THE CAPITOL FORUMS
On Health and Medical Care

Public Oversight of Managed Care

Issue Brief prepared by
Joanne T. Fuccello, MSW

Graphic Design by
Susan Rheaume

background information for the discussion at the

CAPITOL FORUM
on Wednesday, October 19, 1994
Masonic Temple Library
Trenton, New Jersey

Sponsored by
The League of Women Voters of New Jersey Education Fund

Underwritten by a grant from
THE ROBERT WOOD JOHNSON FOUNDATION

TABLE OF CONTENTS

I THE ISSUE 1

II THE HISTORY 1

- Federal HMO Law
- Federally Qualified HMOs
- Response of the States

III THE STATES 4

- Primary Areas of Regulation
- Current Status of the States

IV THE NEW JERSEY EXPERIENCE 7

- Oversight/Regulatory Environment
- Legal Requirements for HMOs in NJ
  - History
  - NJ HMO Act
  - Insurance Department—Selective Contracting Arrangements
  - Current Developments

V THE REGULATIONS TO ASSURE QUALITY 11

- What is Required?

VI THE ISSUES REGARDING REGULATIONS 12

- Any Willing Provider
- Integrated Delivery Systems
- Anti-Trust Laws

VII THE CONCLUSION 13

VIII QUESTIONS FOR DISCUSSION 14

IX. Appendix

- Rules and Rulemaking
- Chart—Overview of Regulations in States with HMO Laws

X. References

PUBLIC OVERSIGHT OF MANAGED CARE

An issue brief prepared by Joanne T. Fuccello, MSW
for discussion at the October, 19 1994 Capitol Forum.

The Issue:

The growth of managed health care has been significant during the last five years, with estimates ranging from a 12 to 30 percent managed care market penetration in New Jersey. Managed care enrollment in New Jersey has increased from under 200,000 in the early 1980s to 1.13 million in 1994. To what degree should the public assume oversight and regulatory responsibility for the operation, evaluation and monitoring of managed care in New Jersey? [1]

What is the current climate nationally and in New Jersey vis-a-vis managed care and public oversight and regulation? There seem to be more questions than answers as states take on the challenge to oversee an ever-changing health care delivery system providing care to their citizens. What are the current laws and regulations on a federal and state level regarding managed care? When, why and how do we regulate? Specifically, who is in charge of these oversight responsibilities? Is New Jersey willing to rely on managed health care providers for peer review and internal quality assurance plans in order to provide quality health care to its citizens? What are the pros and cons of over-regulation or relaxing regulation significantly?

THE HISTORY

FEDERAL HMO LAW

The Federal Health Maintenance Organization (HMO) Act of 1973 (P.L. 93-222) was implemented by Congress to encourage HMO development. The HMO Act authorized Federal funds to the states in order to establish and develop HMOs. It also required that employers of twenty-five employees or more must offer an HMO option to their employees, if an HMO is in operation in their locale and if requested by the HMO to do so. The Health Maintenance Organization was the first health care delivery entity distinct from the traditional indemnity insurance model with fee-for-service reimbursement, which brought together the previously separate functions of the financing and delivery of health care "under one roof" as a means to contain costs and provide continuity of care to its clients.

---

[1] *In this issue brief, managed care refers to care being provided by several different types of entities: Health Maintenance Organizations (HMOs); Preferred Provider Organizations (PPOs); Independent Practice Associations (IPAs); Physician-Hospital Organizations (PHOs) and various hybrid plans with managed care components. It is recommended that this Brief be reviewed with the first Issue Brief on Managed Care as a guide. In the current regulatory environment in New Jersey, under statute, the Department of Health, with the cooperation of the Department of Insurance, has the authority to regulate Health Maintenance Organizations (HMOs). The Department of Insurance oversees Preferred Provider Organizations (PPOs) and preferred providers under its Selective Contracting Arrangements of Insurers rules (N.J.A.C. 11:4-37), which will be discussed in more detail below. The rapid evolution and growth of non-HMO, managed care entities, some of which insure and assume risk, leaves gaps in the current regulatory strucuture.*

The Federal HMO Act has been amended over the succeeding years, strengthening requirements relating to financial disclosure and solvency protection. Initially, in order for an HMO to become Federally qualified, it was required to provide comprehensive benefits, community-rated premiums and an annual open enrollment period. There requirements were later amended to provide Federally qualified HMOs with additional rating flexibility. Amendments in 1988 also authorized Federally qualified HMOs to provide up to 10 percent of their physician services through physicians who are not affiliated with the HMO and broadened the definitions of restrictive state laws and practices.

Federally Qualified HMOs

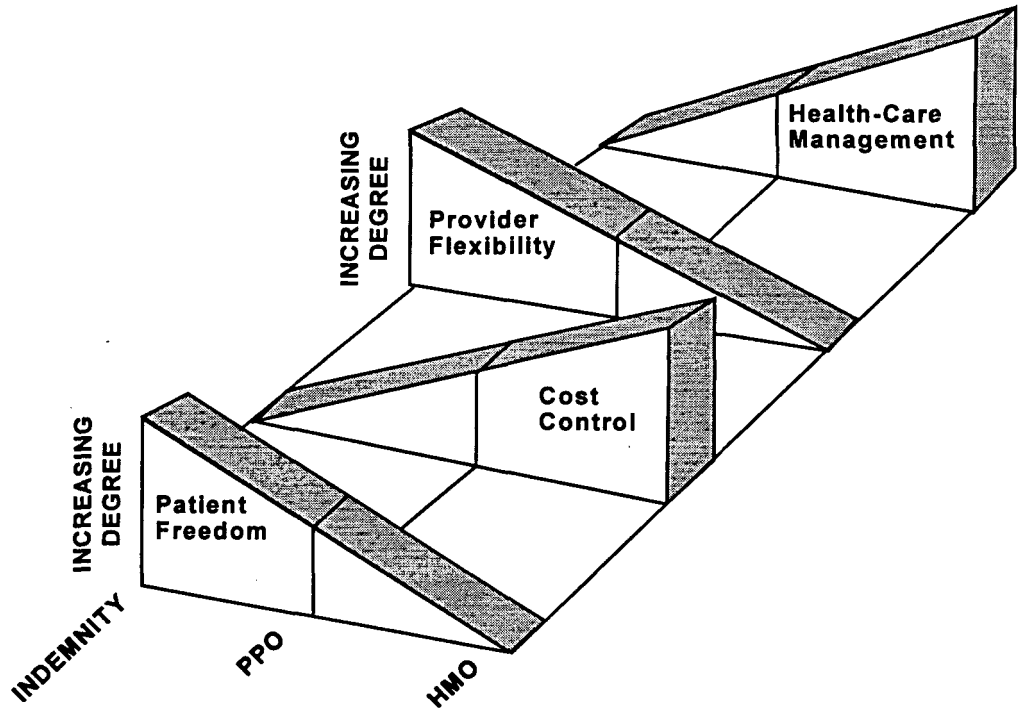
On the operation of Federally qualified HMOs, Congress enacted Section 1311(c) of the HMO Act in 1976. This section directs the Secretary of Health and Human Services to develop a digest of state laws, regulations and other provisions that may be inconsistent with Section 1311 of the Act and to report this information to the Governor of each state on an annual basis. Section 1311 addresses State laws, regulations and other provisions that require: (1) medical society approval of the furnishing of services by the HMO; (2) that physicians constitute all or a percentage of the governing body; (3) that all or a percentage of physicians in the locality participate or be permitted to participate in the HMO; (4) that the entity meet the requirements for insurers of health care services respecting initial capitalization and the establishment of financial reserves; or (5) the imposition of requirements that would prevent HMOs from complying with the Federal HMO Act (1993 HMO Governor's Report). Also, Section 1311 also prohibits a sixth category of state laws—those that prevent a Federally qualified HMO from soliciting members through advertising of services. The 1993 HMO Governor's Report indicates that the type of state law which most frequently conflicts with section 1311 is the advertising provision. If these state laws prevent an HMO that is qualified to operate under Federal law from operating, the state laws and regulations do not apply.

Since the passage of the Federal Health Maintenance Organization (HMO) Act in 1973 and its subsequent amendments, the regulation of HMOs and other alternate health care delivery systems has been uneven at best. Federal regulation, which carries a process of Qualification or Certification of health plans, sets some standards of operation for HMOs. However, the regulation of HMOs has not been stringent under Federal laws and for the most part the individual states have become the major influence on managed health care regulation and legislation. The states continue to play a key role in the nationwide oversight and regulation of HMOs.

While the climate has been in the past to allow for self-evaluation and peer review of managed care providers and for the states to choose not to take a watchdog approach, the current managed care environment involves a proliferation of hybrid plans, i.e., Preferred Provider Organizations (PPOs), Independent Practice Associations (IPAs), Physician/Hospital Organizations (PHOs) and various integrated delivery systems, separate and apart from HMOs. Managed indemnity plans, which

allow free choice of provider and reimbursement of providers on a fee-for service basis, but impose utilization review requirements such as preadmission certification, are also included in this mix of health plans. This newly restructured health care delivery system is calling out for the establishment of standards of quality and an evaluation of the role of regulation in protecting the public good in its receipt of health care services. The National Association of Insurance Commissioner's Model HMO Act (NAIC Model HMO Act) also guides states' efforts to develop effective HMO regulation. NAIC is committed to provide standard guidelines to the states for regulating HMOs and other managed care entities. Also, the Group Health Association of America (GHAA), the national trade association for HMOs, is currently working with colleague associations and policymakers to develop a set of uniform standards for all health plans in recognition of regulatory gaps in the managed care industry.

The Elements of Managed Care



Source: Johnson & Johnson, Managed Care Update, Vol. 1, #7, July, 1992.

Response of the States

Each of the states has taken its own specific path in the regulating of managed care through state laws and regulations. These actions range from legislation as in California, Massachusetts and New York regarding financial solvency laws and reporting requirements, to the actions of certain Southern states (where managed care has been evolving at a slower pace) which have very little if any legal require-

ments overseeing managed care entities. In most cases, the efforts of each state are driven by the evolution of the managed health care environment within that state.

In the absence of strong oversight, much fragmentation and inconsistency can occur in the regulatory and policy arena. Such regulatory fragmentation has been driven by the evolution of alternative health care delivery systems in each state, with the HMO usually as the initial managed care entity.

A 1993 U.S. General Accounting Office report on health insurance regulation found wide variation in the states' authority, oversight and resources by which state insurance departments regulate health insurance (GAO/HRD-94-26, December 27, 1993). The report cautioned that standards must be developed for strict and thorough oversight of insurers and adequate resources must be available to provide ongoing monitoring of plans.

Because the HMO was the initial "first step" in the establishment of managed health care systems in this country, forty-seven states and Puerto Rico have adopted comprehensive, self-contained HMO laws, with over 555 operational HMOs throughout the country. Research has indicated that HMOs can be effective cost-control health care delivery systems, in part by encouraging the practice of preventive medicine and by implementing improved utilization controls, quality assurance and peer review programs.

As the HMO and managed care industry evolve and continue to play a more significant role in the country's health care system and as it begins to interface with each state's public health system, state regulatory responsibilities continue to grow. The challenge is to be aware of the balance between too much or inappropriate regulation -- which may have an unintended negative impact on the development of alternative health care delivery systems -- and too little regulation, which may impact on the public good by compromising access to and quality of health care and thwart the states' role regarding the protection of the public (Scheur, 1994).

THE STATES

PRIMARY AREAS OF REGULATION

While the current regulatory structure regarding managed care is fragmented, the majority of states have a specific Health Maintenance Organization law in place. There is variation among these laws throughout the country; however, there are several discrete components which exist in one form or another in the HMO laws. These essential components include:

- Requirement of the issuance of a Certificate of Authority or Licensure by the state;
- Requirements that protection against insolvency be established between the state and the managed care provider;

- Compliance with Federal and state financial reporting requirements;
- Requirements that certain mandated services be provided to all enrollees;
- Requirements that quality assurance standards be complied with and monitored on an ongoing basis;
- Requirements that recertification be effected on an ongoing basis;
- Requirements that procedures for enrollee grievance filings and follow-up monitoring be in place;
- Requirements that there be specified forms of protection both for enrollees and contracted providers; and,
- Requirement in the area of health benefits, that both public and private sector employers offer to each eligible employee a choice of at least one of each of the following types of health plans: an HMO or PPO and a "traditional" indemnity plan. New Jersey's HMO law requires this "dual choice" opportunity be provided to state of New Jersey employees. The employer must provide an "annual opportunity to choose an alternate health benefits program" (N.J.S.A. 26:2J-29). Several states require under their HMO Acts that all employers offer this dual choice to employees.

As in New Jersey, throughout the country under HMO laws and regulations, there are three primary functional areas under which HMOs are regulated: their formation; their operation and their growth. Under the discrete area of organization, fall the regulatory categories of whether or not the individual state has a exclusive provision for HMO organization under its HMO Act and which state department has primary regulatory authority. New Jersey is one of 47 states that has a provision for HMO organization under an HMO Act. Regarding primary regulatory authority, as indicated, the Department of Health in New Jersey has the primary regulatory authority over HMOs, as the regulator of health facilities. The Department of Health works cooperatively with the Department of Insurance, which regulates the fiscal aspects of insurers. In that HMOs combine both provider and insurer roles, their operation is regulated by both Departments. However, the HMO Act designates the Commissioner of Health as the primary authority for the regulation of HMOs. Across the states, primary regulatory authority varies between the Departments of Health and Insurance. Thirty-nine states have the Department of Insurance as their primary regulatory body; Delaware, Michigan, and Pennsylvania require joint or separate certificates of authority from two departments; and New Jersey is one of six remaining states which do not statutorily designate the Department of Insurance as the primary regulatory body for HMOs.

HMO laws throughout the states regarding the operation of HMOs cover several broad areas: requirements that consumer representatives sit on HMO boards; advertising practices and prohibitions against deceptive advertising; requirements that employers offer to their employees the choice of at least one "traditional" indemnity health plan and one HMO plan; requirements that basic benefits be enumerated; restrictions on providers contracted by HMOs; types and reasonable-

ness of co-payments; requirement of open enrollment periods; specification of grounds for termination; requirements for grievance mechanisms; requirements for quality and utilization review and requirements for rate approval. (See Appendix I Chart, "Overview of Regulation in HMO Law States"). Also under operational requirements are capital and reserve regulations, specifically covering requirements that adequate working capital be present and reserves or guarantees be present. There is great variation across states as to whether their discrete Certificate of Need law applies to HMOs.

A recent report complied for the United States Department of Health and Human Services on states' regulation of HMOs looked at the Federal HMO Act requirement that an HMO have an ongoing quality assurance (QA) program that focused on health care outcomes (1993 HMO Governor's Report). The provision of internal peer review is also required under the Act. It was found that quality of health care issues are least often addressed in the HMO acts of States in which the Insurance Department is the only expressly authorized regulatory agency. The area of quality assurance via regulation is the most "murky" of regulatory areas, and the report found that there are a myriad of variations in the regulatory schemes by which states seek to assure citizens high quality health care. Some states, such as West Virginia, have amended their HMO acts to have the Department of Insurance work jointly with the Department of Health to review medical records and health outcomes.

Current Status of the States

In response to new and emerging health care systems, some states are creating new agencies to "administer and oversee reconfigured health care systems" (Iglehart, 1994). Florida is one such state and has created the Agency for Health Care Administration by consolidating the state's health care financing and planning functions. The state of Washington created a new state regulatory commission specifically to oversee the restructured health care market (Ibid.) While Maryland has designated a new state commission which is responsible for establishing guidelines for medical practice.

Another further implication of the newly emerging systems such as Integrated Service Networks and Organized Delivery Systems (ODS) regards access to care. Such systems may require that health care coverage and services be extended to all populations, including the Medicaid, Medicare and uninsured populations, as well as to inner-city and rural areas. Such extension of coverage would have a significant impact on the public health system, as it would relieve public health agencies from providing direct clinical services. Each state must closely evaluate the interplay between the health care delivery system and the public health system in order to protect the core public health functions, such as surveillance of communicable and chronic diseases and public education, and to ensure the continuity of the public health system. Certain states, such as Washington and Florida, are working with their public health systems to evaluate their best role as Medicaid and unin-

sured populations are being enrolled in general managed care plans. Florida's County Public Health Units (CPHUs), for example, will respond to local community conditions. They may work with Medicaid managed care providers, become HMOs themselves, or focus on other public health services (Health Reform Update, January 1994).

The National Association of Community Health Centers, which represents over 2,000 clinics serving close to seven million low-income individuals recently filed suit against the U.S. Department of Health and Human Services (The Trenton Times, July 12, 1994). The suit claims that the Department through its Health Care Financing Administration has reduced benefits for Medicaid patients by allowing states to experiment with Medicaid managed care "waiver" programs, such as in Tennessee and Oregon. The Association contends that under Medicaid managed care waivers, the states do not need to cover the full array of primary and preventive services provided by the community health centers and clinics. One issue of the suit claims that the waivers were made in contravention of the current Federal Medicaid rules and regulations.

The New Jersey Experience

Oversight/Regulatory Environment

New Jersey's status regarding this issue is ripe for analysis and evaluation. Since the beginning of the 1990s, the state has literally transformed from one which had a traditional fee-for-service health care system, with reimbursement made through insurers for health care provided by traditional physicians and hospitals, to a state in which HMOs and various "hybrid" managed care plans are proliferating. It is also a state which has moved through various degrees of regulation and deregulation in regard to health care, in particular with its hospital system. The 1990s have seen an evolution in the offering of health care through various managed care entities, including Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), Independent Practice Associations (IPAs) and network plans, such as First Option, New Jersey's first doctor/hospital-owned network, and the recently announced Physician Healthcare Plan of New Jersey (The Trenton Times, August 23, 1994), with some 3,500 of New Jersey's 17,300 physicians involved. It is the first HMO in New Jersey owned and operated by physicians. Currently, the Department of Health licenses 20 HMO plans (the majority of which are Independent Practice Associations) and is continually reviewing applications for new plans and expansions (Ibid). At the same time, there are over 56 PPOs offering services in New Jersey. In the fast-paced growth environment of managed care in New Jersey, it is not an exaggeration to submit that each month another hospital, health insurer or physician group is unveiling a new network or integrated delivery system.

Legal Requirements for HMOs in New Jersey

History

In New Jersey, as with most states, the regulation of HMOs is the primary component of managed care regulation in the state, by virtue of their being the first managed care entity in operation. All HMOs must conform to the provisions of the Health Maintenance Organizations Act, N.J.S.A. 22:2J-1-30; amended by P.L. 1992, c. 160 and c 162. The rules for HMOs are codified in the New Jersey Administrative Code at N.J.A.C. 8:38 and also at N.J.A.C. 8:43A, regarding the Licensure of Ambulatory Care Facilities. The HMO rules in New Jersey have not been adjusted or amended in any substantive manner since 1978, when HMOs were relatively new entities. The primary authority for the rules lies with the Department of Health, which issues a Certificate of Authority to the provider HMO. In tandem, the Department of Insurance also approves the Certificate of Authority. While the Department of Health has the statutory responsibility to oversee health facilities operations, the Department of Insurance is responsible for overseeing the fiscal aspect of HMO operations. While such a split in oversight responsibilities is not uncommon across the states, many states have sole responsibility for HMO regulation under the Department of Insurance, while others are experimenting with joint and equal authority between the Departments of Health and Insurance.

In August 1994, the Department of Health readopted N.J.A.C. 8:38, its rules on Health Maintenance Organizations, without any amendments. The Department attached a three-year adoption period to the chapter, rather than the statutorily allowed five-year period, in order to work on amending the rules appropriately in response to the changing managed care environment in New Jersey. In its Summary statement in 26 N.J.R. 1624 (April 18, 1994), the Department stated that it will "assemble an advisory group to carefully review the managed care field and to assist in the development of revised regulations that reflect contemporary managed care issues, particularly with regard to quality assurance and consumer satisfaction."

The Summary statement continues that: "When the New Jersey statute and rules were originally enacted and promulgated, HMOs were considered a plausible 'alternative' to traditional fee-for-service health care delivery and financing. At this juncture in time, it is becomingly increasingly obvious that HMOs and other HMO-like managed care plans are fast replacing traditional indemnity health insurance plans and fee-for-service medicine."

NJ HMO Act

New Jersey's Health Maintenance Organization Act (N.J.S.A. 26:2J) and its rules (N.J.A.C. 8:38), Health Maintenance Organizations, offer a regulatory framework under which HMOs must comply in order to operate in the state. Key elements include:

- The defining of basic health care services that must be provided by or arranged for by the HMO;
- The listing of supplemental health services which may be provided by the HMO;
- Requirements that providers must be under contract with or employed by the HMO;
- A description of when and how an HMO may disenroll a member;
- The issuance of a Certificate of Authority by the Commissioner of Health and Commissioner of Insurance.
- A description of requirements for minimum protection for HMO enrollees against the possible insolvency of an HMO;
- A requirement that every HMO must have reasonable procedures for the resolution of complaints initiated by enrollees concerning health care services;
- Requirements that there be a Quality Assurance Program and Examination; every HMO must arrange for an ongoing health care assurance program and provide plans for an appropriate evaluative mechanism. Also, in accordance with the State Health Plan (N.J.S.A. 26:2H-12.2), each HMO must prepare a utilization review long-range plan for the provision of health care services;
- Advertising restrictions that no HMO may cause or permit deceptive advertising;
- Recourse for noncompliance: Authority that the Commissioner of Health may suspend or revoke a Certificate of Authority for noncompliance with HMO law and rules (N.J.S.A. 26:2J et seq.)
- Financial Reporting Requirements that include the filing of annual and financial reports; and,
- At N.J.A.C. 8:38-3.3, a provision that HMO premium rate filings be actuarially certified and be accompanied by sufficient assumptions and supporting documentation to show that such proposed charges to enrollees are "not excessive, inadequate or unfairly discriminatory."
- While a Certificate of Need is required for the construction of, expansion of, or institution of a new health care service at a health care facility, an HMO or combination of HMOs may apply for an exemption from Certificate of Need requirements from the Commissioner of Health. The Certificate of Need process is set forth at N.J.S.A. 26:2H-1 et seq., The Health Care Facilities Planning Act.

Except as provided in the HMO Act, provisions of the insurance law and of hospital or medical service corporation laws apply to any HMO granted a Certificate of Authority under the HMO Act. Insurance code rules (N.J.A.C. 17B et seq.) that are applicable to HMOs in New Jersey cover trade practices and discriminations, procedure and administration an rehabilitation and liquidation. The New Jersey Medical Practice Statute on Licensing (N.J.S.A. 45:9-16) covers licensing and revocation for medicine, surgery and chiropractic. The HMO Act empowers an HMO to assume responsibility for the furnishing of health care services through providers under contract with or employed by the HMO.

Insurance Department—Selective Contracting Arrangements

As discussed earlier, the Department of Insurance has the sole authority through its rules on selective contracting arrangements of insurers to regulate preferred providers and Preferred Provider Organizations (PPOs) at N.J.A.C. 11:4-37. The purpose of the subchapter is to "set forth the standards and procedures whereby a carrier shall obtain approval from the Commissioner of its offering health benefits plans utilizing selective contracting arrangements that promote health care cost containment while adequately preserving quality of care." Within these rules, selective contracting arrangement means "an arrangement for the payment of predetermined fees or reimbursement levels for covered services by the carrier to preferred providers or preferred provider organizations." (N.J.A.C. 11:4-37.3).

The rules require that the selective contracting arrangement include a mechanism for the review or control of utilization of covered services; that it provide for an adequate number of preferred providers by specialty to render covered services in the geographic service areas where it functions; that it include a procedure for resolving complaints and grievances of covered persons and that patient confidentiality shall be protected. Insurance carriers who utilize arrangements with preferred providers or preferred provider organizations must submit a selective contracting arrangement approval application to the Managed Health Care Bureau of the Department of Insurance and to the Department of Health. The application must include a description of the provider's quality assurance program, including a clear description of how quality of care will be monitored and controlled; the criteria used to define and measure quality; the criteria used to determine the success or failure of the quality assurance program; a description of the complaint and grievance system available to covered persons; a description of the incentives for covered persons to use the services of preferred providers. Approval for application to engage in selective contracting arrangements is granted by the Commissioner of Insurance, in consultation with the Commissioner of Health.

Current Developments

The Department of Health is creating a Task Force to make a comprehensive review of the HMO rules and to offer recommendations on new rules in several months. The Task Force will be comprised of consumers, doctors, hospitals, HMOs and other managed care insurers. The rules are expected to cover whether an HMO has enough doctors, hospitals and other services convenient to patients, quality of care, especially preventive and prenatal; establishment criteria to evaluate rate of member satisfaction vs. disenrollment, and to ensure the financial stability of the HMO. The primary expansion piece in the HMO rules is the development of a comprehensive quality assurance plan.

The Regulations to Assure Quality

What is Required?

Designing a regulatory framework in the area of quality assurance requires that "quality" be defined. Quality of health care is defined by the National Academy of Science as, "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Defining quality for a particular service requires identifying goals and operationalizing these in the form of outcomes. Under a comprehensive and effective quality assurance program, these service goals must be articulated clearly enough to identify the types of performance or outcomes to be assured, measured or prevented. Quality, access and cost have traditionally made up the three pillars of health care policy. Attempts to improve a program's performance on one dimension, such as cost, may affect its performance on others, such as accessibility and quality (U.S. General Accounting Office, GAO-PEMD 94-19, March 1994).

Federal law requires that all HMOs have an internal program of quality assurance. This requirement is also reflected in New Jersey rules at N.J.A.C. 8:38. The Health Care Financing Administration's (HCFA) elements of its health care quality improvement system include both internal quality assurance programs to be established by the provider entity and monitoring by the states, either directly by themselves or through a contractor. The National Committee for Quality Assurance (NCQA) has developed standards by working with the managed care industry, health care purchasers, state regulators and consumers. Its Standards For Accreditation of Managed Care Organizations are used by NCQA to evaluate a managed care organization in the areas of quality improvement; utilization management; credentialing; members' rights and responsibilities; preventive care service guidelines and medical records.

The NCQA and the American Association of Preferred Provider Organizations (AAPPO) have as goals to assist HMOs in designing and operating internal quality improvement systems utilizing a review process. These quality assurance plans have the components of:

- assessment of the plan's quality assurance systems;
- reviews of medical records, using explicit criteria to assess the quality of care provided to patients in certain diagnostic categories: such as, hypertension, diabetes and prenatal care at initial visit and at 28 weeks;
- and the review of preventive services, such as breast cancer screening an cholesterol screening;
- measures of patient satisfaction with the HMO, and
- the incorporation of diverse indicators developed jointly by the purchasers and the providers.

The Issues Regarding Regulations

While managed care regulation remains uneven nationally as a result of differing statutory authorities and varying levels of resources available to exercised control, key policymakers and players in the health care arena must be uncompromising in their charge of identifying specific public protection issues (Scheur, 1994). In states where there are parallel and sometimes overlapping regulation of managed care located in the Departments of Health and Insurance, there are strong dynamics between the authority of insurance regulation and the regulation of delivery system issues (Ibid.).

Any Willing Provider

Several issues are currently playing out nationally in the managed care regulatory environment, which significantly impact the operation and function of HMOs and other managed care systems. "Any Willing Provider" laws, which prohibit an HMO from denying any provider willing to meet the terms and conditions of the HMO from contracting with the HMO as a network provider, and "Freedom of Choice" laws, which grant an HMO enrollee the freedom to choose a non-network provider of his or her choice. Selective contracting on behalf of the provider is eroded and pricing controls may be rendered ineffective. What is the role for state regulators in this arena? Currently, there are more than 60 laws or regulations in at least 35 states which restrict HMOs' ability to maintain their exclusive provider networks (Stateside, December, 1993).

Integrated Delivery Systems

Another emerging issue is the growth of integrated delivery system arrangements and new provider systems. New Jersey is testament to the rapid formation of these systems and integrated delivery system arrangements to contract or enter into partnerships with managed insurance systems, such as new physician/hospital organizations. Currently, these entities fall out of the scope of most laws and regulations, which focus on HMOs. As with HMO law, a reasoned regulatory approach must include rules that regulate construction, organization, risk assumption, financial stability and quality assurance (Scheur, 1994). How will New Jersey monitor these changes and intervene in the appropriate manner? The Minnesota Care Act of 1993 requires the Commissioner of Health and the Minnesota Health Care Commission to prepare a detailed plan on the implementation of the state's Integrated Service Networks (ISNs), which began forming July 1, 1994.

The ISNs pose a significant regulatory issue in that under an ISN, the health plan and the providers may be a combined legal entity and appear "HMO-like"; however, their regulation falls outside of the purview of existing HMO laws. While no state has yet adopted a law covering such plans, several states (including Minnesota and Colorado) are grappling with the issue through statutory and regulatory remedies.

Anti-Trust Laws

Antitrust laws and the ever-changing health care environment are also emerging issues for the states. The major Federal antitrust laws include the Sherman Act, the Clayton Act an the Federal Trade Commission Act. These laws prohibit price fixing, boycotts and similar agreements among competitors that produce anticompetitive effects. They also prohibit mergers, acquisitions or joint ventures that would lessen competition or create monopolies. While the antitrust laws do not prevent hospitals, physicians an other providers from forming networks or integrated delivery systems, on September 15, 1993, the Department of Justice and the Federal Trade Commission issued statements of antitrust enforcement policies to clarify their application to health care markets. Regarding hospital mergers, enforcement agencies have found that most hospital mergers are procompetitive because they result in more efficient delivery of health care and eliminate wasteful duplication of equipment and services. In a recent U.S. Department of Health and Human Services report, it was indicated that of the 229 hospital mergers that occurred nationally from 1987 to 1991, only 5 have been challenged in the courts. Where do New Jersey policy makers stand on the antitrust issue?

The Conclusion

As the HMO and managed care industry evolve and continue to play a more significant role in the country's health care system, state regulatory responsibilities continue to grow. The impact of the "restructuring" of health care financing and delivery as we know it cuts across public and private interests. Can an incremental approach to changing policies and rules work in such a rapidly evolving environment? When the regulations are primarily limited to HMOs (as New Jersey is facing), the existing regulatory structure leaves gaps in the system, as various, hybrid managed care entities appear and evolve. The challenge to lawmakers and public policymakers is to determine how these regulatory "gaps" may be cured, particularly in the areas of regulating the financing of health care and the delivery of health care services, which are the two previously separate functions now brought together in the operations of the managed care entities. Resolving these issues demands an awareness of the balance between too much or inappropriate regulation, which may impede the development of the alternate health care delivery system in a dynamic marketplace, and too little regulation, which may impact on the public good and erode the cost-effectiveness of managed care entities.

QUESTIONS FOR DISCUSSION

The existing regulatory structure, with its focus on Health Maintenance Organizations, leaves gaps regarding the regulation of the various hybrid plans and health care delivery networks. What are New Jersey's plans to cure this "fragmentation" in its regulation of a rapidly evolving and dynamic health care system? Should analysis be limited to only HMO rules?

Should the Departments of Health and Insurance have joint authority to promulgate rules on all managed care entities, as opposed to the manner in which they currently split the functions. As noted in the Department of Health's Summary in its Readoption proposal in the New Jersey Register, the HMO law and its resultant rules appeared at a time when the concept of HMOs was new both nationally and in New Jersey. New Jersey's health care system is changing dramatically. Should a consolidation of authority be contemplated to ensure the most efficient level of oversight?

The development and monitoring of quality assurance plans requires the development of reliable and standard indicators of quality, including clinical as well as preferential indicators. What entity will be responsible for evaluation and monitoring of data to be used in quality assurance measurement? What entity will develop these indicators, to provide a Consumer Report type document on HMOs for consumers? What entity will commit the resources necessary to maintain ongoing monitoring?

The issue of quality assurance is complicated; how will quality assurance programs be developed; what will be their criteria; what entities will establish standards; who will evaluate and provide ongoing program monitoring to assure consumers are receiving quality health care? Should accreditation of quality assurance programs be required by states? Some states currently require an accredited status as a condition for licensure. Does this help or hinder the delivery of health care?

The Health Care Financing Administration (HCFA) has identified the issue of quality assurance and monitoring as a critical one for its Medicaid managed care program and has developed a framework for states to develop a comprehensive quality assurance system. Will the same level of regulatory oversight as is envisioned in Medicaid managed care programs be present in private sector managed care plans? How will such stringent oversight and monitoring be accomplished for the Medicaid population in a time of limited resources?

In general, a coordinated and accurate system of data collection is critical, especially in this time of health care reform and the changing health care environment. Owing to multiple factors, including the fragmented system of providers, insurers and funders, health care data is difficult to compare at best. Currently, there is

even broad disagreement as to what percentage of HMO penetration exists in the state, with estimates ranging from 11 percent to 30 percent. The state of Minnesota, in its recognition that both public and private players in the health care industry are invested in accurate data to assess access, quality and cost in the health care system, created a public/private data institute via its 1993 Legislature. The Institute is charged with providing direction and coordination for public and private data collection and developing a plan for a public/private data information system. Would New Jersey stand to gain from investigating such a system?

A recent Department of Health report on New Jersey and health care reform points out that New Jersey residents present a "relatively high incidence" of public health problems such as AIDS, TB and lead poisoning. Over 800,000 New Jerseyans have a disability of some kind. Again, to what degree and in what way can the state require or oversee that these individuals have equal access and quality of care through the state's rapidly growing managed care entities?

The current health system is not geared towards health care as a social and collective responsibility. In their current practice, insurers evaluate and select those individuals who are the "best" risks, and offer often unaffordable rates and/or unavailability for those individuals identified as "high risk." What are New Jersey's basic values regarding community rating and an open enrollment to all individuals to guarantee access to health care?

New Jersey has a large and fast growing elderly population with approximately 13.3 percent of the state's population being over age 65. To what degree can the state require that HMOs and managed care entities serve this population, which is a difficult population to treat in a managed care delivery system because of the chronicity and complexity of its health problems?

APPENDIX I

RULES AND RULEMAKING

History

Administrative Law is that branch of the law which controls the administrative operations of government. Through delegation, the Legislature grants the power to the administrative agency (i.e., authorizes by statute all departments and instrumentalities of state government) to determine, either by rule or decision, the rights and obligations of affected persons. The administrative agencies possess both legislative powers, i.e., the legislative authority to promulgate rules which have the force and effect of law, and the judicial power to hear and decide cases involving administrative law. Through statute, the administrative agency is delegated the authority to propose rules. It is also through statute, that new rules and amending of existing rules may be triggered (see below, "Situations that Trigger a Rulemaking"). The enabling statute from which rules are promulgated may be general and broad in its scope or extremely specific as to what it requires; each rule must be reviewed in order to ensure that it not conflict with its statutory authority.

The Administrative Procedure Act (APA) (N.J.S.A. 52:14B-1 et seq.) was enacted by the Legislature in 1969 and substantially amended in 1981. The Administrative Procedure Act was enacted to regulate and coordinate the administrative practice and procedure of all state agencies with regard to their rulemaking function and the hearing of contested cases in administrative hearings. The type and number of rules and their complexity has evolved significantly over the years. The APA established a coordinated system of proposing, adopting and compiling government rules, which are formally published in the New Jersey Register on a twice-monthly basis and codified in the New Jersey Administrative Code. As part of the rulemaking process, government agencies are required to publish in the New Jersey Register a notice that they are proposing a rule. The agencies are also required to invite public comments on the proposal and provide a 30-day comment period before adopting the rule. Upon adoption, notice must once again be published in the New Jersey Register and all public comments must be summarized and responded to by the agency. Upon adoption, the rules become effective and have the force and effect of law.

The Office of Administrative Law (OAL) (created by N.J.S.A. 52:14F-1 in 1978), is the oversight agency for all rulemaking activity in the state of New Jersey. The OAL is responsible for promulgating rules for the implementation of the Administrative Procedure Act. It has the statutory authority and has the responsibility to oversee state agency compliance with the APA and the rulemaking process. The OAL Rules on Rulemaking (N.J.A.C. 1:30) are the regulatory basis for the promulgation of rules for all rulemaking agencies.

Under the provisions of the Legislative Oversight Act (N.J.S.A. 52:14B - 4.1-4.9), a copy of each proposed rule making is sent to the legislature for a 60 day review and comment period. In November 1992, New Jersey voters approved an amendment to the State Constitution giving rule vetoing power to the legislature. Through this amendment the legislature now has the authority to invalidate, by joint resolution, rules that are inconsistent with legislative intent.

What is a Rule?

The Administrative Procedure Act defines an administrative rule at N.J.S.A. 52:14B-2(e) as "each agency statement of general applicability and continuing effect that implements or interprets law or policy, or describes the organization, procedure or practice requirements of any agency." The dictionary definition of a rule is defined as a prescribed guide for conduct or action; an established standard. "One shall or shall not do something." In the context of government rules, the Office of Administrative Law Rulemaking Manual describes that a rule is the way in which a government agency speaks to those outside of the agency, that is, to those people whom the agency has the statutory obligation and is authorized by law to regulate. In situations when an agency requires individuals to do things or perform in a certain way, then it becomes a rule.

In Metromedia v. Director, Division of Taxation 97 N.J. 313, several factors were established for identifying what is a rule. "An agency determination must be considered an administrative rule if it appears that the agency determination:

1. is intended to have wide coverage encompassing a large segment of the regulated or general public, rather than an individual or a narrow select group;
2. is intended to be applied generally and uniformly to all similarly situated persons;
3. is designed to operate only in future cases, that is prospectively;
4. prescribes a legal standard or directive that is not otherwise expressly provided by or clearly and obviously inferable from the enabling statutory authorization;
5. reflects an administrative policy that (i) was not previously expressed in any official and explicit agency determination, adjudication or rule, or (ii) constitutes a material and significant change from a clear, past agency position on the identical subject matter; and

(6) reflects a decision on administrative regulatory policy in the nature of the interpretation of law or general policy." (Office of Administrative -- Law Rulemaking Manual.)

What Situations Trigger Rulemaking?

The following are examples of when an agency may undertake proposing a rulemaking:

1. The implementation of a current statute or new legislation.
2. A change in agency or governmental policy.

3. A court decision which renders a rule ineffective or invalid.
4. A petition from an interested person.
   An interested person may petition an agency to promulgate, amend or repeal any rule. Within 30 days of receiving the petition, the agency may either deny the petition, giving a written statement for its reasons, or may act on the petition, which may include a formal rulemaking procedure. The agency is required to publish notice in the New Jersey Register that it has received a petition for rulemaking, as well as a notice regarding its action on the petition.
5. An emergency or imminent peril. An emergency adoption of a rule is effective for only 60 days. The agency must state that there is an imminent peril to the public health, safety or welfare which justifies adopting the rule on an emergency basis. Such rules may be continued, if the agency concurrently proposes them to allow for the public comment period.
6. Federal requirements set forth in Federal laws and regulations.
7. Executive Order No. 66 (1978) Readoptions. This Executive Order mandates that any new rule or existing rule shall expire within five years of its adoption. The intent is to assure that only rules which are necessary, adequate, reasonable, efficient, understandable and responsive to the purpose for which they were promulgated be retained and continued. In order to continue in effect the provisions of the rules, the agency must readopt them. (As the Department of Health is doing with its HMO rules; however, it has limited the readoption period to three years, as opposed to the statutory maximum of five years.)

CHART

CHART 1
OVERVIEW OF REGULATION IN HMO LAW STATES

Key: ○ Yes ● No ◒ Unclear

	Alabama	Alaska	Arizona	Arkansas	California	Colorado	Connecticut	Delaware	Florida	Georgia	Idaho	Illinois	Indiana	Iowa	Kansas	Kentucky
ORGANIZATION																
HMO Act: Exclusive Provision for HMO Formation	○	○	○	○	○[1]	○[1]	○	○	○	○	○[1]	○[1]	○	○	○	○
Operation Limited to Nonprofit Entities	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Insurance Dept. Primary Regulatory Body	○	○	○	○	●	○	○	●[2]	○	○	○	○	○	○	○	○
Regulates Reorganization/ Dissolution as an Insurer	○	○	○	○	●	○	○	○	○	○	○	○	○	●	●	○
OPERATION																
Requires Consumer Representative on Board	●	○	●	○	○[3]	○[3]	○	●	●	●	●	●	●	●	●	●
Policymaking Role for Subscribers Required	●	○	●	○	○	○	○	●	●	○	○	○	●	○	○	○
Solicitation/Advertising for Enrollees Permitted	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Deceptive Advertising Prohibited	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Employer Offer of HMO Alternative Required	●	○	●	●	●	●	●[9]	●	●	●	●	●	●	●	●	●[9]
Basic Benefits Enumerated	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Employment of Providers Restricted	●	●	●[8]	◒	●	●	●	●	●	●	●	●	●[8]	●	●	●[8]
Reasonable Copayments Permitted	○[5]	○	○[5]	○	○	○	○[5]	○	○	○	○	○		○	○	○[5]
Open Enrollment Required	●	●	○[4]	○	●	○	●	●	●	●	○	●	●	○	○	○
Termination Grounds Specified	○	○	●	○	○	○	●	○	○	○	○	○	○	○	●	○
Grievance Mechanism Required	○	○	●	○	○	○	○	○	○	○	○	○	○[5]	○	○	○
Quality/Utilization Review Required	○	○	○	○	○	○	●	○	○	○	○	○	●	○	○	○
Rate Approval Required	○	○	◒	○	●	○	○	○	○	○	○[5]	○	○	○	○	○
CAPITAL, RESERVE																
Adequate Working Capital Required	○	○	○	○	○	○	○	○	○	○	○	○	○	○		○
Reserves or Guarantees Required	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
APPLICABILITY																
Provides for Accommodation of Federal HMO Law	●	○	●	●	○	●	○	●	●	○[5]	●	●	●	●	○[5]	○
Certificate of Need Law Applies	○	○					●[1]	○	○[1]	○[1]		○		○		○

[1]With certain exceptions.

[2]Separate certificates of authority required from two departments.

[3]California: on standing committee or board; Colorado: on policy board; Nevada: on joint advisory consumer/provider board.

[4]Applies to State employees, as specified.

[5]By implication.

[6]Joint issuance of certificates/licenses.

[7]But, must be financially sound or capable.

[8]HMO may provide services "directly."

[9]See Chart 11.

[10]No general CON law. There are statutes addressing CONs or specific types of entities.

Source: U.S. Department of Health and Human Services. "A Report to the Governor on State Regulation of Health Maintenance Organizations."

CHART 1 *(continued)*
OVERVIEW OF REGULATION IN HMO LAW STATES

Key: ○ Yes; ● No; ◒ Unclear

	Louisiana	Maine	Maryland	Massachusetts	Michigan	Minnesota	Mississippi	Missouri	Montana	Nebraska	Nevada	New Hampshire	New Jersey	New Mexico	New York	North Carolina
ORGANIZATION																
HMO Act Exclusive Provision for HMO Formation	○	○	○	○	○	○	●	○	○	○	○	○	○	○	○[1]	○
Operation Limited to Nonprofit Entities	●	●	●	●	●	○	●	●	●	●	●	●	●	●	●	●
Insurance Dept. Primary Regulatory Body	○	○	○	○	●[6]	●	●	○	○	○	○	○	●	○	●	○
Regulates Reorganization/ Dissolution as an Insurer	○	○	○		○	○[1]	●	○	○	○	○		○	○		○
OPERATION																
Requires Consumer Representative on Board	●	●	●	●	○	○	●	●	●	●	●[3]	●	●	●	○	●
Policymaking Role for Subscribers Required	●	○	○	●	○	○	○	○	○	○	○	●	○	○	○	●
Solicitation/Advertising for Enrollees Permitted	○	○	○	○[5]	○	○	○	○	○	○	○	○	○	○	○	○
Deceptive Advertising Prohibited	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Employer Offer of HMO Alternative Required	●[9]	●	●	●	○	●	●	●	●	●	●	○	○[4]	●	○	●
Basic Benefits Enumerated	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Employment of Providers Restricted	●	●	●	●	●	●[6]	●	●	●	●	●	●	●	●	●	●
Reasonable Copayments Permitted	○	○	○		○	○	○	○	○	○	○	○	○[5]	○		○
Open Enrollment Required	●	○	●	○[1]	○	○	●	●	●	●	○	●	○	●	●	●
Termination Grounds Specified	●	○	○	○	○	○	○	○	○	●	○	○	○	○	●	○
Grievance Mechanism Required	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Quality/Utilization Review Required	○	○	○	○	○	○	○	●	○	○	○	●	○	○	○	○
Rate Approval Required	●	○	○	○	○	○	◒	○	○	○	○	○	○	○	○	○
CAPITAL, RESERVE																
Adequate Working Capital Required	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Reserves or Guarantees Required	○	○	○	○	○	○	○[5]	○	○	○	○	○	○	○	○	○
APPLICABILITY																
Provides for Accommodation of Federal HMO Law	●	○	○	●	●	●	●	○	●	●	●	○	●	○[5]	○	○
Certificate of Need Law Applies		○	○[1]	○[1]	○[1]		●	○		○[1]	○[1]	○[1]	○[1]		●	●[1]

[1]With certain exceptions.

[2]Separate certificates of authority required from two departments.

[3]California: on standing committee or board; Colorado: on policy board; Nevada: on joint advisory consumer/provider board.

[4]Applies to State employees, as specified.

[5]By implication.

[6]Joint issuance of certificates/licenses.

[7]But, must be financially sound or capable.

[8]HMO may provide services "directly."

[9]See Chart 11.

[10]No general CON law. There are statutes addressing CONs or specific types of entities.

Source: U.S. Department of Health and Human Services. "A Report to the Governor on State Regulation of Health Maintenance Organizations."

CHART 1 *(continued)*
OVERVIEW OF REGULATION IN HMO LAW STATES

Key: ○ Yes ● No ◓ Unclear

	North Dakota	Ohio	Oklahoma	Pennsylvania	Rhode Island	South Carolina	South Dakota	Tennessee	Texas	Utah	Vermont	Virginia	Washington	West Virginia	Wyoming	Puerto Rico
Organization																
HMO Act: Exclusive Provision for HMO Formation	○	○	○	○[1]	○[1]	○	○	○	○	○	○	○	○	○	○	○
Operation Limited to Nonprofit Entities	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Insurance Dept. Primary Regulatory Body	○	○	●	●[6]	○	○	○	○	○	○	○	○	○	○	○	○
Regulates Reorganization/ Dissolution as an Insurer	○	○	○	○	○	○	○	○	○	○[5]	●	○	○	○	○	○
Operation																
Requires Consumer Representative on Board	●	●	●	○	●	●	○	●	●	●	●[1]	●	○	●	●	●
Policymaking Role for Subscribers Required	○	○	●	○	○	○	○	●	●	○	●[1]	○	○	○	○	○
Solicitation/Advertising for Enrollees Permitted	○	○	○[5]	○	○	○	○	○	○	○	○	○	○	○	○	○
Deceptive Advertising Prohibited	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Employer Offer of HMO Alternative Required	●	○	●	●	○	●	●	○	●	●	●	●	○	○	●	●
Basic Benefits Enumerated	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	●
Employment of Providers Restricted	●	●	●[4]	●	●	●	●[5]	●	●	●[5]	●	●	●	●	●	●
Reasonable Copayments Permitted	○	○	◓	○	○	○	○	○	○	○[5]		○	○	○	○	○[5]
Open Enrollment Required	○[1]	○	●	●	●	●	●	●	●	○	●	●	●	○[1]	●	○
Termination Grounds Specified	○	○	○	○	○	○	○	○	○	○	●	○	○	○	○	○
Grievance Mechanism Required	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Quality/Utilization Review Required	○	○	○	○	○	○	○	◓	○	○	○	○	○	○	○	○
Rate Approval Required	○	○	◓	○	○	○	○	○	○	○	○	○	○	○	○	○
Capital, Reserve																
Adequate Working Capital Required	○	○	○	○	○	○	○	○	○	○	○	○	○[5]	○	○	○
Reserves or Guarantees Required	○	○	○	○	○	○	○	○	○	○		○	○	●[7]	○	○
Applicability																
Provides for Accommodation of Federal HMO Law	●	●	○	○	○	●	●	●	●	○	●	●	○	●	●	●
Certificate of Need Law Applies	●[1]	●[1]	○[10]	○[1]	○[1]	○		○			○	○	○[1]	○[1]		○

[1]With certain exceptions.

[2]Separate certificates of authority required from two departments.

[3]California: on standing committee or board; Colorado: on policy board; Nevada: on joint advisory consumer/provider board.

[4]Applies to State employees, as specified.

[5]By implication.

[6]Joint issuance of certificates/licenses.

[7]But, must be financially sound or capable.

[8]HMO may provide services "directly."

[9]See Chart 11.

[10]No general CON law. There are statutes addressing CONs or specific types of entities.

Source: U.S. Department of Health and Human Services. "A Report to the Governor on State Regulation of Health Maintenance Organizations."

REFERENCES

Group Health Association of America. HMO Law Manual. 1993. Washington, D.C.

Group Health Association of America. Stateside. v. 2, no. 11. December 1993. Washington, D.C.

Iglehart, John. "Health care reform: the states." New England Journal of Medicine 330(1):75-79. January 6, 1994.

Iglehart, John. "The struggle between managed care and fee-for-service practice." New England Journal of Medicine. 331(1):63-67. July 7, 1994.

Marion Merrel Dow, Inc. Managed Health Care Digests. 1993.

Minnesota Department of Health. Health Reform Update. Issue 1. January 1994.

New Jersey Register. 26. N.J.R. 1624. April 18, 1994.

Scheur, Barry S. Managed Care and State Regulation: Emerging Issues and Conflicts. Presentation given at the National Association of Insurance Commissioners. Summer Meeting. June 13, 1994. Baltimore, Maryland.

State Health Care Reform. Conference for States. February 1994. Sponsored by The Robert Wood Johnson Foundation, under the State Initiatives in Health Care Reform Program. Washington, D.C.

State of New Jersey. Office of Administrative Law. Rulemaking Manual.

U.S. Department of Health and Human Services. Health Care Financing Administration. A Report to the Governor on State Regulation of Health Maintenance Organizations. Fifteenth Edition. 1993. Washington, D.C.

U.S. General Accounting Office. Health Insurance Regulation: Wide Variation in States' Authority, Oversight and Resources. (GAO-HRD-94-26.) December 1993.

U.S. General Accounting Office. Managed Health Care. Effect on Employers' Costs Difficult to Measure. (GAO-HRD-94-3). October 1993.

U.S. General Accounting Office. Status of Quality Assurance and Measurement in Home and Community-Based Services. (GAO-PEMD-94-19). March 1994.