It is unlikely the drafters could have conceived that this law, designed to protect beneficiaries, would essentially create a regulation-free zone which many believe has thwarted efforts at state health reform and consumer protection and which has sometimes muddied the boundaries between state and federal health care regulatory jurisdictions.

Compounding the problem for state lawmakers has been the U.S. Supreme Court’s interpretation of ERISA. The Supreme Court has long held that Congress intended that regulation of health and benefit plans be \textit{exclusively} a federal concern,\textsuperscript{36} and that judicial interpretation should be “deliberately expansive.”

**How Courts Have Determined Whether ERISA Preempts a State Law.**

Although a thorough legal analysis is beyond the scope of this paper\textsuperscript{36}, the following questions provide a general framework for policymakers when thinking about whether a state law is preempted.


\textsuperscript{36}Again, for a thorough recitation of courts’ analyses, see: Patricia Butler, \textit{Policy Implications of Recent ERISA Court Decisions}, NGA Center for Best Practices (1998)
1. Does the law govern the activities of an ERISA plan?
   
The answer to this question is guided by the actual preemption language of the statute, which states that ERISA: "... shall superecede any and all State laws insofar as they relate to the administration of any 'employee welfare benefit plan.'" Courts have broadly interpreted the provision to construe the term "relate to" as including merely "a connection with, or reference to such a plan."

Because of ERISA, state insurance regulators have jurisdiction only over those plans that cover people in the individual market and those that cover employees under licensed insurance products such as managed care, or any government or charity employee plan (about 60 percent of all those enrolled in plans).

2. Does the law govern the "business of insurance"?
   
If it does, the state law may be "saved" (or survive a court challenge), and therefore used by a state to regulate plan conduct, if it is found to regulate the business of insurance.

3. But can't a state policy maker just "deem" (in legislation or regulation) an ERISA benefit plan as being in the "business of insurance" in order to get around the ERISA preemption?
   
No. ERISA's so-called "Deemer" clause states that a plan cannot simply be "deemed" to be engaged in the business of insurance or banking for purposes of meeting the exception laid out in

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37The statute defines an employee welfare benefit plan as: "Any plan, fund or program which...is established or maintained by an employer or employee organization...to the extent that such plan, fund or program was established or maintained for the purpose of providing for its participants or their beneficiaries through the purchase of insurance...or otherwise, medical, surgical or hospital care or benefits or benefits in the event of sickness, accident, disability or death or unemployment..." ERISA, Section 3(1)[29 U.S.C. Section 1002(1)]

38For a useful series of questions to help determine whether a potential statute would "relate to" ERISA plans, please see Patricia Butler's State Managed Care Oversight, Policy Implications of Recent ERISA Court Decisions, at page 20, NGA Center for Best Practices (1998)

39The Savings clause in the statute states that "except as provided in the Deemer clause, nothing in ERISA shall be construed to exempt or relieve any person from State laws which regulate insurance, banking or securities."

40In order to be considered the "business of insurance," the activity which is the subject of the legislation must: 1) spread risk across a broad population, 2) integrally involve the relationship between the insurer and the insured, and 3) be limited to entities within the insurance industry.
the savings clause.” When ERISA plans buy insurance products from an HMO or other kind of insurance carrier, however, those purchased plans are subject to state regulation.

In Spite of ERISA, States Forge Ahead
ERISA has kept the conduct of risk-bearing self-insured plans out of state courts and beyond the jurisdictions of state regulators, but there is some indication the tide is turning: A widely cited 1995 US Supreme Court decision known as “Travelers” and related subsequent cases 41 have begun the process of removing ERISA protections from these plans. The Court in Travelers began the process of not simply looking mechanistically to determine whether a law "relates to" an ERISA plan, but determining whether "a state law infringes on the underlying purposes of preemption." 42 All the while, states are enacting an increasing variety and number of laws which they’ve argued do not infringe on the underlying purpose of ERISA, but do go a long way toward protecting ERISA’s intended beneficiaries.

Incremental Legislation
The following pages include descriptions of incremental state legislative oversight activity undertaken by states up to and through the legislative sessions of 1998. (See Table A for an overview of incremental legislative activity in the 50 states.)


42 Put another way, the Travelers criteria are these:
1. Does the law specifically apply to employee benefit plans or is it a law of general applicability?
2. Is the state law regulating an area of traditional state authority (such as the business of insurance)?
3. Was there a specific intent by Congress to preempt (or displace) state authority in this area?

Travelers says that if the state law is one of general applicability in an area of traditional state authority with no Congressional intent to preempt, then it survives the test and is not preempted by ERISA.

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Table A: State Incremental Managed Care Laws
Enacted as of June 1998

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<th>Disclosure Mandates; Plan Information</th>
<th>Network Adequacy</th>
<th>No Gag Clause</th>
<th>Independent or External Reviews</th>
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Sources: Blue Cross/Blue Shield, NCSL, NASHP Mini State Survey, and Cited Text Sources
External Utilization Review/Grievance Review

These laws permit health plan members to appeal a health plan's utilization review (UR) decision or other complained of conduct to an outside, independent administrative body. Some laws permit use of the external mechanism as a substitute for or concurrently with the plan's internal grievance process. The laws may permit expedited appeals to the external body in the event of adverse coverage decisions which could substantially affect the life or health of the member. Some legislatures are adopting these mechanisms as a compromise in lieu of liability laws (see below). The 17 states that have mechanisms for an independent review are: Arizona, California, Connecticut, Hawaii, Maryland, Missouri, North Carolina, Ohio, Vermont, Rhode Island, Florida, New Jersey, New Mexico, Pennsylvania, Texas, Tennessee, and most recently, New York.

Rhode Island's legislation (the Utilization Review of Health Care Services Act of 1994) provides consumers with access to independent appeals of decisions made on the basis of medical necessity either in- house (by the plans themselves) or by subcontractor utilization review companies. Consumers may also contest plan benefit denials under a related regulation. Rhode Island's Department of Health is in charge of implementing the Act, and the state uses two private agencies for the external reviews. Consumers are responsible for the payment of filing fees which can range from $75 to $100. The Act and resultant regulations, particularly those which permit the appeal of benefit denial, have been hotly contested by health plans as falling squarely under the purview of ERISA. (See discussion of ERISA later in this section.)

Tennessee, New Jersey, New Mexico, Florida (whose law has been in existence for approximately 10 years), and North Carolina use mechanisms which are advisory only, although in New Jersey the state has the power to sanction plans which show a pattern of non-compliance. Even if the plan elects not to follow the review decision, it must state the clinical reason for electing not to do so. New Jersey had been using Peer Review Organizations as reviewers, but will broaden the range of qualified entities. Tennessee's Commissioner of Insurance "or his designee" is responsible for reviews in that state, and the Commissioner may consult with the Department of Health on questions of medical appropriateness. Maryland recently approved a bill that gives the insurance commissioner authority to make an independent review of disputes between consumers and their health plans and carriers.
Under the Texas liability law, consumers may request independent reviews of denials based on medical necessity. After screening reviewers for potential conflicts of interest by the MCO, provider, or plan UR contractor, the Department of Insurance randomly assigns cases to one of the Independent Review Organizations (IROs) certified by DoI to conduct the review. The IRO's decision is binding, and the IRO has been granted immunity from liability in the applicable regulation for the binding decision, unless it is determined to have been made in bad faith or with gross negligence. Those states seeking to implement external review legislation might consider whether liability implications exist in their state for their independent review contractors or responsible state officials if reviews will be final and binding.\textsuperscript{43}

Any Willing Provider

These laws require health plans to contract with any provider in the service area who is willing to comply with the terms and conditions of the plan-provider contract. Perhaps the most consistent consumer complaint about managed care is its practice of limiting choice of providers. Whether or not this interferes with care is debatable, but nevertheless, it is, on principle, one of the most unpopular aspects of the new system. While some of the impetus for these laws is consumer dissatisfaction with limited networks, allied health provider associations tend to be at the forefront of these initiatives in an effort to keep their members from being excluded from a plan's network due to the nature of their specialty, distribution within a given service area, or perceived higher-than-average use of resources. Although initially in favor of these laws, both the American Medical Association and the American Hospital Association now oppose them in favor of a more pluralistic health delivery system. Many of the current laws pertain only to pharmacies, but some cover a broader range of providers. Twenty-three states have enacted some form of "any willing provider" law. They include: Arizona, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, New Jersey, South Carolina, South Dakota, Virginia, Wisconsin, Wyoming.

Courts differ on whether "any willing provider" laws are preempted by ERISA, with the majority favoring preemption and typically agreeing that these laws "relate to" employee benefit plans. Courts have differed, however, on the question of whether any willing provider laws are nonetheless "saved"

\textsuperscript{43} These bodies may be granted immunity as other bodies have been which have engaged in peer review activities.
from ERISA preemption because they regulate the business of insurance. Federal Courts in Virginia and 
Massachusetts have concluded that the laws promulgated in those states should be permitted to stand.

**Direct Access**

These laws permit plan members to seek care from a specialist without first obtaining a referral from 
their primary care physician; that is, no health plan primary care gatekeeping activities are permitted. 
According to the Kaiser Family Foundation/Harvard University “National Survey of Americans’ Views 
on Consumer Protections in Managed Care,” consumers prioritized direct access to specialists over other 
protections contained in the Clinton Administrations “Consumer Bill of Rights” and federal managed 
care reform legislation. Some more tightly organized types of health plans insist that these laws can 
make coordination of care difficult, if not impossible, because primary practitioners will not be kept 
informed of patients’ visits to other providers. Generally, these laws permit women direct access to in-
network Ob/Gyn providers for a specified number and type of visits and procedures annually. 
Legislatures have shown an increased interest in mandating access to specialists by plan members, 
particularly children, with chronic conditions or disabilities. Legislative variations on the “direct access” 
themes include those laws which mandate standing referrals or the use of specialists as primary care 
physicians.

It is important to note that access-to-specialist laws, like most of these single-issue reforms, divest the 
health plan of unilateral or even substantial utilization decision-making authority and may prompt 
ERISA challenges because plans believe these laws interfere with benefit administration, which is 
governed by ERISA. Currently, 33 states have some form of “direct access” laws in place. They 
include: Alabama, Alaska, Arkansas, California, Connecticut, Colorado, Delaware, Florida, Georgia, 
Idaho, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Minnesota, Mississippi, Missouri, 
Montana, Nevada, New Mexico, North Carolina, New York, Oregon, Pennsylvania, Rhode Island, South 
Carolina, Texas, Utah, Virginia, Washington and West Virginia.

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44In other words, a member may be permitted to see an in-network ob/gyn without referral from a primary 
care physician, but the ob/gyn would still be required to seek authorization for certain procedures to secure 
payment. This form of “direct access” permits a patient increased access and flexibility but still permits a plan to 
manage costs and direct “appropriate” levels of care.
Network Adequacy
Nine states (Colorado, Indiana, Kansas, Maryland, Missouri, Ohio, Oklahoma, Oregon, and Texas) have legislated that plans ensure a sufficient number of providers in their networks. Four (California, Delaware, Pennsylvania, and South Dakota) require a certain ratio of physicians to patients. Although the latter version would appear on its face easier for the appropriate state authority to enforce, neither of these provisions provides states with an exact or easy method to monitor network adequacy at any given point in time.

Emergency Room Standards/Payment
A Federal law known as the Examination and Treatment for Emergency Medical Conditions and Women in Labor Act, 42 USCA Section 1395dd (EMTALA)—better known as the Patient Anti-Dumping Act—was enacted to ensure that all hospital emergency rooms be required to give patients necessary emergency room screening, examinations, and care. States have passed ER laws to ensure that plans pay for the care that hospitals argue they are required by federal law to render.

Many states have legislated a “prudent layperson” standard, effectively removing the unilateral authority of the managed care plan to determine whether a visit was in fact “medically necessary” and emergent, and substituting a statutory definition. Some managed care ER laws also impose the requirement that a health plan pay a non-negotiable triage fee to a provider for treatment rendered to screen or to stabilize a patient who walks through the ER door, regardless of whether the visit to the emergency room proves to have been a real medical emergency or whether the hospital contracts with the patient’s health plan.

ER laws are designed to assure that hospitals get paid for the work performed and that insured patients don’t incur unexpected and onerous emergency room bills after discharge. Currently, 24 states (Alaska, Arkansas, California, Connecticut, Colorado, Florida, Georgia, Hawaii, Idaho, Indiana, Louisiana, Maryland, Minnesota, Missouri, Nevada, New York, North Carolina, Ohio, Oregon, Texas, Virginia, Washington, West Virginia, and Wisconsin) have adopted a “prudent layperson” definition of emergency and some have mandated payment standards.

Anti-Gag Clause Rules
These laws prohibit plan rules that proscribe a provider from discussing “all appropriate treatment”
options with patients. The perceived need for these laws arose out of a confluence of physician and consumer concerns. Consumer groups alleged that plan physicians did not disclose more expensive (and presumably more effective) treatment methods and procedures in some instances because they were contractually bound by the health plan to offer only a pre-approved, less costly set of services. Physician groups have expressed concerns about the limitations on their practice options that are inherent in belonging to health plan networks. Attempting to respond to these concerns, twenty-four states in 1997 enacted legislation banning "gag clauses" in MCO/provider subcontracts. 45

The issue of "gag clauses" has received wide-spread publicity and attention in state legislatures in spite of a recent report from the U.S. General Accounting Office, Managed Care: Explicit Gag Clauses Not Found in HMO Contracts, but Physician Concerns Remain (GAO/HEHS/97-175). The report did find that there were some limits in contracts concerning disclosure of financial arrangements or disparagement of plans; but did not find explicit clauses prohibiting disclosures of treatment options, the clauses that state legislation is intended to ban.

It is noteworthy that the National Committee for Quality Assurance, the Joint Commission on the Accreditation of Healthcare Organizations, and the American Association of Health Plans have stated that patients have a right to unrestricted clinical dialogue with their physicians and to disclosure regarding financial incentives. The Council on Ethical and Judicial Affairs of the American Medical Association has concluded that, as part of informed consent, both physicians and health plans have a duty to promote full disclosure to HMO patients, and physicians have an obligation to disclose treatment alternatives to patients regardless of whether a particular option is covered under the plan or financial incentives might pose a conflict of interest.

Other Disclosure
These laws mandate that a health plan disclose to its members (and, often, potential members) any rights a member may have under the terms of the plan contract or state law including, but not limited to: how to file a grievance and grievance time-frames, scope of benefits, notification requirements, access to specialists, and financial incentives.

Some of these state laws are unique in the scope of information MCO's are required to disclose. A 1996 Arizona law, for example, requires that each MCO shall provide disclosure forms that include: "a statement regarding whether or not plan providers must comply with any specified numbers, targeted averages or maximum durations of patient visits." An Arizona HMO must provide the Department of Insurance and employers with the disclosure form prior to executing a contract, and the employer must in turn provide the disclosure forms to its eligible employees.

Texas recently decided to make all HMO complaint records public. The new law protects individual patient confidentiality while disclosing quality complaints filed against plans. This is done in an effort to allow consumers to better evaluate and compare plan quality.

Fourteen states (California, Georgia, Indiana, Maine, Maryland, Minnesota, New Jersey, New York, North Carolina, Oregon, Vermont, Virginia, Washington, and Wyoming) all have disclosure requirements for different aspects of plan-provider financial arrangements, inducements, or incentives. Most states require disclosure to purchasers or enrollees. Texas, however, requires disclosure only to state regulators. Plans in some states have objected to having to disclose what is viewed as "proprietary" information about financial arrangements on the grounds that release of this information would put them at a competitive disadvantage in the marketplace.

Point of Service

These laws generally require that managed care organizations provide a "point-of-service," or open-panel option, in addition to any "closed-system" product to employer groups in order to do business in the state. The point of service product mandates are generally enforced by state Insurance Departments, and permit managed care members the option to select plans through which they can receive care from providers outside the managed care organization's network for an additional expense. Fifteen states have point-of-service mandates. They include: Georgia, Iowa, Illinois, Indiana, Maryland, Minnesota, Missouri, Montana (if the HMO has at least 10,000 enrollees), New Jersey, New Mexico, New York,

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46 New Jersey has taken a particularly novel approach and has also required that ERISA plans disclose to their members the various state protections or benefits to which they are not entitled as a consequence of being enrolled in an ERISA plan. (N.J. Health Care Quality Act 1997 Chapter 192, effective February 8, 1998)
Oklahoma, Oregon, South Carolina, and Virginia. In addition, Idaho goes even further by imposing a "mandatory POS" rule. That is, only point of service plans can operate in the state.

Benefit Mandates

Benefit mandates remain one of the most popular forms of regulation to counter limits in coverage and service. As of June 1998, there are over 1,200 mandates in existence throughout the fifty states. In 1985, the U.S. Supreme Court held in Metropolitan Life Insurance Company v. Massachusetts, 471 U.S. 724 (1985) that state law can require insurance contracts to include mental health benefit mandates for insured products sold to ERISA plans but that the mandate could not be imposed on self-insured ERISA plans.

Profit Limits

Highly paid executives at MCOs are being scrutinized by regulators and consumer advocates who contend that exorbitant compensation packages are fueling premium increases and profit losses. A recent report from Families USA, a health care consumer advocacy group, revealed that compensation for the 25 highest paid executives at for-profit HMOs averaged more than $6.2 million annually (not including stock options). Advocates called the continued rise in executive compensation "a double standard for HMO costs" when contrasted with proposed consumer protections in the President's Consumer Bill of Rights that would amount to less than 1 percent of premiums, but which health plans claim are unaffordable. Plans respond that they are responsible for the significant reduction in the growth of health care costs and, as businesses, must appropriately reward executives for their performances.

Along with an increased emphasis on consumer protections, insurance commissioners across the country are taking a closer look at MCO executive compensation. In New York, for instance, Gov. George Pataki (R), instructed the Department of Insurance to issue a stop-payment order on a $9 million severance package for a departing CEO in light of its request to raise premiums on individual HMO policies by 50 percent and individual point-of-service plans by 69 percent. A New York legislator also proposed a bill to put a three-year freeze on compensation increases for any insurance executive earning more than $125,000 per year whenever the plan requests a premium increase of 5 percent or more. The Pennsylvania House of Representatives passed a consumer rights bill that would, among other things,
require health plans to spend up to 90 percent of all premium dollars on health care, leaving 10 percent for administrative and marketing costs. The Massachusetts legislature is considering an identical measure.

PSO Regulation

New networks created by physician groups or hospitals to contract with employers and government agencies are also targets of regulatory efforts. The National Association of Insurance Commissioners policy is that PSOs that accept risk are in the “business of insurance” and should comply with state insurance and HMO laws. States are seeking to ensure that they meet the same or similar standards for solvency and financial risk-bearing as HMOs.

Health Plan Liability\textsuperscript{47}

An area of increasingly intense state activity and debate is whether MCOs can and should be held liable in a court of law for health plan decisions. Much of this activity has occurred in the courts under existing state medical malpractice law; it is only in the last three years that legislatures have begun to take up the cause of health plan liability. In doing so, they may create both incremental and large-scale change, for health plan liability laws have the potential to alter in significant ways the business and structure of managed care.

Under the fee-for-service health care system, consumers have traditionally had only one real remedy to combat poor quality health care: the medical malpractice lawsuit. This state court challenge, available in some form to consumers in all 50 states, has been used to hold health care providers accountable for departures from professionally accepted standards of care that have been proven to have caused an unacceptably poor health outcome. This mechanism is known as a private right of action, meaning the aggrieved patient (and not a government official or regulatory body) has the individual responsibility to file a lawsuit in a court of law if he or she believes s/he has been harmed by an act or omission of the health provider.\textsuperscript{48} Because indemnity insurers simply pay claims and do not purport to manage patient

\textsuperscript{47} For a definitive analysis of the current state of health plan liability law, see Patricia Butler, “Managed Care Plan Liability: An Analysis of Texas and Missouri Legislation”, prepared for The Henry J. Kaiser Family Foundation, Menlo Park California, November 1997.

\textsuperscript{48} Such an act or omission is known as an iatrogenic injury, or injury caused by a physician.
care, they are not named as malpractice co-defendants in such suits.

Health plan liability laws in the managed care arena open the door for plans to be sued by consumers. Some proponents of such laws see the liability action as an acceptable interim accountability mechanism, useful for setting a health plan/provider standard-of-care “floor” and punishing wrongdoers. Others, see liability actions and the threat of high damage awards as an additional method to be used alongside other regulatory oversight mechanisms to ensure the health plan industry polices itself and delivers services of such quality that costly lawsuits are avoided. Organized physician and provider groups (often at the forefront of anti-lawsuit, tort reform activities) view liability actions against health plans as an appropriate and equitable way to spread their liability risk, arguing that the health plan utilization review process has diminished their control of the patient-care decision-making process.

Many organized employer groups, business groups, and managed care industry officials argue that liability suits will only serve to drive up the costs of premiums and make health care unaffordable to more citizens. And groups not considered part of organized efforts for or against liability legislation, including some health services researchers, have cautioned that liability suits have not proven to be demonstrably effective at preventing or lessening the incidence of bad care under the fee-for-service system and are thus equally unlikely to bring about desired change under managed care.

Early lawsuits against plans for injurious conduct were brought as traditional medical malpractice suits. That is, the plaintiffs complained of errors or delays in diagnosis or treatment by the treating physician in the plan’s network. In these cases, the health plan was alleged to be (and found to be, in some cases) responsible for the acts of the in-network physician, either because the plan actually employed the physician or presented itself as an “agent” of the plan in some way. Courts have held, however, that one IPA model HMO (as contrasted with a staff model) did not exercise enough control over its contracting physicians to be liable for a physician’s malpractice. The more closely integrated a health plan and its providers, the greater likelihood the plan will be held liable for a provider’s misconduct. In some states, however, managed care plans cannot be sued for medical malpractice because utilization review activities have not been considered by states to be the practice of medicine, which required certain

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35 National Academy for State Health Policy
training and a professional license. Many state statutes,\textsuperscript{50} medical board opinions, attorneys general\textsuperscript{51} and case law have all distinguished health plan utilization review activities from the practice of medicine.

Plans have also been sued under traditional negligence theories for breaching their responsibilities as “care arrangers”\textsuperscript{52} for having negligently selected, supervised, or credentialed a network physician who then committed malpractice or for having provided a financial disincentive which adversely interfered with a physician’s clinical judgment.

Some consumer advocacy groups, provider groups, trial lawyers, and elected officials have begun to champion a new era of "direct liability" or "negligent utilization review" suits against plans based, not on a particular physician’s negligence, but on a plan’s delay or denial of authorizing a plan benefit, because the administrative decision to deny payment, in practice, likely determines whether care is delivered. Plan advocates have argued that any denial issued during the utilization review process is technically for payment only (and therefore a benefit administration function covered by ERISA), but for liability purposes, the treating physician maintains the duty to deliver care deemed by him or her to be clinically necessary, even in the face of a prospective adverse payment decision. Physicians and others who advocate for plan liability generally decry this argument as disingenuous, pointing out that since these benefit denials are based on a plan’s determination of medical necessity, utilization reviews are, in fact, the practice of medicine.

Federal appellate courts are divided on the issue of whether ERISA preempts state lawsuits that

\textsuperscript{50} A Florida UR statute: “A system for reviewing the medical necessity or appropriateness in the allocation of health care resources of possible services given or proposed to be given to a patient or group of patients.” Fla.Stat.Ch.395.002(29) (1993). And an excerpt from a California statute: “Compliance with this subdivision by a plan shall not be construed to mean that the plan is engaging in the unlawful practice of medicine.” California Health and Safety, Section 1368.1.

\textsuperscript{51} One representative AG opinion: “Even utilization review that involves prior authorization of treatment before services are provided cannot be said to constitute the practice of the healing arts, or allied sciences or behavioral sciences. Care is not being administered or withheld by the reviewing person....” Kansas Attorney General Opinion 90-130 (11/28/90).

\textsuperscript{52} Patricia Butler, “Managed Care Plan Liability: An Analysis of Texas and Missouri Legislation,” prepared for The Henry J. Kaiser Family Foundation, November 1997.
challenge the quality of medical care provided by HMOs. The majority of courts hold that ERISA does not prohibit injured patients from suing a health plan for the malpractice of its physicians, reasoning that there is no preemption because regulating the quality of care was not part of ERISA's intent. Liability suits based on the plan's delay or denial of benefits, however, have generally been held by courts to be preempted by ERISA, often with the reasoning that these suits actually put into dispute aspects of plan's administrative, structure, and coverage functions (the very activities ERISA was intended to regulate) and not the quality of care. If suit is then brought under ERISA, only two remedies are permitted. First, a claimant may recover only the cost of the benefit delayed or denied. ERISA does not permit a claimant to recover the other types of damages permitted in state liability actions, such as pain and suffering for injuries or lost wages. Second, health plan enrollees can also seek injunctions from courts to compel plans to pay for services. This remedy has rarely been sought, and then generally only when failure to provide care is potentially life threatening, such as in the case of an experimental cancer treatment.

Because the threat of high monetary damages is removed, some argue, limiting plaintiffs' ERISA grievance remedies to the cost of benefits delayed or denied does little to ensure that health plans will work toward limiting damaging conduct or practices. Moreover, attorneys fees are very rarely awarded in ERISA suits. This may serve as a disincentive for attorneys to take suits based solely on ERISA claims and thereby reduce access to the court system for redress of claimants' grievances against plans.

Approximately 21 states debated some form of liability law in 1997, and 30 did so in 1998. Texas has enacted a statue affirmatively establishing a basis for claims against plans. Missouri eliminated the "corporate practice of medicine" defense, but did not enact a statutory claim.

The Texas Managed Care Responsibility Act, the first of its kind to pass in the country, removes the

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53 Ibid.

54 The U.S. Supreme Court held in 1987 that ERISA remedies are exclusive and preempt state common law damages not just as against self-funded plans, but as against insurers as well.

55 If a patient fails to obtain care after the coverage is initially denied and no care is provided, there is then no dispute over a benefit’s cost and, therefore, no basis for an ERISA lawsuit in the first place. State Health Notes, Vol. 19, No. 267, Jan. 5, 1998.
corporate practice of medicine defense and creates a new cause of action, permitting plans to be sued under a direct liability theory if they do not use “ordinary care” in denying or delaying payment for care recommended by a physician or other provider. “If the HMOs choose to make medical decisions—stand in the shoes of the doctor, as it were—they ought to stand in the shoes of the doctor in court, too,” stated Texas State Senator David Sibley, R-Waco.

The Texas Medical and Texas Trial Lawyers Associations (historically at odds, and described as “an unholy alliance” by the bill’s critics) joined forces to aid in the bill’s passage. Employers who administer benefits were explicitly exempted from the law, also aiding in its passage. Despite official support from the TMA, many Texas doctors reportedly questioned the wisdom of the bill, and many are reported to believe the law may open up new areas of liability for those physicians who have organized themselves into IPAs and other doctor-run groups.

The Texas law has already met with an ERISA challenge in court from Aetna Health Plans of Texas and related companies. Aetna’s complaint asks the court to set aside the law, at least as it applies to federally regulated health plans such as ERISA plans and those under the Federal Employee Health Benefit Act (FEHBA). The Texas Department of Insurance and its Commissioner Elton Bomer are named as defendants. No decision has yet been reached, and all parties acknowledge that the law may in fact be struck down because the Fifth Circuit (that region’s federal appeals court) has, in the past, interpreted ERISA very broadly.

Missouri’s new liability law simply removes the corporate practice of medicine defense. Less likely to

56 This refers to laws which prohibit health care organizations not owned by physicians from hiring physicians as employees. These laws have been interpreted by some courts as barring plan liability suits.


58 Ibid.

59 Ibid. Texas Senator David Sibley estimates that 5 to 10 percent of Texans would still be able to sue their HMOs for malpractice even if the court preempts suits against ERISA and FEHBA plans. If the court lets the law apply to ERISA and FEHBA plans, it is estimated that between 20 and 25 percent of insured Texans will have the new cause of action at their disposal if harmed at the hands of their plans.
meet with a barrage of ERISA challenges, it does not create any new health plan legal duties of care nor does it establish new causes of action against managed care plans as does the Texas law.

**State Omnibus Legislation: Consumer Bills of Rights**

Beginning in 1994, states began to consider more comprehensive approaches toward consumer protection legislation. While some elements of these bills have been concerned with quality issues that apply to both managed care and fee-for-service (provisions for information disclosure, provider credentialing, and medical record accessibility), others have no application in fee-for-service systems. For instance, bans on gag clauses and direct access to providers apply only to managed care.

Supporters of consumer rights bills claim that they are necessary to assure quality health care delivery. They argue that patients find it increasingly difficult to assert their rights in the managed care system, due, in part, to a lack of regulatory oversight. Physicians and patients argue that health plans have taken too much control of care decisions and that regulation is necessary to ensure fairness in plans’ decisions about provider participation and the provision or denial of care.

In 1994, the AMA developed a model law designed to regulate the activities of managed care at the federal level and dubbed it, pointedly, The Patient Protection Act. The AMA argued that its model legislation was designed “to assure fairness to patients and providers.” To that end, The Patient Protection Act was the first of its kind to require that MCO’s:

1. Provide disclosure about utilization review and coverage limitations, loss ratios, and enrollee satisfaction statistics;
2. Ensure confidentiality of individual medical records;
3. Meet financial reserve standards;
4. Provide “adequate” access to physicians;

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60 Model Language provided by NCSL/HPTS issues brief, 4/1/98

61 Opponents of this legislation dubbed it the “Physician Protection Act.”

39 National Academy for State Health Policy
5. Assure a host of protections for physicians such as:
   a. credentialing criteria based on ‘quality’ standards (and not resource consumption or 
      other items sometimes considered by plans),
   b. cause-only contract termination,
   c. due process for terminated doctors,
   d. a requirement that a medical director be responsible for review of all of the plan’s 
      UR/clinical decisions,
   e. same-specialty peer review of all coverage or payment denials, and
   f. a point-of-service option to give enrollees access to providers outside the plan.

California enacted a provision based on the AMA model in 1994.

During the 1995 legislation session, model legislation became increasingly consumer focused and moved 
away from patent and provider protections. That year a comprehensive model was drafted by the Public 
Education Fund of New York in cooperation with the Citizens Fund. The Managed Care Consumer Bill 
of Rights required the following protections:

1. Each health plan should include a sufficient number of each category of provider, including 
specialists;
2. A point of service option;
3. A plan’s utilization review system should be based on sound clinical evidence under the 
supervision of licensed health care professionals;
4. Enrollees should be entitled to seek and receive emergency care without prior approval or 
authorization;
5. Each plan should reimburse investigation or experimental treatment under specified conditions;
6. Each plan should establish an internal quality assurance system that is adequate to identify, 
evaluate, and remedy problems relating to access, UR, continuity, and quality of care;
7. Each plan should establish an enrollee grievance procedure.

In 1995 and 1996, 13 states (Arizona, California, Georgia, Maine, Maryland, Minnesota, Mississippi, 
New York, Oregon, Rhode Island, Vermont, Virginia, and Washington) enacted laws that borrowed from
the American Medical Association's model and/or the Managed Care Consumer Bill of Rights.

In 1997, different and additional models of legislation were circulated and introduced in various state legislatures. A group known as Women in Government developed one such model, known as the Managed Care Consumer Protection Act, which significantly expanded upon the Managed Care Consumer's Bill of Rights. The Managed Care Consumer Protection Act included the following requirements:

1. A "sufficient" number of individual and institutional providers, including specialists, must be included in the plan;
2. A "prudent layperson" definition of emergency care;
3. No prior ER authorization;
4. A point-of-service option;
5. Use of specialists as primary care physicians, as appropriate;
6. A gag rule prohibition;
7. Disclosure of experimental treatment coverage limitations and written denial justifications for those patients with life-threatening conditions;
8. Disclosure of plan structure and process information;
9. Non-discrimination provisions;
10. Designation of a state agency or contractor to perform external quality review functions;
11. Mandated access to an open formulary of all FDA approved drugs;
12. Required plans to develop an appeals and grievance procedure that would include a timely response to complaints, mandated plan complaint assistance, mandated written plan-maintained complaint log, and right to appeal to a designated state agency;
13. The promulgation of regulations by the appropriate commissioner for managed care plan and utilization review company certification.

In 1997, Arkansas, Colorado, Connecticut, Florida, Idaho, Kansas, Louisiana, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, Ohio, Oklahoma, Oregon, and Texas each passed some form of comprehensive consumer legislation. (See Table B for a summary of state consumer rights laws.)
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Sources: Blue Cross/Blue Shield and NCSL.
Notes on Table B:

Disclosure Mandates: Different than a gag clause prohibition. Refers to plan requirements to provide enrollees, and often potential enrollees, with information about plan structure, coverage, process and financial incentive information.

No Gag Clause: Prohibits a plan or physician contract from containing provisions that limit what a physician may say to a patient in terms of treatment options.

Grievance Procedures: Consumer and/or provider grievance procedures.

Due Process Provisions: For consumers or providers when contracting or credentialing

ER pay/care: Can mandate triage fees or care without prior authorization.

Prudent Layperson: Legislates the standard of proof required to determine an emergent situation; generally, prudent layperson definitions are intended to liberalize health plan UR requirements which could otherwise be used to deny payment for ER care rendered under less than emergent circumstances.

Out-of-Network: Members may go out-of-network, but not necessarily a mandated point-of-service; also refers to continuity of care provisions which permit members to go out-of-network to see a specialist who had provided care for a chronic condition prior to their membership in a plan.

Direct Access: Members may see a physician without being referred by a gatekeeper; can refer to ob/gyn or specialists

Enhanced Access: Includes provisions mandating access to specialists or continuity-of-care provisions.

Benefit Mandates: Provisions including, but not limited to, mandatory post-partum stay, prescription drugs, medical devices, mandatory minimum mastectomy stay, breast reconstruction, chiropractic benefits.

PPA: Variation on the Patient Protection Act.

Note: New Jersey and New Mexico enacted comprehensive regulations, not state statutes.

The President’s Quality Commission

The President’s Commission on Consumer Protection and Quality in the Health Care Industry was appointed by President Clinton in March 1997 to examine changes occurring in the health care system and to recommend measures that may be necessary to promote and assure health care quality and value and to protect consumers and workers in the health care system. The 34-member Advisory Commission was co-chaired by the Secretary of Labor and the Secretary of Health and Human Services and included members from consumer groups, business, labor, providers, plans, and state and local governments.

The Advisory Commission issued a Report to the President and drafted a comprehensive Consumer Bill of Rights and Responsibilities. Mirroring many state efforts, the bill addresses disclosure, access to emergency care, consumer grievance and appeals, confidentiality of medical records, participation in treatment decisions, and choice of providers and plans. The Advisory Commission’s report did not speak specifically to issues of implementation and enforcement of the Bill of Rights, but the President directed that all federal health programs come into substantial compliance by 1999.

The national aims for improvement contained within the Commission’s report include:

- reducing the underlying causes of illness, injury, and disability;
- expanding research on new treatments and evidence of effectiveness;
- ensuring the appropriate use of health care services;
- reducing health care errors;
- increasing patients’ participation in their care; and
- addressing over-supply and under-supply of health care resources.

The commission also outlined strategies for strengthening the market to improve quality. These included:

- Public and private group purchasers of health care coverage and services must become more active and more coordinated in demanding high-quality services for those they represent.

- Patients and other consumers of health care services need greater access to easily
understood information and the ability to exercise greater choice in the health care market.

- The needs of vulnerable citizens must be taken into account in the design of systems for health care delivery, quality measurement, and financing.

- All participants in the health care industry must be accountable for improving the quality of health care in the United States. Public and private sector quality oversight organizations should be preserved and extended, with better coordination and focus on shared aims and methods of accountability to increase the impact of existing oversight organizations.

The Commission also recommended that two new panels set national standards for quality development, meaning that health plans may soon have to conform to a standardized set of quality improvement measures and objectives. The Advisory Council for Health Care Quality, a public panel established and funded by Congress, would identify goals and establish specific objectives for quality improvement, track progress in attaining those goals, and monitor compliance with the consumer bill of rights. The Forum for Health Care Quality, Measurement and Reporting, a private dues-paying panel, would create a comprehensive plan for measuring health care quality and report the results of the measures to purchasers.

**Quality Improvement System in Managed Care (QISMC)**

The Quality Improvement System in Managed Care is designed as a uniform quality oversight system. QISMC was developed by the Health Care Financing Administration (HCFA) for the purpose of assuring that managed care organizations contracting with Medicare and Medicaid “protect and improve the health and satisfaction of enrolled beneficiaries.” HCFA conducted a public review process of QISMC in May 1998 and intends to mandate the oversight system for Medicare and make it largely optional for states’ Medicaid programs. States will receive further direction about QISMC’s applicability to Medicaid through forthcoming state guidelines and regulations.

Under the draft guidelines each managed care organization will:
• Operate an internal program of quality assessment and performance improvement that achieves demonstrable improvements in enrollee health, functional status, or satisfaction across a broad spectrum of care and services;

• Collect and report data reflecting its performance on standardized measures of health outcomes and enrollee satisfaction, and meet such minimum performance levels on these measures as may be established under its contract with HCFA (in the case of Medicare) or the State Medicaid agency; and

• Demonstrate compliance with basic requirements for administrative structures and processes that promote quality of care and beneficiary protection.

Agency for Health Care Policy and Research (AHCPR)
As a federal agency within the Department of Health and Human Services, AHCPR’s stated goal is "to ensure in an increasingly market based health care system that state-of-the-science information drives informed decision making.” The three priorities of the agency are: 1) to conduct and support research on the outcomes and effectiveness of treatments; 2) to ensure clinicians, patients, health care system leaders, and policy makers have the information that will enhance quality of care; and 3) to identify gaps in access to and use of health care services, achieving value of the nation’s health care dollar, and helping the market and policy makers find ways to address those gaps.

AHCPR’s Research on Health Costs, Quality and Outcomes program, funded at $141 million in 1999, supports research that improves the outcomes, quality, cost, use, and accessibility of health care services. This program includes the Health Care Quality Improvement initiative, funded at $30 million, to promote the widespread application of research relevant to the health care system. AHCPR research will seek more scientific methods to measure and verify changes in a patient’s health resulting from care and will examine the best indicators of health care quality, including patient satisfaction and medical complications. With improved measures of quality, AHCPR can more effectively encourage health care providers to use quality information in their work and can assist in the development of strategies for integrating quality measurement data into professional curricula and practice. AHCPR’s administrator, Dr. John Eisenberg, states that the agency’s quality research takes into consideration both fee-for-service
and managed care since "real quality is quality regardless of what type of health care plan is involved."

Pending Congressional Action

On May 28, 1998, the Clinton Administration released a report compiled by the White House Domestic Policy Council and the National Economic Council that indicated that "only federal legislation—as opposed to measures enacted by the states—can provide comprehensive managed care reform." The report noted that although many states have enacted patient protection legislation, such a "patchwork" is "inadequate" and many of the laws "are preempted by ERISA."

Four major managed care consumer protection and quality bills were introduced in Congress in 1997 and 1998. These bills would explicitly amend ERISA and permit the imposition of certain consumer protections and quality mandates on virtually all managed care plans across the United States. Three of the bills, if enacted, would reach both insurance plans and those self-funded employee benefit plans now shielded from state law by ERISA.

PARCA

The first of these managed care consumer protection and quality bills was introduced by Representative Charles Norwood (R-Ga) on April 23, 1997. Known as the Patient Access to Responsible Care Act of 1997, PARCA, which has garnered in excess of 200 co-sponsors, amends the Public Health Service Act and ERISA in order "to establish standards for relationships between group health plans and health insurance issuers with enrollees, health professionals, and providers."

PARCA has been the subject of much controversy, due to its final section, "the Non-Preemption of State Law Respecting Liability of Group Health Plan." The bill would insert a paragraph into ERISA that would permit lawsuits against health plans, and, in its amended version, against employers only if the employer or other plan sponsor exercised discretionary authority to review and make decisions on claims for plan benefits which resulted in personal injury or wrongful death. Under PARCA, plans would need to:

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62 Senator Alfonse D'Amato, (R-NY) introduced a related bill the following day, numbered S.644.
1. Maintain "adequate arrangements, as defined by the applicable State authority, with a sufficient number, mix and distribution of health professionals and providers to assure covered items and services are accessible;"

2. Assure 24-hour emergency coverage, require no prior authorization cover, and make reasonable payments for such services;

3. Use a prudent layperson standard for the definition of "emergency medical condition;"

4. Provide access (and direct access when indicated) to specialists by legislating that the treating professional "in consultation with the enrollee" may make specialist referrals;

5. Provide a mandatory point-of-service option, the unlimited ability to change providers by health plan members, and various continuity of care provisions;

6. Adopt a policy forbidding discrimination against enrollees and health professionals on the basis of race, national origin, gender, language, socioeconomic status, age, disability, health status, or anticipated need for services;

7. Not place limitations on physician-patient communication

8. Plans must comply with certain utilization review criteria and time frames;

9. Comply with mandates assuring certain due process requirements for health professionals desiring to contract with plans, including but not limited to mandatory annual open applications, the disclosure of selection standards, and case-mix adjustment for utilization of service measures;

10. Provide coverage disclosure to enrollees and potential enrollees; and

11. Establish confidentiality measures and quality improvement programs and meet state solvency requirements.

QUEST

On March 15, 1998, Vermont Senator Jim Jeffords (R) introduced S.1712, The Health Care Quality Education, Security and Trust Act. QUEST's purpose is to provide for a national continuous quality improvement effort, and to:

Provide for the development and implementation of the tools necessary to measure health care quality; provide consumers with the information necessary to guide and inform consumers regarding health care purchasing decisions, ensure that health care professionals can act as advocates for their patients, provide consumers with timely coverage decisions and defined procedures for appealing adverse determinations and provide a 'prudent layperson' standard for emergency care throughout the United States.
QUEST establishes a Health Quality Council to advise the President and the Congress, and directs the Secretary of Health and Health Services to contract with the Institute of Medicine of the National Academy of Sciences to conduct studies to develop health care benchmarks to help plans and providers move toward evidence-based care.

*Patients Bill of Rights Act (PBRA)*

On March 31, 1998, The Patients' Bill of Rights Act of 1998 (H.R. 3605) was introduced by Representative John D. Dingell (D-MI), ranking member of the Commerce Committee. The Act has received the support of and was co-drafted by numerous organized interests, including the AFL-CIO, the American Association of Retired Persons, Families USA, the American Nurses Association and the American Medical Association.

The PBRA would legislate similar network, access, disclosure, and provider due processes and liability provisions to those of PARCA, but goes further. In terms of its additional access provisions, it would require plans to have a process for selecting specialists as primary care providers and permit access “without impediments.” Members would be permitted to go out-of-network at no extra cost in the event a required specialist were unavailable in-network. Plans would be required to see to it that children had adequate access to pediatric sub-specialists.

Among its provisions, the proposal would:

- Permit women direct access to ob/gyns and permit their designation as primary care providers;
- Include bills regarding mastectomy length of stay and breast reconstruction;
- Mandate a process for permitting enrollees to participate in a defined set of approved clinical trials and for covering the associated routine patient costs;
- Mandate that plans develop processes to permit patients access to drugs not included on plan formularies;

In terms of the legislation’s quality mandates, the PBRA would require that plans establish and maintain

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63 A related Senate bill was introduced by Senator Edward M. Kennedy (D-MA)
quality assurance programs and that they collect data to monitor quality in a standard format so comparisons could be made across all plans. A public/private Advisory Board similar to that described in QUEST would be established to advise the Secretary on a standardized minimum data set and other quality improvement activities.

PBRA would have plans not only maintain an internal grievance process that is "expedient" and "conducted by appropriately credentialed individuals;" but plans would also be required to establish expedited grievance processes. The Department of Labor, in conjunction with the states, would establish one independent external appeals process for plans. Plans would pay the entire cost of this new process, and plans would be bound by the decisions. Plans would also be forbidden from retaliating against patients who elected to use the process, or their respective providers who advocated on their behalf.

The U.S. House of Representatives Republican Response

On June 25, 1998, the House Republican managed care task force, convened by Speaker Newt Gingrich (R-GA), announced an alternative consumer protection bill. The proposed legislation would guarantee coverage for emergency care, outlaw gag clauses, mandate direct access to gynecologists for women enrolled in HMOs, and provide for an external appeals process for consumers, with appellate reviewers to be providers appointed at the sole discretion of the health plans. The legislation does not permit liability suits against plans.64 The bill includes some provisions considered unrelated to consumer protection such as limits on medical malpractice awards to a cap of $250,000 for pain and suffering and mechanisms to establish medical savings accounts.

The House of Representatives approved this measure by a vote of 216 to 210 on July 27, 1998. Before taking this vote, the House defeated the Patients Bill of Rights Act by a vote of 216 to 212. At this writing, the Senate is expected to take action in September of 1998 after the August recess.

The National Governors Association did not testify in support of any of the above pieces of legislation.

64 American Medical Association President Nancy Dickey was reported to have criticized the bill for its failure to include a liability provision. Congress Daily/A.M., 6/25/98.
Projected Cost of Federal Initiatives

The projected costs of the major federal initiatives differ significantly from one analysis to the next. The major provisions of the President’s Consumer Bill of Rights would likely result in an annual premium increase of 0.61 percent for a typical HMO policy, according to a study recently prepared by Coopers & Lybrand for The Henry J. Kaiser Family Foundation.

The analysis estimates that PARCA would increase HMO premiums by 0.77 percent. However, this figure fails to take into account the most potentially costly aspect of the bill: its liability provisions. An analysis by the Barents Group of KPMG Peat Marwick conducted for the American Association of Health Plans projects that health plan liability provisions will increase costs as much as 8.6 percent. The analysis estimated that other provisions such as eliminating a plan’s ability to determine “medical necessity” and “any willing provider” mandates would likely increase costs from 4.1 percent to 8.6 percent, respectively.

The May 2, 1998, edition of the Dallas Morning News reported that public support for reform is “unclear” if it results in increased costs: “GOP polls show 86 percent of those polled support HMO reforms. Two thirds of those surveyed would still support the proposals if they raised premiums $200 per year, or about $17 per month,” but a Kaiser survey showed only 33 percent of respondents support a “patient bill of rights” if it would increase premiums.65

Implications of Federal Action

Federal legislation may have a widespread—and beneficial—impact on a variety of state health reform efforts. Provisions within ERISA, often major challenges and barriers for state regulators, can only be addressed at the federal level. Because many health plans are multi-state plans, federal action could help assure that regulations were standardized across states.

But while many of the current federal proposals mirror state legislative action and are in line with state reforms, not all states have adopted the same approach to ensuring quality in managed care. The federal government, while seemingly taking its lead from states, could impose reforms with implications beyond

65 As reported in American Health Line, 6/26/98.
quality oversight. And questions remain about the federal government's capacity to monitor or enforce any consumer protection or quality reforms. Health reform has traditionally been the state's realm, and state-level reform has led to numerous innovations in health care delivery. Increased Federal regulation could interfere with those efforts.

The long-term impact of federal action is still unclear, however. The federal government appears interested in assuming a stronger role in health reform issues. The 1996 Health Insurance Portability and Accountability Act (HIPAA, or Kassebaum-Kennedy) represented the most significant federal intervention into the private insurance market in years. Many observers consider it the first step in broad insurance reform.

As managed care continues to evolve, states continue to be creative, innovative, determined in their approaches to oversight and reform, but federal action may be considered necessary and inevitable. The federal government would be wise, however, to draw upon states' longstanding experience—and to forge state/federal partnerships—as it works to ensure quality and consumer protection in managed care.
Section 3: COMPLEX CHALLENGES, COMPLEX SOLUTIONS

With 34 states considering consumer rights bills, 21 states contemplating HMO liability bills, numerous others addressing a variety of proposed health plan regulations, and a host of proposed federal initiatives, the public and policy makers are expressing widespread concern over the way managed care plans are delivering health care.

While there appears to be general and growing consensus that improvement in quality oversight is needed, there is no clear consensus on how best to achieve that goal and no conclusive data that demonstrate that protection is warranted. Too often, state and federal policy makers lack the tools and research they need to assess the real—and perceived—concerns surrounding managed care. If we are to have a cost-effective delivery system based on market competition and managed care principles, policymakers need to develop a coherent, enforceable strategy that protects consumers and ensures quality, but one that also permits plans to manage patient care. How is such a strategy achieved?

Clearly, there are no simple solutions.

But perhaps the answer lies somewhere in the middle, with both public and private reforms appropriate and necessary to address market problems. There is an established and growing role for private accrediting bodies who are rapidly improving their quality measures and methods. There is a clear role for employers and other purchasers who can leverage improvement through their purchasing power. There must also be a role for consumers who experience the system and provide direct feedback as to the quality of care they receive. And state governments will undoubtedly retain and develop their roles, as they have done with other industries that have a powerful impact upon the lives of their citizens.

The power of employers and purchasers

Despite the consumer focus of much current legislation, most health plans see employers as their customers. Because employers purchase millions of dollars worth of services, they have significant
power to affect change in health plan behavior.66

In recent years, employers have been one of the most powerful constituencies pushing for health plan accountability. Corporations have been the driving force behind the move to compare health care providers and plans based on performance. Large companies are applying techniques such as standard setting and benchmarking to health care. Some have developed their own standards for health plan quality. Employers have also begun to use measures, such as the Health Plan Employer Data and Information Set (HEDIS), to assess the quality of services they purchase for their employees. And some have begun to eliminate contracts with plans that do not meet performance goals. Purchasers have the flexibility to demand purchaser-specific services, network arrangements, point-of-service options, or other consumer focused changes. By eliminating contracts with poor performers and rewarding plans with high quality standards, employers create strong financial incentives for quality improvement.

However, while employers are powerful and major players in the evolving marketplace, they are not necessarily representatives of consumer interests. Whatever the good intentions of many large employers, the cost of coverage is of real importance as they assess and choose among competing plans.

Members of employer sponsored health plans can be limited by the choices their employers make. Employees who rely on employer premium contributions may enroll only in the health plans selected by their employers. If employers offer their employees a range of health plans to choose from, choice—and an important degree of accountability—is preserved. In this situation, health plan enrollees maintain their freedom of choice by exercising options to join different health plans. Problems arise when employees lose that freedom of choice. Employers as purchasers play a critical role in preserving that choice.

The Role of Market-Based Quality Reforms
Encouraging improved quality in managed care may be a shared goal, but opinions on how to achieve that goal are varied. Many believe that change should be left to the market place where economic incentives will ultimately create higher quality standards. The emerging employer practices discussed

Section 4: STRATEGIES WITH PROMISE

Successful oversight may best be achieved through a partnership of purchasers, regulators, and plans, one that capitalizes on the strengths of each and allows for high quality care and contained costs. Perhaps more than in any other area, a cooperative effort among these partners is needed in the development of quality indicators and measures. Although such standards don’t guarantee quality, they improve its likelihood and establish clear expectations. Purchasers and regulators must use the information they have to enforce standards and take direct action to improve quality and care. Many organizations, such as AHCPR, are contributing to the available body of research on effective quality measures.

As indicators are developed and evolved, states and plans must invest in information systems that will make it possible to use data to monitor and improve performance. Managed care has placed enormous demands on state information systems and analytic resources. It is not a lack of data, but the absence of useful information and sophisticated information systems that inhibit quality measurement.

Among the strategies that show promise in this area:

Quality Indicators

Report cards
Report cards on health plan performance are designed to give consumers and purchasers the information they need to make informed health care decisions. As market forces continue to dominate the health care system, consumers and purchasers need comparative information on the quality of various plans. Many states are developing such report cards or are passing legislation to do so. One problem with report cards is the difficulty of producing standardized comparisons of quality, both in terms of collecting information and presenting it in a way that is helpful (and understandable) to its intended audience.

Although many states are now requiring plans to submit extensive data on performance and customer satisfaction, there is concern that many of the measures do not answer the right questions. Among the measures typically used:
The Health Plan Employer Data and Information Set (HEDIS) which measures quality, access, patient satisfaction, membership and utilization, and finance;

The Consumer Assessment of Health Plans Survey (CAHPS) a demonstration for the Agency for Health Care Policy and Research that provides ratings on access, availability of care, wellness advice, communications skills of providers, patient involvement in the decision making process, and continuity of care; and

The Foundation for Accountability (FACCT) survey which provides a framework to combine some of its own measurements with data from HEDIS, CAHPS, and other databases to provide comparative information about health care quality.

Although CAHPS is developing a set of national survey-based standards that apply across systems and populations, no such standard yet exists and many providers and plan representatives argue that until a uniform standard does exist, publishing comparative information is of questionable value. As noted earlier in this paper, satisfaction measurement is now one of HEDIS’s eight domains, an addition that is expected to help gear competition to areas of particular importance to purchasers and consumers.

Many physicians believe that report cards need to include more clinical outcomes information than is currently available. Even proponents of report cards agree that their usefulness will be enhanced by a national standard and the availability of more outcome information, but not to the extent that publication should wait until they are available. Very real technical barriers remain to obtaining outcome measures for health plans, primarily the temporary nature of enrollment patterns. For example, while measuring the five-year mortality rate for breast cancer in a particular plan would be more compelling than measuring the mammography rates of its female members, there are simply too few women with breast cancer who remain continuously enrolled in a health plan for five years to obtain meaningful results.

Despite existing shortcomings, employers take report cards very seriously, as do health plans who are motivated to improve when they fare poorly compared to other plans. Meanwhile, states and private organizations are moving ahead to provide consumers with the best comparative information available from existing measures.
the importance of different elements of care. One such study found differences between doctors and their patients on the importance of 73 of 125 elements of care. Patients ranked provision of information as the second most important aspect of care (behind clinical skill) whereas physicians ranked information sixth. Consumers, not surprisingly, seem to prefer plans which they experience as "user-friendly" than those which may be recognized for their medical expertise.

Consumer satisfaction offers a new evaluation tool for the health care delivery system. It may provide doctors and administrators with new information to improve their services, information that may never have surfaced in a fee-for-service environment. In fee-for-service systems, consumers are able to leave providers who do not meet their expectations, and few tools exist to evaluate consumer satisfaction. In an environment that limits choice, however, systematic measures of consumer satisfaction seem appropriate and necessary to assure quality and heighten plan accountability.

**Patient Identifiers**

The Health Insurance Portability and Accountability Act (HIPAA) included provisions to establish national patient and provider identifiers to be shared throughout the health care system. These identifiers would be unique to each person, similar to an individual's social security number or taxpayer ID number. Supporters contend that individual patient identifiers will not only reduce administrative burdens on providers and payers and therefore save money, but will also make possible the ability to track and monitor patient care in all settings. Use of these identifiers they argue will lead to increased accountability and coordination of care at the individual patient level. Privacy concerns raised by both providers and consumers has tempered Congressional action on the development and use of these identifiers, however.

**Medicaid Lessons**

In recent years, Medicaid agencies have become increasingly sophisticated purchasers of services for low-income populations. As these agencies have turned to managed care systems as a vehicle to improve service delivery, they have devised very complex contracts that specify service delivery expectations. Private and other public purchasers of health services may have much to learn from the contracting

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practices developed by Medicaid.

One of the key lessons Medicaid agencies have to offer is that states continue to face major challenges in the area of data collection and performance monitoring. Even among those states with significant experience, few have developed a comprehensive approach to data collection that addresses: 1) the data that managed care organizations must provide; 2) the form in which it should be provided and to whom; and 3) the frequency with which it should be reported. A lack of data collection and reporting requirements can adversely affect the ability of health care systems to perform their regulatory functions. Data collection and reporting are key issues not only for Medicaid agencies but for all purchasers and public agencies involved in the health care enterprise.\textsuperscript{71}

Medicaid experience has highlighted the need for adequate data and reporting systems without necessarily developing adequate models. Clear performance measures for contract specifications that are tied to reporting requirements must still be developed and must provide sanctions for non-performance.

\textbf{Development of State-of-the Art Information systems}

Increasingly, existing health care information systems (both private and governmental) are viewed as inadequate in light of the many tasks they are being asked to undertake. The American health care industry still does not have the ability to systematically measure and report on the quality of health care that is delivered to patients. This lack of comprehensive information is viewed by many as unacceptable in an industry that accounts for more than $1 trillion in annual expenditures and comprises nearly one-seventh of the U.S. economy.\textsuperscript{72} The demand for improvement is coming from virtually all stakeholders in the system, each of which requires information for different purposes.

Consumers, group purchasers, policymakers, and others need information on health care quality and on the individual and comparative performance of health plans, facilities, systems of care, and individual practitioners. Such information is critical to market-based efforts to improve quality. In many cases,

\textsuperscript{71}Ibid.

\textsuperscript{72}Quality First: Better Health Care for All Americans, Final Report to the President of the United States, The President’s Advisory Commission on Consumer Protection and Quality in the Health Care System.
however, much of the necessary information is difficult to collect and to aggregate. The increased need for performance measurements will also require data that has not been routinely collected, such as information on the experiences and perspectives of patients and health care professionals; clinically detailed data of the type needed to measure quality for chronic care; and information on health care outcomes, including functional status.\textsuperscript{73} There is a need for one single standard for data collection, which is why HEDIS data (particularly audited HEDIS data), serves such an important function.

Despite the general recognition of the importance of computerized health care systems, the health care market has not been structured to reward significant investments in information technology. The President’s Commission found that the health care industry invests less than 4 percent of earnings in information technology, notably less than the 7.8 percent invested in the financial services sector. This is beginning to change as consumers and group purchasers are demanding more detailed clinical and administrative information as part of their value-based purchasing strategies. However, barriers remain because of reluctance on the part of plans to invest in a system that may need to be quickly replaced or modified and the significant up-front investments that could adversely affect the short-term competitive position of an organization. Reducing or eliminating these barriers will require a comprehensive plan, long-term commitment, and significant and sustained investment over time.\textsuperscript{74}

\textsuperscript{73}Ibid.

\textsuperscript{74}Ibid.
Section 5: WHAT'S A POLICY MAKER TO DO?

Legislators and policy makers, by necessity, respond to constituents. There is little question that many constituents/consumers are uncomfortable with managed care. In March of 1998, John Erb of William M. Mercer Inc. presented data from the Mercer/Foster Higgins annual survey that demonstrated that "when employees have a choice, when they can vote with their feet, less than one in three will opt for an HMO. They will hold onto choice."75

Employers, however, have little interest in traditional indemnity plans. The number of employers offering indemnity coverage has declined sharply and steadily. In 1988, 92 percent of employees in small firms (fewer than 200 workers) had access to a conventional plan. In 1996, only 33 percent had that choice.76 Managed care has provided purchasers with the only successful means to date of lowering their health care costs. The Congressional Budget Office reported that with the advent of managed care, 1993-1997 was "the longest period in which the health sector has grown no faster than the rest of the economy in the last 30 years."

In an effort to accommodate both consumer preferences and pressures to keep costs down, managed care plans have begun to experiment with more loosely controlled networks. Point-of-service plans, which open access to specialists and out-of-network providers, are extremely popular managed care products, and their growth reflects a pervasive theme in the evolution of managed care. The same Mercer/Foster Higgins report found that between 1993 and 1997, while market share for indemnity insurance dropped from 48 percent to 15 percent, HMO share grew from 19 percent to 30 percent, and the share of more loosely controlled preferred provider organizations (PPOs) grew from 27 percent to 35 percent. Point-of-service (POS) plans' share grew from 7 percent to 20 percent. The data also show that "many HMOs

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are loosening restrictions on referrals and diagnostic testing in an attempt to become more user friendly.\footnote{\textit{Medicine and Health}, March 8, 1998.}

Policy makers, in an effort to respond to consumer concerns, are introducing legislation and regulatory reforms which accelerate the trends towards looser managed care controls. Many of the most popular bills mandate direct access to specialists or coverage for various treatments. Plans, on the other hand, leave the responsibility with providers to strike the balance between cost and quality. Many claim that only further improvements in providers’ ability to make use of evidence-based, best-practice data can resolve the apparent contradiction between quality and cost. Sound clinical decisions with demonstrated efficacy may give consumers the quality they demand without returning to the over-service and cost increases of the fee-for-service system. Plans argue that the legislative efforts to loosen managed care controls will not achieve this balance; rather, such efforts, by neither bringing practice more closely in line with quality standards nor limiting utilization and over-service, will only undermine improvements in both cost and quality. The contradictions between consumer demand and cost control, and who will have the responsibility for quality oversight, have generated heated debate around the country.

While the debate of the past year and the trend in legislative proposals has turned towards regulating access and delivery, improvement in clinical knowledge and incorporation of that improved knowledge into practice may improve quality without significantly raising costs. Some approaches include:

- \textit{Quality Measures}: Investment in and support for the development of clinical quality measures is necessary. As knowledge and information outpace practice standards, the gap between optimal care and practice widens. This takes a toll on quality and minimizes cost-effectiveness. Providers who are best able to incorporate evidence-based, best-practice data into their practice will not only improve overall quality, but will avoid the pitfalls of over-service and resulting cost overruns.

- \textit{Information Systems}: As information becomes available, it must be accessible to all parties in the health care system. Existing health care information systems are inadequate. Information on
health care quality and the individual and relative performance of health plans, facilities and systems of care, and individual practitioners is critical to market-based reform efforts. Investment in the development of such systems will allow consumers and purchasers improved choice based on data and experience. This would include agreement on standards of measurement and collection methods.

- **Disclosure:** In April of 1998, the U.S. General Accounting Office reported that much of the information recommended for disclosure by the President’s Commission’s Consumer Bill of Rights is not typically disclosed. Large purchasers and their associated health plans currently provide about half of the data elements the Commission recommended be routinely provided to consumers to facilitate choice and accountability. Information that the Commission recommended be provided about the business relationships and financial arrangements among health professionals, health care facilities, and health plans, as well as measures of service performance, are among the items not routinely reported to consumers. Increased disclosure is recommended to protect consumers and to help them make informed choices.\(^{78}\)

**Choices, Choices**

Consumers’ preference for less restrictive forms of managed care, and legislative responses to those preferences, may have ominous cost implications. Although surveys indicate that consumers are willing to accept modest premium increases in exchange for improved quality, there is little or no guarantee that quality will be achieved through pending legislation. Unfortunately, little has been done to evaluate the efficacy of many of the legislative proposals for regulating health plans. Few organizations have evaluated whether or not they actually achieve improvements in quality measures, in part because they are new, in part because of a lack of objective standards by which they may be evaluated. Clear and reliable data on the impact of expanded provider networks and other reforms is basically unavailable. With little evidence upon which to weigh reform proposals, legislators are faced with a number of choices.

Waiting for the Feds

Many believe that federal action is likely, if not inevitable, in the next year. Consumer protection and managed care regulation have become powerful election-year issues. Many of the Congressional bills contain provisions already passed by many state legislatures around direct access, provider choice, and utilization review. States may find that their efforts are either reinforced or preempted by federal action in the next year, or even months. Some states that chose not to pursue managed care regulation may find new controls on their markets. Others believe that Congress will fail to pass meaningful reform by the end of the current session. Many state lawmakers are proceeding with their own reforms which may or may not coincide with possible federal changes.

ERISA reform is also getting notable attention at the federal level. President Clinton has acknowledged that ERISA is a barrier to many state health care quality goals. Although passage of ERISA reform is unlikely (its political supporters are powerful), it has become a front-burner issue, and should action be taken, it would have a tremendous impact on state insurance markets. Though many states welcome the idea of a "level playing field" created by federal standards, others worry that innovation at the state level could be deterred by too much federal involvement.

Relying on the Marketplace

In an increasingly market driven health care system, there is some basis to the argument that the market should be left to resolve its problems. This is especially true considering that the public rejected a government approach to health reform in the beginning of the Clinton Administration. Many believe that while plans have initially competed on price, the next phase of competition will be in quality. Economic incentives may emerge (some say are emerging) for plans to demonstrate not only their value but their consumer friendliness and efficacy of care. Accrediting bodies should also play a significant role in private sector quality monitoring. The incorporation of consumer satisfaction data into more and more measurement tools seems to be furthering this trend.

Others remain unconvinced. Some insist that any profit-driven business will, by necessity, put profit over consumer interest. Multi-million dollar profits in many health plans exacerbate this image, especially when coupled with plans' apparent resistance to incorporating many popular consumer "protections." Even if plans do address many current consumer concerns, there is a natural tension that is
likely to remain between consumer wants and health plan incentives. The role of government may appropriately be to effect a compromise.

Comprehensive Reform Bills
The move away from piecemeal regulatory bills to comprehensive consumer protection bills reflects the need to develop a coherent strategy of oversight. When all proposals are weighed together, duplication may be reduced and results enhanced. Each of the bills will need to be carefully considered to ensure that they hold the potential to meet the goals for which they are designed. Incorporating the most up-to-date outcomes research will increase the likelihood of success. Projected cost should also be considered. It is likely that market proponents will continue to oppose heavy regulatory approaches.

Conclusion
Perhaps the most complicated, but possibly the most promising, approach to ensuring quality is through the development of an oversight system, with minimal duplication and appropriate division of labor. Each state regulatory agency plays a role in this system, as do private sector entities, independent accrediting bodies, and of course consumers and policy makers. The goal is to strike the appropriate balance between oversight and market innovation, with the incorporation of the best data available. As data becomes available, it must be shared through adequate information systems and incorporated into regulation and statute as well as accrediting standards. A successful system may be based on:

- clear standards for all MCOs;
- independent monitoring;
- consumer education and grievance procedures to enhance accountability and provide feedback for system improvement;
- enforceable actions/sanctions to address problems in the system;
- good data shared on good information systems; and
- coordination of actions by private accrediting bodies, state and federal governments & purchasers.