Legislative Budget and Finance Committee

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Commonwealth Efforts to Assure Quality of Care in the Changing Health Care Environment

Pursuant to House Resolution 185

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Summary and Recommendations

House Resolution 1997-185 directs the Legislative Budget and Finance Committee (LB&FC) to examine existing Commonwealth efforts to monitor changes in the delivery and reimbursement of health care services to ensure that such changes do not negatively impact on the quality of health care in the Commonwealth. The report consists of four chapters. Chapter I provides introductory material. Chapter II describes the role of the state, Medicare, and voluntary national organizations in assuring quality of health care in the Commonwealth. Chapter III provides specific information on the Commonwealth's efforts to regulate managed care and recent changes resulting from Act 1998-68. Chapter IV describes the Department of Public Welfare's waiver requiring individuals with special needs to receive medical assistance through HealthChoices managed care plans and the Department's efforts to assure quality care for these individuals.

Efforts to Assure Quality of Care

In the United States, there is no single point of accountability for assuring quality health care. Responsibility is a shared professional and public responsibility. Professional providers, the parties closest to the delivery of health care, typically see themselves as the parties most responsible for the quality of health care. Their voluntary commitment to meet high standards of professional care has long been the primary means of assuring quality health care. State and federal agencies, as well as national voluntary accreditation organizations, also play major roles in assuring quality of care.

The Role of Commonwealth Agencies

Several Commonwealth departments and agencies participate in health care quality assurance. State licensing boards within the Department of State license individual practitioners such as physicians and registered nurses. The Department of Health (DOH) licenses health care facilities such as general hospitals, ambulatory surgical facilities, and home health agencies.

Managed care organizations are not licensed in Pennsylvania. However, the Departments of Health and Insurance are jointly responsible for issuing certificates of authority to HMOs. Unlike individual practitioner and health care facility licenses, which must be periodically renewed, certificates of authority never expire, although they can be revoked. Other managed care organizations, such as nongatekeeper preferred provider organizations, are not required to obtain certificates of authority. In addition, state standards for managed care organizations are primarily found in state guidelines and policy statements that do not have the force of laws or regulations.

The Commonwealth also requires many health care providers, such as physicians and hospitals, to carry medical malpractice insurance. The Insurance Department requires medical malpractice insurers to incorporate risk management plans, which are intended to help ensure providers are following accepted medical standards, into such policies. Managed care organizations are not required to purchase medical malpractice insurance. They may, however, purchase corporate liability insurance. They have asserted that they could not be held negligent in Pennsylvania malpractice cases. In 1998, however, the Pennsylvania Superior Court held that the theory of corporate negligence, which previously had been applied only to hospitals, could apply to HMOs in medical malpractice suits. Also, in December 1998, the Pennsylvania Supreme Court indicated it was not willing to interpret the federal ERISA preemption[1] for employer-sponsored health plans as limitless. Specifically, the court ruled that the ERISA does not preempt state laws designed to provide safe medical care.

The Medicare Program and Voluntary Accreditation Organizations

The quality of health care in the Commonwealth is also directly and indirectly affected by federal programs, particularly the Medicare program, and by various voluntary accreditation organizations. For example, federal law and regulations include detailed requirements and protocols as to how hospitals and physicians participating in the Medicare program must respond to individuals with emergency medical conditions, even if they are not Medicare beneficiaries. Hospitals, moreover, are required to adopt Medicare's inpatient facility standards facility-wide.

Medicare contracts with Peer Review Organizations (PROs) in each state. Pennsylvania's PRO, known as KePRO, has offices in Harrisburg. PROs decide whether the care being provided meets standards of quality generally accepted by the medical professions. They also carry out important evidenced-based quality improvement programs. Medicare also uses state agencies and national voluntary accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), to determine whether its quality assurance standards are being met.

Regulation of Managed Care Plans

Health care providers have come under increasing pressure to reduce the cost of health care services. Employers and governments have looked to managed care, in particular, as a means of achieving such reductions. Managed care plans have

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[1] The Employee Retirement Income Security Act of 1974 provides the basis for a complementary system of regulation in which the federal government oversees employers' health benefit plans while the states regulate commercial insurers. Pennsylvania exempts employer-funded plans subject to the ERISA from managed care regulations if such plans provide benefits only for employees.

often reacted by directly or indirectly limiting the autonomy of physicians. In response, some health care providers have joined to form provider networks, in some cases assuming the financial risk of insurers. The line between health care providers and insurers becomes further blurred when insurers become involved in the delivery of health care. They may own physician practices or operate "administrative programs" that affect patient care. Such changes have caused consumers, providers, and policymakers to question whether managed care plans are adequately regulated.

In response to such concerns, lawmakers and regulators nationwide have taken steps to strengthen their quality assurance standards for managed care. Pennsylvania took such a step with Act 1998-68, which contains new protections for consumers.

Quality of Care for Individuals with Special Needs

Many individuals with special needs receive some or all of their health care through the Department of Public Welfare's Medical Assistance program due to their extraordinary medical and ancillary service needs. In the past, individuals with special needs received such assistance through a fee-for-service program or they could voluntarily enroll in a managed care plan. This is changing with HealthChoices--the Department's mandatory HMO program for Medical Assistance clients.

HealthChoices, which operates under a federal waiver, effectively began in late 1996 in Philadelphia and its four surrounding counties. In January 1999, the program was expanded to Allegheny and nine other southwestern counties. The waiver permits the Department to begin operating HealthChoices in ten mid-state counties beginning in January 2000. The Department chose four physical health plans to implement HealthChoices in southeastern Pennsylvania and three in the southwest. Most serve only Medical Assistance enrollees.

The Department pays plans monthly fees in advance for each Medical Assistance enrollee. The fees vary by category of assistance, age, and county, but not by an individual's health status.

The Department's HealthChoices contracts include several provisions to assure quality of care for individuals with special needs. For example, enrollees are allowed to change HealthChoices plans if not satisfied with the quality of care they are receiving. The contracts define the term "medical necessity" broadly, thus allowing the provision of services that maintain existing levels of functioning or substitute for lost functioning. Plans must also have procedures to permit enrollees with complex medical conditions to have trained medical specialists serving as their primary care provider (PCP). The contracts also require plans to have units to

assist individuals with special needs in accessing services and benefits, and in March 1998 the Department created its own special needs unit to work with the plans.

Findings and Conclusions

The study identifies several findings and conclusions regarding the Commonwealth's efforts to assure high quality of care, including:

Systematic monitoring of major changes in Pennsylvania's health care delivery system is not being carried out by the state agencies responsible for assuring health care quality. Several state agencies, most notably the Department of Health and the state licensing boards within the Department of State, share responsibility for assuring that Pennsylvania's health care providers render quality care. However, the focus and staffing of these agencies are limited. Key components of the Commonwealth's emerging health care system are being developed without important information for policy decisions. This is particularly the case with managed care. No state agency monitors the formation of provider networks or the acquisition of physician practices by insurers. No state agency determines how the network selection practices of managed care plans are affecting the availability of medical service providers, including pharmacies, other ancillary care providers, and critical access hospitals in rural areas. Reliable information on these trends is necessary for state agencies to assess and respond to the short and long-term effects such changes might have on the quality of care.

To help address such issues at the national level, Congress created a special commission to monitor and assess changes in health care delivery and to provide advice on the effect of changes in Medicare payment policies on access and quality of care. At the state level, Connecticut established an agency to oversee its health care delivery system and assess and analyze evolving trends in health care. California created a special unit within an existing agency to consider issues of quality in a managed care environment. Maryland established a new public commission to create a database on non-hospital health care services and to develop quality and performance measures. Consumers and purchasers can use such information to judge the quality of care provided by managed care organizations.

The Commonwealth separates financing and quality of care concerns, an increasingly problematic approach to regulation. The Insurance Department reviews health care insurers for financial strength, whereas the Department of Health is concerned with the quality of care being provided. However, the distinction between insurers and health care providers is no longer clear and calls for a closer relationship between the two departments.

The Department of Health's efforts to regulate quality of care rely heavily on Medicare standards and procedures. The federal Medicare program reimburses the Department of Health for part of the cost it incurs in assessing the quality of care in Commonwealth hospitals, ambulatory surgical facilities, and home health agencies. As a result, Medicare requirements influence much of the Department's effort to ensure quality of care. Although the Department has established state-specific standards for some services, focus on Medicare's standards may result in state priorities being overlooked. For example, the Department relied on Medicare's priorities for complaint investigations and did not have state priorities and procedures for responding to complaints until 1998.

Important state regulations have not been updated to reflect the changes in health care delivery. With some exceptions, Pennsylvania has not updated its regulations for general hospitals, home health agencies, and managed care organizations to reflect changes in health care financing and delivery. The Medicare program is revising its regulations for hospitals and has proposed that they publicly disclose their nurse staffing arrangements because of cutbacks, an issue of concern in Pennsylvania and across the nation. The Department of Health's outdated managed care regulations are also a matter of concern. Its HMO regulations have not been substantially revised since 1983. The Department of Health convened task forces of consumers, providers, insurers, and others to review managed care regulations in June 1997. The task forces completed their work in October 1997. The Department distributed a proposed draft of HMO regulations in April 1999. It remains uncertain when revised managed care regulations will be finalized.

The interrelationship between quality assurance responsibilities of various private, state, and federal agencies is complex and requires effective coordination. Cooperation between the involved private and public organizations is essential because quality assurance is a shared responsibility. We found several instances in which a state agency made, or attempted to make, a quality-of-care policy decision that was contradictory to the policies or requirements of another agency. For example, the Departments of Health and Public Welfare issued policies inadvertently permitting Certified Registered Nurse Practitioners (CRNPs) to independently carry out almost all the responsibilities of primary care physicians. However, allowing CRNPs to carry out such responsibilities conflicts with State Board of Medicine and State Board of Nursing regulations. Similarly, the Department of Insurance permitted an HMO to allow nurses in another state to engage in certain activities that the State Board of Medicine believes constitutes the practice of medicine.

The Department of Health should strengthen its procedures for relying on voluntary national accreditation surveys when licensing health care facilities. To avoid duplication, state law permits the Department to use national voluntary accreditation bodies in the state licensure process. The Department began using the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for this pur-

pose in 1993. However, the Department did not initially review JCAHO's accreditation standards and processes and did not identify strategies to assure that more stringent state requirements would be met. DOH staff have been working to resolve this and other procedural problems that resulted in the Department's extending expired hospital licenses without conducting the required on-site surveys.

The extension of managed care networks into new markets is threatening the availability of community health care services, particularly in rural communities. Payments for primary care services might not be sufficient to support the continuation of community hospitals and emergency service facilities in sparsely populated regions. Efforts by managed care plans to cut costs can also affect the availability of ancillary health care services, such as pharmacies and home health care agencies. Early hospital discharges and reduced access to home health care increase the pressure on Area Agencies on Aging.

HMOs must undergo an external quality review every three years, but the Department of Health has not established a minimum set of standards they must achieve. Department of Health regulations require HMOs to have an external assessment of their quality assurance programs within one year of receiving their certificates of authority and every three years thereafter. The Department has not established a minimum set of standards the plans must meet. States such as Florida and Rhode Island require their health care plans to meet defined minimum standards before allowing them to continue operating. Although the Department originally approved three organizations to do external quality reviews, the National Committee for Quality Assurance (NCQA) is the only one it now permits to do such reviews.

Not all ambulatory surgical facilities are submitting quality of care data to the Health Care Cost Containment Council. All freestanding ambulatory surgical facilities are required to report certain quality-of-care data to the Council, but less than half actually do within the required time frame. Such information is important because of the increasing role such facilities play in today's health care system.

The Pennsylvania Health Care Cost Containment Council could produce additional reports on the quality of care in Pennsylvania hospitals. The Council participated in a national study, the Healthcare Cost and Utilization Project (HCUP), to explore how existing data could be used to provide consumers with information on the quality of care in hospital settings. Pennsylvania hospitals as a group performed well in relation to the other states in the 1996 HCUP report. HCUP data include indicators such as mortality following common elective procedures, obstetrical complications, wound infection, and patient injuries. Other data collected by the Council make Pennsylvania one of the relatively few states capable of adjusting the HCUP data to account for patient differences and produce valid comparative reports on these and other key quality-of-care indicators.

With regard to Act 68, we found:

Not all managed care plans are subject to the quality assurance safeguards in Act 68. The act, passed in 1998, provides new quality assurance protections for many Pennsylvanians in managed care plans. However, the act applies only to managed care plans that manage service utilization through a "gatekeeper."[2] Persons enrolled in risk-assuming, non-gatekeeper plans do not have the same protections. Several states apply uniform regulatory standards to all managed care organizations, and model legislation from the National Association of Insurance Commissioners (NAIC) has a similarly broad focus.

The responsibilities for reviewing appeals of complaints about managed care plans are divided between the Department of Health and the Insurance Department. Under Act 68, both departments will be reviewing enrollees' appeals of unresolved complaints about decisions limiting their access to care. Some appeals to the Insurance Department might involve medical judgment. The Department of Health is the more appropriate agency to review such decisions. Previously, all appeals went to the Department of Health, which sought advice from the Insurance Department on coverage issues. The Department of Health proposed a joint complaint tracking system in draft regulations it distributed for informal comment in April 1999. The two agencies would jointly determine the appropriate agency to review each appeal.

Managed care plans have broad discretion in defining "medical necessity." Act 68 defines the utilization review and grievance process for medically necessary services, but does not specify the criteria plans must use to develop their definition of medical necessity. Also, managed care plans may define coverage benefits in terms of medical necessity and classify disputes about such benefits as complaints rather than grievances. Such distinctions can limit enrollees' rights to appeal denials of service. Enrollees can appeal grievances, but not complaints, to an external review panel of clinical peers.

Denials of physical health care services do not have to be made by physicians in a similar specialty until grievances reach the final appeal stage. Act 68 requires initial utilization review decisions denying payment for physical health care services to be made by licensed physicians, but it does not require such physicians to be clinical peers. New York and Ohio require initial denials based on medical necessity to be made by clinical peers. The NAIC model legislation contains a similar provision. Act 68 requires first and second level reviews of grievances to "include" a licensed physician or, where appropriate, a licensed psychologist "in the same or similar specialty that typically manages or consults" on the service in question. The DOH has proposed applying the "same or similar specialty" requirement to both

[2] Gatekeeper plans require enrollees to designate a primary care provider who will be the source of referrals for non-emergency specialty, hospital, and other covered services.

physicians and psychologists in its April 1999 draft regulations. Such a physician or psychologist would have to be a member of the internal grievance review committee at each level. The first time Act 68 specifically requires a clinical peer reviewer for physical health services is the external review stage, the final appeal phase in the grievance process. The entire process can take up to 145 days after the initial denial, assuming grievances and appeals are promptly filed.

Managed care plans have broad discretion in determining when to conduct expedited grievance reviews, and enrollees' rights to further appeals are unclear. Act 68 requires managed care plans to have a process for reviewing grievances within 48 hours if they involve jeopardy to life, health, or the ability to regain maximum function. The act does not specify any other criteria, such as a physician's request or emergency hospitalization, that would require managed care plans to conduct expedited reviews. Act 68 also does not define the enrollee's right to appeal expedited decisions or to have such appeals expedited. The DOH proposed making expedited reviews available at all stages of the grievance process, including the external review, in its April 1999 draft regulations.

Managed care plans do not have to give health care providers an opportunity to discuss an initial denial of services with the reviewer, and providers may not file a grievance without an enrollee's consent. Several states have established an "informal" review procedure wherein providers can discuss initial denials of service with the managed care reviewer. Under Act 68, managed care plans are not required to hear providers until a formal grievance reaches the second level of internal review. Also, a provider must have an enrollee's written consent to request a review of a decision to deny payment for services already rendered, even if the plan approved the services in advance. Such restrictions can ultimately affect the quality of care if providers do not have a reasonable process for resolving payment disputes.

Federal law requires physicians and hospitals to provide emergency services that may not be covered under Act 68. The act requires providers to render emergency services but allows managed care plans to later deny payment for these services based on a retrospective review. Federal Medicare and Medicaid regulations avoid putting providers in this situation by requiring their managed care plans to pay for the emergency services the physician deemed necessary at the time.

With regard to individuals with special needs, we found:

DPW's contract with HealthChoices plans contains various provisions to help insure quality of care to individuals with special needs, but implementing these provisions has proven problematic. Enrollees with complex medical conditions can use specialists as their primary care provider (PCP). However, only 221 of the over 478,000 HealthChoices southeast enrollees have been assigned specialists as PCPs. HealthChoices plans are also required to have special units to assist individuals

with special needs, but at least some of these units appeared to be understaffed and less involved in resolving the problems faced by individuals with special needs than the Department anticipated. (The Department has strengthened its special needs unit requirements in its HealthChoices Southwest RFP and 1999 Southwest contracts.) The Department's definition of medical necessity was also not being followed, and plans were improperly reducing and denying medical services, according to a federal court settlement agreement.

The monthly fee DPW pays to plans to provide care to HealthChoices enrollees is not based on an enrollee's health status. DPW's payments are based on factors such as category of assistance, age, and geographic location, but not health status. Such payments can produce inequities between plans if they attract members with the greatest care needs because of differences in the care provided by plans. While the Department is making efforts to compensate plans for adverse selection of persons with HIV/AIDS, newer, more expensive treatment methods will continue to create demands for such services. Plan strategies to avoid such exposure may make quality care less accessible for members who need costly services. Similar issues exist for persons with other costly conditions.

Access to HIV/AIDS specialists is limited. Relatively few (22) infectious disease specialists with expertise in treating HIV/AIDS reported being available to treat HealthChoices Southeast patients on an ambulatory basis. Only 13 of these reported serving more than a few HealthChoices patients. Advocates for persons with HIV/AIDS have expressed concerns about experienced HIV/AIDS providers' participation in HealthChoices.

Obtaining prescription drugs can be difficult for HealthChoices enrollees. The Department permits HealthChoices plans in southeastern Pennsylvania to use drug formularies that are more restrictive than the one used in its fee-for-service program as long as such drugs are available through prior authorization programs. Plans are required to respond to prior authorization requests within 24 hours. Busy signals, extended waits on hold, unreturned phone calls, and other administrative barriers can make obtaining prior authorization difficult. Delays in communicating formulary changes and failure to provide published formularies to doctors create additional difficulties. Physicians report they do not receive responses to their prior authorization requests for medication within 24 hours, and notices of denials may not be sent for days or even weeks after the request. Notices do not always conform to DPW's standard denial notice. The requirement for plans to provide at least a 72-hour supply of the drug, moreover, is applied inconsistently. This may be due in part to the Department's contract not specifically requiring plans to pay for such drugs and because the plans' formulary and prior authorization policies and procedures do not appear to be fully consistent with federal law and DPW contract requirements.

Children in substitute care enrolled in HealthChoices may not always receive medical care when they need it. Children in substitute care, such as foster care, are often eligible for Medical Assistance. They now must enroll in HealthChoices if they reside in a HealthChoices county or, as of September 1999, are placed in one. Such children are mobile and may frequently move from one setting to another until suitable placement is found. This presents problems as HealthChoices plans are not statewide, and DPW's method for enrolling and changing from one plan to another can take several weeks. Caregivers and providers do not always know if a child is enrolled in Medicaid fee-for-service, or the HealthChoices plan and the PCP responsible for the child's medical care. Further difficulties arise because plans do not always provide information to caregivers such as timely notice of service denial, reduction, or termination, or information about the status of service prior authorization requests. Despite DPW efforts to address these issues, problems remain.

HealthChoices is a regional system, whereas Medical Assistance transportation is provided through single county systems or a voluntary consortium of counties. HealthChoices relies on regional managed care systems to deliver care for Medical Assistance beneficiaries, but the Medical Assistance transportation program continues to operate as a county-based system. Rules developed for the fee-for-service program--such as providing transportation only within the transportation service area and requiring special permission for travel outside the service area--do not always work well under the HealthChoices program.

Few ongoing mechanisms exist for public input into key HealthChoices policies, and the Department has not always adequately communicated its policies to all involved parties. The Medical Assistance fee-for-service program operates through statutes, regulations, and widely distributed MA Bulletins. Compliance with such policies is required by the HealthChoices RFP, which is developed with considerable public input. HealthChoices policies are also set forth in contract language and at times letters to plans interpreting contract requirements. Such letters and contract changes are not subject to public review processes. Some of the implementation difficulties experienced by HealthChoices might have been avoided or alleviated had the Department had the benefit of such input.

HealthChoices plans have had difficulty correcting quality assurance problems. Over the past decade, at least six independent external reviews have documented quality assurance problems with one or more of the HealthChoices plans. Several of the identified problems, including the absence of fully functioning quality assurance programs and inadequate systems for credentialling physicians, are recurring. The Department's onsite clinical reviews of the HealthChoices plans, conducted in early 1998, continued to find many of these same problems.

The Department has been more aggressive than most states in requiring special needs individuals to enroll in risk-based managed care such as HMOs. Penn-

sylvania is one of only 11 states that require disabled individuals to receive Medical Assistance services through fully capitated risk-based HMOs. Pennsylvania's HealthChoices has several provisions to help protect individuals with special needs, such as open enrollment which allows enrollees to switch plans during the year. However, unlike several of the other 10 states, HealthChoices does not have processes for exempting most individuals who have complex medical conditions or those with private health insurance. Pennsylvania is also one of only three states with county-administered child welfare programs where children in substitute care must receive Medical Assistance services through HMOs. The California legislature removed most children in substitute care from mandatory managed care programs because of the problems encountered.

The federal HealthChoices waiver required an independent evaluation be conducted by November 1998. DPW submitted a report based primarily on work done by Office of Medical Assistance staff. The Department attributed its reliance on the work of its own staff to the absence of reliable and valid encounter data for an independent analysis. The report also provided little information on the quality of care received by persons with special needs.

Recommendations

We recommend:

1. **The General Assembly consider creating an independent commission to provide ongoing reports on how the financing and delivery of health care are affecting the quality of care in the Commonwealth.** Several states, including Connecticut, Maryland, and California, have created special state units to monitor and report on changes in their health care systems and how these changes affect access and quality of care. Maryland has a commission that also develops a managed care "report card" to give consumers information on the quality of care provided by managed care organizations. Although the Pennsylvania Department of Health has the statutory authority to carry out such functions, it has historically had a difficult time fulfilling such a role. As an alternative to creating a new commission, the General Assembly could expand the responsibilities and composition of the Health Care Cost Containment Council.

2. **The Department of Health and the Insurance Department develop policies and procedures for notifying each other of financial or quality-of-care concerns.** The relationship between health care financing and the quality of care has become almost inseparable as insurers purchase health care practices and health care providers ban together in risk-sharing arrangements. To better regulate these entities, the Departments of Health and Insurance need to develop and formalize policies for informing each other of

changes in financial circumstances that could affect quality of care or, conversely, quality of care concerns that could be indicative of broader financial solvency problems.

3. **The Department of Health review JCAHO's standards and processes to ensure that they cover all important state licensing requirements.** The Department should determine how to assess compliance with state standards that are not included in JCAHO's hospital surveys. The Department should also work with JCAHO to ensure that hospital surveys are conducted in time to allow the Department to renew hospital licenses before they expire and develop a written policy on validating the JCAHO survey results.

4. **The Department of Health expand the list of organizations qualified to conduct external reviews of HMOs.** The Department requires HMOs to undergo an external quality review every three years. In 1989, the Department approved three organizations to conduct the reviews. However, two of the organizations are not now doing such reviews in Pennsylvania, leaving only the National Committee for Quality Assurance (NCQA). The Department plans to issue a request for proposals from other organizations capable of doing quality assurance reviews.

5. **The Department of Health update and strengthen its existing quality assurance regulations.** The Department has broad powers to regulate managed care plans that combine the financing and delivery of health care. The 1997 task force recommendations addressed the need to keep pace with the rapid changes in health care delivery while ensuring and promoting the quality of care and consumer protection. However, these recommendations have not been developed into proposed regulations. In addition, the impending changes in Medicare certification standards may require further review and revision of state quality-of-care regulations, particularly for hospitals and home health agencies. We recommend the Department begin to form work groups for reviewing the proposed Medicare changes and identifying related issues. Such issues could include the merits of regulating home health aides, in-home providers of IV therapy, and other service providers that are licensed in many states but not in Pennsylvania.

6. **The Department of Health require HMOs to demonstrate their compliance with a minimum set of quality assurance standards every three years.** HMOs must undergo an external quality review every three years, but the Department has not established in regulations the minimum standards plans must achieve. The quality reviews have little meaning without such standards. We recommend the Department develop minimum quality assurance standards, which could be based on the requirements for accreditation by the external review organizations the Department has approved.

7. **The General Assembly consider amending the HMO Act to require the renewal of HMO licensure every three years.** HMOs receive certificates of authority that never expire. Health care facilities, such as hospitals, and individual providers, such as physicians and nurses, receive licenses with specific expiration dates. The renewal of such licenses depends upon the facility's or individual's meeting certain standards and requirements. HMOs are increasingly taking on the characteristics of health care providers. It may be more appropriate to issue them time-specific licenses, possibly for three years, rather than indefinite certificates of authority that can only be revoked through a process of hearings and appeals. Such an amendment would also need to provide for interim steps such as a provisional certificate and continued coverage for plan enrollees.

8. **The Department of Health consider the health care needs of both enrollees and nonenrollees when issuing the HMO licenses recommended in 7 above.** When issuing a certificate of authority, the Department of Health reviews the adequacy of the HMO's proposed provider network. The Department may, for example, approve an HMO if all enrollees would be within 30 miles of an HMO-contracted hospital. However, directing a significant portion of a region's population to one hospital could jeopardize other hospitals and health care providers who may be filling critical needs, particularly in rural areas. If HMOs are required to renew their licenses every three years, as recommended in 7 above, the Department should consider how the HMO's provider network could affect access to health care for area residents who are not enrolled in the HMO. Information useful in making such assessments could be provided by the Health Care Cost Containment Council, the commission recommended in 1 above, and, if appropriate, testimony from public hearings held in the affected region.

9. **The Health Care Cost Containment Council consider publishing selected risk-adjusted HCUP data.** The Council has the information necessary to risk-adjust data collected by the national Healthcare Cost and Utilization Project. This would allow the Council to present comparative information on key quality-of-care indicators for individual hospitals, as Utah has done.

10. **The Health Care Cost Containment Council develop quality-of-care reports for ambulatory surgical facilities.** Ambulatory surgical facilities are becoming increasingly important, but many of them have not responded to the Council's data requests. Understandably, the Council prefers to work with these facilities in a cooperative manner. However, it needs to consider eventually fining them or taking other steps to ensure that they provide the required data. It has such power under its enabling legislation.

With regard to Act 68, we recommend:

11. **The Department of Health promulgate regulations and the General Assembly consider amending Act 1998-68 to strengthen its quality assurance provisions.** Although the act imposed many requirements designed to protect managed care consumers and promote quality care, Department regulations are needed to implement Act 68. In particular, we recommend the Department of Health promulgate regulations and, where appropriate, develop procedures with the Insurance Department to:

    - **Establish quality assurance standards for "non-gatekeeper" preferred provider organizations that assume financial risk.** The protections given to consumers under Act 68 apply only to managed care plans that use gatekeepers. Department regulations are needed if consumers in non-gatekeeper preferred provider organizations that assume financial risk are to have similar protections. The Department effectively has authority under the HMO Act to regulate organizations that combine the financing and delivery of health care services.

    - **Direct appeals of complaints to the Department of Health for initial screening.** Under Act 68, complaints can be appealed to either the Department of Health or the Insurance Department. We recommend the departments establish a process for having all such formal plan appeals initially screened by the Department of Health to determine whether the complaints involve issues of medical necessity. As an alternative, the two agencies could develop a joint tracking system such as the one proposed in the April 1999 draft regulations from the DOH.

    - **Establish the criteria to be used in defining "medical necessity."** Access to quality health care may depend on how a managed care plan defines the term "medical necessity." While no single definition is universally recognized, the Department should establish the limits for a range of acceptable practices and sources of standards plans may use in developing their definitions. The DOH proposed making the definition consistent with national and industry standards in its April 1999 draft regulations.

    - **Require clinical peer evaluations of internal grievance decisions to uphold denials based on medical necessity.** Act 68 does not clearly require that decisions to deny services based on medical necessity be made or reviewed by clinical peers until a grievance reaches external review, the final appeal phase of the process. The Department of Health proposed making a clinical peer a member of the internal grievance review committee at each level in its April 1999 draft regulations. Such regulations should also

specify the information to be included in written reports from the grievance committees.

The Department of Health might not have sufficient authority to make the following changes through the regulatory process. Accordingly, we recommend the General Assembly consider amending Act 68 to:

- **Require utilization review decisions to be made by clinical peers if they result in the denial of physical health services based on medical necessity.** Although Act 68 requires the initial decisions denying payment for physical health services to be made by licensed physicians, it does not require them to be clinical peers in appropriate specialties. The act applies a different standard to behavioral health services. Licensed psychologists may review behavioral health services within their scope of practice only if they have sufficient clinical experience. New York and Ohio require that the initial decisions to deny services based on medical necessity be reviewed by clinical peers.

- **Specify circumstances that warrant expedited grievance reviews and establish procedures to appeal such decisions.** Act 68 establishes only very broad criteria for determining when managed care plans must expedite their reviews of grievances. Medicare requires plans to conduct expedited reviews if a physician makes such a request, and the NAIC model legislation calls for expediting the reviews of grievances involving patients who have received emergency care but have not yet been discharged. Act 68 is also silent on the consumer's right to appeal an expedited decision or to have such appeals expedited. New York and New Jersey expressly describe expedited reviews as accelerated steps in the standard review process. The DOH proposed a similar provision in its April 1999 draft regulations.

- **Entitle health care providers to obtain "informal" reviews of denials and file grievances of decisions to deny payment.** In some states, health care providers are entitled to discuss initial denials of requested services with the reviewer who made the decision, or the managed care plan's medical director, before a grievance is filed. Under Act 68, managed care plans are not required to discuss denials with providers until a formal grievance reaches the second level of internal review. Also, providers must have an enrollee's written consent to file a grievance after payment has been denied for services already rendered, even if the plan approved the services in advance.

- **Make emergency care benefits consistent with Medicare standards.** Although Act 68 contains a "prudent layperson" definition of medical emergency and requires health care providers to render emergency care, it does not necessarily require managed care plans to pay for such care. The act allows managed care plans to deny payment following a retrospective review. Physicians and hospitals participating in the Medicare program must render appropriate emergency care to all patients with emergency medical conditions, even if they are not Medicare beneficiaries. Such care includes appropriate screening examinations and stabilization procedures. Participating managed care plans must pay for such services regardless of any determinations made during retrospective review. Similar requirements apply to Medicaid. New Jersey and Ohio have managed care requirements consistent with the Medicare standards.

With regard to assuring quality of care for individuals with special needs, we recommend the Department of Public Welfare:

12. **Develop a capitation payment system based on an individual's health status.** Capitated payments based on an enrollee's health status alleviate issues of adverse selection by paying plans more to serve individuals with costly complex medical needs. Without such a system, plans place themselves at financial risk if they provide high quality care to individuals with costly medical problems, as this will attract more high-cost individuals to that plan. Congress recognized the importance of health-based payments when it mandated such systems be developed for Medicare managed care.

13. **Exempt individuals with complex medical needs from mandatory participation in HealthChoices until the Department implements health-based capitation payments.** Several states requiring persons with disabilities to receive Medical Assistance services through HMOs exempt individuals with significant medical needs from participating. A formal process to exempt such individuals from HealthChoices should be in place until such time as health-based capitation payments are incorporated into HealthChoices.

14. **Exclude children in substitute care from mandatory enrollment in HMOs.** Most states do not include children in substitute care in Medicaid mandatory HMO programs. Such children may move quickly and frequently. Access to medical care may be compromised during such transitions because the existing systems do not provide for immediate enrollment or change from one plan to another.

15. **Implement a primary care case management program for individuals with rare and expensive medical conditions.** Several states are developing hybrid programs to incorporate the positive aspects of managed care while

minimizing the possible negative aspects. Maryland, for example, allows individuals with rare and expensive medical conditions to enroll in a primary care case management program operated by a major teaching and training hospital. Care is coordinated through a primary care case manager, but services are paid for on a fee-for-service basis. Maryland had almost 1,500 individuals participating in this program as of June 30, 1998.

16. **Develop a state ombudsman program to assist individuals with special needs and their service providers**. California, Maryland, Oregon, and Utah have established ombudsman programs that consumers and providers can use if they experience difficulty with a Medicaid managed care plan. Oregon's serves only persons with disabilities. The Department of Public Welfare has a state special needs unit and a Clinical Sentinel Hotline. Such units, however, do not have advertised 800 numbers for consumers and providers to routinely access when they believe a plan is not acting in the interest of the consumer, or to assist in filing grievances and appeals. A state ombudsman program would also help identify system problems while still in their early stages and provide opportunity for early intervention by the Department.

17. **Review the appropriateness of the HealthChoices formularies, particularly for children and adults with special needs.** Restrictive formularies that require prior authorization make it difficult for patients with complex medical needs to obtain their prescribed medications. They also create administrative burdens for their physicians and pharmacists who report that standard drugs for treating serious medical conditions are not on HealthChoices formularies. The Department should convene experts to review plan formularies and make recommendations to ensure that they are not overly restrictive for persons with complex medical conditions.

18. **Monitor and enforce plans' adherence to the requirement that plans respond to requests for prior authorization of medications in 24 hours**. Federal statute and the Department require plans to respond to prior authorization requests for medication within 24 hours. Some plans are not providing denial notices within 24 hours. The Department may have difficulty monitoring for this because its standard denial notice does not indicate the time and date when a prescription is presented to the pharmacy or the name of the pharmacy, or the date and time of submission of the prior authorization request. Some plans also appear to be interpreting the requirement for a response within 24 hours as applying only to the initial response. The Department should assure that plans respond to all medication prior authorization requests in 24 hours or provide the prescription until the response is provided.

19. **Enforce the requirement that HealthChoices enrollees receive at least a 72-hour supply of medication that requires prior authorization, es-**

pecially in emergency situations. Under DPW's contract with southeast plans, HealthChoices enrollees are to receive at least a 72-hour supply of medication that requires prior authorization when such authorization cannot be obtained when the patient presents a prescription to the pharmacist. This is not always occurring and, when it does occur, plans are not always reimbursing pharmacists for the medication they supply. In its 1999 contract the Department permits certain exceptions to its 72-hour policy. Federal statute provides for no exceptions in emergencies, and the Department should clarify that no exceptions are permitted in emergency situations and that all restrictions are subject to prior authorization procedures and require a 24-hour response.

20. **Issue HealthChoices policies in bulletins or regulations.** In view of the significance of matters such as the definition of medical necessity used in HealthChoices and access to drugs on restrictive formularies, all policies interpreting the HealthChoices RFP and contract should be issued as Medical Assistance Bulletins or regulation depending on their content. Most recently the Department has begun to clarify HealthChoices policies through MA bulletins. Such an approach should be followed routinely.

21. **Contract for an independent study of the HealthChoices program.** The Department submitted a report that was largely by its staff in lieu of the independent study required by the HealthChoices southeast waiver. We recommend the Department contract with a firm such as Mathematica Policy Research which is conducting independent evaluations of other state Medicaid waivers on behalf of the federal Department of Health and Human Services and has developed a survey specifically designed to assess the care provided to disabled individuals.

I. Introduction

House Resolution 1997-185 directs the Legislative Budget and Finance Committee to examine the effectiveness of Commonwealth programs and efforts to ensure the quality of health care services provided in Pennsylvania. The resolution called for the study in view of the dramatic changes in the health care environment.

Such changes include the rapid growth in managed care, the increasing number of hospital mergers and consolidations, and the shift from acute inpatient care services to outpatient care settings. In state government, two major policy changes—the sunset of the certificate of need program in December 1996 and the Department of Public Welfare's inclusion of children and adults with special needs and disabilities in its Medicaid mandatory managed care demonstration—had significant implications for quality of care. A copy of the resolution can be found in Appendix A.

A. Study Objectives

The resolution directs the LB&FC to:

1. Identify and assess existing Commonwealth programs and efforts to monitor changes in the delivery and reimbursement practices of health care services to ensure that these practices do not negatively impact on the quality of health care.
2. Assess the adequacy of federal and state laws, regulations and standards relating to the assurance of quality care provided by individual practitioners, health care facilities, and managed care plans.
3. Assess the use of nationally recognized voluntary accreditation standards and practices for assuring quality in health care.
4. Identify effective methods, policies and practices to promote and achieve quality standards of care.
5. Identify current efforts to improve public accountability of health care providers and health plans in the delivery of quality services.
6. Identify those special concerns in assuring quality of care for those with special needs.

B. Scope and Methodology

To accomplish the study objectives, we interviewed officials of the Department of State's Bureau of Professional and Occupational Affairs, most notably the State Board of Medicine and the State Board of Nursing; the Departments of

Health, Public Welfare, Insurance, and Aging; and the Health Care Cost Containment Council.

We met with representatives from the Pennsylvania Medical Society, the Hospital and Healthsystem Association of Pennsylvania, the Allied Health Care Providers Coalition, the Pennsylvania Nurses' Association, Pennsylvania Association of Home Health Agencies, the Pennsylvania Pharmacists Associations, KePRO, the Managed Care Association of Pennsylvania, and Highmark. We also met with representatives of the small hospitals, including rural hospitals in northeastern Pennsylvania, the American Association of Retired Persons, the PA Chapter American Academy of Pediatrics, the City of Philadelphia Department of Public Health, the Pennsylvania Health Law Project, and the Disability Law Project.

We spoke with parents, physicians, and agency staff working with medically fragile children and disabled individuals. We met with representatives of the Children, Youth and Family Council Education Consortium and the Juvenile Law Center working with children in foster care and other forms of substitute care enrolled in managed care. With the assistance of the Pennsylvania Association of Area Agencies on Aging, we surveyed all Area Agencies on Aging in Pennsylvania to identify how the elderly have been affected by the rapid changes occurring in health care financing and delivery.

To identify how quality of care is assured nationally and in the Commonwealth, we reviewed federal and state legislation and regulations and other policies establishing quality assurance standards for individual practitioner, health care facilities, and managed care organizations. We also reviewed the standards of national organizations responsible for assuring quality of care. These included standards and programs to assure quality of certain medical specialty societies and national voluntary accreditation organizations.

We also reviewed state agency contracts and other relevant materials provided by state agencies concerning state standards and processes for assuring quality of care. Staff reviewed Department of Health files, including HMO contracts with providers and reports submitted to the Department by managed care plans. These included reports to document the plans' compliance with state requirements for external review of their internal quality assurance systems. Similarly, we reviewed the most recent federally required external quality assurance reviews completed for all Medicaid managed care organizations.

To identify effective methods, policies, and practices to promote and achieve quality of care, we reviewed recent and proposed changes to quality of care standards at the federal level for health care facilities and managed care organizations. We reviewed the National Association of Insurance Commissioner's models to assure health care quality in managed care settings. We also reviewed recently

enacted statutes and regulations in states such as New York, New Jersey, and Maryland.

To identify efforts to improve accountability of health care providers, we reviewed changes being introduced by national voluntary accreditation organizations to allow them to monitor performance of accredited organizations on an ongoing basis. We reviewed national accreditation organization reporting systems for certain health care facilities and managed care organizations. We spoke with officials from the federal Health Care Financing Administration involved in federal efforts to gather data from managed care plans to provide comparative information for Medicare beneficiaries. We reviewed activities of other states to improve provider and plan accountability.

To identify issues and opportunities to assure quality of care for those with special needs, we consulted the federal Agency for Health Care Policy and Research, the Public Health Service, and the Center for Medicaid and State Operations in the Department of Health and Human Services. We also consulted and reviewed relevant work of several policy research centers sponsoring demonstrations and conducting systematic evaluations in this area. This included the Center for Health Care Strategies in Princeton, New Jersey, the Center for Hospital Finance and Management at the Johns Hopkins Health Institutions, the National Academy for State Health Policy, the Maternal and Child Health Policy Research Center, the Medical College of Virginia, the George Washington University Center for Health Policy Research, the National Governor's Association, the Medicaid Working Group in Boston, Massachusetts, New England SERVE, Mathematica Policy Research, the Urban Institute, and FACCT—Foundation for Accountability.

We also consulted with and reviewed materials provided by officials and individuals involved in managed care programs attempting to serve individuals with certain disabilities. These include individuals in states such as Oregon, Washington, Massachusetts, Tennessee, Arizona, Delaware, Ohio, Minnesota, New York, and Maryland. We also spoke with officials in all states which require individuals with disabilities and children in substitute care to receive Medical Assistance through capitated risk-based managed care plans.

Staff attended meetings of the State Board of Medicine, the Medical Assistance Advisory Committee (MAAC), and the Consumer Subcommittee of the MAAC.

This study addresses quality assurance for physical health care only. The study does not address behavioral health or long term care. The broad scope of the study required us to limit our focus on independent licensed practitioners to medical doctors and registered nurses. Similarly, we limited our focus on licensed health care facilities to general acute hospitals, freestanding ambulatory surgery centers, and home health agencies.

Managed care plans have recently emerged as major providers of health care. We have defined managed care broadly in the report to include HMOs and certain managed care arrangements recognized but not currently regulated by the Commonwealth.

The Pennsylvania Department of Insurance's Bureau of Consumer Services provides a wide range of assistance to more than 200,000 consumers each year when they encounter problems with insurers. Health maintenance organizations are certified Pennsylvania insurers; however, the Insurance Department does not have jurisdiction over complaints involving HMO quality of care issues such as dissatisfaction with services rendered by the provider. Such complaints are forwarded to the Department of Health for handling. The discussion of "complaints" in the context of managed care is limited to health care quality-related issues and appeals of complaints under Act 1998-68, which do not include consumer "inquiries/ complaints" to the Insurance Department concerning matters such as premium rate increases.

Many significant issues related to health care quality were identified for us during the study. Because of the broad scope of the study, we were not able to address each of these issues in this report. For this reason, our report recommends the Commonwealth establish an on-going forum to systematically address major issues in quality assurance in the changing health care financing and delivery environment.

C. Acknowledgments

We greatly appreciate the cooperation we received from the Secretaries and staff of the PA Departments of Aging, Health, Public Welfare and Insurance, and the Pennsylvania Health Care Cost Containment Council. We especially acknowledge the support we received from the Department of Health's Office for Quality Assurance and Department of State's Bureau of Professional and Occupational Affairs. We also appreciate the excellent support and advice we received from the many individuals and associations we contacted during the study.

Important Note

The Legislative Budget and Finance Committee staff developed this report. The release of this report should not be construed as indicating that the Committee's members endorse all of the report's findings and recommendations.

Any questions or comments regarding the contents of this report should be directed to Philip R. Durgin, Executive Director, Legislative Budget and Finance Committee, P.O. Box 8737, Harrisburg, Pennsylvania 17105-8737.

II. Efforts to Assure Quality of Health Care in the Commonwealth

In 1986 Congress charged the National Academy of Science's Institute of Medicine[1] to define quality of health care and to recommend strategies for quality assessment and assurance for public health insurance programs. At the time, public health insurance programs such as Medicare were in the forefront in introducing new techniques for payment of health care. These techniques had the potential to adversely affect quality of health care.[2] According to the Institute of Medicine:

> Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.[3]

Similarly the Agency for Health Care Policy and Research in the U.S. Department of Health and Human Services (DHHS)[4] defines quality of care as:

> . . . health care that is accessible, effective, safe, accountable, and fair. This means:
>
> - Patients can obtain care in a timely way.
> - Providers deliver the right care, to the right patient, at the right time, in the right way.

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[1]The National Academy of Science was chartered by Congress in 1863 to be an advisor to the federal government on scientific and technical matters. The Institute of Medicine, which is part of the Academy, advises on issues of medical care, research, and education. Its mission is to advance and disseminate scientific knowledge to improve human health.

[2]For example, in the 1980's Medicare changed the way it paid for inpatient hospital care. Medicare established fixed payment rates for episodes of acute hospital care regardless of the costs the hospital actually incurs in providing care. This prospective payment system (PPS) relied on Diagnostic-Related Groups (DRGs) to establish payment rates. The DRG system classifies patients into groups based on the principal diagnosis, type of surgical procedure, presence or absence of significant co-morbidities or complications, and other relevant criteria. DRGs are intended to categorize patients into groups that are clinically meaningful and homogeneous with respect to inpatient resource use. However, not all cases are homogeneous with respect to resource use. The prospective payment system, therefore, provided a form of risk adjusted payment for cases substantially different than the average. Hospitals receive additional PPS payments for cases with extremely long lengths of stay (day outliers) or extraordinarily high costs (cost outliers) compared to others with the same DRG.

[3]Institute of Medicine, *Medicare: A Strategy for Quality Assurance,* Vol. I, National Academy Press: Washington, DC, 1990, p.4.

[4]The Agency for Health Care Policy and Research works with the private sector and other public organizations to determine what works best in clinical practice, helps consumers make better informed choices, measures and improves the quality of health care, and improves the cost-effective use of health care resources. It accomplishes these goals through activities such as support for patient outcome research, technology assessment, and data standard and health information systems development.

- Consumers have accurate and understandable information about risks and benefits and are protected from unsafe health care services and practices.
- Providers can demonstrate that they deliver effective care.
- Consumers have reliable and understandable information on the care they receive.
- Patients and doctors have their rights respected.

A. Evaluating Quality of Health Care

Determining the quality of health care being provided to individuals or populations (such as the general population or special populations such as the elderly or disabled) typically involves measurement of one or more of the following attributes:

- appropriateness of care (whether the patient received the right care at the right time),
- technical excellence (whether the provider furnished care in the correct way),
- accessibility (whether the patient obtained the care when needed), and
- acceptability (whether the patient was satisfied with the care).

These attributes are assessed by health care providers, government regulators, and others using structure, process and outcome indicators.

- *Structural indicators* measure the capacity of a health care practitioner, facility, or health system to deliver quality health care. Examples for individual practitioners include professional characteristics such as licensure and medical specialty certification. Examples for health care facilities include licensure and accreditation status, and physical attributes (such as special care units) and organizational factors (such as staff-to-patient ratios, employee turnover, and employee morale).
- *Process indicators* measure what a provider does to and for a patient. Process measures can be applied to an individual practitioner, a health care facility, or a large health care system. Identifying and evaluating what diagnostic tests a physician performs when examining a patient with chest pain is an example of a process indicator.
- *Outcome indicators* measure the results of provider actions. Potential examples of outcome indicators include mortality, complications resulting from surgery, patient satisfaction, and functional status.

The art and science of health care outcome measurement have not been perfected. Most quality of care indicators described in this report, therefore, are structural or process measures. Even indicators that are expressed numerically (such as rates of childhood immunization) are typically process indicators, and not measures of patient outcomes.

The few outcome indicators that are available are often difficult to interpret. This is because of the difficulties in controlling for differences in case mix, severity of illness, and medical complications when individuals are served by different health care providers. Hospital mortality statistics published by the Health Care Financing Administration (HCFA)[5] have been questioned for these reasons. HCFA, therefore, stopped publishing unadjusted mortality rates.

B. Responsibility for Assuring Quality of Health Care

In the United States, there is no single point of accountability for assuring quality of health care. Responsibility for quality of health care is a shared professional and public responsibility. Quality of physical health care in the Commonwealth is assured in part through voluntary accreditation, federal, and state organizations.

1. Voluntary Efforts to Assure Quality of Health Care

Professional care providers, the parties closest to the delivery of health care, typically see themselves as the parties most responsible for the quality of health care. Historically, such professionalism and the desire to achieve the highest standards of care have been relied upon as the primary quality assurance mechanisms.

Professional emphasis on self-examination has resulted in the development of professional standards and criteria for health care practice and an emphasis on continued professional growth by medical specialty boards and specialty colleges. Professionalism supports participation in voluntary accreditation programs such as the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) and the American Osteopathic Association (AOA). It fosters implementation of internal quality assurance programs designed to prevent, detect and correct problems with quality of care.

Many individual practitioners and health care facilities in Pennsylvania voluntarily seek to achieve the highest standards for professional care. For example, physicians in Pennsylvania often participate in advanced medical training. The

[5]HCFA is part of the United States Department of Health and Human Services. It is responsible for the administration of the federal Medicare and Medicaid programs.

American Board of Medical Specialties (ABMS) issued 7,011 subspecialty certificates in 1997 to active Pennsylvania physicians.[6]

Similarly, general hospitals in Pennsylvania participate in national voluntary accreditation programs. Most general acute care hospitals (186 of 209) in Pennsylvania are accredited by the JCAHO. The AOA has accredited 22 general hospitals. The JCAHO and the AOA have not accredited ten general acute care hospitals. Four of the 10 non-accredited hospitals have fewer than 50 acute care beds.

The National Committee for Quality Assurance (NCQA) is the other major national voluntary accreditation organization involved in helping to assure quality of health care in the Commonwealth (see Appendix B). NCQA has accredited 17 of the 30 state-approved health maintenance organizations.

2. Federal Efforts Through the Medicare Program

In all states the federal government plays a major role in helping assure quality of care, primarily through the standards it establishes for the Medicare program. In general, health care facilities seeking to serve Medicare or Medicaid beneficiaries must meet Medicare's quality of care standards. If they are not in compliance with these standards, they cannot participate in these major government health insurance programs. Medicare's standards are of particular importance because they often apply facility-wide. Thus, they directly affect the quality of care provided to everyone, not just Medicare and Medicaid beneficiaries.

The Medicare Program employs multiple strategies to assure that care is delivered within its established standards. These include, for example:

- State Peer Review Organizations.
- Medicare's Quality of Care Surveillance System.
- Evidenced-based quality improvement projects.
- State Survey Agencies.

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[6]After completion of a general residency program and obtaining initial specialty board certification, some physicians elect to participate in accredited fellowship programs. Such programs allow physicians to obtain additional board certification in one or more medical subspecialties. Attainment of subspecialty certificates requires additional post-doctoral training, demonstrated clinical competence, and successful completion of comprehensive examinations beyond those required for general certification. Physicians who successfully complete such certification receive certificates that are dated and valid for 10 years. Reassessment is required for renewal of medical specialty board certification. Such reassessment typically involves evaluation and examination of the physician's skills, performance, practice, cognitive ability, and participation in continuing medical education in which the participant has been evaluated. Physicians who are board certified in a medical specialty are typically eligible to participate as fellows in specialty medical colleges. Such colleges have roles in promoting continuing medical education, developing practice guidelines and other activities to promote quality medical care. Among the other activities is promotion of research, including outcome-oriented research.

- Voluntary National Accreditation Organizations.

State Peer Review Organizations. The DHHS contracts with Peer Review Organizations (PROs) in each state to assist in its quality assurance efforts. PROs are groups of practicing physicians and other health care professionals under contract with HCFA to monitor the care given to Medicare patients. Each state has a PRO. Pennsylvania's PRO is known as KePRO and has offices in Harrisburg.

PROs are involved in decisions as to whether the care given to Medicare patients is reasonable, necessary, and provided in the most appropriate setting. They are also involved in decisions as to whether the care provided meets the standards of quality generally accepted by the medical professions. Medicare standards require hospitals and physicians to cooperate with their PRO.

In the Medicare program, PROs must review individual cases when beneficiaries or their representatives complain about quality of care of Medicare-covered services they received. This applies to care provided through fee-for-service and managed care payment arrangements. Complaints must be in writing.[7] Quality of care concerns are those with a significant, or potential for a significant, adverse effect on a patient. A significant adverse effect may include:

- Unnecessarily and significantly prolonged treatment (such as a prolonged stay, readmission, additional treatment).
- Serious medical complications.
- Serious physiological or anatomical impairment.
- Significant disability.
- Avoidable death.

For fee-for-service claims and managed care encounters, quality of care reviews involve determining whether the quality of services meets professionally recognized standards of health care. Managed care quality review determinations also assess whether appropriate health care services were provided, and, if so, if they were provided in an appropriate setting. They also involve determining whether the enrollee had adequate access to health care. Where quality concerns are confirmed PROs can initiate corrective actions through the DHHS. (DHHS maintains an Internet Site identifying providers who have been sanctioned, including those sanctioned for reasons related to quality of care.)

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[7]According to the Medicare Peer Review Organization Manual, while complaints must be in writing, PRO staff may take information over the telephone, summarize the complaint, and forward it in a self-addressed, stamped envelop to the beneficiary for verification and signature. Moreover, anonymous and oral complaints believed to be serious and urgent in nature are to be reviewed. Written complaints from sources other than the Medicare beneficiary or their representative (e.g., health care practitioners) may also be reviewed and corrective action taken if warranted. However, final responses are not provided to such other complainants.

The PRO also reviews all cases involving Hospital Issued Notices of Noncoverage. The PRO reviews the hospital records of patients to whom Notices of Noncoverage are issued at the request of the patient, their representative, or the hospital. They are also involved in all such cases in which the patient receives care and becomes liable for out-of-pocket payment after the effective date of the notice. For example, a hospital or a managed care plan must issue such a notice (with the concurrence of the physician responsible for the hospital care) when it determines that hospital care is no longer necessary for a Medicare enrollee. The notice must include the reason why inpatient care is no longer needed, the effective date of the enrollee's liability for continued inpatient care, and the enrollee's appeal rights.[8]

If the beneficiary or their representative thinks that continued hospital care is necessary, they may request the PRO to review the hospital or managed care plan's notice. The beneficiary is not liable to pay for care received during the review if the beneficiary is in the hospital and makes a timely request for a PRO review.

In 1996-97, KePRO completed 61 such reviews for individuals who were hospitalized at the time of the review. The organization did not agree with the hospital or managed care plan notices in 5 percent of the cases reviewed.

DHHS also relies on the PRO to review questions about the care provided in response to an emergency medical condition. Federal law and regulations include detailed requirements and protocols as to how hospitals and physicians must respond to anyone with an emergency medical condition. (For information, see page 74.) The PRO is responsible for assessing whether the individual involved had an emergency medical condition which had not been stabilized.[9] Such reviews involve care of both Medicare and non-Medicare beneficiaries.

Medicare's Quality of Care Surveillance System. Medicare uses a profiling system to identify potential quality of care problems known as the Quality of Care Surveillance System. All Medicare enrollees in the fee-for-service system are included in this quality surveillance system.[10] HCFA provides certain data from the surveillance system to the Peer Review Organizations.

The PRO uses such data to monitor patterns, trends, and variations in health care among Medicare beneficiaries. It also uses the data to identify sentinel events or clusters of events that may indicate less than optimal care and identify, prioritize, and act upon opportunities for improvement.

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[8]See Department of Health and Human Services, Health Care Financing Administration, Center for Health Plans and Providers, Medicare Management Care Operational Policy Letter 71, issued May 19, 1998.

[9]State survey agencies are also involved in complaint investigations involving hospital provision of emergency care and transfer of patients who are not medically stable.

[10]Medicare enrollees in managed care are not included in the Medicare Quality of Care Surveillance System. On July 1, 1995, just under two million Pennsylvania Medicare enrollees were included in the Medicare Quality of Care Surveillance System.

Included in the Medicare quality surveillance data are measures such as:

- Hospital readmissions within 2 and 30 days of discharge.
- Hospitalization within 2 days of non-diagnostic ambulatory surgical procedures.
- Venuous thrombosis or pulmonary embolism following selected surgical procedures.
- In-hospital mortality following elective inpatient procedures.

DHHS recognizes that such data are only screens and that additional analysis is necessary to interpret such data. PROs, therefore, work cooperatively with hospitals and physicians to interpret and apply the findings.

Evidenced-Based Quality Improvement Projects. DHHS sponsors quality improvement projects. Such projects involve the PROs and Medicare providers (including Medicare managed care organizations). These projects focus on improving mainstream care, measuring the processes and outcomes of care, and evaluating and acting upon project results.

For example, all hospitals in Pennsylvania in recent years participated with KePRO in the Cooperative Cardiovascular Project (CCP). CCP is a national effort to improve the quality of care for Medicare beneficiaries who have had acute myocardial infarctions (heart attacks). The project used science-based quality of care indicators based on guidelines published by the American College of Cardiology and the American Heart Association.

State Survey Agencies. The Medicare Program uses state licensure agencies to assist in assuring quality of care. In Pennsylvania, the Department of Health (DOH) serves as DHHS's State Survey Agency. DHHS has entered into an agreement with DOH to serve in this capacity. The services covered in DHHS's agreement with DOH include:

- hospitals,
- skilled nursing facilities,
- home health agencies,
- providers of outpatient physical therapy and/or speech pathology services,
- comprehensive outpatient rehabilitation facilities,
- hospices,
- independent laboratories,
- suppliers of portable X-ray services,

- end-stage renal disease treatment facilities,
- chiropractors,
- rural health clinics,
- physical therapists in independent practice, and
- ambulatory surgical centers.

Voluntary National Accreditation Organizations. The DHHS utilizes certain voluntary national accreditation organizations, in addition to state departments of health, to assist it in determining whether certain health care facilities are in compliance with Medicare quality of care standards.

The Social Security Act permits DHHS to utilize the on-site surveys of voluntary national accreditation organizations to determine if certain health care providers meet Medicare's conditions of participation. For example, the act permits DHHS to use the JCAHO accreditation survey to determine if a hospital complies with Medicare's standards. The act, however, does not permit the DHHS to use accreditation organization surveys where Medicare's standards and survey procedures are more stringent than those of the voluntary accrediting organization.[11] Exhibit 1 lists the national voluntary accreditation organizations currently approved by DHHS for general hospitals, ambulatory surgical centers, and home health agencies.

Medicare does not require providers to undergo voluntary accreditation. If they seek voluntary accreditation, they are not required to submit their voluntary accreditation to DHHS. Providers, however, must submit the findings from their voluntary accreditation surveys to DHHS if they intend to use their voluntary accreditation for purposes of determining compliance with Medicare's standards.

Most Pennsylvania hospitals choose to have their voluntary accreditation surveys provided to DHHS to determine if they meet Medicare's standards. No freestanding ambulatory surgical center in Pennsylvania has used an accreditation survey to demonstrate compliance with Medicare's standards. Only six or seven of Pennsylvania's over 360 home health agencies have done so.

Medicare has a defined public process for determining if national voluntary accreditation standards and processes are at least as stringent as Medicare's. In order for DHHS to utilize the surveys of accreditation agencies for determining compliance with Medicare's standards, the DHHS must review applications from such organizations. These organizations must demonstrate that their standards and their survey processes meet or exceed Medicare standards for participation and processes for surveying for compliance. The DHHS publishes notices and receives

[11] 42 U.S.C.A §§1395bb.

public comments when such organizations apply for "deemed" status. The DHHS also publishes the results of its reviews and responses to public comments in the *Federal Register*. Such notices include information about additional standards and/or process requirements that must be met by the accreditation organization and providers using their accreditation surveys to demonstrate compliance with Medicare's standards.

None of the voluntary accreditation organizations shown in Exhibit 1 has been determined to meet all of Medicare's standards and process requirements. In the case of general hospitals, voluntary accreditation surveys are used by DHHS to determine compliance with most Medicare standards. However, DHHS relies on agreements it requires between hospitals and Peer Review Organizations (PROs) to demonstrate hospital compliance with Medicare's utilization review standards.

Exhibit 1

Voluntary National Accreditation Organizations Used by Medicare

General Hospitals

Joint Commission on Accreditation of Healthcare Organizations
American Osteopathic Association

Ambulatory Surgical Centers

Joint Commission on Accreditation of Healthcare Organizations
Accreditation Association for Ambulatory Health Care

Under Review as of June 1998
American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

Home Health Agencies

Joint Commission on Accreditation of Healthcare Organizations
Community Health Accreditation Program

Source: Developed by LB&FC staff from the U.S. Department of Health and Human Services notices published in the Federal Register.

DHHS requires state survey agencies to conduct first time on-site surveys of hospital units such as psychiatric and rehabilitation units. JCAHO and AOA surveys have not been deemed to meet all Medicare standards for such units. After the initial on-site survey, DHHS requires hospitals with such units to annually

self-attest that they remain in compliance with Medicare's standards. It further requires its state survey agency to conduct on-site verification surveys of a 5 percent sample of such units.

Voluntary national accreditation organization standards and survey processes for ambulatory surgical centers and home health agencies are also not in total conformity with Medicare's standards and processes. Providers seeking to use such surveys to demonstrate compliance with Medicare's standards must agree to standards and survey process requirements not part of the voluntary accreditation standards or processes. For example, accreditation organization surveys used to demonstrate compliance with Medicare home health agency requirements must be unannounced. Survey findings must also be publicly disclosed.

Medicare has a process to assure voluntary accreditation organizations are properly assessing compliance with its health and safety standards. DHHS requires its state survey agency to conduct validation surveys for 5 percent of the accredited hospitals.

DHHS can also refer complaints to the state survey agency for validation surveys. Hospitals found to have significant health and safety deficiencies through such surveys are no longer deemed to be in compliance with Medicare's requirements for participation. The facility must develop a detailed corrective action plan agreed to by the state survey agency. The agency then monitors the facility for compliance with the corrective action plan. If the plan is not implemented, the state survey agency then initiates implementation of HCFA's provider termination process.

DHHS also requires accreditation organizations to notify HCFA in writing within ten days of a deficiency identified in any accredited organization which poses an immediate jeopardy to the organization's patients or the public.[12] In proposed regulations, DHHS has announced that it plans to revise the time frame from 10 days to 3 days.[13]

3. State Efforts

Licensing Health Care Practitioners and Facilities. Pennsylvania requires individual practitioners and certain health care facilities to be licensed. State licensure boards within the Department of State are responsible for licensing individual practitioners such as doctors and nurses. DOH is responsible for licensing health care facilities such as hospitals, freestanding ambulatory surgical facilities, and home health agencies.

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[12]42 CFR §488.4(b)(3)(vii).
[13]Federal Register, June 26, 1998, Volume 63, Number 123, p.34999.

Licensure requirements for individual practitioners typically are the cornerstone for assuring quality of physical health care. State licensing boards establish criteria for initially awarding and renewing individual practitioners' licenses. They also require such practitioners to limit the care they provide to their authorized scope of practice.

Medicare certification and state licensure standards for health care facilities typically defer to the state boards' licensure and authorized scope of practice requirements. Exhibit 2 lists relevant state and federal requirements for state licensure for individual practitioners and for providing care within their permitted scope of practice.

Exhibit 2

State Licensure and Scope of Practice Requirements

Health Care Provider	Individual Practitioner Licensure Requirement	Scope of Practice Requirement
Individual Practitioners		
Physicians	63 P.S. §§422.25,422.38; 42 CFR Ch.IV §466.1	49 Pa. Code §16.61(a)(3)
Registered Nurses	42 CFR §482.23(b)(2)	49 Pa. Code §21.18(a)(1)
Health Care Facilities		
General Hospitals	28 Pa. Code §103.1; 42 CFR §§482.11(c), 482.22(b), 482.23(b)(2)	28 Pa. Code §§107.12(2), 107.12(5), 107.12 (6)(iii), 107.12(11), 107.12(14) and 107.12(16); 42 CFR §§482.22(c), 482.23(b)(5), 482.23(c)
Ambulatory Surgery Facilities	28 Pa. Code §§551.3, 553.3(1); 42 CFR §416.42	28 Pa. Code §§555.2, 555.3(b); 42 CFR §§416.45, 416.46
Home Health Agencies	28 Pa. Code §601.6; 42 CFR §§484.4, 484.12(a), 484.14(e)	28 Pa. Code §601.32(d); 42 CFR §§484.12(a), 484.18(b), 484.36(c)(2)

Source: Developed by LB&FC staff from cited sources.

State licenses for health care practitioners and facilities are issued for specific time frames. They must be renewed periodically for such practitioners and facilities to continue delivering health care in Pennsylvania. Exhibit 3 identifies Commonwealth agencies responsible for licensing health care practitioners and facilities. It also identifies the specific time frames for which licenses are issued.

Exhibit 3

State Agencies Responsible for Licensing Selected Health Care Practitioners and Facilities

Type of Health Care Provider	Commonwealth Licensure or Approval Entity	Period of Approval
Individual Licensed Practitioner		
Physicians	State Board of Medicine[a]	2 years
Registered Nurses	State Board of Nursing	2 years
Health Care Facilities		
General Hospitals	Department of Health	2 years
Ambulatory Surgical Facilities	Department of Health	1 year
Home Health Organizations	Department of Health	1 year

[a]Throughout this report we have referred to physicians and reported information for the State Board of Medicine. We recognize that the State Board of Osteopathy is responsible for the licensure of osteopathic physicians. To simplify the presentation of information, however, we have focused on the requirements of the State Board of Medicine for medical doctors. Where substantive differences in the requirements of the State Board of Medicine and the State Board of Osteopathy occur we have noted them for the reader.

Source: Developed by LB&FC staff based on relevant state statutes and regulations.

State quality assurance standards for individual practitioners and health care facilities are found in state regulations. In establishing state standards, state agencies often turn to national standard setting organizations and national standards.

The State Board of Medicine, for example, recognizes the quality standards of national organizations responsible for accrediting medical schools and examining physicians for licensure.[14] It does this by requiring graduation from nationally accredited schools and successful completion of national testing. Those seeking a license to practice medicine in Pennsylvania, therefore, must meet the standards of such national organizations even though such standards are not explicitly detailed in state law or regulation. When national training and competency standards for physicians change, these changes are immediately reflected in state standards.

Federal requirements for individual practitioners also influence state licensure standards. For example, physicians (and other individual practitioners and health care facilities) administering and dispensing controlled substances must

[14]A comity exists between the Board and the Accreditation Council for Graduate Medical Education (ACGME) of the American Medical Association. The Federation of State Medical Boards, Inc. has a contract with the National Board of Medical Examiners to develop the exam for the federation. The Board recognizes this examination and the passing score is determined by the National Board of Medical Examiners.

register with the Drug Enforcement Administration in the US Department of Justice. They must also comply with relevant requirements of the federal Controlled Substance Act of 1970. These requirements are incorporated by reference into the state practice standards for physicians.

The Commonwealth's Health Care Facilities Act[15] instructs the Department of Health to consider federal certification standards such as Medicare's certification standards when developing state licensure regulations. The act also directs the Department to consider the standards of national voluntary accrediting agencies. The act, however, does not specifically require facilities to meet these standards. The federal certification standards and national accreditation standards are typically reflected in state standards only if they are explicitly specified in state regulations.

Many of the quality assurance standards now included in state regulations for general hospitals, ambulatory surgical facilities, and home health agencies are the same as Medicare's. In some instances state licensure standards are more comprehensive than Medicare's standards. In others, Medicare's standards are more stringent.

State regulations for general hospitals are somewhat more encompassing than Medicare's certification standards. Medicare's standards, for example, do not address newborn care. However, state licensure standards for general hospitals tend to closely mirror Medicare's standards. State licensure standards and Medicare certification standards for ambulatory surgery facilities are almost identical. State licensure standards for home health agencies are not as stringent as Medicare's standards. The state's requirements for training of home health aides, for example, are not as rigorous as Medicare's. Agencies seeking Medicare reimbursement must meet the Medicare standards.

The Pennsylvania Department of Health also uses the Medicare's certification and voluntary accreditation agencies to assist in its licensing of certain health care facilities. Since 1986, for example, the Department has relied on Medicare's certification of home health agencies to deem such agencies in compliance with state licensure standards. It is able to do this because Medicare's standards and processes for such facilities are more stringent than state standards. Therefore, any home health agency meeting Medicare standards would be in compliance with state standards.

In the early 1990s, Pennsylvania initiated efforts to utilize the surveys of voluntary national accreditation agencies in its licensure of certain hospitals. The Health Care Facilities Act indicates the Department may rely on such reports to the extent it determines the accreditation agency standards to be similar to state regulations. The act permits use of accreditation organizations surveys only for

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[15]35 P.S. §448.101 et seq.

providers that have demonstrated full compliance with state licensure requirements for at least two years and for providers agreeing to direct their national voluntary accreditation survey to DOH. (This later requirement was necessary because voluntary accreditation reports with survey findings for hospitals are not publicly disclosed by the accreditation organization or by Medicare.) The provider must also permit the DOH as the state licensure agency to inspect areas or programs not covered by the accreditation agency inspection and where the report discloses more than minimal violations of department regulations.

In 1993, DOH entered into an agreement with the JCAHO to begin to utilize JCAHO surveys in the state licensure process for hospitals. According to JCAHO, 44 states (including Pennsylvania) recognized its accreditation program for hospitals as of June 1, 1998. The extent of recognition varies by state, agency, accreditation program, and type of accreditation, according to JCAHO. For example, California recognizes JCAHO's hospital accreditation program, but only through a joint survey process.

As shown in Exhibit 4, the Department's 1993 agreement with JCAHO provides for several important safeguards to permit the Department to continue to assure patient safety and quality of care.

Approving Managed Care Organizations. Health Maintenance Organizations (HMOs) must have certificates of authority, jointly issued by the Commissioner of Insurance and the Secretary of Health, to operate in Pennsylvania. The Secretary determines whether the applicant has the potential to assure the availability, accessibility, and quality of health care services provided on a prepaid basis. The Commissioner determines whether the applicant has a reasonable plan to operate an HMO in a financially sound manner. HMO certificates of authority do not have to be renewed.

The Insurance Company Law, as amended, requires risk-assuming preferred provider organizations (PPOs) to have the approval of the Commissioner and the Secretary before they commence operations in Pennsylvania. Each department is to notify the PPO that its application has been approved or disapproved. The application is deemed to have been approved by a department if the PPO has not received such notice within 60 days of submitting a complete application.

Risk-assuming PPOs must demonstrate that they have adequate working capital, a state license as an insurer or a fraternal benefit society, or a certificate

Exhibit 4

The Department of Health and the Joint Commission on Accreditation of Health Care Organizations 1993 Agreement

JCAHO with the consent of participating hospitals:

- Provides the Department with any and all reports related to full or focused accreditation surveys conducted at participating hospitals immediately following the provision of the report to the hospital.
- Provides the Department all pertinent communications and documents from the participating hospitals concerning the JCAHO survey and any deficiencies cited including written progress reports that detail the methods of correcting deficiencies identified in the accreditation surveys.
- Submits information to the Department on accreditation decisions, conditional accreditation decisions, or decisions not to accredit within 72 hours, and on any serious situations that may jeopardize the health and safety of patients or the public identified during an inspection process within 72 hours of the inspection.
- Permits survey reports and correspondence regarding the accreditation decisions used as a basis to continue to license hospitals to be considered public documents.

Further, the Agreement stipulates:

- The Department does not relinquish any of its authority to independently inspect any hospital for any reasons for state licensure purposes by using JCAHO's reports.
- Hospitals must maintain compliance with the Department's licensure regulations at all times.
- Enforcement of state licensure laws and regulations are the sole responsibility of the Department.
- The Department agrees to take into consideration the results of the JCAHO survey conducted at participating hospitals and use the JCAHO survey in place of licensure survey when the Department is convinced that the facility meets minimum state licensure requirements based on the JCAHO survey.
- The Department agrees to coordinate hospital licensure dates with JCAHO accreditation dates when accreditation inspections are used by the Department in lieu of state inspections.

Source: Developed by LB&FC staff from the 1993 Agreement.

indicating they are regulated under the federal Employee Retirement Income Security Act (ERISA) of 1974.[16] Their enrollee literature must contain adequate coverage disclosures. They must have adequate quality and utilization controls and a formal grievance system to address any risk-sharing arrangements or provisions that might lead to undertreatment or poor quality care.

Non-risk-assuming PPOs must have their applications approved by the Insurance Commissioner, who notifies the applicant and the Secretary of Health if an application is approved. The Commissioner notifies the applicant of a decision to disapprove an application.

A DOH policy statement[17] holds HMOs accountable for assuring the quality of care delivered through subcontracts with integrated delivery systems (IDSs). The policy statement calls for HMOs to have their contracts with IDSs and their plans for monitoring delegated responsibilities reviewed and approved by the Department.

Medical Malpractice Insurance. In the United States the courts have played a role in promoting quality health care. Patients may resort to private legal means when they believe that the quality of health care they received has fallen below acceptable practice in their communities. This occurs largely through medical malpractice suits.[18] One result of malpractice litigation has been the development of risk management programs by medical malpractice insurers.

In Pennsylvania certain health care providers must have medical malpractice insurance in order to deliver care. For example, if more than 50 percent of the physician's practice is in the Commonwealth, the physician currently must show proof of a total of $1.2 million per occurrence and $3.6 million annual aggregate coverage in basic and excess coverage. The excess coverage must be obtained from the Commonwealth's Medical Professional Liability Catastrophe Loss Fund. Physicians who conduct less than 50 percent of their practice in the Commonwealth are

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[16]The ERISA provides the basis for a complementary system of regulation in which the federal government oversees employers' health benefit plans while the states regulate commercial insurers. Pennsylvania exempts employer-funded plans subject to the ERISA from managed care regulations if such plans provide benefits only for employees.

[17]Pursuant to the Commonwealth Documents Law, 45 P.S. §1101 et seq., and court decisions pursuant to that law, statements of policy do not have the force of laws or regulations but are merely interpretations of general applicability. Central Dauphin School District v. Pa. Department of Education, 147 Pa. Commw. 426 (1992).

[18]Throughout this report we use the term "medical malpractice." As we noted in the LB&FC's *Study of the Medical Professional Liability Catastrophe Loss Fund*, the term "medical malpractice" is not synonymous with negligent medical care. "Negligence is not the only basis for a medical malpractice claim in Pennsylvania. For example, the Pennsylvania Supreme Court has ruled that claims may be based on lack of informed consent, notwithstanding the care exercised. The Federal District Court in Philadelphia also held that a hospital can be liable on a strict liability theory. In that case, the court found that the hospital could be liable for 'selling' an unsafe product. . . . The Pennsylvania Supreme Court has also ruled that plaintiffs are not required to prove that the medical care provided directly caused their injuries. If a health care provider's action may have simply increased the risk of harm that actually occurred, it is up to a jury to decide whether the care constituted a substantial factor contribution to the injury sustained."

required to have $300,000 per occurrence and $900,000 annual aggregate in medical malpractice coverage.

The Department of Insurance regulations require medical malpractice insurance companies to incorporate risk management plans in policies issued after January 1, 1978. Such programs help promote quality of care. PMSLIC's (the Pennsylvania Medical Society Liability Insurance Company) risk management plan, for example, requires physicians it insures to meet a continuing education requirement equivalent to the requirement of the Pennsylvania Medical Society (PMS). PMS requires 150 hours of continuing medical education in each three-year period immediately following the date the physician becomes a member.[19] The PHICO Insurance Company also has requirements for continuing medical education.

Exhibit 5 shows those health care providers required by the state to show proof of medical malpractice insurance to provide care in Pennsylvania. Those for whom there are no state requirements may obtain such coverage on a voluntary basis, and thus be exposed to risk management programs designed to promote appropriate health care.

Exhibit 5

Health Care Providers Required to Carry Medical Malpractice Insurance

Type of Health Care Provider	State Requirement for Medical Malpractice Insurance
Individual Licensed Practitioner:	
Physicians	Yes
Registered Nurses	No
Health Care Facilities:	
General Hospitals	Yes
Ambulatory Surgical Facilities	No
Home Health Agencies	No

Source: Developed by LB&FC staff based on 40 P.S. §1301.103.

Pennsylvania does not require managed care organizations to purchase medical malpractice insurance. Texas is currently the only state with a law holding

[19]PMS requires that at least 60 hours of reported continuing education be Category 1 continuing education credits. Category 1 includes a CME activity sponsored or jointly sponsored by an organization accredited for continuing medical education by one of the state medical associations or by the Accreditation Council for Continuing Medical Education (ACCME) and designated as Category 1 by that organization. It also includes a medical specialty fellowship. A fellowship taken in the United States is credited at 50 credit hours per year for full time fellowship training. Similar credits can be awarded for a full academic year of education leading to an advanced degree other than an MD degree in a medically-related field.

HMOs liable for health treatment decisions. Fifteen other states, however, have banned HMOs from including "hold harmless" clauses in their contracts with providers. Such clauses permit HMOs to shift all liability for care to their contracted providers. In some states, like Pennsylvania, the courts are determining the liability of managed care plans before legislatures address the issue.

The Pennsylvania Superior Court, for example, in a 1998 decision held that the theory of corporate negligence can apply to HMOs in medical malpractice suits. The courts previously had applied the theory only to hospitals. The case involved the death of a premature baby whose mother had sought help from her managed care plan because her physician was refusing to consider premature labor as the source of her discomfort. She spoke with plan representatives three times before an in-house orthopedic physician sent her to a participating hospital for a back examination. There she gave birth to the baby, which died two days later because of its severe prematurity. The court found the HMO liable for not acting in a medically reasonable manner when it interjected itself into the rendering of a medical decision.

The Superior Court also reversed the dismissal of a malpractice complaint against an HMO that had claimed exemption under the federal ERISA in 1992. The court ruled that the HMO, which was marketing insurance coverage to employers, did not meet the test of an ERISA plan.

In December 1998, the Pennsylvania Supreme Court cited a U.S. Supreme Court decision when it placed limits on ERISA preemption. The Pennsylvania court was not willing to interpret preemption as limitless, particularly if it would preempt state laws providing for safe medical care and negligence claims.

A concurring opinion cited the distinction between individual medical decisions and administrative decisions affecting an ERISA plan. The ERISA concerns the "quantum" of benefits promised by the plan. The silence of the act regarding the quality of care implies congressional intent to let the states continue regulating quality in their traditional manner, according to the concurring opinion. The HMO for the ERISA plan filed a petition for reconsideration in January 1999.

Health Care Cost Containment Council.[20] To promote quality health care, government agencies also gather and disseminate information about the effectiveness and appropriateness of health care practices. In Pennsylvania, the Health Care Cost Containment Council issues reports that profile hospitals and in some

[20]The Pennsylvania Health Care Cost Containment Council is an independent state agency responsible for addressing the cost and quality of health care in Pennsylvania. The Council promotes health care competition through the collection, analysis, and public distribution of uniform health care cost and quality information. The Council consists of the Secretaries of Health, Insurance, and Public Welfare and representatives of business, labor, consumers, hospitals, physicians, HMOs, and other nonprofit and commercial insurers.

instances certain physicians. The most recent report also included information on health insurers and managed care organizations. According to the Physician Payment Review Commission,[21] profiling is an analytic tool that

> . . . uses epidemiological methods to compare practice patterns of providers on the dimensions of cost, service use, or quality (process and outcome) of care. The provider being profiled can either be an individual practitioner, a group of practitioners, or a health care organization, such as a hospital or health maintenance organization (HMO). The provider's pattern of practice is expressed as a rate--some measure of utilization (cost or service) or outcome (functional status, morbidity, or mortality) aggregated over time for a defined population of patients under the provider's care. The number of [claims for a specific procedure] an internist submits to the Medicare program per 100 Medicare patients he or she sees per year is an example of a profiling rate.

Comparisons in profiling are made by relating utilization or outcome rates for a particular provider to a norm. The norm can either be a rate derived from the practice patterns of other similar providers, called a practice-based norm, or a rate that would be expected if providers followed an accepted practice guideline, called a standard-based norm. Practice-based norms do not necessarily reflect appropriate care. Such norms may be too high or too low. Standards-based norms reflect appropriate care to the extent that they are based on practice guidelines grounded in sound scientific evidence.[22]

Profiling may be used in quality assurance programs to assess provider performance and in utilization review. It can play a role in targeting potential quality problems, and can also be used to help identify providers who may not meet science-based standards of care. With such information quality improvement initiatives can be implemented and the quality of care improved.

The Council's published reports include risk-adjusted outcome performance measures for a limited number of medical procedures and conditions. The reports rely on practice-based norms. They provide important quality assurance information on a limited number of procedures such as coronary artery bypass graft surgery (CABGS) reports and heart attacks. (For more detailed information on these reports see Appendix C.)

In addition to the Council's published reports, health care providers can also access the Council's data for quality improvement projects. Many health care providers and purchasers use the Council's data. The Hospital and Healthsystem Association of Pennsylvania (HAP), for example, has used the Council's data to

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[21]In 1986 Congress established the Physician Payment Review Commission to advise it on Medicare policies. The Balanced Budget Act of 1997 combined the Physician Payment Review Commission and the Prospective Payment Assessment Commission to form the Medicare Payment Advisory Commission (MedPAC).
[22]PPRC, *Physician Payment Review Commission Annual Report to Congress 1992*, Washington, DC, pp. 246-247.

develop *The Dartmouth Atlas of Health Care in Pennsylvania* which provides information on diagnosis and treatment of common medical conditions throughout the state. Such information can assist providers in identifying areas for improvement and developing evidenced-based quality improvement projects.

Other State Efforts. State agencies, such as the Departments of Aging and Public Welfare, attempt to provide for quality care by including quality of care related requirements in their contracts when they purchase health care services. The Department of Public Welfare (DPW), for example, has established quality assurance standards in its contracts for HealthChoices, which is a Medicaid mandatory managed care demonstration being carried out in select counties in Pennsylvania. We discuss DPW's efforts to assure quality of care in Chapter IV.

C. Changes in the Delivery and Financing of Health Care

Managed care has changed traditional provider-insurer relationships. Traditional fee-for-service systems largely remove health insurers from medical decisions as to whether or not a patient needs a covered service. The Nonprofit Professional Health Service Corporation Act of 1972, 40 Pa.C.S.A. §6301 et seq., a Pennsylvania statute, expressly prohibits entities such as Blue Shield plans from restricting methods of diagnosis or treatment. No such prohibition, however, exists for managed care organizations. Moreover, managed care plans can limit the number of providers who offer care through their plans—unlike traditional fee-for-service plans which include any provider meeting established standards and willing to participate.

Managed care plans often rely on primary care physicians to act as gatekeepers for services that used to be directly accessible to their patients. Patients have traditionally relied on physicians to educate them about the appropriate treatment for their conditions and to act as advocates for coverage of necessary care. Managed care organizations' contract language, power in the health care market place, and ability to terminate physician contracts can bring pressure to bear on physicians to modify their practice patterns or discussions with patients. When this occurs, providers might be less inclined to advocate for their patients.

HMOs have the advantage of providing ready access to primary physician care. Indemnity plans have the advantage of ready access to speciality care. Under the traditional fee-for-service method physicians are compensated for services they render. Such an indemnity system might encourage physicians to provide services of uncertain value as long as they have reason to believe the patient or an insurer will pay for the services. Managed care capitation systems turn the fee-for-service incentives around. The managed care plan pays its physicians a set amount for each patient it assigns to them, regardless of how many services they provide or how much time they spend with patients. Physicians can increase their revenues

by accepting more patients. If the larger patient load increases the demand for services, the incentive to control costs becomes stronger, particularly for physicians whose patients need expensive services.

Plans have used various payment systems and incentives to influence practice patterns. One method involves withholding a portion of the physicians' payments during the year. The plan determines whether the costs of referrals and hospitalizations have exceeded or stayed within its budgetary allocation before distributing the withheld payments. The amount, if any, to be distributed depends on the size of the budget deficit or surplus.

The physicians might share the risk equally for the entire plan or might be paid on the basis of their individual utilization patterns. In either case, the withheld funds create an incentive to limit services delivered outside the primary care physicians' offices. Plans have established stop-loss thresholds for individual cases to moderate the withholding effect.

Risk-sharing arrangements and other financial incentives serve to remind providers that managed care plans view low hospitalization and referral rates favorably. Because of their potential to compromise quality of care, the Physician Payment Review Commission proposed restricting payment methods as early as 1989, when it recommended that the HCFA require Medicare and Medicaid plans to limit risk assumption by individual physicians. It also recommended requirements for disclosure of information on risk-sharing arrangements to help beneficiaries identify and prevent inappropriate care based on financial incentives.[23]

Health care providers statewide have responded to managed care growth and employer interest in managed care products by forming provider networks. Some providers "rent out" their networks to insurers and self-insured employers to provide health care and various health insurance products.

Health care provider networks take many different forms. They may consist of a single hospital and physician group or multi-hospital and physician groups, along with nursing homes, home health agencies, and other providers. Some provider networks assume part of the insurer's financial risk; others do not.

For example, PrimeSource Health Network consists of eight hospitals and approximately 1,400 primary care physicians and specialists in central Pennsylvania. Six of the hospitals, including a three-hospital system, are the principal owners of the network, which contracts as a non-risk-bearing integrated delivery system (IDS) for HMOs purchasing health care on behalf of their enrollees. It also

[23]In the *Federal Register*, March 27, 1996 (VOL 61, No 60), HCFA published Medicare and Medicaid Program requirements for physician incentive plans.

contracts as a non-risk-bearing preferred provider organization (PPO) for health insurance carriers and employers.

PrimeSource offers a fee schedule for employers' self-funded plans, and the employers determine which services they will cover. Their employees have access to all network providers but must request prior authorization from PrimeSource for designated elective or non-emergent inpatient services. PrimeSource does not become involved in decisions as to whether or not an employer's plan covers specific services, according to its chief executive officer.

Although PrimeSource does not assume financial risk as a network, its providers may assume risk if they choose to participate in an IDS arrangement between PrimeSource and an HMO. The HMO determines the payment system and the amount of risk the providers must assume. The enrollees in such plans have access to all network providers who choose to participate, according to the chief executive officer.

Some provider networks have developed into risk-assuming entities. The University of Pittsburgh Medical Center (UPMC) brought together specialty and community hospitals to form the Tri-State Health System, which now extends from the Pittsburgh metropolitan area to Johnstown. The medical center acquired an HMO, Best Health Care of Western Pennsylvania, in 1997 and changed its name to the UPMC Health Plan. The acquisition has enabled the UPMC Health Plan to emerge as a competitor with Highmark Blue Cross and Blue Shield.

Insurers themselves are becoming more directly involved on the clinical side of health care delivery. Highmark, for example, acquired some 300 medical practices in western Pennsylvania. It has also offered financial support to the West Penn Health System, which has proposed a merger with Allegheny General Hospital and three of its AHERF affiliates. The UPMC Health Plan was opposing the merger as of April 1999.

The changes in the current health care environment, the increasing financial pressures placed on providers, and the increasing integration of health care delivery and financing raise concerns about the continued provision of quality health care. Such changes and concerns have caused providers, consumers, and insurers to ask whether there is a need for greater state involvement to assure the provision of quality health care.

D. Conclusions

1. The Commonwealth Does Not Have an Effective Way of Monitoring How Changes in the Delivery and Financing of Health Care Affect Quality of Care or Disseminating Information to Help Consumers Cope With These Changes

Several state agencies are involved in helping to assure the quality of health care in the Commonwealth. They include the state licensing boards, the Departments of Health and Insurance, and the Health Care Cost Containment Council. The Departments of Aging and Public Welfare are also involved in assuring quality of care through contracting when purchasing health care. Because of their limited focus and staffing, however, broader system issues that have the potential to affect quality of care are not being addressed. Such issues include how the termination of the Certificate of Need program has affected teaching hospitals and hospitals serving high proportions of low-income patients, how managed care is affecting critical-access rural hospitals, and how new arrangements for financing health care are affecting its quality.[24]

The Department of Health, for example, surveys hospitals and publishes a directory of hospitals and ambulatory care facilities. It does not, however, routinely monitor or collect information on the number of health systems and provider networks developing in the Commonwealth or publish a directory of such systems. The Hospital and Heathsystem Association of Pennsylvania (HAP) has compiled information on multi-hospital systems. In the summer of 1998, there were 47 multi-hospital health systems in Pennsylvania, up from 41 in 1997. Well over half of all acute care beds and close to three-quarters of all hospital beds in Pennsylvania are now part of multi-hospital health care systems. Neither the Department nor the HAP has a listing of all health care provider networks in Pennsylvania or information on the characteristics of these networks.

In recent years, health systems have begun to purchase physician practices. In Philadelphia, the dominant mode of physician employment now is the group practice within one of four large competing networks (Allegheny,[25] University of Pennsylvania, Jefferson-Main Line and Temple), according to the Leonard Davis

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[24]The Department of Health issued the State Health Improvement Plan in January 1999. The Plan was developed during the last several years with input from the Health Policy Board and three committees. The Plan outlines the basic process by which the Department of Health will work together with community-based health improvement partnerships. It provides information on data available to support community needs assessment and the current health status of Pennsylvanians compared to the United States (such as, age-adjusted death rates, cardiovascular age-adjusted death rates, motor vehicle crash age-adjusted death rates). The Plan does not, however, address issues such as rural health, economically disadvantaged populations, and the community health status impacts of other policy initiatives such as managed care on at risk populations. It does, however, acknowledge the importance of such issues.

[25]Tenet Healthcare Corp. acquired the bankrupt Allegheny network in October 1998. The Tenet network includes 161 physician practices, employing 310 doctors.

Institute of Health Economics.[26] Insurers also have purchased physician practices. No state agency, however, tracks the number of physician practices currently controlled by health systems or insurers in Pennsylvania.

Managed care organizations are playing an increasingly important role in the provision of health care in the Commonwealth. The Departments of Insurance and Health require certain managed care organizations to submit reports to them on an annual basis. The state, however, does not collate, verify, or publish much of the data it gathers from managed care organizations.

Changes in the financing and delivery of health care and potential problems associated with such changes are also brought to the attention of state licensing boards. The State Board of Medicine, for example, has sponsored public meetings about the "corporate practice of medicine" and its implications for quality of care. However, the State Board, despite the expertise and commitment of its members, can only serve as a "sounding board." The Board is not structured to monitor and analytically assess the implications of such practices, identify and analyze alternatives to better assure quality patient care, and make recommendations for change to the Governor and the General Assembly.

Other states have created new agencies or revised the role of existing agencies to begin to better understand and assess the effect of changes in health care delivery and make available information for consumers and policy makers. In 1994 Connecticut established an agency to oversee its health care delivery system and assess and analyze evolving trends in health care. Each year the Connecticut Office of Health Care Access prepares reports on the financial status of short-term acute care general hospitals in the state. The reports contain individual profiles on hospitals. The profiles include corporate organization charts for the parent companies and other organizations with which the hospital is affiliated. The profiles also include information on staffing, uncompensated care, managed care revenues and discounts. Although the Pennsylvania Health Care Cost Containment Council prepares financial status reports on hospitals, its reports do not include the detailed information contained in the Connecticut reports.

California's Office of Statewide Health Planning and Development established a unit to conduct applied health policy research to address issues of cost, quality, and access in an effort to preserve and improve the health of Californians in a managed care environment. The unit has considered hospital closures, openings, and changes in ownership between 1988 and 1997. It is also involved with the state attorney general in antitrust analyses. It assists in answering questions such as how do consolidations affect consumers, and is lower quality a byproduct of larger organizations with greater market dominance.

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[26]Guadagnino, C. The Rise of the Physician Employee, *Physician's News Digest*, July 1997.

Several states have responded to changes in the health care delivery environment by gathering data and placing important quality of care information into the hands of consumers. Maryland, for example, established the Health Care Access and Cost Commission in 1993 to develop and carry out new health care policies, including creation of a non-hospital health care services data base and the development of quality and performance measures for HMOs. Maryland, New Jersey and New York have all published comparative information on managed care organizations in their states.

New Jersey publishes enforcement actions and penalty letters resulting from its licensure inspections and complaint investigations on the Internet. Massachusetts has developed comprehensive physician profiles and made the information available on the Internet.

The Pennsylvania Medical Society has indicated that patients can benefit from the release of appropriate and useful information about physicians. It is working to create a physician profiling system that will be available on the Internet. Its system will initially be voluntary. Its profiles will include education, residency, board certification, medical society membership, office hours, insurance plans accepted, office locations, hospitals where the physician has admitting privilege and languages spoken in the office. Malpractice information will include any suits reported by hospitals or licensure boards and resulting in the loss of hospital privileges or license suspensions. PMS would like to link with the state boards to check for the validity of licenses and any disciplinary actions. PMS has indicated that with the development of its system it would be poised to administer a mandatory reporting system should the General Assembly decide to create such a system for all doctors practicing in Pennsylvania.

2. The Extension of Managed Care Networks Into New Markets Is Threatening the Availability of Community Health Care and Access to Local Ancillary Services

Rural Network Development. The competition for new managed care enrollees has reached beyond the densely-populated markets. Thirteen of the 23 commercially-licensed HMOs in Pennsylvania as of 1996 had enrollees in rural counties,[27] and the growth in rural enrollments was accelerating. The number of enrollees in rural counties increased more than 50 percent while statewide enrollment increased 24 percent between 1995 and 1996, as reported by the Center for Rural Pennsylvania. Market penetration was about 21 percent in rural counties and 40 percent in urban counties.

[27]Counties the U.S. Census Bureau reported as having more than 50 percent rural populations.

The viability of rural providers is being threatened as the competition for new enrollees intensifies. Rural hospitals, in particular, might not have the patient base and the comprehensive services managed care plans want for their networks. As a result, managed care plans might not be interested in contracting with sole community providers.

One approach to developing rural networks limits local providers to a primary care role and directs referrals to urban-based facilities. Although such an approach enables plans to use their established networks, per-capita payments for primary care might not support the continuation of emergency services in the region. More than 400 rural hospitals in the United States closed between 1985 and 1992, years when managed care enrollments were increasing rapidly. The closures represented a 14 percent decrease while the number of urban hospitals increased two percent.

Although only two rural hospitals in Pennsylvania closed during the 1980s, the national trend and the deteriorating financial condition of small rural hospitals prompted the Center for Rural Pennsylvania to compile a list of critical access hospitals in 1992. The Center identified such hospitals by determining where residents of counties at risk sought inpatient care during medical emergencies. Counties at risk had:

- High unemployment rates, low income levels, and large numbers of uninsured residents;
- High percentages of elderly and disabled residents and high rates of injury-related deaths;
- Limited access to medical care.

Pennsylvania had 25 counties at risk and 24 of them were rural, as reported by the Center.[28] It analyzed discharge records collected by the Health Care Cost Containment Council to determine where residents of counties at risk were receiving inpatient care. The analysis produced a list of 33 critical access hospitals.

We reviewed data on the hospitals in five rural northeastern counties classified by the Center as being at risk.[29] These counties have seven of the state's 33 critical access hospitals, six with fewer than 100 beds. A Council financial report shows how five of the six hospitals performed during a three-year fiscal period ending June 30, 1997, which does not reflect the lower Medicare reimbursement levels in the Balanced Budget Act of 1997. One critical access hospital, which relied on Medicare for 66 percent of its net patient revenue, had expenses exceeding its total revenues for the three years.

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[28]The only urban county at risk (Carbon) had a rural population of almost 48 percent.
[29]Bradford, Sullivan, Susquehanna, Wayne, and Wyoming.

Another small rural hospital had a 32-percent decrease in its patient days during the three years. Managed care enrollment, one of several possible factors in such changes, had reached 34 percent in the county by 1996. Statewide, patient days decreased 14 percent for hospitals with fewer than 100 beds and managed care enrollment in rural counties was 21 percent in 1996.

Ancillary Services. Early discharges and reduced access to home health care have increased the pressure on Area Agencies on Aging, which have reported that elderly patients are being discharged without transitional home care or with fewer home care visits than they need.[30] Sometimes plans approve home health nurses but deny home health aides for the same patient. Discharged patients turn to the AAAs, which lack the resources for providing services on demand and can only add the patients' names to long waiting lists.

Disruptions in patient care can have several negative results. AAAs cited the following examples:

- Patients become lost in the system without receiving any care, because they forgo seeking further treatment if their plans require them to have physicians' appointments authorized in advance.
- Patients have to go back into the hospital, where problems are diagnosed after having been overlooked during their previous stays, because primary care physicians under pressure from managed care plans focus on specific complaints instead of a patient' s overall condition.
- Patients show up at emergency rooms, where they receive treatment but are denied admission to the hospital.

Pharmacies also play an important role for many patients, particularly if they are elderly, live in rural areas, or have chronic conditions or special needs. Such patients may depend on their local pharmacists to stock the particular items they need and advise them of alternatives they might want to ask their physicians about. Disruptions in health care can occur if patients lose their access to a familiar pharmacist because of changes in their managed care plan.

Beneficiaries of HealthChoices, the mandatory managed care program for Medicaid recipients, experienced such a disruption in 1998. Keystone Mercy Health Plan announced it would be reducing its payments to pharmacists in southeastern Pennsylvania through Eagle Managed Care, its pharmacy benefits administrator, as of May 1, 1998. Two of the three major pharmacy chains participating in the

[30]Twenty AAAs, representing 57 percent of the state population 65 and over, responded to an LB&FC survey about the effects recent changes in health care delivery and payment systems were having on the quality of care for older persons.

program withdrew from Keystone Mercy. They stopped filling prescriptions for its members, approximately 240,000 Medicaid recipients (about 50 percent of the eligible population in the five-county area). HealthChoices beneficiaries used to having their prescriptions filled at the stores had to go elsewhere as of May 1. Further disruptions occurred during the summer, when two of the other three participating plans became clients of Eagle, a subsidiary of the only major pharmacy chain willing to accept the reduced rates.

Providers of other health care services have expressed concern about how managed care plans limit access to care. Psychologists, dentists, optometrists, chiropractors, and others have cited a need for standardized credentialing[31] and point-of-service options to prevent managed care plans from restricting access to their specialized services. They also have concerns about the frequency of utilization review and the qualifications of reviewers.

3. State Agencies Responsible for Licensing Health Care Facilities Have Separated the Financing and Delivery of Health Care From Their Quality of Care Concerns, Even Though the Two Are Integrally Related

State agencies traditionally consider the financing and delivery of health care as totally separate and unrelated activities. The Pennsylvania HMO Act, for example, illustrates this approach. The Secretary of Health and the Insurance Commissioner have joint responsibility for issuing certificates of authority to HMOs. The Secretary must determine whether an applicant has the potential for making health care services available and accessible on a continuing basis, an effective means for providing prepaid services, and an ongoing quality assurance program.

The Insurance Commissioner has responsibility for solvency issues. The Commissioner must determine whether an applicant has a reasonable plan for operating in a sound financial manner and meeting its obligations to its enrollees. The Commissioner must supervise any rehabilitation, liquidation, or conservation of an HMO, which must be conducted in the same manner and subject to the same laws that apply to insurance companies.

The Secretary of Health may have "free access to all the books, records, papers and documents that relate to the business of the corporation, other than financial." The lack of direct access to financial information might prevent the Department of Health from finding out about mergers, acquisitions, and other changes until they have already begun to affect the continuity and coordination of health care services.

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[31]Credentialing is the process by which a managed care plan determines whether providers are qualified to participate in its network. A typical credentialing process for physicians includes a review of licensure status, hospital privileges, and malpractice history.

The integral relationship between health care delivery and financing was recently illustrated when the Allegheny Health, Education, and Research Foundation, one of the major health systems in Pennsylvania, was forced to declare bankruptcy for its eight Philadelphia area hospitals, medical school and physician practice subsidiary. Several of the hospitals in this system and the medical school are nationally respected. Nevertheless, the quality of care at these facilities can at any point be compromised if, because of their financial difficulties, they do not have essential supplies such as blood products and medications.

Prior to June 1998, the Department of Health did not require a hospital to notify it when the hospital was unable to pay key suppliers and staff. In June 1998 Pennsylvania health care facility licensure regulations were revised to require a health care facility to immediately notify DOH of a situation or occurrence which could seriously compromise quality assurance or patient safety.[32]

At the federal level, the integral relationship between financing of health care and its delivery has been recognized for some time. Medicare has begun to incorporate explicit financial standards into its quality assurance regulations. (These regulations are discussed in more detail later in this chapter.)

In the mid-1980s Congress recognized that how health care is financed can affect the quality of care. It established two commissions, the Prospective Payment Assessment Commission and the Physician Payment Review Commission. It directed them to monitor the effect of changes in Medicare payment policies on the quality of health care and to monitor and assess changes in health care delivery, including the quality of care. It also directed them to report their findings to Congress.

Congress combined the two commissions in the Balanced Budget Act of 1997 (Pub.L. 105-33) to form the Medicare Payment Advisory Commission (MedPAC).[33] In doing so, it expanded the responsibility of MedPAC concerning managed care.

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[32]On June 6, 1998, the Department of Health issued regulations requiring health care facilities to immediately notify the Department when any of the following occur: death due to injuries, suicide, or unusual circumstances; deaths due to malnutrition, dehydration or sepsis; deaths or serious injuries due to a medication error; elopements; transfers to a hospital as a result of injuries or accidents; complaints of patient abuse, whether or not confirmed by the facility; rape; surgery performed on the wrong patient or the wrong body part; hemolytic transfusion reaction; infant abduction or infant discharge to the wrong family; significant disruptions of services due to disaster such as fire, storm, flood, or other occurrence; notification of termination of any services vital to the continued safe operation of the facility or the health and safety of its patients and personnel; unlicensed practice of a regulated profession; receipt of a strike notice; and other events which seriously compromise quality assurance or patient safety. The facility must also notify the Department of the steps taken to rectify the situation.

[33]MedPAC consists of 15 members appointed by the Comptroller General. The membership must include physicians and other health care professionals, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effectiveness research and technology assessment. It must also include consumer representatives. The majority of members cannot be individuals directly involved in provision or management of the delivery of services.

MedPAC is to review and report on a variety of matters related to the Medicare+ Choice program. Such reports, for example, include:

- Mechanisms used to adjust payments for risk and the need to adjust such mechanisms to take into account health status of beneficiaries.
- Development and implementation of mechanisms to assure the quality of care for those enrolled with the Medicare+Choice organizations.

The PA Senate Health and Welfare Committee held hearings to consider the role state government should play in the changing health care environment in late 1998. The hearings were initially prompted by the legislative proposals introduced following the AHERF bankruptcy. Those testifying pointed to the many complex problems involved in assuring accessible quality care for which there are no single or simple solutions.

The Hospital and Healthsystem Association of Pennsylvania and major insurers called for public dialogue among hospitals, government, business, insurers and public interest organizations to address key issues resulting from the changing environment including assurance of accessible, quality health care. Highmark officials recommended the convening of a blue ribbon panel or commission of professionals with expertise and diverse background and interest to formulate a comprehensive plan to address important health care issues.

4. Medicare Dominates Pennsylvania's Quality Assurance Activities for Health Care Facilities to Such an Extent That State Priorities May Not Be Identified and Addressed

Federal Medicare requirements dominate state quality assurance activities for several reasons. Medicare effectively requires state licensure of key health care services as a "pre-condition" for providers to participate in this major health insurance program. Hospitals, for example, must be licensed or approved as meeting standards by the state or local agency responsible for licensing hospitals as part of Medicare's requirements.[34] Similarly, ambulatory surgical centers must be accredited by a national accrediting body or licensed by a state agency.[35] DHHS reimburses state survey agencies, such as the PA Department of Health, for half of the costs of the licensure/certification survey that are common to both Medicare and state licensure.[36]

As a result, most Department of Health professional employees involved in health care facility or home health licensure are funded with federal and state

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[34]42 CFR §482.11(b).
[35]42 CFR §416.26(a)(1).
[36]April 5, 1983, memorandum from the DHHS Office of General Counsel to the HCFA Director of Surveys and Certification concerning the obligation of state licensure program to share in survey costs.

matching funds. They perform activities required by DHHS under its agreement with DOH to serve as its state survey agency. Each year DHHS sets forth its quality assurance priorities for the state survey agency. The federal priorities for state survey agencies are shown in Exhibit 6. If a state seeks to support priorities that differ from federal priorities, it must fund those with state resources.

Exhibit 6

Health Care Financing Administration Key Requirements for State Certification Agencies

(As of June 20, 1998)

State survey agency must:

- Survey all skilled nursing facilities and nursing facilities not later than 15 months after the previous standard survey with a statewide average interval between standard surveys of 12 months.
- Survey home health agencies (HHAs) not later than 36 months after the previous standard survey with the frequency of surveys of HHAs within this 36 month interval commensurate with the need to assure the delivery of quality of home health services.
- Conduct surveys to recertify 10 percent of the non long-term care (NLTC) providers (including non-accredited hospitals, ambulatory surgical centers, psychiatric hospitals, end-stage renal disease facilities, hospices, and other providers).
- Conduct surveys of a 5 percent sample of hospitals accredited by national voluntary organizations.
- Conduct complaint investigations.
- Conduct initial certification surveys.
- Maintain a home health hotline.
- Assist DHHS in implementing outcome-based quality improvement systems for long term care and home health facilities.[a]

[a]This list is not comprehensive. DOH, moreover, as HCFA's state survey agency is responsible for surveying facilities for compliance with health standards and standards for life safety from fire. Life safety standards are not the focus of this report, therefore, and are not included in this exhibit.

Source: Department of Health and Human Services, June 15, 1998, Program Requirements and Regional Allocations for the Preparation of Fiscal Year (FY) 1999 State Activity Plan and Budgets.

The processes DOH utilizes to assure quality of care also demonstrate Medicare's influence on the Commonwealth's quality assurance efforts. DOH as the DHHS state survey agency must apply Medicare's standards and implement surveys in accordance with nationally uniform survey procedures established in federal regulations and federal instructions. Because Medicare certification and state licensure surveys are scheduled to the extent possible to coincide so as to prevent duplication and unnecessary site visits to facilities, Medicare's survey processes influence state processes.

For example, Medicare's regular surveys of hospitals are announced. Medicare inspection surveys of freestanding ambulatory surgical facilities and home health agencies must be unannounced. Regular state licensure inspections for hospitals, therefore, are announced. Routine state licensure inspections of ambulatory surgery facilities and home health agencies are always unannounced.

Until recently, DOH relied almost exclusively on Medicare's complaint procedures in responding to consumer complaints. DOH had not established its own priorities for responding to complaints and their investigation. In July 1998, the Secretary of Health for the first time established Commonwealth policies and procedures. The policy, in part, provides for the unit within DOH responsible for licensure of general hospitals and ambulatory surgical centers to maintain an after-hour complaint system with on-call personnel schedules to guarantee 24-hour/seven-day coverage to respond to all complaints. This had not been done previously because it was not a Medicare requirement. The policy also requires that complaints be referred to the Department of State when allegations involve behavior of licensed health practitioners.

The influence of Medicare on state quality assurance activities is also reflected in the health care services Pennsylvania does not license. Medicare does not have certification standards for private duty agencies, homemaker and chore services, home medical equipment companies, and infusion therapy providers, even though it pays for some of these services. With the increasing provision of medical care outside of hospitals and in the patient's home, some states have decided such providers should be licensed to assure patient safety.

- Eighteen states, including New York, New Jersey, Florida, Texas, and Minnesota, license home care aides, personal care aides, and homemakers.
- Seventeen states, including New York, Maryland, Florida, California, Texas, and Minnesota, license IV therapy in-home service providers.
- Twelve states, including New York, Florida, Maryland, New Jersey, and Minnesota, license temporary staffing services.[37]

5. Nursing Personnel Are Concerned that Quality of Care is Being Compromised

In response to financial pressures, providers have had to control their costs. Personnel account for major costs at inpatient facilities. To control such costs, some hospitals have reconfigured the way they provide services. One way this is done is through use of unlicensed personnel to carry out tasks previously performed by licensed nurses. Specific training requirements currently exist for aides working in

[37]National Association for Home Care, September 1995.

nursing homes because they are required by federal Medicaid standards. Similar requirements, however, are not in place for hospitals.

Other efforts to hold down cost, include working back-to-back shifts and requiring nurses to be on call throughout the night to provide additional coverage. Such practices reduce the need to hire additional nursing staff, but can also lead to compromises in patient care and safety.

The federal Department of Health and Human Services has expressed its concern about hospital reductions in nursing personnel that are occurring nationwide. Medicare (and Pennsylvania licensure) standards do not specify patient to nurse ratios or the number of hours a nurse can be required to work within a given period. They do require, however, that the nursing service have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.[38]

Under this standard a hospital's staffing must reflect the volume of patients, patient acuity, and intensity of the services provided to the patient to ensure desirable patient outcomes. HCFA is proposing to strengthen enforcement of this requirement in proposed regulations with the addition of a new standard. For the first time, Medicare is proposing to require hospitals to publicly disclose their methodologies for assuring adequate nursing staff and evidence of their use.[39]

One reason HCFA is concerned about the availability of adequate nursing staff is that research has demonstrated nurses play an important role in prevention of patient injury during hospitalization as a result of adverse drug events (ADE). An ADE is an injury resulting from medical intervention related to a drug. Such injuries are common in hospitals and many are preventable.[40, 41]

The National Institute of Nursing Research is also sponsoring research to assess the relationship between hospital restructuring and hospital staffing and its

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[38]42 CFR §482.23(b)(1).

[39]*Federal Register*, Vol. 62, No. 244, December 19, 1997, pp. 66749-66750.

[40]See Bates, D. et al. "Incidence of Adverse Drug Events and Potential Adverse Drug Events," *JAMA*, July 5, 1995--Vol. 274, No. 1 and Leape, L. et al, Systems Analysis of Adverse Drug Events," *JAMA*, July 5, 1995--Vol. 274, No. 1.

[41]Bates and Leape and their colleagues reported ADE event rates of 6.5 ADEs and 5.5 potential ADEs per 100 nonobstetrical admissions. In their research they found that of all ADEs, 1 percent were fatal (and that none of these were preventable), 12 percent life-threatening, 30 percent serious, and 57 percent significant. Of the serious and life-threatening ADEs, 42 percent were preventable. Errors resulting in preventable ADEs occurred most often in the ordering and administration of drugs. Leape and Bates and their colleagues report most errors resulting or potentially resulting in adverse drug events occur in the physician ordering and nurse administration stages of drug ordering and delivery. Most of the errors in their study which were intercepted (i.e., prevented from actually taking place) were intercepted by nurses. Overall nurses were responsible for 86 percent of all interceptions.

impact on patient outcomes. Investigators at the University of Pennsylvania are conducting this research, part of which includes several hospitals in Pennsylvania.

6. Quality of Care Standards Are Developed by Several Public and Private Agencies, Which Can Make It Difficult to Formulate Coordinated Policies

No single public or private organization is responsible for assuring quality of care. It is a shared responsibility in which many different groups and organizations perform activities that are often intertwined. When state agencies do not effectively coordinate with one another, the private sector, and federal policies, this can create confusion about state quality assurance standards among those responsible for complying with them. This potentially compromises the quality of care for Pennsylvania citizens. We found several instances, such as those described below, where state agencies did not effectively coordinate their efforts with one another, with relevant federal policies, or with the health care professionals that provide the services.

Policies Regarding CRNPs Functioning as Primary Care Physicians. The Departments of Health and Public Welfare issued policies in which they permit HMOs to use independent Certified Registered Nurse Practitioners (CRNPs) practices to perform almost the full role of an HMO primary care physician and be reimbursed on a capitated basis. These policies, apparently inadvertently, effectively permit these CRNPs to provide basic health services, including all ambulatory physician services. They also permit referrals for medical specialty care. At least three state-certified HMOs now allow CRNPs to serve as PCPs.

These policies, however, conflict with regulations issued by the State Board of Medicine and the State Board of Nursing. These boards are legislatively authorized to jointly regulate the practice of CRNPs performing acts of medical diagnosis or the prescription of medical therapeutic or corrective measures. According to these boards' regulations, such measures can only be performed under the direction of a physician licensed to practice medicine in the Commonwealth.

Nurse Triage Programs. The Department of Insurance permits health insurers to establish administrative programs such as nurse triage programs without consultation with the relevant state licensure boards. Nurse triage programs operate nationwide and their nurses are not always based in the same state as the managed care plan enrollees. Program nurses can make direct referrals to specialists and authorize member use of emergency services based on information provided by plan enrollees. The State Board of Medicine examined one such program in Pennsylvania after complaints were logged. It determined that the program involved the exercise of professional judgment in making diagnoses and recommending treatment measures. Accordingly, the program was involved in the practice of medicine.

For such programs to operate appropriately, the Board determined that the triage nurses must be registered nurses licensed to practice in Pennsylvania and have adequate training. According to the Board, a Pennsylvania physician must be involved in the review and supervision of the actions of the triage nurse; and the triage nurse must act within the authority as delegated by the Pennsylvania physician and be able to timely consult with the physician. In the case of patients who have primary care physicians, the primary care physician must be timely informed of all calls and be involved with the coordination of recommended treatment measures including referrals to specialists, emergency rooms, or directions for self-care.

HMO Complaints and Grievances. When DPW implemented HealthChoices in the Southeast, it required its contracted HMOs to comply with Department of Health policies concerning complaints and grievances. It also required them to comply with federal requirements for fair hearings and appeals. Federal requirements provide Medical Assistance recipients with the right to appeal and a fair hearing when a medical service is denied, reduced, or terminated (see Appendix D). If the recipient is receiving services at the time of the denial or reduction in services and files a timely appeal, he or she has a right to continue to receive service while the appeal is being decided. However, Department of Health policies for complaints and grievances differ from federal fair hearing requirements and can conflict with such requirements. DPW and DOH did not sufficiently anticipate such conflicts and inform the HealthChoices managed care plans about the situation. As a result, disabled individuals were improperly denied medical care and the matter had to be resolved through involvement of the federal courts.

Physician Input Into Key State Quality of Care Standards. Under Act 1996-87, the Secretary of Health is no longer required to be a physician. The act authorizing this change also created the position of Physician General within the Department of Health. Among the duties of the Physician General is to advise the Governor and Secretary of Health on health policy, to participate in the decision-making process of the Department on health-related policies, and to review professional standards and practices related to matters within the jurisdiction of Commonwealth agencies. This position, however, was vacant during much of this study.

The position of Physician General was created only recently and has yet to establish its role and function within the Department. As such, it is especially important that the Department seek other opportunities for physician input into its quality of care regulations.

We found, however, that physicians were not always included in the workgroups the Department established to develop quality of care standards for key medical services after the Certificate of Need Program sunsetted in December 1996. For example, physicians were not designated to serve on the cardiac catheterization, lithotripsy, MRI and Positron Emission Tomography, comprehensive medical rehabilitation inpatient, drug and alcohol inpatient rehabilitation, or emergency

services work groups. Physician participation in these workgroups may not have significantly altered the final product, it would appear only prudent to include physicians when developing regulations in these areas.

Relationships Between Volume and the Quality of Advance Cardiac Service. The Pennsylvania Department of Health did not incorporate volume standards in its facility regulations for advanced cardiac services. According to DOH's June 6, 1998, preamble to its health care facility regulations, there are no definitive volume standards numbers that can be assigned which demonstrate a facility may be providing substandard advanced cardiac care.

This position, however, does not appear consistent with findings of the Health Care Cost Containment Council which in May 1998 reported that surgical volume is directly related to patient outcomes in coronary artery bypass graft surgery. Lower volumes are related to higher than predicted patient mortality. The Council's findings are supported by published peer-reviewed research demonstrating that higher than expected mortality occurs when cardiac procedure volume is low. (See Appendix E.) New Jersey recently incorporated volume standards for advanced cardiac services into its published regulations.

7. State Regulations to Assure Quality of Care Need to Be Reviewed and Updated to Reflect Changes in Health Care Delivery and Financing

The Medicare program has recognized major changes are occurring in health care. It has proposed or recently implemented significant changes to many of its existing quality of care standards. Exhibit 7 identifies recent Medicare proposed or final regulatory changes to assure quality care for health care organizations covered in this report.

Many state regulations to assure quality of health care have not undergone substantial changes in recent years. Exhibit 8 indicates the date of initial state regulations for key health care deliverers in this study and identifies the most recent regulatory changes. Only partial or limited changes have recently been made.

In June 1998, the Department of Health made partial changes to health care facility regulations as a result of the sunset of the certificate of need (CON) program. At the same time, it has also published regulations for requiring unlicensed individuals to adequately distinguish themselves from licensed practitioners. This will permit patients and their families to distinguish between licensed and unlicensed caregivers in health care facilities.

Exhibit 7

Major Changes to Medicare's Standards

Health Care Provider	Date of Proposed or Final Rule	Standard Changed
General Hospitals	Federal Register, December 19, 1997 (Vol. 62, No. 244)	Proposed Rule: Medicare and Medicaid Programs hospital conditions of participation; provider agreements and supplier approval.
Home Health Agencies	Federal Register, March 10, 1997 (Vol. 62, No. 46)	Proposed Rule: Medicare and Medicaid Program conditions of participation for home health agencies.
		Medicare and Medicaid Programs: Use of the OASIS (Outcomes and Assessment Information Set) as part of the conditions of participation for home health agencies.
	Federal Register, January 5, 1998 (Vol. 63, No. 2)	Final Rule: Medicare and Medicaid surety bond and capitalization requirements for home health agencies.
	Federal Register, January 20, 1998 (Vol. 63, No. 12)	Proposed Rule: Medicare Program additional supplier standards.
Managed Care Organizations	Federal Register, June 26, 1998 (Vol. 63, No. 123)	Interim Final Rule: Establishment of the Medicare+Choice Program--Regulations address coordinated care plans (including plans offered by health maintenance organizations, preferred provider organizations, and provider-sponsored organizations) and medical savings account. and private-fee-for-service plans. Includes provisions on benefits and beneficiary protections, quality assurance, participating providers, appeals and grievances, and contracting rules.[a]
	Federal Register, April 30, 1997 (Vol. 62, No.83)	Final Rule with Comment Period: Medicare Program establishment of an expedited review process for Medicare beneficiaries enrolled in health maintenance organizations, competitive medical plans, and health care prepayment plans.
	Federal Register, March 27, 1996 (Vol. 61, No. 60)	Final Rule With Comment Period: Medicare and Medicaid Program requirements for physician incentive plans in prepaid health organizations.

[a]On September 29, 1998, HCFA issued a proposal rule for Medicaid Managed Care Programs. Many of the proposed provisions are similar to those set forth for the Medicare Programs.

Source: Developed by LB&FC staff from cited sources.

Age of Current Pennsylvania Health Care Regulations

Practioner/Health Care Entity	Date Regulations Initially Published	Last Date Revised
A. Individually Licensed Practitioners		
Physicians:		
MDs	1964	1994 - Amended provisions relating to license examination requirements and medical practice by and through business entities (4/9/94).
DOs	1969	1994 - Added requirements for continuing ed. (12/16/94).
Nurses:		
RNs	1951	1993 - Added provisions relating to standards of nursing conduct (4/30/93).
LPNs	1967	1993 - Added provisions relating to continued competency (6/19/93). Also added provisions relating to standards of nursing conduct (4/30/93).
Certified Nurse Practitioners	1977	1987 - Deleted provisions on fees (12/26/87). Amended provisions on renewal of certification (10/19/85).
Certified Nurse Anesthetists	1977	Not Revised.
B. Health Care Facilities		
General Hospitals	1977	1998 - Amended provisions relating to health facility licensure (6/6/98).
Ambulatory Surgical Facilities[a]	1987	Not Revised.
Home Health Agencies	1986	1987 - Corrective admendment published 2/14/87. Regulation not substantially amended.
C. Managed Care		
HMO	1983[b]	1993 - Added provisions on coordinated care organizations relating to worker's comp. Otherwise not amended.
PPO	1987[c]	Not Revised

[a] A facility which provides outpatient surgical treatment and is not located upon the premises of a hospital.

[b] Department of Health regulations. The Insurance Department promulgated HMO regulations in 1987 and added solvency requirements in 1992.

[c] Insurance Department regulations. The Department of Health has not promulgated PPO regulations.

Source: Developed by LB&FC staff from a review of applicable regulations.

The Department of Health has convened a group to review licensure regulations for general hospitals. Department staff recognize that state licensure regulations for hospitals need revision. The existing regulations, for example, do not have standards for intensive care units or pediatric services.

The Department did initiate an effort to review its managed care regulations in June 1997. The Departments of Insurance and Public Welfare, the Health Care Cost Containment Council, and numerous provider associations and consumer representatives participated in task forces to address various aspects of the regulations. The task forces completed their report with recommendations in October 1997. The Department of Health held public meetings to obtain input on the task force recommendations in November 1997 and solicited public comment on the recommendations. Those providing comment on the task force recommendations consistently praised the Department for forming and supporting the task forces. They also emphasized the need to revise existing regulations and for further professional and public involvement in the revision process. In late April 1999, however, the Department of Health circulated proposed draft regulations for informal comment.

8. Implementation Problems Have Developed as the Department of Health Has Attempted to Rely on the JCAHO Surveys to Assure Compliance With State Health and Safety Standards

National voluntary organizations can provide important assistance to states in assuring compliance with its standards for quality care. The Department of Health, however, does not have in place procedures such as those used in the Medicare program for determining if national voluntary agency standards and processes are more or less stringent than Department standards and survey processes and for identifying ways to address these differences.

Differences between the JCAHO and state standards and processes do exist. For example, the DOH regulations establish numerous requirements not addressed by the JCAHO. The JCAHO survey dates do not coincide with hospital licensure dates, and JCAHO has not always provided accreditation survey information to the Department on a timely basis. The DOH/JCAHO agreement does not identify which levels of deficiencies require follow-up on-site inspections by the Department or the JCAHO, nor does it address how the JCAHO reviews are to be validated.

Problems have arisen as a result of the absence of detailed crosswalks between the JCAHO and DOH licensure standards and processes. As a result of the absence of such a crosswalk, for example, the Department has found itself in the position of having to extend hospital licenses that have expired without on-site inspections. Such extensions, however, are not explicitly authorized by the Health Care Facilities Act. The act and its regulations require licenses to be issued for a specified length of time and the regulations deem an expired license "void."

Absent defined procedures similar to those in the Medicare program, other potential problems can be anticipated. For example, the Department in proposed licensure regulations has indicated that it will recognize the accreditation of two voluntary national accreditation agencies for certain ambulatory surgery centers. It has not indicated whether or how it has determined that such agencies' standards are at least as stringent as state licensure standards.

The Department of Health, moreover, has not proposed to recognize the accreditation of other voluntary accreditation organizations that the Medicare program is proposing to utilize to survey ambulatory surgery facilities. The Department has also not developed an agreement with the American Osteopathic Association (AOA) for osteopathic hospitals.

Department officials have indicated they are in the process of attempting to resolve some of the implementation issues. The Department of Health hired a contractor to review JCAHO standards and procedures and state standards and processes and identify areas to be addressed in a revised JCAHO/DOH agreement. The consultant completed the report in December 1998.

9. The Department of Health Currently Recognizes the National Committee for Quality Assurance as the Only External Organization Approved to do HMO Quality Reviews.

Pennsylvania regulations require HMOs to have an external assessment of their quality assurance programs within one year of receiving their certificates of authority and every three years after the first review. The Department of Health may also request such reviews for cause.

The purpose of the external assessments is to study the quality of care and the effectiveness of the quality assurance programs. The Department evaluates the qualifications of independent organizations and approves them for quality reviews, but the individual HMOs are responsible for engaging an approved organization and paying its fees. The regulations call for a statistically significant sample of medical records and a written report. The HMO must send a copy to the Department.

The Department of Health issued a request for proposals in 1987, inviting interested organizations to submit their responses. The Department advised the HMOs that it had selected two review organizations for approval as of January 1989: the National Committee for Quality Assurance (NCQA) and the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC). The Department subsequently approved HealthPro, Inc., giving HMOs their choice of three external review organizations.

The NCQA was formed in 1979 to promote quality assurance, standards, and performance measures. It initiated its survey process for managed care plans in 1991 and has become the primary external source of accreditation for HMOs, which advertise their status as fully-accredited plans. Enrollment announcements for Keystone Health Plan Central and HealthAmerica have cited their full accreditation as a reason to join their plans.

The AAAHC started out as the ambulatory care review program of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and became independent in 1979. Many of the ambulatory care specialty societies are represented on its board. Its standards cover quality of care, quality assurance activities, clinical records, pharmaceutical services, environmental safety, administration, and professional development. The AAAHC has not done any quality reviews for Pennsylvania HMOs since it reviewed Cigna Healthcare in 1995.

HealthPro had particularly strong qualifications for evaluating utilization review programs, according to Department officials. It voluntarily withdrew from the external review program in 1996, when its acquisition by the United Healthcare Corporation raised concerns about potential conflicts of interest. United Healthcare operates managed care plans.

The inactivity of the AAAHC and the departure of HealthPro have left the NCQA as the only external organization approved to do HMO quality reviews. The Bureau of Managed Care is considering opening up the quality review program to new organizations in 1999. The JCAHO and the Utilization Review Accreditation Commission (URAC) have shown interest in doing quality reviews, according to Department officials. In addition, the AAAHC has announced it will be issuing new standards for managed care in 1999.

10. Pennsylvania Does Not Make Continued HMO Certification Dependent on Meeting Specific Standards.

The Department of Health uses an external review process to measure HMO performance objectively against nationally-recognized standards, which serve as a benchmark for assessing an HMO's commitment to quality improvement. Department staff participate in the external organization's site visits and make their own assessment of its findings and any other issues raised during the review.

Department regulations governing external quality reviews do not contain specific standards for HMOs to meet. The regulations call for HMOs to have quality assurance systems based on comprehensive medical records conforming with good professional practice and procedures assuring proper utilization of facilities and services. Reviews must consider not only the technical quality of the care being provided but also its availability, accessibility, and continuity. HMOs must collect and analyze utilization data and report aggregate data to the Department.

The regulations do not specify penalties for unsatisfactory reviews, and an unfavorable report does not have specific implications for an HMO's ability to maintain its certification. The basis for any such action would have to be found in the HMO Act. It provides for penalties, which may include the suspension or revocation of a certificate, if any of the following conditions exist:

- Inadequate or poor quality care, threatening the health and safety of enrollees;
- Inability to fulfill contractual obligations to enrollees;
- Deceptive or unfair advertisements of services;
- Failure to comply with the HMO Act.

The Insurance Commissioner or the Secretary of Health, whichever is appropriate, must hold hearings before taking any action to impose penalties on HMOs. The hearings and any appeals must be conducted under Pennsylvania administrative laws and procedures.

Although an external quality review may result in accreditation, the Department of Health does not require accreditation as evidence that HMOs are meeting quality assurance standards. Other states, such as Florida and Rhode Island, have adopted their review organization's standards by requiring HMOs to achieve accreditation.

Florida requires HMOs to be accredited within one year of receiving their certificates of authority. If none of the state-approved review organizations offer accreditation, the HMOs still must undergo quality assurance reviews by whichever organizations the state has approved. HMOs must continue to have such reviews every two years and must maintain their accreditation, if applicable.

An HMO in Florida can lose its certificate for failing to maintain its accreditation or having an unfavorable review. The state may revoke the certificate for a two-year period, after which the HMO may receive a new certificate if it meets all of the requirements applicable to first-time applicants. Lesser penalties include suspensions and fines.

Rhode Island requires HMOs to have their quality management programs accredited by a state-approved review organization within two years of receiving their certificates of authority. HMOs must apply for recertification every two years. The rules and regulations for assessing their health care services define quality management as including the following:

- Standards, criteria, and procedures for assessing services and utilization;
- Assessment of health outcomes;

- Ongoing review of services by health care professionals;
- Data collection systems for measuring performance and results;
- Methods for identifying, evaluating, and resolving problems;
- Written procedures for initiating remedial action.

In 1997, a draft report from a managed care work group reflected a recommendation that certificates of authority with expiration dates be issued to Pennsylvania HMOs. The specific recommendation called for requiring HMOs to have their certificates renewed at least once every three years, in conjunction with their external quality reviews. The draft report reflected a corollary proposal to not renew the certificates of HMOs without enrollees. Inactive HMOs would have their certificates invalidated to prevent their transfer to other managed care organizations, even if periodic renewal is not adopted.

The Department of Health proposed an inactive status for HMOs with no enrollment when it distributed draft regulations for informal comment in April 1999. Inactive status would take effect for any HMO reporting no enrollment for 15 consecutive months. An inactive HMO would need specific approval from the Department before enrolling new members.

Corrective Action Plans for Pennsylvania HMOs. The National Committee for Quality Assurance (NCQA) sends an HMO a preliminary report for comments on its factual content. The Department of Health receives a copy and may ask the HMO to address specific issues, if they raise sufficient concern, before the NCQA releases its final report. Once the Department receives the final report, it identifies the key recommendations and requests a proposed narrative response to each of them. It reviews the responses and schedules a meeting that typically includes the HMO chief executive officer, the medical director, and the director of quality improvement.

The purpose of the meeting is to achieve a consensus on a quality improvement plan addressing the significant issues identified by the NCQA. The HMO is expected to describe how it will make the necessary improvements. The responses, a work plan, and the pertinent correspondence serve as public documentation of the external review process. The Department treats the actual NCQA report as a confidential document.

Although fully-accredited HMOs may still be able to improve their quality assurance programs, their corrective action plans tend to focus on less serious problems than provisionally or non-accredited HMOs must address. Work plans for fully-accredited HMOs typically contain processes to avoid backlogs, clarifications of policies and procedures, and more sophisticated systems for measuring utilization.

Delays between identifying problems and approving work plans can lengthen the time it takes to make improvements. The Department has approved corrective action plans for HMOs more than one year after the completion of their reviews, primarily because it had to wait at least six months to see the final NCQA reports. Such delays raise concerns about the effectiveness of the monitoring process, particularly if an HMO does not receive a favorable report after its external review.

A review organization's site visit can raise issues the Department considers serious enough to warrant immediate attention. Such circumstances prompt it to request a corrective action plan from the HMO before the NCQA releases the final report.

Healthcare Management Alternatives (HMA), Inc., was given provisional accreditation after its NCQA external review in December 1997. Although the NCQA did not release its final report until July 1998, the Department expressed concern two weeks after the site visit. Their concern had to do with a credentialing issue the reviewers had identified.[42] Seventeen percent of the participating physicians did not have signed contracts, and 23 percent had not undergone site visits.

The Department advised HMA to prohibit primary care physicians who were not fully credentialed as of February 1998 from accepting any transfers or new plan members. Specialists who were not fully credentialed were not supposed to accept referrals. HMA was expected to prepare for the orderly transfer of all plan members receiving care from providers whom it could not reasonably expect to have fully credentialed by May 1998.

The Department conducted a site visit in June 1998 and concluded that no plan members were receiving primary care from physicians who had not been properly credentialed and that no such physicians were listed in the plan directory. HMA was advised to complete its credentialing of network specialists by mid-September 1998.

The UPMC Health Plan, doing business as Best Health Care of Western Pennsylvania, had undergone an NCQA preaccreditation review in August 1997. Although the Department had not yet received a copy of the final report, it expressed concern about issues the reviewers had identified during the site visit. The issues included reports of members who could not get in touch with their primary care physicians or were told to decide for themselves whether to seek emergency room care. In addition, payment system problems highlighted the need for a physician to review all denials of service.

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[42]Credentialing is the process by which a managed care plan determines whether providers are qualified to participate in its network. A typical credentialing process for physicians includes a review of licensure status, hospital privileges, and malpractice history.

Representatives from the Department and the UPMC Health Plan met to discuss issues such as complaint tracking, utilization review, and access to the primary care network in November 1997. A second meeting took place in April 1998, when the UPMC Health Plan presented its response to recommendations in the NCQA final report.

The Department sent the UPMC a follow-up letter requesting a revised work plan to clarify the relationship between the health plan and its provider network, the Tri-State Health System. The letter cited "the commonality of ownership and overlap of individuals who may represent the interests of both the licensed entity and the health service delivery system in the policy making process."

The delegation of activities to an unlicensed entity such as Tri-State requires the HMO to maintain accountability for the quality of care, the letter explained. The revised work plan would need to include oversight documents illustrating periodic and objective assessments to determine how well the delegated activities were being performed. Such documents would also reflect corrective actions taken by the HMO. The Department also cited an overall need to build an adequate foundation for quality assessment and improvement.

11. The Health Care Cost Containment Council Gathers Useful Quality of Care Data Which Are Not Published and Publicly Reported.

The Agency for Health Care Policy and Research (AHCPR) partnered with 12 states,[43] including Pennsylvania, to illustrate how existing sources of data on inpatient hospital stays can be used to provide information on quality of care. Not all 12 states had the capacity to adjust their data to account for difference in patient severity. The Healthcare Cost and Utilization Project (HCUP) published data for the 12 states are not risk adjusted. They, therefore, are not sufficiently precise to support judgments about how well individual hospitals are performing.

The HCUP quality indicators, however, do provide sufficient information to highlight areas of concern and target areas for more intensive study. HCUPs quality indicators include measures of outcome, utilization, and access to primary care. Based on the Agency for Health Care Policy and Research's 1996 report,[44] Pennsylvania hospitals as a group perform well in relation to other states. Pennsylvania hospitals' benchmarks were better than most reporting states on:

- 11 of the 16 HUCP-3 Quality Outcome Indicators,
- 7 of the 9 Quality Utilization Indicators, and
- 5 of the 8 Quality Access to Primary Care Indicators.

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[43]The states included Arizona, California, Colorado, Florida, Illinois, Iowa, Massachusetts, New Jersey, New York, Pennsylvania, Washington, and Wisconsin.
[44]The AHCPR report relies on 1992 inpatient data.

(See Appendices F, G, and H for more detailed information on Pennsylvania hospital benchmarks compared with those of other states.)

The Health Care Cost Containment Council has the ability to risk-adjust the HCUP data and thus to compare performance of individual hospitals. To date, the Council has not published the HCUP information for individual hospitals. States such as Utah, however, have worked with their hospitals to develop public reports with individual hospitals. Utah reports, for example, on wound infection and other complications resulting from the medical care provided as well as other HCUP quality indicators for individual hospitals.

12. Not All Freestanding Ambulatory Surgery Providers Are Reporting Data to the Health Care Cost Containment Council as Required.

In recent years many surgical procedures traditionally performed in hospitals have been performed in outpatient settings. The Council produced its first report on procedures performed at such facilities in April 1998. This report did not include quality outcome measures, nor did it include data for individual facilities.[45] It also did not include data for all such facilities.

Freestanding ambulatory surgical facilities are required to report certain data to the Pennsylvania Health Care Cost Containment Council. Not all freestanding ambulatory surgical facilities, however, have reported. Less than half of DOH licensed freestanding ambulatory surgical facilities reported data to the Council for use in its first report on ambulatory surgical facilities.[46] In June 1999 the Council reported to the LB&FC that fewer than half of the freestanding facilities submit data within the required time frame. However, within 60 days of the data submission deadline, the Council reviews data from approximately 80 percent of freestanding surgical facilities.

[45]The Council also indicated that the published reported data had several important limitations.
[46]The Council has the statutory authority, upon conviction, to levy finds of up to $1,000 per day for facilities that fail to submit required data.

III. Recent Changes in Commonwealth Regulation of Managed Care

This chapter contains historical background on the laws and regulations pertaining to managed care plans. It includes information on recent legislation (Act 68 of 1998) to provide additional protections for consumers enrolled in gatekeeper plans.[1]

A. Managed Care

The concept of managing health care to control costs began with prepaid group practices at least 70 years ago. The Community Hospital Association of Elk City, Oklahoma, provided full medical care to its members, who paid a fixed annual premium, during the Great Depression of 1929. The fixed budget and an uncertain caseload promoted the cost-effective management of resources.

Group practices on a larger scale emerged in the 1940s. Kaiser Permanente built its own hospitals, ran its own clinics, and employed hundreds of physicians. Its base of 30,000 members after World War II had grown to 250,000 by 1952 and exceeded 1,000,000 in the 1960s.

The most familiar form of managed care, the health maintenance organization (HMO), received a boost from the U.S. Congress when it passed the HMO Act of 1973. The act required companies with health insurance plans and more than 25 employees to offer at least one HMO as an alternative choice. Although the act also authorized grants and loans to promote the development of managed care plans, the anticipated growth did not occur until the mid 1980s.

1. Managed Care Plans

Pennsylvania opened a door for managed care plans when it enacted the Voluntary Nonprofit Health Service Act of 1972. The act gave not-for-profit corporations an opportunity to enroll subscribers and provide health care services[2] through group practices reimbursed with aggregate fixed sums or per-capita payments. The South Philadelphia Health Plan received the first certificate of authority under the act in December 1973.

[1]Enrollees in gatekeeper plans must have a designated primary care physician who will be the source of referrals for nonemergency specialty, hospital, and other covered services.

[2]The services had to include, but were not limited to, emergency care, inpatient hospital and physician care, ambulatory physician care, and outpatient preventive medical services.

Extensive amendments transformed the 1972 act into the HMO Act[3] in 1980. It defined an HMO as a system combining the delivery and financing of health care and providing basic health services, as defined in the original act, to voluntarily-enrolled subscribers for a fixed paid fee.

Pennsylvania recognized another form of managed care plan in 1986, when it amended the Insurance Company Law of 1921 to add preferred provider organizations (PPOs). The amendment affirmed the right of health care insurers, fraternal benefit societies, and purchasers to enter into agreements with providers for rendering health care services to covered persons. Such PPO agreements can include the amounts to be charged for the services. They can offer incentives for covered persons to use the services of preferred providers or can limit reimbursement to services rendered by preferred providers.

PPOs may assume financial risk without becoming licensed as insurers. Risk-assuming PPOs do not need a license if they meet the minimum requirements for working capital and reserves, as defined in regulations, or have filed a certificate indicating they are regulated under the federal Employee Retirement Income Security Act (ERISA) of 1974.[4]

An Insurance Department policy statement[5] differentiates between HMOs and gatekeeper PPOs. Department of Health (DOH) regulations require HMO enrollees to have a gatekeeper, a designated primary care physician (PCP) who supervises and coordinates their health care. Gatekeeper PPOs do not need certificates of authority as HMOs if:

- Their preferred PCPs are reimbursed only on a fee-for-service basis.
- Their preferred PCPs are not assuming financial risk in the form of incentives to control utilization.
- The PPO is not an exclusive provider organization.[6]

The policy statement contains an exception for PPOs providing gatekeeper services through a subcontract with an affiliated HMO. Their primary care gatekeepers may accept financial risk or per-capita payments, or both, if the subcontract provisions are acceptable to the Department of Health and the Insurance Department. The affiliated HMO must extend its quality assurance systems and similar consumer protection measures to PPO enrollees in a manner DOH finds acceptable.

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[3]40 P.S. §1551 et seq.

[4]The ERISA provides the basis for a complementary system in which the federal government oversees employers' health benefit plans while the states regulate commercial insurers. States exempt ERISA plans from managed care regulations if such plans provide benefits only for employees.

[5]Pursuant to the Commonwealth Documents Law, 45 P.S. §1101 et seq., and court decisions pursuant to that law, statements of policy do not have the force of laws or regulations but are merely interpretations of general applicability, Central Dauphin School District v. Pa. Department of Education, 147 Pa. Commw. 426 (1992).

[6]Exclusive provider organizations reimburse only the services rendered by preferred providers.

Although Pennsylvania has not enacted legislation specifying other categories of managed care plans, DOH has defined one such category, the integrated delivery system (IDS), in a statement of policy. An IDS is a legal entity which:

- enters into contracts with HMOs;
- employs providers or contracts with them;
- provides or arranges for health care services, principally through its participating providers, to HMO members covered by a benefits contract;
- assumes some responsibility for quality assurance, utilization review, or related functions under HMO monitoring; and
- assumes some financial risk through per-capita reimbursement or other risk-sharing arrangements.

An IDS may perform gatekeeping functions delegated by an HMO. An IDS may use primary care gatekeepers if the HMO has an acceptable oversight plan to ensure that reimbursement incentives do not promote inadequate or poor quality care. Providers in an IDS network may assume financial risk from an HMO even though the IDS does not qualify as a licensed insurer, an HMO, or a risk-assuming PPO. Such providers may receive fixed per-capita fees or a percentage of premiums, or they may participate in bonus payment systems or withholding pools.

The policy statement identifies several examples of IDS entities, based primarily on their ownership arrangements and controlling interests. For example, a physician-hospital organization (PHO) is jointly owned and controlled by both categories of health care providers. PHOs and similar networks protect the interests of the providers and strengthen their contracting position.

Managed care plan operators either contract with existing provider networks or develop their own. Although developing their own networks enables them to control the selection and termination of providers, contracting with established networks has potential advantages. Providers in established networks might be more accustomed to working with managed care plans, and the network administrators might be willing to assume a share of the financial risk.

The relationship between a plan and its provider network depends on its management philosophy and its marketing strategy. Plans seeking a particular niche in the market might emphasize stability and build their networks gradually in response to demand. More expansive plans in highly competitive markets might seek rapid growth. They might be continually reorganizing their networks as they move into new markets or offer their enrollees more options.

2. Managed Care Oversight

Regulatory agencies find themselves continually facing new challenges in overseeing the changing managed care environment. Mergers and acquisitions create new entities displaying various characteristics of previous health service plans the regulators are still trying to define. They face a dilemma in determining where such plans fit into the overall picture.

Efforts to regulate managed care raise questions not only about how different kinds of plans should be regulated but also about what purpose regulation should serve. Advocates for tighter regulation argue that patients no longer have sufficient protections to prevent cost containment incentives from overriding their need for services. The plans contend they can not do their best to contain costs and assure quality if they are burdened with unnecessary regulation.

Attempts to fit emerging structures into the established categories not only can introduce uncertainties into the regulatory process but also can impede the development of more effective systems. States have tried different approaches to bringing IDSs within the scope of their regulatory authority. Some, like Pennsylvania, have allowed IDSs to operate in a relatively control-free environment, and others have amended existing laws specifically to include them. One state developed a generic definition to cover HMOs and IDSs, making them both subject to licensure. Another state defined a new category of licensed risk-bearing systems for entities requiring less restrictive oversight than insurers and HMOs.

Regulatory agencies have shown less concern about PHOs, especially if they focus strictly on provider service contracts. Provider networks pose few problems for regulators as long as they limit themselves to providing health care services and do not cross the line into operations traditionally associated with insurers. They will generally be subject to regulation only as individual physicians and hospitals.

Regulators show more interest in risk-assuming PHOs, which contract with employers on a per-capita basis or assume financial risks transferred from HMOs. Accountability may become an issue if they take on functions such as quality assurance and utilization management. PHOs performing such functions might be subject to state laws requiring the certification of utilization review organizations. Other states have assigned responsibility to the contracting HMO.

B. Managed Care Development and Regulation in Pennsylvania

Health care consumers have come to rely on regulatory oversight for assurance that they are receiving quality health care. Such oversight takes on added importance for managed care plans, which may not allow enrollees to seek care outside a limited network of providers unless they can afford to pay the costs themselves.

Regulators are trying to develop the means for meeting consumers' expectations because traditional methods have not enabled them to keep up with the rapid changes in managed care. Legislation such as Act 1998-68 in Pennsylvania focuses on the relationship between patients, providers, and managed care plans.

1. Managed Care Growth and Diversification

Traditional approaches to organizing, delivering, and paying for health care services have been changing rapidly since the 1980s, when employers began giving high priority to reducing the costs of their health benefit plans. The changes have emphasized managing care to reduce costs and assure quality.

National reports of unusually slow growth in health care spending provided additional impetus for change in the early 1990s, despite differing opinions as to the reasons for the favorable trend. Attempts to evaluate the cost effectiveness of the changes were inconclusive. Although health maintenance organizations (HMOs) had lower hospital utilization and used less costly procedures than fee-for-service plans, physicians' offices did not show similar savings. The evidence suggested, but did not prove, that outpatient services were being substituted for hospital care.

The shift to managed care in Pennsylvania can be illustrated by comparing the growth of HMOs with a more traditional type of insured health benefit, Blue Cross/Blue Shield coverage. The premiums written by HMOs in Pennsylvania increased steadily from the late 1980s through the mid 1990s while the premiums written by the more traditional plans virtually leveled off, as shown in Table1.

Table 1

HMO and Blue Cross/Blue Shield Premiums Written in Pennsylvania

(1987-1995)

Year	HMO Premiums Written	Average Annual Growth	Blue Cross/Blue Shield Premiums Written	Average Annual Growth
1987.....	$ 623,397,000	--	$4,575,439,000	--
1991.....	1,868,080,000	31.6%	7,409,105,000	12.8%
1995.....	4,789,897,000	26.5	7,864,618,000	1.5

Source: Compiled by LB&FC staff from information provided by the PA Insurance Department.

Carriers that historically offered indemnity plans have responded by developing and promoting their own HMOs and other managed care products. Blue

Cross/Blue Shield-affiliated HMOs accounted for almost 39 percent of the 1995 HMO premiums written in Pennsylvania.

For-profit insurance companies have used similar strategies to compete with HMOs. Aetna Life Insurance Company acquired U.S. HealthCare Systems, which included a Pennsylvania HMO that wrote premiums of more than $1.3 billion in 1995. Such acquisitions do not always go smoothly. The value of Aetna's stock dropped more than 10 percent after problems resulting from the $8.9 billion acquisition came to light in December 1997.

Coventry Corporation owns HealthAmerica, another major HMO operating in the Pennsylvania market. Coventry divested itself of its expanding group hospitalization business in 1992 but retained the 42 state licenses of its subsidiary insurance company, enabling it to develop multiple-option products for its HMO markets. Coventry offers point-of-service products that allow its HMO enrollees to use providers outside the network. It also offers administrative service contracts to commercial organizations.

2. Pennsylvania Regulation and Act 68

Act 1998-68 strengthens the Commonwealth's oversight of certain managed care plans covered by earlier statutes. It covers such plans if they manage service utilization through a gatekeeper, integrate the financing and delivery of service through selected providers, and offer financial incentives for enrollees to use participating providers. The act specifically identifies HMOs, PPOs, health insurers, fraternal benefit societies, and plans such as Blue Cross and Blue Shield as covered entities if they offer gatekeeper products. Entities contracting with or functioning as gatekeeper plans are also subject to the act.

Consumers' Rights. The disclosure requirements in Act 68 go well beyond the previous requirements in their specificity. Regulations prior to the act require HMOs to develop written procedures for informing enrollees of the following rights:

- timely and effective redress of grievances;
- truthful, accurate information an average person can understand;
- complete, understandable information about the enrollee's condition unless medically inadvisable;
- identifying information about the enrollee's health care providers;
- informed consent before undergoing treatment;
- refusal to participate in experimental treatment or research;
- refusal of drugs or treatment after being told of the consequences;
- confidential medical records except as required by law or necessity;

- access to personal records unless restricted for medical reasons; and
- emergency services without unnecessary delay.

The Insurance Company Law requires PPOs to disclose provisions, limitations, and conditions of available benefits unless they are regulated under the ERISA and have filed their certificate to that effect with the Insurance Commissioner. Regulations prior to Act 68 mandate adequate disclosure of enrollees' rights and responsibilities, neither of which are specified, under utilization review programs.

Managed care plans covered by Act 68 must do more than supply easily understandable descriptions of coverage benefits, limitations, and exclusions and the process for accessing emergency services. Their marketing materials have to include the following statement in boldface type and a telephone number for the plan:

> This managed care plan may not cover all your health care expenses. Read your contract carefully to determine which health care services are covered.

The plan must give enrollees mailing addresses and telephone numbers for inquiring about information such as the approval or authorization of health care services. Non-English-speaking enrollees must be told how to get information they can understand.

The description of the complaint and grievance process must include the filing procedures, a toll-free telephone number, appeal rights, and the enrollee's right to designate a representative. The plan must notify enrollees that it will have qualified personnel review disputes involving payment denials and will inform enrollees of the basis for decisions.

Act 68 also lists the specific information plans must give their enrollees and, if requested in writing, prospective enrollees and providers. The list includes the following information not specified in regulations prior to the act:

- a summary of the utilization review policies and procedures;
- a description of how to select a participating health care provider;
- a description of how to change a primary care provider or specialist;
- the procedures for referrals outside the provider network;
- the procedures for standing referrals to specialists;
- a list, updated annually, of participating providers by specialty; and
- a list of the information available on written request.

Enrollees and prospective enrollees may submit written requests for additional information, which must include:

- a list of the plan board of directors or officers and their addresses;
- the procedures for protecting the confidentiality of records;
- the credentialing process for providers;
- a list of the participating providers' hospital affiliations;
- the coverage status of specific drugs;
- the process for prescribing nonformulary drugs;
- the procedure for deciding on experimental treatments;
- the method of reimbursing providers for health care services; and
- a description of the quality assurance program.

Managed care plans must maintain the continuity of their enrollees' care during transition periods. Enrollees may receive ongoing care from a provider whose contract the plan has terminated, as long as the termination is not for cause.[7] Such care may continue for 60 days after the plan has notified the enrollee of the termination and may be extended if appropriate. Enrollees in the second or third trimester of pregnancy may receive postpartum care from a terminated provider. New enrollees may receive ongoing care from a provider outside the plan network for similar periods.

Enrollees with life-threatening, degenerative, or disabling conditions may request a specialist as a primary care provider or a standing referral to a specialist. Enrollees may have direct access to obstetrical and gynecological services without requesting prior approval from a primary care provider.

Act 68 also contains provisions designed to strengthen the role of health care providers as their patients' advocates. The act prohibits managed care plans from imposing "gag clause" restrictions to discourage health care providers from discussing the process of denying payment for services, decisions by the plan to deny payment, or the medical necessity or appropriateness of care. Plans may not terminate the contracts of providers who protest restrictive policies and practices or advocate for patient care.

Financial Incentives. Act 68 contains a disclosure provision enabling enrollees and prospective enrollees to request a summary of the payment methodologies a managed care plan uses. The plan does not have to disclose the specific details of an individual provider's contract. Act 68 specifically prohibits financial in-

[7]Termination for cause may include fraud, criminal activity, breach of contract, and posing a danger to an enrollee or the public.

centives from being used to compensate providers for rendering anything less than medically necessary and appropriate care.

The HMO Act gives the Secretary of Health the power to require the renegotiation of provider contracts if they are inconsistent with the purposes of the act, which include the advancement of quality assurance, cost effectiveness, and access. The Department of Health and the Insurance Department may impose penalties if HMOs provide inadequate or poor quality care.

Regulations prior to Act 68 call for DOH to review the applications of risk-assuming PPOs, whether or not they use gatekeepers, to determine whether any of their proposed financial arrangements or contractual provisions might encourage undertreatment or poor quality care. The regulations cite examples of such arrangements. They include capitation (fixed payments prior to the requesting or the rendering of health care services), fee-withholding risk pools, exclusive provider organizations, and reimbursement discounts or member copayments exceeding 20 percent for services rendered by nonpreferred providers.

The Department is expected to take certain steps in determining whether PPO arrangements might lead to undertreatment or poor quality care. Such steps include making the following determinations:

- The PPO offers a sufficient number and range of providers by class, specialty, and geographic location to give its enrollees adequate access to the covered services.
- The PPO adequately discloses its enrollees' rights and responsibilities and has a grievance system for enrollees' appeals.
- The PPO must have an adequate peer review process to monitor factors affecting the quality of care.
- A PPO using selection criteria for its providers must have adequate criteria, a verification system, and adequate capacity to remove preferred providers who render poor quality care.

PPOs must identify and address any financial incentives that might lead to undertreatment or poor quality care. Their capitation programs are expected to meet the following quality assurance standards:

- The system director is a provider knowledgeable and experienced in assessing quality of care.
- The quality assurance staff is appropriate for the size of the PPO and the potential effect of its risk-sharing incentives.

- The quality of care is assessed with usual and customary techniques such as medical care evaluations and audits and medical record review.

Contractual arrangements between HMOs and IDSs may include financial incentives to promote appropriate and cost-effective utilization under a Department statement of policy. IDSs do not need insurance licenses or certificates of authority to have their providers participate in capitation systems, percentage-of-premium arrangements, bonuses for favorable utilization, or target-based withholding pools. The policy statement calls for IDSs to submit their participating provider contracts for review and approval.

Provider Credentialing. Provider selection and retention are critical elements in developing a managed care network. Most HMOs began credentialing their providers when the competition to enroll employees in benefit plans prompted employers to ask about quality. The National Committee for Quality Assurance (NCQA) gave HMOs an additional incentive by making credentialing a requirement for accreditation.

A typical credentialing process for physicians includes a review of licensure status, hospital privileges, and malpractice history. HMOs may verify the accuracy of the information physicians report by querying the National Practitioner Data Bank, an option not available to PPOs, which the Data Bank does not recognize as "health care entities." On the other hand, insurance company PPOs have access to claims data HMOs do not have.

HMOs may apply more subjective criteria based on site visits and medical record reviews if they are concerned about a physician's practice style. Physicians in highly competitive markets might find themselves being visited repeatedly. The Pennsylvania Medical Society has addressed this concern by promoting standardized credentialing procedures, beginning with a standard application form.

Act 68 requires managed care plans to have their credentialing processes approved by DOH. They may not use their selection criteria to exclude or terminate providers for having high proportions of patients who need special services or refusing to render services they find objectionable on moral or religious grounds.

The Department has the responsibility to set standards for credentialing processes under Act 68, or it may adopt nationally-recognized accrediting standards. Managed care plans must submit credentialing reports to the Department every two years or as otherwise required. The two-year reporting requirement coincides with NCQA standards, which call for recredentialing physicians every two years and other providers every three years.

The NCQA standards call for thoroughly documenting the credentialing process. Plans must verify from primary sources any education, licensure, malpractice, or hospital privilege information physicians give them and must conduct a site visit

and a recordkeeping review. They must have a policy and procedures for reporting quality and service issues and for enabling physicians to appeal related actions.

The HMO Act and regulations do not specifically address credentialing systems, but the Department issued technical guidelines implying that an application for a certificate of authority had to include a description of such a system. HMOs delegating the function to IDSs are supposed to submit the delegated standards and proposed monitoring plans for approval, as described in a policy statement.

An HMO may pledge its compliance with NCQA delegation standards in lieu of submitting a monitoring plan. The NCQA standards call for a mutually-agreed-upon document describing the delegated activities, the responsibilities of the respective parties, an annual evaluation process, and remedies for poor performance of the delegated function. The HMO is expected to retain the ultimate authority for accepting and terminating providers credentialed by the IDS.

Utilization Review. Utilization review assesses the need for medical services. A review can result in approving or denying referrals and hospitalizations in advance, services a patient is already receiving, or claims for reimbursement. Approved hospital care might call for discharging the patient after a certain length of stay, and a longer stay would be monitored daily and approved concurrently. Services such as psychiatric care might receive ongoing review.

Act 68 establishes a program for the certification of utilization review entities (UREs), defined as entities performing such reviews for managed care plans. Certification must be renewed every three years. Although licensed insurers and managed care plans with certificates of authority[8] must comply with the same standards and procedures, they do not need separate certification as UREs.

The Department of Health must set standards for certifying UREs. It may adopt the standards of a nationally recognized accreditation body if they meet or exceed the standards in Act 68. The NCQA has standards that go into more detail than Act 68 about the process, criteria, and accountability for review determinations. The NCQA standards for managed care plans include:

- The program is evaluated, updated, and approved annually by senior management or a quality improvement committee.
- Appropriate practitioners take part in developing and adopting criteria, and the plan evaluates the consistency of their use by reviewers.
- Board-certified specialists are available to assist in making determinations of medical appropriateness.

[8]Pennsylvania issues certificates of authority not only to HMOs but also to fraternal benefit societies and plans such as Blue Cross and Blue Shield.

- The plan surveys enrollees and practitioners at least every two years to determine their satisfaction with the program.

Act 68 requires UREs to notify a health care provider within 48 hours of being requested to conduct a review if they need additional facts or documents. They have to maintain written records of decisions adverse to enrollees at least three years. Such records must include detailed justifications of decisions to deny payment and the required notifications given to providers and enrollees.

Providers and enrollees must have toll-free telephone access to UREs at least 40 hours per week during normal business hours. Answering services or recording systems must be available to take messages outside of business hours, and UREs must respond to inquiries about review determinations within one business day. UREs must protect the confidentiality of enrollees' medical records as required elsewhere in Act 68. They must verify information requests on behalf of managed care plans to ensure the caller is a legitimate representative of the plan.

Act 68 also contains standards for performing utilization reviews. It defines three categories of review and establishes timeliness standards for reporting decisions, which must be issued in writing and must include the basis and clinical rationale for the decision. Exhibit 9 shows the standards for the three categories.

Exhibit 9

Timeliness Standards for Completing Utilization Reviews Under Act 68

Review	Definition	Timeliness Standard
Prospective	Review to approve or deny payment occurs before service is rendered.	Notification of decision within 2 business days of receiving the necessary information
Concurrent	Review to approve or deny payment occurs during course of treatment or hospital stay.	Notification of decision within 1 business day of receiving the necessary information
Retrospective	Review to approve or deny payment occurs after service has been rendered.	Notification of decision within 30 business days of receiving the necessary information

Source: Compiled by LB&FC staff from Act 1998-68.

The personnel conducting reviews must have current licenses in good standing or other unrestricted credentials as required by the appropriate agency. Their compensation may not contain incentives, direct or indirect, which might influence their decisions to approve or deny payments for services. Decisions resulting in de-

nials of payment have to be made by licensed physicians. Licensed psychologists may perform utilization reviews for behavioral health services within their scope of practice if they have sufficient clinical experience. They may not review denials involving inpatient care or prescription drugs.

Dispute Resolution. Consumers must have a means of expressing their concern if they think they are not receiving the health care services they need. Traditional indemnity plans enable dissatisfied patients to see more than one provider, but managed care plans may limit their enrollees' choices to one primary care physician who controls their access to a network of providers following the same practice guidelines. Visits to providers outside the network might not be economically feasible for many enrollees.

The alternative to going outside the network is formally disputing the decision of the managed care plan. The formal process involves requesting a review of the decision to deny a service the plan does not consider part of the benefit package or deems medically unnecessary or inappropriate.

Act 68 strengthens the dispute resolution process in Pennsylvania by introducing mandatory procedures to replace suggested guidelines, clarifying steps previously left to the managed care plans, and giving consumers recourse to a review outside the plan. The dispute resolution provisions took effect on January 1, 1999, or were scheduled to take effect on plan renewal dates later in the year.

Act 68 defines a complaint as an unresolved dispute about "a participating health care provider or the coverage, operations or management policies of a managed care plan." The act defines a grievance as a request to have a managed care plan or URE "reconsider a decision solely concerning the medical necessity and appropriateness of a health care service." Such a request may come from an enrollee or a provider with an enrollee's written consent. The act prohibits an enrollee from filing a separate grievance after giving such consent.

Filing a written grievance initiates the review process to resolve a dispute about a decision to:

- disapprove full or partial payment for a requested health care service, or
- approve a service of lesser scope or duration than requested, or
- approve payment for an alternative to the requested health care service.

Act 68 provides for a two-stage internal process for enrollees to follow before filing formal appeals to DOH or the Insurance Department. Although Act 68 does not specify a time period within which the departments must complete their reviews of appeals, their goal is to complete such reviews within 60 days, as proposed

in draft regulations the DOH distributed for informal comment in April 1999. Exhibit 10 shows the process for reviewing complaints.

Exhibit 10

The Complaint Process Under Act 68

Stage	Reviewers	Timeliness Standard
Initial Internal Review	One or more employees of the managed care plan	Review completed within 30 days of receiving the complaint; written notification within 5 business days
Second Level Internal Review	Three or more persons (at least 1/3 nonemployees) who did not participate in the initial review	Review completed within 45 days of receiving the request; written notification within 5 business days
Appeal	Department of Health or Insurance Department	Not specified (The Departments have a stated goal of 60 days.)

Source: Compiled by LB&FC staff from Act 1998-68.

Grievances also must go through a two-stage internal process before enrollees may request external reviews. Exhibit 11 shows the review process.

Exhibit 11

The Grievance Process Under Act 68

Stage	Reviewers	Timeliness Standard
Initial Internal Review	One or more persons who did not participate in the decision to deny payment for the requested service	Review completed within 30 days of receiving the complaint; written notification within 5 business days
Second Level Internal Review	Three or more persons who did not participate in any decision to deny payment for the requested service	Review completed within 45 days of receiving the request; written notification within 5 business days
External Review by an Independent URE	One or more licensed clinical peer physicians or psychologists or one or more board-certified specialists	Written decision to the managed care plan, the enrollee, and the provider within 60 days of the filing date

Source: Compiled by LB&FC staff from Act 1998-68.

The grievance review at each internal level must include a licensed physician or, where appropriate, an approved licensed psychologist "in the same or similar specialty that typically manages or consults on the health care service." Act 68 also requires an expedited process to be available if the enrollee's life, health, or ability to regain maximum function might be jeopardized. The managed care plan must notify the enrollee and the provider of its expedited decision within 48 hours.

Act 68 allows enrollees 15 days to file their requests after receiving second level denials, but it does not impose any time limits on filing internal grievances. Managed care plans may continue to use their previously-established limits until new regulations are promulgated. Meanwhile, plans without such limits will have to accept grievances regardless of the elapsed time. The DOH proposed minimum time periods for filing complaints and grievances in draft regulations it distributed for informal comment in April 1999. The minimum time periods would equal the amount of time Act 68 allows for internal reviews.

Managed care plans have five business days to notify DOH that they have received a request for an external review. The Department must randomly assign UREs to external reviews on a rotational basis within two business days of such notification, or the managed care plans may designate UREs to conduct the reviews. The plan must pay the fees and costs, excluding attorneys' fees, of the external grievance process if an enrollee files the request. The nonprevailing party pays if the filer is a health care provider.

Department-approved contracts between plans and their health care providers may contain an alternative system for resolving external grievances filed by providers. Plans may not use such alternative systems for external grievance reviews requested by enrollees.

Managed care plans will determine whether disputed decisions under Act 68 are reviewed as complaints or grievances, based on their own definitions of medical necessity. The Department of Health proposed a procedure for resolving doubts about such classifications in its April 1999 draft regulations. Plans would have to consult the DOH or the Insurance Department if their classification was questioned. Enrollees would have the right to request such intervention. The department (Health or Insurance) would determine whether to change the classification and would return the reclassified dispute to the managed care plan.

Act 68 applies to risk-assuming gatekeeper PPOs, for which DOH has not issued detailed technical guidelines. PPO regulations prior to the act call for "adequate" grievance systems through which enrollees can appeal utilization review decisions resulting in the denial of payment or alleged undertreatment or poor quality of care.

Although Act 68 does not specifically address gatekeeper IDSs, they fall within its definition of managed care plans as licensed or unlicensed entities that contract with, or function as, gatekeeper plans providing services to enrollees. A statement of policy on IDSs calls for HMOs to apply their Department-approved grievance systems to enrollees served through IDS contractors instead of delegating the responsibility.

C. Conclusions

1. Certain Kinds of Managed Care Plans Are Not Subject to The Quality Assurance Safeguards in Act 68

Act 68 strengthens the regulatory oversight of managed care plans covered by earlier statutes but does not broaden the regulatory scope to include the full range of plans operating in Pennsylvania. The primary criterion for limiting its scope is the gatekeeper provision. Managed care networks fall outside the scope of the act if they provide health care services to enrollees without requiring access through a designated primary care provider.

The Act 68 definition of managed care plan, with its reference to a gatekeeper, is more restrictive than the definition in model legislation distributed by the National Association of Insurance Commissioners (NAIC).[9] The model definition describes a managed care plan as requiring enrollees to use, or creating incentives for them to use, providers under the direct or contractual control of a health carrier.

Although state regulatory approaches vary, states such as New Jersey and Ohio do not limit the scope of their oversight to plans with gatekeepers. For example, a 1997 New Jersey act containing patient protections defined a managed care plan as integrating "the financing and delivery of appropriate health care services to covered persons by arrangements with participating providers, who are selected to participate on the basis of explicit standards, to furnish a comprehensive set of health care services and financial incentives for covered persons to use the participating providers and procedures provided for in the plan."

The gatekeeper provision in Act 68 enables it to exclude plans resembling fee-for-service arrangements, such as the traditional Blue Shield coverage, in which most providers participate at discounts based on reasonable and customary charges. The consumer protections in the act may not be needed for such plans. The NAIC model excludes the more traditional plans through its "direct or contractual control" provision. However, the Act 68 definition of a managed care plan also excludes provider network plans designed to limit members' choices without imposing gatekeepers.

Advocates for uniform consumer protection want such nongatekeeper and passive gatekeeper plans to be regulated in the same manner as gatekeeper plans. Passive gatekeeper plans do not require enrollees to designate one physician to co-

[9]The NAIC promotes uniform standards for regulating the insurance industry. It proposed a series of rules codified in the 1945 McCarren Act, which exempted insurance companies from federal anti-monopoly laws on the condition that each state would maintain regulatory standards. The NAIC has developed reserve valuation standards, investment valuation guidelines, and uniform financial disclosure reports for insurers to file annually.

ordinate all of their care. However, enrollees in such plans must obtain referrals from primary care physicians in the network if they need hospitalization or specialty services and want to receive the highest level of benefits or reimbursement. Enrollees in nongatekeeper plans might have to request prior authorization directly from the plan or the network administrator for non-urgent hospital services.

2. Responsibilities for Reviewing Formal Appeals of Complaints Are Divided Between the Department of Health and the Insurance Department

The traditional health care scene featured three distinct roles: the provider, who rendered health care services; the beneficiary, who received the services; and the insurer, who paid for the services. Regulation called for assuring the provider had the expertise to render the services and the insurer had the financial resources to pay for them. Agencies specializing in different kinds of oversight could share the responsibility.

Act 68 not only maintains the traditional separation of responsibilities but also gives both departments oversight of the enrollee complaint process. The Department of Health will focus on complaints about the quality of care or service and the inaccessibility of certain providers.

An Insurance Department policy statement of October 3, 1998, included provisions regarding emergency services, continuity of care, and the complaint and grievance processes. The Insurance Department policy statement focused on complaints about benefit coverage such as:

- failure to approve a standing referral to a specialist;
- refusals to provide experimental, investigational, or cosmetic services;
- services from a specialist without a primary care provider's referral;
- requests for benefits exceeding limits specified in a subscriber's contract; and
- refusals to pay for continuation of care from nonparticipating providers.

Prior to Act 68, HMOs were to resolve complaints about coverage or medical necessity disputes informally within 30 days. If they could not resolve complaints within 30 days, the HMOs were to review them formally as grievances. Enrollees could appeal grievance decisions to the appropriate department. The Department of Health advised HMOs to submit all such appeals to the DOH, because the "vast majority" of them involved medical issues. The Insurance Department occasionally received appeals directly and forwarded them to the Department of Health if they involved issues of medical necessity or quality of care. The DOH had them reviewed by an internal committee of professional staff, including a registered nurse. It sought advice from specialists on medical issues and the Insurance Department on coverage issues.

Although Act 68 designates complaints and grievances as separate kinds of disputes with separate review procedures, the distinctions are not always clear (see page 70). Coverage questions and denials of claims may not always be strictly administrative matters. For example, an HMO subscriber's agreement may describe oral surgery as a benefit if it is "medically necessary." Similarly, the agreement may exclude cosmetic surgery unless it is "medically necessitated by a covered sickness or injury or medically diagnosed congenital defect."

The Department of Health and the Insurance Department have indicated they recognize the complexities involved in making such determinations. The DOH proposed a joint complaint tracking system in the draft regulations it distributed for informal comment in April 1999. The two agencies would confer with each other or develop procedures for assigning each appeal to the appropriate agency for review. The draft regulations call for joint review if necessary.

The Insurance Department is modifying its October 1998 policy statement in developing its draft regulations for Act 68. For example, it is removing failures to approve standing referrals and refusals to approve experimental or cosmetic surgery from its list of complaints that should be appealed to the Insurance Department.

The merging roles of insurers and health care providers in managed care raise doubts about the feasibility of separating medical necessity disputes from coverage questions. The Pennsylvania Superior Court cited the dichotomy of managed care in a 1998 medical malpractice suit, when it applied the theory of corporate negligence to an HMO (see page 22).

The U.S. Department of Labor has recognized the changes occurring in the delivery of health care and how they can affect beneficiaries. It proposed new regulations for ERISA plans in September 1998 because "access to health care services may be directly 'managed' (and thereby controlled) by those in charge of coverage under a health benefit plan, rather than by the health care professional." The Department cited comments by claimants and their representatives who had urged bringing the ERISA regulations into line with NAIC model acts and Medicare standards.

3. Managed Care Plans Have Broad Discretion in Defining Medical Necessity

Although Act 68 defines utilization review and the grievance process in terms of medical necessity, it does not contain any criteria for developing a definition of medical necessity. Managed care plans thus have broad latitude in adopting and maintaining their own definitions for "determining health care services." A major

HMO in Pennsylvania has defined medical necessity as a member's need for treatment determined by one or more physicians if it meets the following criteria:

- The service or supply must be rendered in accordance with widely and generally accepted practices and standards prevailing at the time.
- It must be commonly recognized by the physician's specialty as appropriate for the case in question and must be provided at an appropriate level.
- It must conform with the professional and technical standards and/or utilization management criteria adopted by the HMO or its designee.

Such criteria leave ample room for interpretation. "Generally accepted practices" and "commonly recognized" standards may change over time. Disagreements may occur regarding not only what changes to make but also when to make them.

The federal Health Care Financing Administration (HCFA) has focused on the individual patient's needs instead of a generally-accepted standard in determining medical necessity. The Social Security Act defines it as care that is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Judgments as to medical necessity may differ under managed care, as explained in a HCFA policy letter. Such differences are permissible as long as the judgments remain within the range of high quality standards for medical practice and serve patients' best interests.

Other definitions of medical necessity rely on the health care provider to make the determination. Act 1990-6 created a peer review system in Pennsylvania to evaluate automobile insurance claims involving health care services provided to injured persons. The act defined "necessary medical treatment and rehabilitative services" as:

> Treatment, accommodations, products or services which are determined to be necessary by a licensed health care provider unless they shall have been found or determined to be unnecessary by a state-approved Peer Review Organization (PRO).

Health care providers may differ over an individual patient's need for medical services. Although no definition of medical necessity will eliminate reliance on professional judgment, a definition setting limits on the range of acceptable practices and sources of standards might facilitate dispute resolution and reduce the need for appeals.

The DOH proposed making the definition consistent with national and industry standards in its April 1999 draft regulations. Plans would be prohibited from using unduly restrictive definitions or relying solely on their own interpretations.

UREs would review definitions of medical necessity as part of the external grievance process.

4. Managed Care Plans Will Determine Whether Disputes Are Reviewed as Complaints or Grievances

Managed care plans sometimes define covered services in terms of medical necessity. One HMO group contract and subscription agreement listed laboratory and x-ray procedures, surgical operations, home dialysis equipment and supplies, chiropractic care, and psychological testing for therapeutic purposes as benefits if they were determined to be medically necessary.

Another HMO group contract identified its benefits as being generally available from participating providers only when medically necessary and appropriate. The HMO reserved the right to determine the medical necessity of any benefit provided under the contract and to designate a participating hospital for inpatient services. The contract covered plastic or cosmetic surgery only if it was necessary to correct the results of injuries or congenital defects and restore normal bodily functions. Such coverages depend not only on judgments of medical necessity but also on the definitions of "correct" and "normal."

Managed care plans may review coverage disputes as complaints rather than grievances. Internal reviews of complaints do not have to include a physician or a psychologist, as reviews of grievances do, and Act 68 does not affirm the right of the enrollee's health care provider to appear before the review committee. Enrollees cannot appeal complaints to an external review by clinical peers unless DOH or the Insurance Department sends them back to the plans for review as grievances.

The DOH proposed a procedure for resolving doubts about the classification of disputes in its April 1999 draft regulations as a means of ensuring that plans would not use their discretion to the disadvantage of enrollees. The Department would notify plans of the need to correct noncompliant or unacceptable procedures.

5. Denials of Physical Health Care Services in Pennsylvania, Unlike Some Other States, Do Not Have to Be Made by Reviewers in a Similar Practice or Specialty Until Grievances Reach the External Appeal Stage

Although Act 68 requires utilization review decisions denying payment for physical health care services to be made by licensed physicians, it does not require them to be clinical peers in appropriate specialties. Licensed psychologists may review behavioral health services within their scope of practice if they have sufficient clinical experience.

New York and Ohio have utilization review procedures similar to Act 68, but they include additional provisions based on the National Association of Insurance

Commissioners (NAIC) model. Both states require adverse determinations, a widely-used term for denials based on medical necessity or appropriateness, to be reviewed by clinical peers when services are first denied.

Act 68 resembles the model act in terms of establishing a two-level internal grievance system and allowing similar time periods for reviewing appeals. Act 68 calls for the internal reviews to include a licensed physician or, where appropriate, a licensed psychologist "in the same or similar specialty that typically manages or consults" on the service in question. However, it is not clear whether the "same or similar specialty" requirement applies only to the psychologist or also to the physician. (The act makes clear that it does not apply to the physician who made the utilization review determination that prompted the grievance.) The precise meaning of "include" is also unclear.

The Department of Health has proposed applying the "same or similar specialty" requirement to both physicians and psychologists in its April 1999 draft regulations. Such a physician or psychologist would have to be a member of the internal grievance review committee at each level.

The NAIC model avoids some of the Act 68 uncertainties by calling for a majority of the persons reviewing denials based on medical necessity or appropriateness to be physicians or other licensed, accredited, or certified practitioners with appropriate expertise. The model act would also give enrollees an option Act 68 does not offer. An enrollee would be able to request an initial review by a committee of clinical peers who were not involved in the adverse determination instead of submitting a first-level grievance. The purpose would be to facilitate the resolution of such appeals. The enrollee would be able to submit a second-level grievance if the clinical peer reviewers upheld the adverse determination.

Act 68 calls for sending written notice of the grievance decision to the enrollee and the provider. The notice must include the basis and clinical rationale for the decision and the procedure for requesting a second-level review or appealing the decision, whichever is applicable.

The NAIC model act goes into more detail than Act 68 about the contents of the written decision issued after a grievance review. The model lists the following information:

- names, titles, and qualifying credentials of the reviewers;
- a statement of the reviewers' understanding of the grievance;
- the decision and rationale in sufficient clarity and detail for the enrollee to respond;
- a reference to the evidence or documentation;

- instructions for requesting a written statement of the clinical rationale and the review criteria for a decision upholding a denial;
- a description of the second-level review procedures and requirements if applicable; and
- notice of the enrollee's right to contact the state regulatory agency and the contact telephone number and address.

Act 68 provides for an external review, a stage not included in the model act. The external review, the final step in the appeal process, is the first stage at which the enrollee can be sure of a clinical peer review or its equivalent. Act 68 requires external grievance decisions to be made by either of the following:

- one or more licensed physicians or approved licensed psychologists in active clinical practice or in the same or similar specialty that typically manages or recommends the treatment being reviewed; or
- one or more physicians currently certified by a board approved by the American Board of Medical Specialists or the American Board of Osteopathic Specialists in the same or similar specialty that typically manages or recommends the treatment being reviewed.

New Jersey also has an external review stage in its grievance process. The enrollee can reach the external review more quickly than under Act 68, because the appeal must go through only one level of formal internal review. The Independent Health Care Appeals Program assigns a utilization review organization, which must be independent of any health carrier and must render a decision within 90 days. Act 68 procedures for reviewing adverse determinations can take up to 145 days, at least 30 days more than grievance procedures in New York, New Jersey, or Ohio. More time might be required if enrollees do not file their grievances promptly at each level.

6. The Criteria for Expediting Grievance Reviews Give Broad Discretion to Managed Care Plans, and Enrollees' Rights to Further Appeals Are Unclear

Both Act 68 and the NAIC model act contain provisions for the expedited review of grievances involving jeopardy to life, health, or the ability to regain maximum function. The managed care plan determines whether a patient's condition meets the criteria. If the review is expedited, Act 68 requires the plan to give the enrollee and the provider a decision within 48 hours after the request is filed.

The NAIC model would allow the plan 72 hours but would require services already being rendered to continue without liability to the enrollee until notification is given. The model act would also require automatically expedited reviews for en-

rollees who had received emergency services but had not yet been discharged from health care facilities.

New York requires an expedited review if a health care provider considers it warranted or the enrollee is undergoing a continued course of treatment. Medicare enrollees in managed care plans may request expedited reviews, and plans must grant them if a physician submits or supports the request. Although the proposed ERISA regulations would apply a prudent layperson rule to expediting the review of urgent claims and appeals,[10] any claim would receive expedited review if a physician with knowledge of the case determined it was urgent.

Act 68 does not specifically address the means for appealing an expedited decision. The DOH proposed making expedited reviews available at all stages of the grievance process, including the external review, in its April 1999 draft regulations. New York statutes and New Jersey regulations expressly describe expedited reviews as accelerated stages in the standard grievance process. The NAIC model act would entitle an enrollee to submit a written grievance at the next level if the expedited review did not resolve the dispute.

7. Managed Care Plans Do Not Have to Give Health Care Providers an Opportunity to Discuss an Initial Denial of Services With the Reviewer, and Providers May Not File a Grievance Without an Enrollee's Consent

Act 68 does not give health care providers the means to request reconsideration of a utilization review decision to deny services unless a formal grievance is filed. A provider does not have the right to appear before a review committee until the second level of the internal grievance process.

New York, New Jersey, and Ohio have adopted versions of a section in the NAIC model act enabling health care providers to request, on behalf of enrollees, informal reconsideration (prior to filing a grievance) if a prospective or concurrent review has resulted in denial. The reconsideration would involve the provider requesting or rendering the service and the reviewer who made the decision or a designated clinical peer. The provider or the enrollee would have the right to appeal the issue as a grievance if the informal reconsideration failed to resolve it.

New York allows an enrollee's provider to request informal reconsideration if the reviewer did not try to discuss the case with provider. It requires a one-day response by the plan. Ohio gives managed care plans three days, but they must have written procedures for expediting such reconsiderations. New Jersey regulations call for an informal appeal process during which the enrollee or a provider may dis-

[10]The severity of the symptoms or pain would make a person with an average knowledge of health and medicine expect serious impairment without immediate medical attention.

cuss the determination with the medical director or the physician reviewer. The HMO has three or five days to respond, depending on the urgency of the case.

Act 68 enables health care providers to file grievances with the written consent of enrollees but does not specify any circumstances under which providers may appeal decisions on their own. A provider must have an enrollee's consent even if the plan denies payment for services approved in advance. New York allows providers to initiate appeals of retrospective decisions.

Insurance Department regulations protect HMO enrollees from liability for services their primary care physicians have authorized but the plan has refused or is unable to cover. Accordingly, enrollees might not have an incentive to appeal retrospective denials. Act 68 does not give a health care provider any recourse in seeking payment for services already rendered if an enrollee does not file a grievance or consent to having the provider file it.

8. Act 68 Requires That Hospitals Provide Emergency Care, but Also Allows Managed Care Plans to Define What Constitutes Emergency Care

Act 68 addresses one of the more contentious issues in managed care: the prior authorization of emergency care. The act contains a prudent layperson definition of emergency service and states that, if an emergency care provider determines a need for emergency service, the provider must evaluate and stabilize the patient without prior authorization.

Although Act 68 provides assurance of emergency care, it does not assure payment by the managed care plan. The plan must pay "all reasonably necessary costs" of the services provided during the emergency, but the act allows for retrospective utilization review. The plan is supposed to consider "both the presenting symptoms and the services provided" when it processes a reimbursement claim for emergency services.

Medicare and Medicaid require that emergency services be provided and that managed care plans pay for such services, regardless of whether or not the emergency provider belongs to their network. Medicare requires its participating hospitals and physicians to assess emergency conditions and provide necessary care regardless of whether the patient is a Medicare beneficiary. If the provider determines an emergency exists, stabilization procedures must be initiated or the patient must be transferred to a facility where such procedures can be undertaken. The attending physician must certify that the benefits of the transfer will outweigh the risks. Physicians face civil monetary penalties and expulsion from the program if they certify emergency transfers in cases where they know, or ought to know, the benefits do not outweigh the risks.

Hospitals face civil monetary penalties if they fail to comply with the Medicare emergency requirements. Any patient suffering personal harm because of hospital noncompliance may sue for personal injury under the applicable state laws where the hospital is located. Medical facilities may sue hospitals for financial losses resulting from such noncompliance.

The Health Care Financing Administration (HCFA) has directed managed care plans participating in Medicare to pay for necessary emergency services without requiring prior authorization. Plans also must pay for "an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists." Participating plans must pay for such tests even though a retrospective review finds the condition did not meet the Medicare definition of an emergency. The judgment of the attending physician prevails over any objections from the plan regarding the transfer of an emergency patient.

Similar directives, issued in February 1998, apply to managed care contractors under Medicaid. Participating managed care plans must pay for emergency services without requiring prior authorization and regardless of any retrospective review findings. If a screening examination prompts the attending physician to render emergency services, the plan must pay for the examination and the services necessary to stabilize the patient. The plan has a continuing obligation to pay for services until the patient can be safely discharged or transferred. The attending physician's judgment prevails in all disputes.

New Jersey and Ohio have incorporated the HCFA requirements into their managed care laws and regulations. Emergency services in New Jersey must include "coverage of a medical screening examination, as required under federal law . . . to determine whether an emergency condition exists." Managed care plans must provide "coverage for trauma services at any designated Level I or II trauma center as medically necessary."

Such coverage must continue until the attending physician determines the patient is medically stable, no longer requires critical care, and can be safely transferred. If a plan requests an emergency patient's transfer to a network hospital, the transfer must be done in keeping with federal regulations.

An Ohio statute specifies coverage of "a medical screening examination, as required by federal law," and defines transfer as having the same meaning it has in Section 1867 of the Social Security Act. Managed care plans must cover emergency services regardless of whether the enrollee or the provider obtained prior authorization. They must cover emergency services at nonparticipating hospitals if such services are necessitated by the enrollee's condition, as determined by a prudent layperson, or circumstances beyond the enrollee's control.

IV. Assuring Quality of Care for Those with Special Needs in HealthChoices

Persons with special medical needs often receive health care through DPW's Medical Assistance program because they have no health insurance. Commercial health insurers and managed care plans traditionally have limited experience in serving individuals with exceptional medical needs. When they do serve those with special medical needs, their benefits may not cover all of their medical and ancillary services needs. As a result, those with exceptional medical needs who have primary health insurance coverage may also receive care through the Medical Assistance (MA) program. In such cases the program serves as a secondary insurer or a catastrophic health insurer.

The care of children and adults with complex medical conditions is different than the care most of us need and experience. Children with complex physical conditions, for example, may:

> . . . require extraordinary amounts of medical management and care coordination by parents who must make frequent trips to doctors and other health care providers, assess almost continuously the severity of various acute illnesses; administer medications; use various medical and nonmedical technologies, such as respiratory technology assistance and tube feedings; and provide personal care assistance on a 24-hour basis. Without appropriate medical care, children with complex conditions are at increased risk of developing secondary, often serious, health problems. They are also at increased risk of developmental and mental health problems.[1]

Until recently those with special medical needs received care primarily through the MA fee-for-service system. Eligible children with exceptional medical needs could have almost all medically necessary care paid for through the program. This is because federal legislation in 1989 required state Medical Assistance programs to pay for any service eligible for federal matching funds under Medicaid needed to treat a condition identified during a screen as part of an Early and Periodic Screening Diagnosis and Treatment (EPSDT) visit.[2] The state must pay for such services even if they are not included in the state's federally approved Medical Assistance Plan[3] or if they are included but only in restricted amounts.

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[1]McManus, M. and H. Fox, *Medicaid Managed Care for Children with Chronic or Disabling Conditions*, Maternal and Child Health Policy Research Center, July 1996.

[2]Omnibus Budget Reconciliation Act of 1989, Pub.L. 101-239, §6403.

[3]The federal Medicaid program provides coverage for a variety of services some of which states may or may not elect to cover. The federal Medicaid program requires each state participating in the program to set forth in its state plan the services to be provided through the plan and the extent to which they will be covered.

In addition, Pennsylvania's Medical Assistance program has served persons with AIDS and technology-dependent individuals (such as persons on ventilators) through federal waivers. Such waivers permitted the Department to provide services not available, or available only in limited amounts, through the state Medicaid plan.

Persons with special needs also had the option to voluntarily enroll in available Medicaid managed care organizations.[4] Individuals enrolled in such programs were permitted to disenroll if dissatisfied with the care they received. On those occasions, they could elect to move to another managed care plan or return to the fee-for-service system.

Individuals with special medical needs often did not elect to receive care through such plans for a variety of reasons. They often need to rely on medical specialists familiar with their conditions for their medical care. Most capitated managed care plans limit access to specialty care. Plan financial risk-sharing arrangements with PCPs may also serve as an incentive to limit their referrals to specialty care.

A. HealthChoices

The way the Pennsylvania Medical Assistance program provides care for those with special needs is changing. DPW is now implementing a federal program waiver called HealthChoices, a mandatory HMO program. DPW initially implemented this program in Bucks, Chester, Delaware, Montgomery, and Philadelphia counties[5] under a federally approved two-year waiver effective February 1, 1997.

On October 30, 1998, the federal Department of Health and Human Services (DHHS) granted DPW a two-year waiver to operate a HealthChoices waiver program in southwestern Pennsylvania beginning January 1, 1999. The ten counties in the southwest waiver include Allegheny, Armstrong, Beaver, Butler, Fayette,

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[4]In the federal Medicaid program the term "managed care organization" has been used to refer to several very different types of organizations. The term has referred to an organization which contracts on a prepaid capitated risk basis to provide comprehensive health services to Medical Assistance beneficiaries. Examples of such managed care organizations include health maintenance organizations (HMOs) and health insuring organizations (HIOs). The term "managed care organization" has also been used in the federal Medicaid program to refer to Primary Care Case Management Systems (PCCM). PCCM arrangements permit the Medicaid program to restrict the provider from or through whom a recipient can obtain medical services. Such services, however, are typically reimbursed on a fee-for-service basis by the Medicaid program. As we have used the term managed care organization in this section of the report, we are referring primarily to health maintenance organizations prepaid on a capitated risk basis to provide comprehensive health services to beneficiaries. When referring to managed care entities such as primary care case management organizations, we use the term PCCM.

[5]During the second quarter of 1994, the Department of Public Welfare required 72,000 Medical Assistance beneficiaries to enroll in capitated risk-based managed care organizations. With the initial implementation of HealthChoices in Philadelphia, Bucks, Chester, Delaware, and Montgomery counties the Department of Public Welfare required over 447,000 Medical Assistance beneficiaries to enroll in fully capitated risk-based plans during the second quarter of 1997.

Greene, Indiana, Lawrence, Washington and Westmoreland counties. Mandatory enrollment in these counties will take place in May 1999 for individuals who have not already selected a HealthChoices plan.

The October 30, 1998, waiver also permits the Department to begin to operate HealthChoices in Adams, Berks, Cumberland, Dauphin, Lancaster, Lebanon, Lehigh, Perry, Northampton and York counties beginning January 1, 2000. By July 1999, DPW plans to have almost 800,000 Medicaid recipients enrolled in HealthChoices.[6]

In granting the Southwest waiver, DHHS waived federal upper payment limits requirements for risk-based capitation payments. DPW capitation rates for Southwest HMOs may, therefore, in certain instances exceed the cost to DPW for providing the same services on a fee-for-service basis.

DPW's HealthChoices Southeast waiver was due to expire on January 31, 1999. On January 6, 1999 and April 21, 1999, the federal DHHS granted DPW 90-day temporary extensions of the HealthChoices Southeast waiver. The extensions were granted to provide DPW with time to request modification of the HealthChoices Southwest waiver to incorporate the southeast counties.

HealthChoices requires Medical Assistance recipients, including persons with disabilities and exceptional medical needs, to enroll in and receive their health care from HMOs that are prepaid, capitated risk plans under contract with the Department. DPW selects its HealthChoices plans through a competitive selection and bid process, and pays its managed care organizations a monthly fee in advance for each enrollee. Each enrollee is assigned a Primary Care Provider (PCP) who is responsible for providing and pre-approving along with the HMO almost all of the enrollee's medical care. Enrollees are also required to receive most of their medical care through their managed care organization's designated provider network. The plans may shift some of their financial risk to doctors, hospitals, and other providers participating in their service delivery network.

DPW has selected four plans to participate in HealthChoices Southeast and three plans to participate in HealthChoices Southwest.[7] These plans primarily serve persons eligible for Medical Assistance. They do not serve a significant number of commercial members.

The goals of the HealthChoices program are to:

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[6]The major exceptions to mandatory enrollment are individuals in nursing homes or nursing facilities, and individuals enrolled in a Home and Community Based Waiver operated by the Pennsylvania Department of Aging.
[7]The four physical health plans selected for HealthChoices southeast were Health Partners, HMA (Health Management Alternatives), Keystone Mercy Health Plan, and Oxford Health Plan. The three physical health plans selected for the southwest are Best Health Care, Gateway, and Three Rivers Health Plan. Technically, Keystone Mercy Health Plan is not an HMO. It is an Integrated Delivery System (IDS) of Keystone Health Plan East which does hold a state certificate of authority as an HMO. Refer to Chapter III for additional information on IDS arrangements in Pennsylvania.

- Improve access to preventative services, primary care, and early prenatal care for Pennsylvania's Medical Assistance population.
- Ensure that every MA recipient is able to choose a primary care provider who will serve as his or her family physician and be responsible for providing all basic medical services.
- Improve quality outcomes of health care services for all Medical Assistance recipients by enhancing the ability of urban and rural communities to retain existing providers and attract new ones.
- Stabilize Pennsylvania's current Medical Assistance spending, and place future spending on a more predictable and sustainable course.[8]

The Department reports it decided to mandate the enrollment of most Medical Assistance recipients into HMOs, rather than permit voluntary enrollment, to reduce adverse selection against the Medicaid fee-for-service program. In the past when enrollment in managed care organizations was voluntary, "cherrypicking was rampant." In other words, the HMOs tended to enroll healthier Medical Assistance recipients rather than sicker ones. When HMO members became seriously ill, they could be disenrolled from their HMO and have care paid for through the Medicaid fee-for-service system. DPW paid HMOs based on the cost of care in the fee-for-service system, which tended to care for individuals with more costly medical needs. This had the effect of providing high profits for the HMOs without containing the Department's Medical Assistance costs.

The federal Physician Payment Review Commission and the Prospective Payment Assessment Commission (discussed in Chapter II) documented a similar problem in the Medicare program. To address the problem, Congress mandated the Medicare program base its capitation payments on enrollee health status.

Pennsylvania's HealthChoices managed care program does not base its capitation payments on enrollees' health status, although DPW has expressed interest in such an approach. The average monthly capitation rates for southeast physical health HMOs serving disabled individuals without Medicare is $354.34, according to DPW published data. HealthChoices plans in southeastern Pennsylvania had net losses totaling about $70 million in 1997, the first year for the program.

Persons With Special Needs Enrolled in HealthChoices

Persons with special health care needs now included in the Department's HealthChoices demonstration in southeastern Pennsylvania include some of the most medically fragile children and adults in the Commonwealth. They include, for example, children and adults with:

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[8]Commonwealth of Pennsylvania, Department of Public Welfare, Statewide Mandatory Medicaid Managed Care Discussion Paper, December 1996.

- Quadriplegia
- Cystic fibrosis
- Paraplegia
- Hemophilia
- Sickle Cell Disease
- Juvenile diabetes
- Cerebral palsy
- Spina bifida
- Congenital lung abnormalities
- Malignant neoplasms
- AIDS or symptomatic HIV.

Those with special needs often qualify for Medical Assistance because they meet the disability definitions used in the federal Supplemental Security Income (SSI) program. State Medical Assistance programs refer to these individuals as "SSI eligibles." Those receiving SSI without Medicare account for the second largest category (15 percent) of HealthChoices enrollees, according to DPW.

Individuals with special needs may also receive Medical Assistance because they qualify for financial assistance through "AFDC/TANF" eligibility categories. For example, a child in foster care and persons with AIDS or symptomatic HIV could receive Medical Assistance under one of the AFDC/TANF eligibility categories of assistance.

DPW in its HealthChoices Request for Proposals (RFP) uses the term "individuals with special needs" broadly. Its use of the term includes those with complex medical needs. It also includes those with significant social but not necessarily complex medical needs, such as persons who are homeless and those who do not speak or read English. Such individuals need significant assistance in understanding how to obtain care through a managed care organization.

For purposes of this report and its recommendations, however, we are using the term special needs in a more limited way than DPW. We use the term to refer to medically fragile children and adults such as those listed above. These individuals require complex highly specialized health care services. (Often, though not always, such individuals receive Medical Assistance as "SSI eligibles.") We also include in the definition children in substitute care because these children often have significant health care needs. As a result, the cost for their care is often significantly greater than for low-income children residing with their families.[9]

The LB&FC's use of the term "special needs" is generally consistent with the federal Balanced Budget Act of 1997. The Balanced Budget Act permits states to amend their state Medicaid plans to expand managed care coverage for Medicaid beneficiaries without obtaining federal waivers. It requires states electing this option to provide beneficiaries with a choice of at least two managed care entities--either a managed care organization and/or a primary care case manager.

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[9]This report focuses on physical health care. Many medically fragile individuals also have behavioral health care needs. This adds further complexity to provision of their care.

The act,[10] however, does not permit states to require enrollment of:

- children (under 19 years old) who are receiving SSI,
- children in foster care or out-of-home placement,
- children receiving foster care or adoption assistance,
- children with handicapping conditions receiving services through Title V of the Social Security Act, and
- persons eligible for both Medicare and Medicaid.[11]

In order to require such individuals to enroll in mandatory managed care programs, states must obtain one of two types of waivers from the federal DHHS. These are called "Section 1915 (b)" and "Section 1115" waivers.[12] Pennsylvania's HealthChoices program operates under a Section 1915(b) waiver.

B. DPW's Efforts to Assure Quality of Care for Individuals With Special Needs

DPW attempts to assure quality of care for those with special needs in HealthChoices in several important ways.

Freedom to Change Health Plans. HealthChoices enrollees may change managed care plans if they are dissatisfied with the care they are receiving. The federal Balanced Budget Act of 1997 permitted enrollment lock-in for up to 12 months, allowing for a 90-day without cause disenrollment period. DPW, however, requires no enrollment lock-in for the HealthChoices program.

Medical Necessity. Definitions of medical necessity used by commercial insurers and managed care organizations often establish standards that present potential problems for disabled individuals. Such standards call for "substantial improvement" or "restoration of function" as a condition for receipt of a service. Disabled individuals, however, may have need for medical and ancillary services to maintain their existing level of functioning or to substitute for lost functioning. Definitions of medical necessity used by managed care organizations which do not take functional ability into account can compromise the quality of care provided to disabled individuals in managed care plans.

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[10]Balanced Budget Act of 1997, §4701.

[11]States are also not permitted to require the enrollment of Indians who are members of Federally-recognized tribes.

[12]These terms refer to sections of the Social Security Act that permit the federal Department of Health and Human Services to waive certain federal Medicaid program requirements. Section 1915 (b) waivers are program waivers. Section 1115 waivers are research and demonstration waivers that permit the state to use Medical Assistance savings achieved through the waiver to provide health insurance for the uninsured.

The Department recognized the importance of the definition of medical necessity to be used by managed care organizations participating in the HealthChoices program. It, therefore, defined its medical necessity standards in HealthChoices Southeast contracts in the following way:

> Determinations of medical necessity for covered care and services, whether made on a prior authorization, concurrent or post-utilization basis, shall be in writing, be compensable under MA, and be based on the following standards. The plan shall base its determination on medical information provided by the individual's family and the primary care practitioners, as well as any other providers, programs and agencies that have evaluated the individual. Medical necessity determinations must be made by qualified and trained providers. Satisfaction of any one of the following standards will result in authorization of the service:
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> - The service or benefit will, or is reasonably expected to, prevent onset of an illness, condition, or disability.
> - The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury, or disability.
> - The service or benefit will assist the individual to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age.

Use of Specialists as Primary Care Providers. The Department indicated in its Request for Proposals (RFP) and contract with HealthChoices plans in southeastern Pennsylvania that it:

> . . . is particularly concerned that certain enrollees with extremely complex debilitating illnesses or conditions have access to adequate specialty care necessary for management of their conditions. In this regard, there will be permitted on a limited basis, as specified below, the permanent assignment of such individuals with complex debilitating illness or conditions to appropriately credentialed and contracted specialist physicians having the clinical skills, capacity, and accessibility and availability to serve as the overall coordinator of all medical care necessary for those individuals.

The Department, therefore, required its HealthChoices plans to obtain a waiver from the Department of Health regulations to allow specialists as PCPs for certain individuals with special needs.

Special Needs Coordinator. The Department in its initial contract[13] with HealthChoices plans in southeast Pennsylvania requires plans to have a full-time Special Needs Unit (SNU) Coordinator. The coordinator must have qualifications which:

> . . . include experience with special needs populations similar to those served by Medicaid. The Coordinator will oversee staff to act as liaisons with various government offices, providers, and public entities to deal with issues relating to MA members with special needs, including wraparound services and to assist individuals with disabilities who are having difficulties accessing services through the HMO.

DPW's initial HealthChoices Southeast contract broadly defines the work of the unit. It does not specify ratios of special needs unit staff to enrollees with special needs, nor does it address the extent to which plans must weigh the recommendations of their special needs units when considering individual service authorizations. The contract, however, does state that employees within the unit "shall assist recipients in accessing services and benefits . . . ."

The Department has strengthened its special needs unit requirements in its HealthChoices Southwest and 1999 Southeast contracts. For example, the Department now requires plans to have "dedicated" special needs units, and the SNU Coordinator must be accountable to the Medical Director. The SNU staff must serve as case managers for individuals with identified special needs. In this role they are responsible for coordinating the delivery of all plan services for which the enrollee is eligible. The SNU staff must facilitate dispute resolution and inform enrollees of the complaint, grievance and appeal mechanisms that are available when special need members are dissatisfied with the plan's response to their needs. The SNU must also be able to demonstrate that its staff "ensure adherence to state and federal laws, regulations, Departmental agreements and court requirements relating to individuals with special needs."

Clinical Sentinel Hotline. In August 1997, DPW established a Clinical Sentinel Hotline.[14] The Hotline number is answered by nurses in the Office of Medical Assistance and an answering machine during DPW's normal business hours.

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[13]Throughout the report we refer to requirements in the Department's contract. This term refers not only to the contract itself, but also those sections of the HealthChoices RFP that have been incorporated into each plan's contract.

[14]The Clinical Sentinel Hotline number (1-800-426-2090) is shared with the Bureau of Fee for Service's Place of Service Review Program.

The hotline nurses have several responsibilities. These include:

- Evaluating and referring direct questions regarding HealthChoices to the appropriate parties.
- Screening and immediately referring Clinical Sentinel events to the Office of Medical Assistance Programs' Medical Director.
- Reviewing, researching, and resolving critical Clinical Sentinel events with the Medical Director and staff.

Clinical Sentinel events are those which "occur when a contracted plan's expedited appeals process and the Office of Medical Assistance Program's (OMAP's) evolving quality management mechanisms are unable to resolve a clinical issue within a time frame that reasonably safeguards the lives and health of enrolled individuals." The Department notified Medicaid Southeast enrollees of the existence of the clinical sentinel hotline through a brochure in February 1999.

Reporting of Encounter Data. DPW's HealthChoices contracts require plans to submit a separate record, or "pseudo claim," each time a member has an encounter with a provider. An encounter is defined as each procedure or service performed during, or as a result of, a professional face-to-face contact between a recipient and a provider. HMOs are required to submit the data quarterly in prescribed formats. DPW staff must validate the data and HMOs are required to assist in the validation of data by making available medical records and a sample of claims data.

Monitoring. The Bureau of Managed Care Operations in the Office of Medical Assistance has primary responsibly for monitoring HealthChoices plans. DPW has established core teams to carry out these activities. The monitoring is a comprehensive team approach model, which incorporates all areas including the clinical component. The teams consist of a team leader, one other bureau staff member, special needs unit staff, and staff from the Office of the Medical Director, systems operations, financial operations, and the Comptroller's office. The core teams at times involve Medical Assistance fee-for-service; Office of Children, Youth, and Families; Office of Income Maintenance; and Office of Legal Counsel staff. At times, Departments of Aging, Health, and Insurance staff are also involved.

The core team develops a monitoring plan for each HealthChoices plan. The teams meet every other week and review current issues. In 1998, the teams completed onsite visits to plans twice a month to provide technical assistance. Currently, an outside contractor is working with DPW to develop an automated

tracking system for plan monitoring. In the future, DPW staff plan to have available encounter data and HEDIS[15] data to assist in monitoring plans.

DPW staff also carries out readiness reviews prior to plans' implementing HealthChoices. As a result of the initial readiness reviews in the Southeast, DPW recognized there would be problems in implementation and that plans needed technical assistance. Although the HealthChoices plans had participated in DPW's voluntary managed care program, they did not fully anticipate the differences in the populations to be served in the mandatory managed care program, nor were they prepared for DPW's higher performance expectations.

In part for this reason, DPW staff decided on early implementation follow-up with plans in the form of onsite clinical reviews. The objectives of these reviews were to become more familiar with the processes developed by the plans to implement DPW's requirements and provide technical assistance in these areas. From January through April 1998, DPW staff completed the onsite clinical reviews of the four southeastern HMOs. The reviews considered access to physical health care, services to individuals with special needs, processes for complaints, grievances, and appeals, quality management, and utilization management. During the onsite reviews, DPW staff identified actions plans must take to resolve issues identified during the onsite reviews. Appendix I contains selected critical action steps and recommendations made by DPW during the onsite reviews.

DPW staff did not envision the onsite clinical reviews as audits of the plans' performance. It, therefore, did not set up a separate tracking system to monitor plan implementation of the critical action steps and other recommendations that relate to DPW requirements. Based on core team work with plans during 1998, however, DPW staff estimate that 75 to 80 percent of the critical action steps listed in the clinical onsite review reports have been fully addressed by the plans.

Creation of a Special Needs Unit in DPW. In March 1998, DPW established a Special Needs Division within the Office of Medical Assistance Programs' Bureau of Managed Care Operations. It consists of five staff.

The Division routinely monitors the plans' Special Needs Units and liaisons with DPW enrollment broker's special needs unit. DPW's special needs staff are involved in community education, participate in HealthChoices Southwest readiness reviews, and provide technical assistance and training for plan staff. DPW special needs unit staff address individual enrollee issues brought to their attention by various departmental hotlines, DPW plan managers, and advocates. They work

[15]HEDIS (Health Plan Employer Data and Information Set) is a set of standardized performance measures to provide comparative information on plans for consumers and employers. Such measures include, for example, childhood immunization status, adolescent immunization status, prenatal care in the first trimester, low-birth weight babies, check-up after delivery.

with the plans' special needs units to resolve such issues. They also are involved in developing policy clarifications related to special needs issues.

Payments for Plans Serving Higher Than Anticipated Numbers of Persons with HIV/AIDS. DPW developed a 1998 contract amendment to provide additional funding in certain circumstances to HealthChoices Southeast plans serving higher numbers of HIV/AIDS enrollees. For 1999, DPW has established HIV/AIDS risk pools for the Southeast and Southwest.

Independent, Comprehensive Evaluation of the Waiver. The federal DHHS required the Commonwealth to arrange for an independent, comprehensive evaluation of the HealthChoices Southeast waiver program. The evaluation was to be completed by October 31, 1998.

C. Conclusions

Despite the efforts of DPW staff, HealthChoices plans, providers, and consumers to effectively implement HealthChoices, the Department cannot assure that children and adults with complex medical problems and children in substitute care enrolled in HealthChoices are receiving high quality care. In particular, we found four major issues of concern.

1. HealthChoices Has Encountered Various Implementation Problems That Affect the Quality of Care of Individuals With Special Needs

HealthChoices has encountered many implementation problems that influence access and quality of care. Persons with complex medical conditions are especially affected by such problems because of their more frequent use of medical services and the vital nature of medical services for them. Many of these issues are unresolved or have not been fully resolved as of May 1999.

Continuity of Care. The HealthChoices Southeast contracts indicate that plans are to provide for continuity of care. They do not, however, specify how plans are to transition new plan enrollees who are currently receiving medical treatment. DPW outlined its expectations for plans' transitioning enrollees in the process of receiving medical treatment in a January 1997 letter to the plans from the Office of Medical Assistance's Medical Director and the HealthChoices Project Manager.

In the letter, DPW outlined procedures to be followed for individuals receiving treatment at the point they were first enrolled in HealthChoices or transferred from one managed care plan to another. It also outlined procedures to be followed in cases where the services previously had been prior authorized or required prior authorization to be provided in the enrollees' new plan.

The letter did not distinguish between services for children and adults. As a result, it conflicted in part with a previously issued Medical Assistance Bulletin addressing continuity of care for individuals under age 21. The letter, moreover, did not outline how the procedures set forth in the letter would need to be carried out to remain consistent with relevant federal hearing and appeal rights and relevant court cases.

Consumers subsequently identified problems with the January 1997 letter. DPW also recognized the need to develop a Medical Assistance Bulletin addressing continuity of care for Medical Assistance beneficiaries transferring between and among fee-for-service and managed care organizations. In late 1997, it developed a draft bulletin with improved procedures.

Unlike the earlier letter, the draft Bulletin included separate procedures for children and adults and clarified that applicable MA policies prohibit concurrent review of individual treatment plans for children under the age of 21 receiving previously authorized services. Moreover, if a concurrent review of services for an adult results in the managed care plan authorizing an alternative course of treatment, or a reduction or termination of previously approved treatment, the plan must provide proper notification of the denial to the recipient and the proscribing provider. It must also honor the recipient's right to exercise full appeal, grievance and fair hearing rights, including the right to continue services at the current level pending the outcome of an appeal which has been filed within ten days of receiving notification of the denial. The draft bulletin, however, was not issued prior to the passage of Act 1998-68, which imposed new continuity of care requirements that affected HealthChoices and other Commonwealth managed care plans.[16] As of April 1999, a redraft of the Department's draft bulletin had not been issue, and DPW's policy to ensure that the HealthChoices plans provide continuity of care is unclear at this time.

HealthChoices Plans Appear to Be Having a Difficult Time Meeting All Federal Requirements for Providing Care for Disabled Individuals Enrolled in HealthChoices. As shown in Exhibit 12, the federal courts have thus far become involved in three HealthChoices cases. The Metts, Bates-Booker, and Anderson cases all involve access to physical health care by persons with disabilities.

The Metts Settlement Agreement demonstrates that HealthChoices plans were not following the definition of medical necessity included in DPW's HealthChoices RFP.[17] They were also improperly reducing and denying medical services.

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[16]Act 1998-68, 40 P.S. §991.2117.

[17]In December 1998, LB&FC staff reviewed the four Southeast HealthChoices plans' generic provider contracts on file with the Department of Health. Only one of the plan's contracts included the medical necessity definition used in DPW's southeast RFP and contract.

Exhibit 12

Recent Federal Court Decisions Concerning HealthChoices Services

Metts, et al. v. Houstoun: A class action lawsuit in the U.S. District Court for the Eastern District of Pennsylvania which alleged (1) that Medical Assistance recipients enrolled in the HealthChoices Program in Southeastern Pennsylvania have been denied due process protections of Title XIX of the Social Security Act and the Fourteenth Amendment when HealthChoices HMOs deny, reduce or terminate outpatient services and benefits and prescription medications; and (2) HMOs wrongfully denied some class members medically necessary home health services, personal care services, outpatient and in-home therapies, durable medical equipment and medical supplies that are covered by the Medical Assistance Program.

A settlement agreement was reached in March 1998. Key provisions of the agreement include:

1. Notices to deny, reduce or terminate benefits will identify specific information needed to assess medical necessity; explain reasons for the denial, etc., in sufficient specificity to provide an understanding of the basis for the decision; identify criteria used by the HMO to make the decision.
2. Medical necessity determinations must be made on an individual basis using the definition of "medical necessity"[a] in the HealthChoices RFP.
3. Case Management is a covered service for members under 21 years of age but cannot be provided by an employee or subcontractor of the HMO if the individuals' responsibilities include outpatient utilization review or review of requests for authorization of outpatient benefits.
4. A request for a medically necessary covered benefit may not be denied based solely on the presence or absence of a particular diagnosis or condition.
5. A request for medically necessary in-home nursing services, home health aide services or personal care services for a member under age 21 may not be denied on the basis that the live-in caregiver can perform the tasks unless the HMO determines the caregiver can provide the level and extent of care given other responsibilities.
6. A request for medically necessary and prescribed home health services for a member 21 or older may not be denied for certain enumerated reasons.[b]
7. Medically necessary incontinence products are covered benefits.

Procedures to monitor the implementation of the agreement include defendant conducting a random telephone survey at least once every ninety day period to ascertain whether HMOs are verbally denying requests for services; defendant providing plaintiffs' counsel copies of notices of denials, reductions and termination of benefits sent by HMOs within fourteen days of their mailing; and DPW reviewing notices for compliance with the requirements of the agreement. The Court maintains jurisdiction over this litigation to enforce the agreement for one year after which the case will be dismissed without prejudice. A supplemental settlement agreement concerning the implementation of notice requirements for prescription medications was entered into on May 7, 1999. A joint plan to address the agreement's requirements is to be given by the parties to the court within 30 days or a mediator will become involved and a joint plan will be submitted in 45 days. The court retains jurisdiction over this matter for six months.

Bates-Booker, et al. v. Houstoun: Lawsuit on behalf of class of children enrolled in Medicaid HMOs seeking to compel DPW to assure HMO contracts do not deny medically necessary services or equipment to children based on rationale that such services should be obtained from special education or early intervention programs.

A settlement agreement was reached in October 1997. Key provisions include:

Exhibit 12 (Continued)

1. DPW sending notice that members under age 21 are entitled to "medically necessary" health care and equipment and RFP definition of "medically necessary" to all HMOs under contract with DPW.
2. DPW or HMOs that denied services on reason cited in this action sending specific notices to providers regarding HMOs obligation to provide services.
3. DPW directing HMOs that denied services for reasons cited in this action to assure appropriate staff have read and understood policy notices. Additionally, in-service training regarding the policy to be held.
4. DPW or HMOs sending notices to class members who were denied services and identifying additional class members who may have been told denials were upon another basis or who are no longer enrolled in HMO that denied service.

Procedures to monitor the implementation of the agreement include DPW at least monthly surveying identified populations and DPW providing monthly for six months and bimonthly for an additional six months copies of all denials, reductions or terminations of target services issued by HMOs. In April 1998 the case was voluntarily dismissed with the agreement of both parties.

Anderson et al. v. DPW: Action in the U.S. District Court for the Eastern District of Pennsylvania alleging defendants are violating Title II of the Americans with Disabilities Act by (1) failing to require all healthcare providers in HealthChoices be accessible to people with mobility impairments; (2) failing to provide all program information in alternative formats, e.g., Braille; and (3) using methods of administration that have discriminatory effects.

The Court found as a matter of law that HealthChoices was inaccessible because it does not comply with the minimum program accessibility regulations promulgated under Title II and Section 504 of the Rehabilitation Act of 1973. These include requiring new construction to be accessible and existing facilities operated so that the program when viewed in its entirety is readily accessible. Although DPW need not require every provider participating in HealthChoices to practice in an accessible facility, the Court held that DPW must ensure compliance with the regulations applicable to "new construction" and "existing facilities" to provide disabled individuals a meaningful opportunity to benefit from the program. The Court issued an order to the defendants to enforce the section 504 requirements, which must be satisfied before a provider may participate in HealthChoices.

The Court also certified the proposed class for purposes of the issues remaining for litigation. The class of plaintiffs includes every mobility or visually impaired recipient of Medical Assistance in Southeastern Pennsylvania. Issues which remain for future action are (1) whether verbal assistance or audio tape are sufficiently effective for communicating the information included in the provider directories, and (2) whether the methods of administration of the program have the "effect of defeating or substantially impairing accomplishment of the objectives of the public entity's program with respect to individuals with disabilities." The Court issued a memorandum and order in April 1998 addressing the motions filed by the parties.[c]

A settlement agreement was reached in June 1998. Key provisions include:

1. Accessibility Development Associates, Inc. (ADA, Inc.) will conduct accessibility inspections of each HealthChoices provider[d] within 270 days of the signing of the agreement. The goal is for the inspections to be completed at an average rate of 500 per month.
2. ADA, Inc., will determine for each HealthChoices provider office or facility whether there are architectural barriers to accessibility for persons with mobility impairments and will identify each barrier and the actions needed to be taken to remove each barrier as well as obstacles to the removal of each barrier.

Exhibit 12 (Continued)

3. DPW or the appropriate HealthChoices HMO will notify each provider with barriers identified by the inspection that it must become accessible no later than 90 days from the date of notification unless the parties otherwise agree. ADA, Inc., will conduct follow-up inspections no later than 90 days after the initial 90-day time frame.
4. When ADA, Inc., notifies DPW that a provider has not removed an architectural barrier as described above, DPW will promptly begin procedures to terminate participation of the provider in the Medical Assistance Program.
5. DPW will provide plaintiffs with quarterly reports listing the accessibility status of each HealthChoices provider's office or facility as a result of the initial and follow-up inspections that ADA, Inc., conducted during the preceding 90 day period.
6. Within 60 days of the signing of the agreement, informational material, such as provider directories, member handbooks, etc., will be available upon request in Braille, large print, and audiotape. The information in these directories need only cover the zip codes or other geographic locations that the person with a visual impairment requests.
7. The next regularly scheduled printing of the HealthChoices HMO provider directory and periodic supplements will accurately reflect which providers are accessible to persons with mobility impairments.
8. Within 60 days of the completion of the facility inspections, DPW will analyze the geographic distribution of providers in the same manner this distribution was analyzed generally when the HealthChoices program was initiated. If the analysis shows inadequate geographic distribution of provider offices and facilities accessible to persons with mobility impairments, DPW will remedy this problem and will use best efforts to do so within 60 days, notifying the plaintiffs of the actions taken.
9. DPW or the responsible HealthChoices HMO will assist HealthChoices members in locating accessible providers.

This settlement places the case in civil suspense until the activities related to accessibility are completed. Once the final quarterly report is received, and the parties agree that the provider locations are accessible or in compliance with the inspections conducted by ADA, Inc., and that noncompliant providers have been terminated from the Medical Assistance programs, the parties will stipulate to the dismissal of the action. Prior to that time, with 60 days notice to the other party, either party may remove the action from civil suspense status and pursue its rights under the memorandum and order issued by the court in April 1998.

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[a]Under HealthChoices, medical necessity is determined if any one of the following standards is satisfied: (1) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability; (2) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability; (3) the service or benefit will assist the individual to achieve or maintain maximum functional capability in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age.

[b]These reasons are: (1) prescribed home health aide services are limited to provision of assistance with daily living activities or could be performed by a personal care assistant; (2) the member has a particular diagnosis or prognosis; (3) member has a condition or disability that is long term, stable, or will not improve; (4) another person is available to provide those services; or (5) member needs, but is not receiving, a higher level of care.

[c]Plaintiffs allege that DPW has allowed the use of "special needs" identifiers in the provider directories and has allowed the assignment of mobility-impaired individuals to providers whose offices are inaccessible. Plaintiffs also allege that DPW has failed to use methods of administration, which would maximize access to HealthChoices providers by people with mobility impairments.

d The definition of provider in the agreement excludes those providers whose offices are located in hospitals or health clinics.

Source: LB&FC review of settlement agreements in Metts et al. v. Houstoun, Civil Action No. 97-CV 4123; Bates-Booker et al. v. Houstoun. Civil Action No. 97-CV-3734; and the Memorandum and Order and Settlement Agreement in Anderson et al. v. DPW, Civil Action No. 97-3808.

When DPW first implemented HealthChoices it did not require plans to use a standard notice when denying, reducing, or terminating services. The 1999 HealthChoices contracts now contain a standard notice that plans are required to use and may be modified only with DPW's permission. As of April 1999, no exceptions to the standard notice have been granted, according to key DPW officials.

DPW has attempted to fully implement the Metts Settlement Agreement. Nonetheless, in September 1998, the Disabilities Law Project formally advised DPW's Chief of Litigation that violations of the Metts Settlement Agreement's due process protections continue with regard to prescription medications. (See the discussion below on pharmacy issues.)

Children enrolled in HealthChoices, especially those with disabilities, are also having problems accessing dental services. DPW recognizes this is a major problem, especially for those with disabilities, and sees this as a national problem. DPW reports it is attempting to address the shortage of dentists willing to participate in the HealthChoices program and the Medical Assistance program. It scheduled a May 1999 dental summit in an attempt to address the issue.

Few HealthChoices Enrollees Have Been Able to Access Specialists as Their Primary Care Providers. Special needs populations, because of their complex medical needs, often rely on specialists to coordinate their overall medical care. HealthChoices, therefore, permits specialists to serve as PCPs for members with complex medical conditions expected to last more than six months.

As shown in Table 2, few HealthChoices participants have benefited from this option. Only 221 of the over 478,000 HealthChoices Southeast enrollees have been assigned to specialists as PCPs.

Table 2

Members With Specialists as PCPs by HealthChoices Physical Health Plan

HealthChoices Plan	Number of Members Using a Specialist as a PCP	Types of Specialists Serving as PCPs
Health Management Alternatives	0	NA
Health Partners	2	Infectious Disease and Gerontology
Keystone Mercy Health Plan	184	Not Identified
Oxford	35	Oncology, Nephrology, Internal Medicine, and Infectious Disease

Source: Developed by LB&FC staff from information provided by the DPW in October 1998.

The reasons for these low numbers are unclear. Advocates indicate that they do not have information from plans about how to access specialists as PCPs.

LB&FC staff attempted to identify PCP/specialists and centers of excellence using the plans' provider directories. We were unable to identify them from the directories. When we asked HealthChoices plans about this, one plan told LB&FC staff that DPW had instructed plans not to include in the provider directory detailed information on special needs services. It provided an April 1998 document in which DPW instructed the plan to remove all special needs indicators from their provider directories and indicated DPW would pay for all reprinting and redistribution cost associated with such revisions.

Several medical specialists advised LB&FC staff they understood that, if they served as PCP/specialists for their patients, the plan would require that they also serve as PCPs for individuals who did not require their specialty care. Plans have reported to DPW that specialists are unwilling to participate as PCPs because of the Department of Health's requirements for specialists serving in such a role.

HealthChoices Plans Have Not Provided Special Needs Services as Envisioned by DPW. The Health Choices Southeast initial contracts require the four HealthChoices plans to develop, train, and maintain special needs units (SNUs) as a means of ensuring that members with special needs receive appropriate care. The HealthChoices Southeast contract specifically requires special needs staff to assist recipients in accessing services and benefits. The Department conducted on-site clinical reviews between January and April 1998 to assess the plans' progress, including the implementation of their SNUs. The review covered 1997, the first year for HealthChoices Southeast.

The DPW on-site reviewers' observations and conclusions reflected the following comment from one of the participating HMOs:

> The mandatory environment created under HealthChoices imposed many new requirements for both the HealthChoices contractors and the Department. Neither the Department nor the plans were fully prepared for the implementation program necessary to meet the expectations of consumers, providers, and other concerned entities.

The on-site visit reports suggest that the DPW reviewers and the plans had differing expectations regarding the SNUs. The DPW reviewers interpreted the contract as requiring the SNUs to play a comprehensive role in serving members with special needs, including those with complex medical conditions and those with difficulty accessing care because of language, transportation, and other cultural and social barriers.

The actions of the HealthChoices Southeast plans suggest they interpreted the contract requirements differently. They appear to have designed their SNUs to perform coordinating functions and give other units guidance but not to take full responsibility for managing the care of every member with special needs.

Staffing: Organizational and operational differences in the SNUs reflected the plans' efforts to develop them without prior experience or a standard model. The sizes of the units were appropriate for the functions the plans, not the DPW, had in mind. During the first year of operation, the largest SNU had 15 employees and the smallest might have had only two, depending on how the reviewers interpreted the conflicting information they received from one of the plans.

Keystone Mercy Health Plan, which covers about half of the eligible population, had the largest SNU. Its 11 case managers were responsible for interacting with specific inpatient facilities and using their clinical expertise to assist members. Health Partners, Inc., designated its Human Services Department an SNU. The unit had five full-time case managers with expertise in various conditions involving special needs. Health Management Alternatives (HMA), Inc., had a full-time SNU manager and four program coordinators. HMA designated the staff as program coordinators, because it had a subcontractor providing traditional case management.

Oxford Health Plan of Pennsylvania had the most problematic SNU for the reviewers to assess. Separate organizational charts from Oxford showed a staff of two, a manager and a coordinator, or a staff of seven. Oxford submitted a third chart after the review. It identified certain employees as SNU staff, even though some of them were not working in the unit. The DPW report called for a current organizational chart, a program description outlining SNU functions, and evidence of liaison activities and access to special needs services.

Identification of Special Needs Members as Defined by the DPW: Although the initial contracts for southeastern Pennsylvania did not specify identification and outreach as SNU functions, DPW's onsite clinical review reports conducted in early 1998 implied that the DPW had anticipated their performing such functions. The DPW intended its broad definition of special needs to be the basis for identifying such members.[18] Keystone Mercy, Health Partners, and HMA were using DPW's definition of special needs members and attempting to identify them in a variety of ways, the DPW reviewers concluded.

Oxford was the only plan cited for failing to comply with the contract definition. Oxford gave its members the opportunity to identify themselves as having special needs but used their medical diagnoses as the basis for actually classifying

[18]The RFP for southwestern Pennsylvania clarified the Department's expectations. The SNUs are expected to identify all members with special needs and provide them with individual case management.

them as persons with special needs. The SNU had no documented criteria for identifying special needs from the broader DPW perspective, the reviewers determined.

Case Management and Coordination: During the first year of operation, the four HealthChoices plans either had subcontractors performing the traditional case management functions for at least some members or had the SNUs sharing such activities with other units. The SNUs often played a subordinate role in the shared arrangements. The SNUs' case management and coordination services were found to need improvement.

For example, one of the Keystone Mercy subcontractors did not have any MA-enrolled case managers, a violation of DPW requirements. Care coordinators in large clinics were serving up to 200 clients each under the Healthy Beginnings Plus program, even though the contract requires they not have more than 75 clients.

Health Partners' SNU case managers were not providing services and coordination in keeping with the more extensive program described in the plan's Human Services Program, the reviewers concluded. The SNU did not have a complete list of the members with HIV/AIDS receiving case management services from community agencies, and members' records did not contain any documentation of efforts to coordinate care, the reviewers determined. Health Partners was also not adhering to its policy of requiring subcontractors to provide services through MA-enrolled case managers.

HMA used multidisciplinary teams to integrate case management with the available medical services. Members' files contained descriptions of SNU interventions but sometimes lacked information about PCPs and the continuity of care.

Oxford used in-house disease management teams to manage care for some special needs, a subcontractor to provide case management for adults with complex health care needs, and its SNU for social case management. The files on members with HIV/AIDS did not contain any evidence of a service coordination plan or services comparable to the DPW Targeted Case Management Program. The report cited a need for evidence of the SNU's role in developing comprehensive service plans, helping members access services and benefits, and serving as a liaison with other agencies and systems.

Capitation Payments Not Sufficient to Cover Costs of Care for HIV/AIDS Patients. DPW does not reimburse plans based on enrollee health status. It reimburses plans based on factors such as category of assistance, age, and geographic location. Such per-capita rates in managed care can produce inequities between plans if they attract memberships with significantly different health care needs. Such inequities can result in either adverse or favorable selection. Adverse selection occurs when a plan tries to provide quality care for all of its members, re-

gardless of need, and finds itself enrolling the most costly cases in its service area. A plan with adverse selection has an incentive to restructure its provider network. It can promote favorable selection by eliminating providers who attract the patients with the greatest health care needs and recruiting providers who serve healthier segments of the population.

HealthChoices has the potential for creating adverse selection. Competitive bidding for contracts forces the plans to try balancing their assumptions about the range within which they can bid successfully and their future members' health care needs. They have little control over the enrollment process. They generally do not have gains from commercial plans to offset their losses if their revenues fail to cover the cost of their enrollees' care. Their only recourse may be to limit accessibility for their members who need high-cost services.

DPW recognized the potential for the adverse selection of HIV/AIDS patients and introduced a retroactive rate adjustment. The DPW initially developed criteria for determining whether the HealthChoices plans in southeastern Pennsylvania were incurring excessive costs and utilization of HIV/AIDS services in 1997 and 1998. Plans meeting the criteria qualified for retroactive adjustments to their contract rates.

The retroactive adjustment criteria for southeastern Pennsylvania used historical data to establish assumed prevalence baselines by aid category (e.g., SSI without Medicare) and service category (e.g., hospital inpatient) for each plan. The DPW compared the baseline with six-month data reports submitted by the plans. They became eligible for retroactive adjustments in a category if their HIV/AIDS utilization rate exceeded the baseline by more than 20 member-months per 10,000 for the six-month period.

The plans' excess costs and utilization determined the size of the additional payments. The DPW methodology called for a 90 percent reimbursement of the amounts by which the plans' average costs per HIV/AIDS member exceeded their assumed contract rates[19] for members without HIV/AIDS, multiplied by their excess HIV/AIDS memberships. Although the Department estimated its total payments between $6 million and $8 million for 1997, it did not have data on which plans had received payments or how much they had received as of April 1999.

The DPW has proposed three risk pools, designated for specific aid categories[20], to adjust the southeastern plans' HIV/AIDS payments in 1999. The Department will withhold amounts from the plans' monthly per-capita payments, deposit such amounts into the risk pools, and distribute them quarterly in proportion to the

[19]The DPW broke down the plan contract rate for each category into two rates based on the assumed prevalence of members with and without HIV/AIDS.
[20]The categories are (1) TANF and Healthy Beginnings, (2) SSI and Federal GA, and (3) State GA.

HIV/AIDS member months reported by the plans. The plans are to receive interim monthly payments from each risk pool to bolster their cash flow.

The risk pools have potential advantages and disadvantages in comparison with the retroactive adjustments. The potential advantages include a more equitable distribution of payments. The plans will have their proportional shares based on a common denominator, not the amount by which their costs exceed an after-the-fact assumption regarding the prevalence of HIV/AIDS. The alleviation of cash flow shortages is another potential advantage.

The potential disadvantages include a greater risk in underestimating costs, because the risk pools redistribute funds based on member months instead of paying additional amounts based on excess costs. If the plans bid too low, they may face another potential disadvantage. The risk pools only transfer funds from one plan to another; they do not add to the total payments as the retroactive adjustments did. The withheld funds might not be sufficient to offset the aggregate costs of adverse selection or the inflationary effects of newly recognized treatment methods.

The HealthChoices plans in southwestern Pennsylvania will have a similar risk pool arrangement. In addition, they may also receive quarterly payments from an HIV/AIDS drug utilization pool, which will distribute DPW funds in proportion to the costs the plans have incurred for dispensing designated drugs.[21] The distributions may not exceed the amounts actually paid for the drugs. The Department will make $1.5 million available for distribution in 1999.

The Department is making other efforts to compensate plans for adverse selection. The southwestern plans have the option of submitting independent actuarial studies based on their experience during the first six months to justify rate adjustments. Their contracts also provide for payments if their costs for emergency services exceed 30 percent of nonparticipating providers' charges. The Department offered the southeastern HealthChoices plans a risk-sharing option that it hoped would provide an inducement for lower negotiated rates. Only one of the four plans chose to participate.

Although risk pools and retroactive adjustments help to mitigate the uncertainties associated with predicting extraordinary costs, they can not guarantee full and equitable reimbursement. Plans still will have to take financial risks. Underestimating the potential need for HIV/AIDS services will expose the plans providing the most comprehensive care to adverse selection. The acceptance of newer, more expensive treatment methods creates a demand for such services, regardless of their cost, and makes managed care plans more aware of their exposure to risk. Plan

[21]The southwestern plans are responsible for covering the cost of Protease Inhibitors, a condition not imposed on the southeastern plans.

strategies to improve selection may make quality care less accessible for the members who need the most costly services.

Difficulty in Accessing Care From HIV/AIDS Experienced Providers. In October and November 1998, a coalition of 45 hospitals and community service providers and advocacy organizations advised the federal Medicaid Program director that major hospital health systems were no longer participating in some HealthChoices plans' provider networks. Consumers also report that, when provider networks change, they experience gaps in their on-going treatment and their health care may be jeopardized. Treatment gaps can occur if they have to switch PCPs or hospitals. The coalition questioned the adequacy of the plans' provider networks for people living with HIV/AIDS in southeastern Pennsylvania.

LB&FC staff attempted to determine the extent to which medical specialists with expertise in treating HIV/AIDS were available to HealthChoices plan enrollees. Staff used unpublished lists of plan provider networks that HMOs must submit to the Department of Health (as required by the plans' state certificate of authority) and plan provider directories to identify infectious disease specialists and PCP/specialists. Based on contacts with the physician offices, we added to the Department of Health lists new physicians who had joined the practice and had been credentialled by the HealthChoices plans.

The US General Accounting Office has reported that a count of physicians participating in state Medicaid HMOs is not a useful measure of access because physicians may participate in multiple plan networks and may not be available to all Medicaid beneficiaries. States often monitor the number of specialists participating in a plan network. Such numbers, however, do not necessarily indicate whether beneficiaries actually gain access to specialty care. We, therefore, unduplicated the number of available physicians across plans and contacted them to determine their availability to serve HealthChoices patients.

In total, we identified 78 unduplicated infectious disease specialists serving in the HealthChoices Southeast region. Most are based in Philadelphia and most are ABMS board certified.

Of the 78 infectious disease specialists, 22 reported being available to treat HealthChoices patients on an ambulatory basis through at least one of the four HealthChoices Southeast plans.[22] Twelve of the 22 served as PCP/Specialists, and 10 of the 22 provided only specialty care, some on a part-time basis. Only ten

[22]Some of these physicians reported they were credentialled by more than one HealthChoices plan even though they were not listed in all plan provider directories. Moreover, they were not always credentialled in the same way by each of the plans. For example, one plan might credential a physician as a PCP/Specialist. Another might credential that same physician only as a PCP. A third might credential the physician as a specialist available only on a hospital consult basis.

PCP/specialists and three of the specialists reported serving more than a few HealthChoices patients in their practices.

One-half of the specialists (39 of the 78) were employed by hospitals and saw patients only through hospital consults. Some of these physicians worked for hospital health systems that no longer had global contracts with HealthChoices plans.[23,24] The remaining 17 of the 78 specialists are engage in research and did not treat patients, did not accept medical assistance patients without Medicare, were no longer with the practice, or no longer had contracts with HealthChoices plans.

One of the four HealthChoices plans had discontinued contracts with two of the ten PCP/Specialists who indicated they served large numbers of HealthChoices patients. One of the two doctors reported that the contract had been cancelled by the plan because the plan was losing money with the contract. In other words, this plan cut its network of experienced HIV/AIDS ambulatory providers by at least 20 percent.[25]

Physician practices we spoke with identified problems they have encountered in treating HIV/AIDS patients under HealthChoices. Some of the practices actively involved in treating HIV/AIDS patients indicated they have difficulty getting proper care for their patients through HealthChoices HMOs. A major program serving HealthChoices plan enrollees reported that only about half of those with HIV/AIDS receiving care are receiving comprehensive care. Another specialist indicated that HealthChoices has no definition of an HIV specialist provider. As a result, an HIV specialist provider in HealthChoices is anyone claiming to have such expertise.

One practice advised the LB&FC staff that claims submitted to HealthChoices plans are regularly processed incorrectly. This practice indicated it is still

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[23]When major hospital health systems "leave" a HealthChoices plan network the emergency department and inpatient components of the hospital may continue to provide some services under fee for service arrangements with the plan. The physician practices and ambulatory specialty clinics that are part of the health system (and often include highly trained specialists), however, may not be available to individuals with special needs. This discussion focuses on individuals with HIV/AIDS because services for this group were tracked by the coalition. However, the departure of major health systems and the availability of their specialists from a plan's network similarly affects others with special needs—not just those with HIV/AIDS.

[24]The coalition reported Keystone Mercy stopped doing business with five area hospitals in September 1998 and Health Partners stopped doing business with two hospitals in Delaware county and four in Philadelphia including Temple Hospital, Pennsylvania Hospital and the North Philadelphia Health Systems. Health Partners typically operates through risk-sharing arrangements with the hospitals that participate in its network. Each participating PCP is assigned to a particular hospital. When Medical Assistance recipients enroll in Health Partners, they are assigned to a PCP. The PCP's affiliated participating hospital is then assigned the risk for that member. Members are directed to the risk bearing hospital for provision of all services, according to DPW. Health Partners is owned by Albert Einstein Medical Center, Episcopal Hospital (which is owned by the Temple University Health System), Frankford Hospital (which is affiliated with the Jefferson Health System), various hospitals owned by the Allegheny Health and Education and Research Foundation (and acquired by Tenet following AHERF's bankruptcy), Temple University Hospital, and the Hospital of the University of Pennsylvania.

[25]This figure does not take into account physicians affiliated with health systems who are no longer available to HealthChoices patients on an ambulatory basis.

awaiting disposition of claims related to the bankruptcy of the original DPW mandatory managed care demonstration. Another practice indicated it had not been paid on time by a plan all year. Another practice specifically indicated that it only saw hospitalized patients because of the difficulty receiving payments for outpatient care from the HealthChoices HMOs with which they contract.

Many of these physicians were among a larger group of physicians, clinic, and hospital-affiliated and community pharmacists who reported their patients had difficulty in obtaining medications through HealthChoices plans. Such problems are discussed in detail below.

Difficulty in Obtaining Prescribed Medication. HealthChoices enrollees with complex and chronic medical conditions have had difficulty obtaining outpatient medications. Such difficulties occurred after DPW permitted HealthChoices plans to use restrictive drug formularies. Some of the policies and procedures used by HealthChoices plans to implement the use of restrictive formularies may not be consistent with federal requirements or the Department's 1999 contract requirements.

The Social Security Act[26] permits state Medicaid programs to establish drug formularies for federally covered outpatient medications and permits the state to require prior authorization for medications included on the formulary. It further permits states to exclude federally covered outpatient medications from the state's outpatient drug formulary as long as such drugs are available to Medicaid recipients through a prior authorization process.

The act establishes criteria for prior authorization processes for outpatient drugs. Such programs must provide for responses to prior authorization requests within 24 hours. They must also provide for the dispensing of at least a 72-hour supply of a federally covered drug in an emergency situation (as defined by the Secretary of Health and Human Services).[27] The Congress indicated when adopting these provisions that it did not intend that prior authorization controls ". . . have the effect of preventing competent physicians from prescribing in accordance with their medical judgment." It also indicated its intent of assuring access for Medicaid beneficiaries to any medically necessary prescription drugs including those not included on formularies.[28] Congress did not intend to permit restrictive formularies or formulary prior authorization processes to effectively result in closed formularies with Medical Assistance recipients having access only to those drugs included on the formulary.

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[26]42 U.S.C.U. 1396r-8(d).
[27]DHHS published proposed regulations covering Medicaid Program payments for outpatient drugs September 19, 1995 in the *Federal Register*. These regulations, however, have not been published in final form.
[28]H.R. Rep. No. 881, 101st Cong., 2d Sess., pp. 96-98 (1990).

DPW has an outpatient drug formulary for the Medicaid program. With DPW's permission, each HealthChoices plan may develop its own more restrictive formulary. In other words, each plan may develop a formulary that excludes drugs that are on the Department's drug formulary, require prior authorization for drugs not prior authorized by the Department, establish more restrictive limits than the Department on the amount of the drug that can be dispensed, and limit the providers who can dispense certain drugs.

The Department has approved the use of restrictive formularies by the four Southeast plans. DPW requires HealthChoices Southeast plans to immediately provide for at least a 72-hour supply of a drug that requires prior authorization. The 1999 Southeast contract also requires plans to respond to such requests in 24 hours from the time the prescription is presented to the pharmacist, or if the plan cannot respond in 24 hours to provide medication until the response is provided.

LB&FC staff spoke with physicians, independent pharmacists, and health system pharmacists serving children and adults with complex medical conditions about their experience in obtain prior authorizations for outpatient drugs on plans' restrictive formularies. These included physicians involved with city health clinics and hospital outpatient programs known to serve large numbers of Medical Assistance recipients.

None of the physicians and pharmacists we spoke with object to the use of formularies per se or have problems with the Medical Assistance FFS pharmacy or commercial HMO formularies. A few individuals who informally have obtained direct access to the individual in charge of pharmacy benefits at one of the plans (and who has the ability to directly override the plan's Pharmacy Benefit Manager's prescription denials) praise this individual's responsiveness. Most, however, identified several issues concerning the HealthChoices plans' formularies and the processes for obtaining prior authorization for medically necessary outpatient drugs. They identified unnecessary barriers to patients receiving medically necessary medications, and readily identified HealthChoices patients whose care had been delayed, compromised, or more difficult to access with restrictive formularies and authorization processes.

Unnecessary Barriers: The HealthChoices plan formularies contain fewer drugs than the Medicaid fee-for-service formulary or formularies used by commercial HMOs. Physicians and pharmacists, therefore, must obtain prior authorization for many of the medications required by HealthChoices enrollees with complex medical conditions.

Plan formularies are not always designed with children in mind, according to a pharmacist at a major specialty hospital for children. As many as 30 percent of

the prescriptions dispensed at this hospital's outpatient pharmacy require prior authorization from HealthChoices plans.

HealthChoices formularies are not all the same. Each plan uses a different drug formulary. Plan formularies are constantly changing, making it difficult for physicians to know what drugs are and are not on the plans' formularies. Physicians and pharmacists, moreover, report they do not always have the most recent updates to the plans' formularies. The clinical pharmacist of a center for excellence serving persons with HIV/AIDS advised the LB&FC staff that as of March one plan did not have a published version of its formulary. Until such time as this plan's formulary is published, the center's doctors must obtain prior authorization for every drug prescribed for the plan's enrollees.

Several specialists treating large numbers of HealthChoices enrollees with HIV/AIDS indicate their offices have never received copies of the HealthChoices plans' drug formularies. They understand that formularies are only distributed to PCPs. However, PCPs also report not receiving copies.

One physician reported receiving a notice from a HealthChoices plan of a formulary change and a listing of 300 patients prescribed medications no longer on the plan's formulary. The formulary change took place the day the plan mailed the notice of the change to the prescribing physician. Such a change is extremely time consuming to implement, according to this physician. He also noted that some of the medications on the revised formulary have been shown in the past to be ineffective for some patients. Some physicians told us they interpreted the letter to mean they are required to prescribe medications for the HealthChoices plan enrollees from the plan's restrictive formulary.

Pharmacists and physicians are administratively burdened by plans' prior authorization procedures. They encounter busy signals when they telephone plans and/or their pharmacy benefit managers for prior authorization. After making contact, they are often placed on hold for extended periods and then disconnected. When they finally reach a person, it is a technician rather than a pharmacist or physician. Pharmacists and physicians report they often leave numerous messages that are not returned. One plan's pharmacist will not discuss prior authorization requests with patients' pharmacists. This pharmacist will only speak with physicians.

HealthChoices plans' and their pharmacy benefit managers' pharmacists are not always available to respond to prior authorization requests. They are not available throughout the weekend or holidays, or on a 24-hour basis during the week, according to pharmacists with whom we spoke.

Some plans require pharmacists to place separate calls for each drug that must be prior authorized, according to several pharmacists we spoke to. In other words, if one patient has prescriptions for six drugs requiring prior authorization, the pharmacists must place six calls to the plan or pharmacy benefit manager. Many pharmacists and physicians report pharmacy benefit managers' technicians are not knowledgeable about medications or medical conditions. They also do not always accurately convey to the plans' pharmacists the information communicated by pharmacists and physicians as to why a particular drug is medically necessary for a particular patient. One doctor told of an experience with a technician in which the technician suggested the doctor prescribe an alternative drug that was on the plan's formulary but was unrelated to the patient's treatment.

Plans and their pharmacy benefit managers are also reported to be inconsistent in their implementation of prior authorization procedures. One physician reported treating a patient who was to be discharged from hospital. The patient required drugs not on the patient's HealthChoices plan formulary. To assure the patient would not go without medication upon discharge, the physician contacted the plan's pharmacy benefit manager in advance of discharge to obtain prior authorization for the needed drugs. He was told that his patient would need to take the prescriptions to a pharmacy and be denied the medication before the pharmacy benefit manager could prior authorize the drug. In previous cases involving the same drug, the pharmacy benefit manager had prior authorized the drug before the patient was discharged. Others report the plans have no consistent criteria for approving or denying prior authorization requests. The decision depends on whom you speak with at the PBM or plan.

DPW's contract requires plans to respond to prior authorization requests for medications in 24 hours. When the initial information is not sufficient, DPW requires that subsequent responses occur within 24 hours from the receipt of the additional information. DPW further requires that when denials occur because the information provided is incomplete, denial notices must specify the additional information required.

Despite DPW's requirements, doctors report that they do not always receive timely responses to their prior authorization requests. One provided LB&FC staff with a copy of a denial notice from HMA for a non-formulary drug requested 17 days prior to the receipt of the denial notice. The notice indicates that the drug is denied because it is not on the formulary. The denial notice does not indicate the specific information the patient's physician must provide to substantiate the medical necessity for this medication, and differs from the standard denial notice DPW requires plans to use. The patient's physician asked the plan to reconsider its denial. As of early April 1999 a response to the reconsideration request had not been provided by the plan, and the patient had been without medication for over five

weeks. A patient also reported being unable to obtain medications requiring prior authorization and not receiving denial notices from this same plan.

Doctors' offices and pharmacies unable to devote the time necessary to handle these administrative responsibilities place responsibility for managing prior authorization processes on the patient. Some patients may find it difficult to manage their own prior authorization processes. They may not have the skills to do this. Plan procedures, moreover, may effectively prohibit this. One patient shared a letter indicating that he was not permitted to inquire about the prior authorization status of his medications. Only his physician is permitted to make such an inquiry.

The process is further complicated because the patient, pharmacist, and doctor are not always advised when prior authorizations have been approved. Unless a prior authorization request is immediately approved when a physician or pharmacist initially contacts the plan or its PBM, they do not know if the request has been approved. Pharmacists must then learn if a request has been approved by continually inputting a request for authorization to dispense the drug into the PBM's automated system and eventually have the request to dispense the drug come up as authorized.

Some physicians and pharmacists report that the prior authorization processes are possibly intentionally difficult to force compliance with the medications listed on the formulary. Pharmacists question the need for submission of a patient's medical records to plans' pharmacy benefit managers to justify medical necessity. One clinic reported having to order additional tests to justify the medical necessity of a drug prescribed to slow the spread of a disease although recent tests had clearly demonstrated the rapid spread of the disease.

Clinics and physicians reported they have changed their prescribed medications to drugs on the formulary that they do not consider optimally effective for their patients. They report doing this because a less effective medication is better than the alternative--a patient not receiving any medication.

Problems in Obtaining Prior Authorized Medications: Patients can have difficulty obtaining medication even after it has been prior authorized. Patients who have received prior authorization for drugs for a six-month period are not always able to obtain drug refills during the approved period unless their physicians submit a second, third, fourth, fifth, and sixth prior authorization request. One HealthChoices patient with a complex medical condition provided the LB&FC staff with a copy of a February 1999 letter from a HealthChoices plan Special Needs Unit indicating that two of the drugs prescribed by the patient's physician were prior authorized through July 1, 1999. In March the patient could not obtain prescribed refills for these drugs. The patient learned that his physician must submit separate

prior authorization requests each time the prescriptions must be refilled through July 1, 1999. This is especially difficult since this patient has been prescribed 22 drugs, several of which require prior authorization, and anticipates requiring these drugs continually over his lifetime.

Obtaining access to medications that have been prior authorized is further complicated because they are often expensive drugs, and pharmacies do not maintain large quantities in stock. Doctors and pharmacists report that patients experience difficulty finding drug stores able to dispense their medications. They attribute this to the reduction in the number of independent pharmacists and the withdrawal of two major drug chains from HealthChoices after HealthChoices plans engaged Eagle Managed Care to manage their pharmacy programs. One pharmacist indicates he may dispense part of a prescription and advise the patient to find another drug store to dispense the remainder when he does not have a sufficient supply of a drug in stock. As fewer pharmacies are available in the neighborhood, this becomes a problem for patients who must find other pharmacies to dispense the remainder of the prescription. Another pharmacist indicated that pharmacists do not stock the expensive drugs used by persons with HIV/AIDS because they are not reimbursed by the plans a sufficient amount to cover the cost of such drugs.

72-Hour Supply of Medication: DPW requires HealthChoices Southeast plans to provide enrollees with at least a 72-hour supply of a non-formulary drug requiring prior authorization. Such supplies are to be given when the patient provides the pharmacist with a prescription that the plan's PBM will not authorize the pharmacist to fill and the patient's physician cannot be reached to change the prescribed drug. Several physicians and pharmacists indicated they were aware of the policy, however, they report such supplies are not always given.

One doctor serving significant numbers of HealthChoices patients reports not knowing about the 72-hour policy. A major clinic shared with LB&FC staff a copy of correspondence from a HealthChoices plan containing information about the 72-hour policy that is inconsistent with the requirements in federal statute and DPW's contract requirements.

The HealthChoices contracts do not explicitly require plans to reimburse pharmacists for outpatient drugs when they dispense a 72-hour supply of a drug that requires prior authorization. Several pharmacists who have issued supplies of drugs requiring prior authorization when patients were without medication report they have not been reimbursed by the plans.

One pharmacist reported the case of a child who was at home and having seizures. The child's mother went to the pharmacy to get the child's seizure medication prescription filled. The prescription required prior authorization. The pharmacist refused to provide a 72-hour supply of the medication because the child had

been issued a 72-hour supply for the drug once before.[29] The child eventually received a 72-hour supply of the seizure medication through a hospital outpatient pharmacy. The hospital outpatient pharmacy, however, has never been reimbursed for the emergency supply of the drug by the HealthChoices plan.

In another case, a pharmacist provided a patient without medication with an emergency supply of a drug that had been previously prior authorized and dispensed. The plan has not reimbursed the pharmacist because it only permits the drug to be obtained through mail order and not a local pharmacy. The plan, however, had never advised the patient, the physician, or the pharmacy of this new requirement.

Impact on HealthChoices Patients: Doctors and pharmacists report that patient care has been compromised with the introduction of the HealthChoices restrictive formularies. An infectious disease specialist reported patients who are not aware of their rights to medically necessary drugs usually go without their medications until their next scheduled visit with their physician. Another specialist reports that he is aware of cases where treatment of HIV/AIDS patients has been interrupted because of formulary-related problems. A public clinic reported patients who do not receive medications when they present a prescription at the pharmacy get discouraged and do not follow-up with the doctor or pharmacy, only to return after they have been without medication and their condition has worsened.

The grievance and appeals processes may not be feasible for many HealthChoices patients and their physicians, according to physicians we spoke to. A physician at a clinic serving over 2,000 HealthChoices patients reports that between 90 and 99 percent of requests for non-formulary drugs are denied. It takes a month or longer to pursue the plan's grievance process. Many patients do not speak English and do not understand their service denial notices. The grievance process is very difficult for most patients who have many children and/or other responsibilities.

Exhibit 13 contains examples of cases of HealthChoices patients and the problems they have encountered in obtaining medications as a result of the problems outlined above.

Plan Policies and Procedures: LB&FC staff reviewed the restrictive formulary implementation and the prior authorization policies and procedures for pharmacy approved by DPW for the HealthChoices plans[30] to determine if the processes were as reported by doctors and pharmacists. We found that the physicians and pharmacists generally provided more detailed information than the plans' policies

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[29]At least two of the HealthChoices plans have policies permitting only one automated dispensing of a 72-hour supply of a drug during the year.

[30]One of the plans for which we received information included only selected correspondence.

Reported Experiences With Plan Restrictive Formularies and Plan Prior Authorization Processes

- A patient had been taking a drug for two years to prevent infections from entering the child's blood stream. If the infection penetrates the child's blood stream, the child could get a potentially fatal infection. At the beginning of April 1999, a hospital specialty clinic submitted a prior authorization request for the drug after it was removed from the plan's formulary. As of April 13, 1999, the plan had not responded to the request. The clinic attempted to speak with the plan's director of pharmacy services and was placed on hold for 45 minutes on one occasion and 20 minutes on another. The clinic then involved the plan's provider relation staff. As the child was without the medically necessary medication, the child's pharmacy on its own initiative issued a one-month supply of the medication so the child would not be without medication during the prior authorization process. After three weeks, the plan approved a one-month supply of the drug for the child. The plan, however, indicated the drug will need to be prior authorized each month. The clinic is requesting the plan to reconsider its decision to prior authorize only a one-month supply since the child will always require these life-sustaining drugs.

- A HealthChoices enrollee was hospitalized and while in the hospital treated with medications not on the plan's formulary. When the patient was discharged, the doctor prescribed the same medications to maintain continuity of care. The patient went to a pharmacy to get the prescriptions filled. The pharmacist could not obtain authorization to dispense the drugs. The pharmacist did not issue the patient an emergency 72-hour supply of the drugs, nor did the pharmacist or patient contact the patient's doctor to inform him that the drugs required prior authorization. The patient went without the prescribed medications.

- A mentally limited, diabetic patient residing in a boarding home was denied medication to control the patient's blood sugar on March 11, 1999, after the patient's medication had been taken off the plan's formulary. The patient had been taking this medication since May 1998. After the pharmacist could not obtain authorization to dispense the drug, the patient informed the doctor who immediately contacted the plan and provided information documenting the patient's need for a non-formulary drug. After four weeks, the clinic had been unable to obtain information concerning the status of the request (and had not received a denial notice). During this period, the patient went without medication, and the clinic monitored the patient's blood sugar levels. It subsequently faxed a letter to the plan indicating that the patient's blood sugar was no longer under control. In the second half of April, the clinic contacted an individual in the plan's quality assurance unit and asked for its intervention. The individual responded and advised the clinic that the plan had earlier authorized a 30-day supply of the medication. The patient, physician, or pharmacist, however, had not been notified of the plan's decision to prior authorize the non-formulary drug.

- A pharmacist's request to fill a prescription to treat a child's renal disease was denied on March 23, 1999. The child did not receive a 72-hour supply of the prescription and as of March 30, permission to fill the prescription had not been granted.

- A child with liver disease was without prescribed medication. The plan would not permit a local pharmacy to dispense the drug because its policies required that the drug be secured through mail order. The drug was requested through mail order. The drug, however, was never provided to the child's family, as the drug mail order pharmacy was no longer in business.

Exhibit 13 (Continued)

- A plan removed a drug from its formulary and then denied a prior authorization request to fill a prescription for the drug that a patient had been taking for two years. The plan recommended, and the patient's physician agreed to prescribe, another drug that is on the formulary. The patient had a reaction to the plan's recommended drug and had to be hospitalized on an emergency basis. The plan will now approve prior authorization requests for the drug for this patient. Such requests, however, must be submitted and approved by the plan every 30 days.

- A HealthChoices patient was readmitted to the hospital in order to obtain the non-formulary drug after the patient's HMO had refused to prior authorize this drug needed to prevent blood clots. The patient's doctor had called to explain the need for the drug, and the plan had refused to accept the doctor's explanation.

- A child with leukemia receiving chemotherapy had been prescribed a 30-day supply of an anti-nausea drug. The HealthChoices plan required the drug be prior authorized and would only permit the dispensing of a three day supply. The mother of this child had to return to the pharmacy every three days over a 30-day period to obtain her child's medication.

- A child with shingles had been prescribed a 30-day supply of a drug to treat the shingles. The plan required prior authorization of the drug and would only permit a three-day supply of the drug to be dispensed, even though the medication was required for a much longer period. Such plan requirements created hardship for the child's mother who did not have a usual means of transportation and had difficulty going to the pharmacy on even one occasion.

- A HealthChoices patient had been taking a medication to regulate blood pressure. The drug was removed from the patient's plan formulary. The patient did not want to take the formulary drug because he did not get the same results from the formulary drug. The patient paid for the drug himself while his physician attempted to obtain prior authorization for the non-formulary drug. After four months, the plan authorized the non-formulary drug. The doctor does not think the patient will be reimbursed the money he spent on medication while awaiting the plan to grant prior authorization.

Source: Developed from information reported to LB&FC staff by clinics and pharmacists from major children hospitals, major health system clinics and pharmacists serving large numbers of HealthChoices patients, and physicians in private practice.

and procedures, and that none of the written policies and procedures conflicted with the information reported by physicians and pharmacists.

Each plan's written policies and procedures were not always internally consistent. Written policies and procedures also differed across plans. None of the written policies and procedures concerning the provision of at least a 72-hour supply of the drug and the prior authorization process referenced federal statutory or state contract requirements. The plans' written policies and procedures also appear to include statements that are inconsistent with federal and state requirements. We discussed these inconsistencies with DPW, and DPW officials reported they have been meeting with plans to assure they understand DPW's requirements.

DPW has indicated a willingness to assist individual HealthChoices enrollees who have difficulty obtaining medication from their plans. Not all HealthChoices enrollees, however, know of the Department's willingness to offer assistance, and pharmacists and providers are not sure whom at the plans, or in the Department, they can speak with to voice their concerns. The denial notices issued to HealthChoices enrollees and copied to their providers do not list any DPW telephone numbers (or telephone numbers for legal aid groups) for patients and providers to contact when they have not received responses from HealthChoices plans.

DPW may also not be aware of the problems because at least one major institutional pharmacy has found itself in the position of a pharmacy safety net service for children. It has been providing 72-hour supplies of medications for children when needed without receiving reimbursement from plans. Another major hospital health system pharmacy has also reported that it routinely provides at least 72 hour supplies of medications for its patients and has not been reimbursed by plans for dispensing such drugs. The hospital has lost reimbursement as a result.

Third Party Liability. DPW requires MA beneficiaries who have insurance coverage to enroll in its mandatory HealthChoices program. Examples of such coverage include other managed care plans, employer-funded ERISA benefits, individual health insurance policies, and Medicare. Although the HealthChoices plans have enrollees with insurance coverage and the Department's contracts include provisions regarding third party liability, the Department has not issued comprehensive policies to identify third party liability and cost sharing responsibilities for the services they receive.[31] It has not given the plans a standard set of procedures to follow or identified the central staff responsible for resolving problems.

[31]The Social Security Act requires state Medicaid agencies to identify sources of third party liability as primary insurers and to use Medicaid as the payer of last resort. The states may reject MA claims and direct providers to bill the third parties unless the claims involve prenatal services and preventive pediatric care, including EPSDT services. The states must pay for such services and seek reimbursement from third parties afterwards.

The lack of policies and procedures has created access problems for HealthChoices enrollees with insurance coverage. Some pharmacists refuse to fill prescriptions covered by primary insurers if the MA beneficiaries can not make the copayments in advance, according to consumer advocates. Some beneficiaries have made the copayments and have submitted receipts to their HealthChoices plans. The participating HMOs have sometimes denied payment, and at least one HealthChoices plan will not review complaints or grievances of such denials. Some parents of children with special needs have spent hundreds of dollars per year in copayments for medications, as reported by consumer advocates.

Procedures vary from one HealthChoices plan to another and sometimes within the same plan, according to consumer advocates. The special needs units of some plans have paid for consumable medical supplies prescribed by out-of-network physicians, but members needing medications have had to request prescriptions from HealthChoices physicians who have not seen them previously. Concerns about malpractice issues make the plan physicians reluctant to write such prescriptions until they have seen the patients and reviewed their medical records.

Some providers have told HealthChoices patients that their HMOs have withheld payments after realizing that a child has private insurance. Although the plans have already accepted the providers' claims, they tell the providers to pursue the primary coverage for services that have been rendered. The commercial plans sometimes have benefit limits that the HealthChoices enrollees have already reached. In such cases, the enrollees must repeatedly obtain verification from their primary insurers to show that they have exhausted their benefits for the coverage in question.

Children in Substitute Care. In August 1997, individuals caring for children in substitute care reported many problems with HealthChoices to the House Health and Welfare Committee. These problems make it difficult to provide children in substitute care with timely access to necessary medical care. The reported problems include the following:

- Foster parents and those directly responsible for caring for children in substitute care were not permitted to communicate with the HMOs. HMOs would not provide foster parents with the names of the PCPs for children in their care or the status of prior authorization requests for services.
- DPW and its contractors did not assign children in substitute care to their requested Primary Care Provider (PCP). Foster parents would take their children for medical care to their requested PCPs and learned that the children had not been assigned to the requested PCP's panel. The doctors were, therefore, unable to treat these children.

- Foster parents and county children and youth agencies encountered difficulty in changing PCPs. Such changes did not occur in a timely way.
- Plans denied authorization for out-of-network physicians to provide urgent care for children outside the plans' geographic service area.
- Caregivers did not know when a child was enrolled in a HealthChoices plan. This occurred because there is no one specific calendar date in the month when a child is enrolled in a HealthChoices HMO and when the child is assigned to a PCP.
- Caregivers did not know which providers belonged to which managed care plan networks. As a result, in some instances, caregivers for children with exceptional medical needs were told that essential medical services children were receiving would be withdrawn unless the county child welfare agency agreed to pay for the medical care if the HMO would not.
- Specialists, dental care and pharmacy services were not always accessible.
- Caregivers did not receive notices from the HealthChoices plans when they reduced, terminated, or denied medical services for these children. HealthChoices managed care organizations would only provide information to the county children and youth agency. In large agencies, important notices, such as client notices of reductions or denials of medical care, were lost in the mail received by the county agency. This delay jeopardized the right of the child with special medical needs to receive a Medical Assistance fair hearing and to continue medical services during the appeal. (Refer to Appendix D for the federal and state rules governing notice of reductions, denials, and termination of medical assistance services and the requirements for continuation of services if timely appeals are filed.)

The Committee was also told of other problems HealthChoices presented for private agencies and local governments. According to one child advocate:

> The costs which have been incurred by the transition to HealthChoices have been enormous. The staff time, foster parent time and expense, agency time and agency expense have been incredible . . . . The danger is that because access to care is so difficult and haphazard, the children and youth system will start to absorb the cost of medical care and treatment, cost shifting to another system. What may be saving the Office of Medical Assistance money is certainly costing the Office of Children Youth and Families, the counties and the private nonprofit providers a considerable amount of money to implement. And these agencies and organizations have not been funded to absorb this cost.

Some of the problems identified in August 1997 appear to have been resolved. Others, however, continue to exist in some form and new problems have arisen. In

summer 1998, for example, caregivers for children in substitute care provided DPW's Office of Children, Youth, and Families with the names of children who had selected a PCP and had been auto assigned to a different PCP. They also identified children in substitute care who should have been in enrolled in the Medical Assistance program, but showed as ineligible on the eligibility verification systems. They reported caregivers did not receive copies of plan notices when services were denied, reduced, or terminated. In September 1998, caregivers notified DPW of continued problems in knowing how to access a specialist as a PCP and in obtaining dental care for managed care enrollees.

According to the Juvenile Law Center and others, additional problems are likely to occur for children in substitute care as HealthChoices expands to southwestern Pennsylvania. DPW has proposed program design changes that have major implications for the children and youth system statewide.

When HealthChoices started, when a child who resided outside of a HealthChoices county was placed in one of the five HealthChoices counties, the child continued to receive Medical Assistance through the fee-for-service system. The child, therefore, could obtain medical care from providers who routinely work with the child's placement site regardless of whether the providers participated in a HealthChoices plan's provider network. Starting in September 1999 in HealthChoices in southwestern Pennsylvania, when a child resides in a county not included in HealthChoices and is placed in a HealthChoices county, the child's county child welfare agency will be required to enroll the child in a HealthChoices managed care plan.

For example, if a child from Erie County is placed in Philadelphia, the Erie county agency will be responsible for selecting a HealthChoices managed care plan in Philadelphia for the child for whom it holds custody. The Erie county child welfare agency will also be responsible for resolving any problems that may occur in obtaining medical care for the child from the managed care plan. This will occur even though Erie County has no current involvement in HealthChoices.

DPW has attempted to address some of the problems identified in August 1997. For example, it intervened with its enrollment contractor and the HealthChoices plans to address the problem of incorrect assignment of PCPs. DPW's Office of Children Youth and Families (OCYF) also formed work groups to discuss identified problems, and it assigned staff to assist counties with HealthChoices implementation. OCYF permitted counties to use part of their state allocations to hire county benefit consultants to help implement managed care in the southeast region. Local governments must provide local funding to match available state funds. The state, however, did not make available additional funding for private children and youth agencies to hire the additional staff needed to implement HealthChoices.

DPW initially envisioned that plan special needs units would be able to address special problems for children in substitute care. The Department anticipated that the Special Needs Units at each plan would identify children in substitute care and assign staff to monitor the services provided and ensure such children received comprehensive EPSDT screens and follow-up services. In its on-site clinical reviews of each plan in early 1998, DPW staff found little evidence that plans were serving children in substitute care as envisioned.

In late December 1998, DPW provided plans with a policy for sharing information concerning children in substitute care effective January 1, 1999. The policy permits the plans to provide some information concerning children in substitute care to: county children and youth staff, juvenile probation officers, staff members of county juvenile detention centers, staff of private agencies that provide placements for children in substitute care, foster parents, formal kinship caregivers, attorneys, child advocates, or guardians who can document their appointment by the court, and parents who have not had their parental rights terminated or otherwise restricted. The DPW policy, however, does not require HMOs to routinely share information on the status of requests for prior authorizations, exceptions to formularies, or other exceptions to standard procedures with such callers. In view of the practice of some physicians to require patients to be responsible for the coordination of prior authorization requests, it is unclear how such coordination will occur for such children given the limits on communication between the plan and its subcontractors and foster parents and other essential caregivers.

DPW also strengthened its requirements for HealthChoices plans in the southwest. Its HealthChoices Southwest RFP delineates more clearly the HMOs' responsibility for monitoring EPSDT services for children in substitute care and for tracking and reporting results. It strengthened requirements for interagency agreements between HealthChoices plans and county child welfare agencies. The agreement, for example, must include for children with complex medical needs, "procedures to request a specialist as a PCP. Include a timeline for submission of request; tracking of requests; and decision of requests. Include a back-up system if the request is denied to ensure the child will not inadvertently be automatically assigned to a PCP who is not appropriate." The Southwest RFP also requires the HMOs to have the capacity to record a second address for communications from the HMO to the member.

DPW, however, has postponed the implementation of the second address requirement in the Southwest, and has a workgroup considering the potential problems associated with the implementation of this requirement. To implement the RFP requirements, county children and youth agencies would be responsible for supplying HMOs with the second address where the child is residing. County agencies, however, do not always have current addresses for children in substitute care in their automated systems because such children frequently move from one

address to another. DPW is considering a pilot program, possibly in Philadelphia. At this point it is unclear if or when the pilot program will be attempted.

Without second addresses for plan mailings, plans will not be providing notices of service reductions and denials to foster parents. This effectively precludes foster parents from assisting children in their care in obtaining timely access to DPW's fair hearing and appeals processes and access to continuing service during the appeal.

The best efforts of the Department and county children and youth agencies to assist individual children in substitute care may not be sufficient to resolve the problems. The difficulties encountered as a result of mandating children in substitute care enroll in fully capitated HMOs come about because of the nature of the Children, Youth, and Families, Medical Assistance eligibility, and managed care systems. These difficulties include:

The Children, Youth, and Families System: Children in substitute care often come into care in response to crises and emergencies. Once taken into care they frequently move. They move from emergency placements into others until suitable placements are found before returning home. Such movement can involve moving from one end of a county to another. While in placement, they may leave the county in which they are placed for home visits with relatives residing in other counties. They may also participate in special programming during summer months. Such activities may take children outside of the county in which they are placed and outside of the counties that are part of their managed care plan's provider networks' service area.

The Medical Assistance System: Most children in substitute care are eligible for Medical Assistance when they are taken into care even if the placement occurs in the middle of the night when DPW staff are not available to process and approve an application. In part for this reason, the Medical Assistance eligibility and fee-for-service payment systems were set up in such a way that any MA provider of service could provide care for such children even if they did not have a Medical Assistance card in hand. Medically necessary care would be paid for by the DPW once the Medical Assistance eligibility and enrollment paperwork caught up with the child. Similar practices were in place for medical care requiring authorization by the DPW. The Department had in place procedures to permit medical providers to provide time sensitive urgent medical care without having first obtained administrative approvals. Such administrative approvals could be obtained after medically appropriate care was provided.

HealthChoices plans, however, are geographically based. They assume a certain geographic stability for the population they serve. They are not required to have network providers available everywhere for their enrollees.

Managed care organizations, moreover, can deny medically necessary care for administrative reasons such as late submission of a service authorization request. From the managed care organization's perspective, such denials help to assure medical providers comply with the rules established by such organizations.

Automated Systems: A further complicating factor is the multiple automated and non-integrated systems the DPW, its benefit consultant, the plans, and plan subcontractors have in place to enroll, disenroll, and authorize services for plan enrollees. On DPW's side alone it can take from three to six weeks to accomplish enrollment or a plan change, and the rules for such enrollment are complex. The Department, moreover, makes plans responsible for providing benefits to Medical Assistance consumers based on DPW coverage policies, even if DPW's Client Information System lacks the indicator showing MA eligibility. (See Appendix J.). Plan provider contracts, however, provide instructions for providers as to when an individual is considered a plan enrollee, which are not always consistent with DPW's coverage policy.

Children in substitute care are not the only ones who experience problems with the systems for HealthChoices and plan enrollment. Providers have also reported to DPW problems in correctly verifying the Medical Assistance status of patients, their HealthChoices plan enrollment, and PCP assignment. Without the correct information providers are unable to obtain necessary prior authorizations for services and correctly bill for authorized services they provided.

County-Based Medical Assistance Transportation System. Title XIX of the Social Security Act entitles MA recipients to the transportation services they need for access to medical care. The federal government subsidizes such transportation services as long as a state complies with a plan approved by the federal Secretary of Health and Human Services. The DPW authorized cash grants to MA recipients as a means of paying for transportation services until November 1983. It replaced them with the Medical Assistance Transportation Program (MATP), which established a county-level system intended to contain costs through coordinated services.

Public Assistance Transportation Block Grants fund the MATP. Sixty-six counties accepted the funds in FY1997-98 and the DPW selected an MATP provider for the remaining county through a competitive bidding process, as reported in the budget request. A county or a prime contractor may provide MATP services directly or through subcontractors.

The MATP is not responsible for providing all medical transportation services an MA recipient might need. The DPW instructions and requirements define medical transportation services as including non-emergency trips to providers of reimbursable services such as medical treatment and evaluation, prescriptions, and

medical equipment. The MATP does not cover ambulance transportation. The DPW pays MA outpatient vendors directly for ambulance services, which it defines as emergency medical services, not administrative services.[32] MA recipients may have to seek non-emergency transportation from a county assistance office (CAO) instead of the MATP, depending on the circumstances.

The emphasis on cost containment generally limits the MATP to providing transportation to the nearest available service of the kind the MA recipient needs. It will take recipients who have voluntarily enrolled in a managed care plan to the nearest network provider, whether or not the provider is MA-enrolled. HealthChoices members must be taken to an MA-enrolled network provider in the MATP service area.

The MATP may provide transportation beyond its county or service area boundaries only if the trip will be less expensive than a trip to the nearest county provider of the same service. The lack of a particular medical service in the county or service area does not justify transportation beyond its boundaries, as specified in the April 1998 DPW instructions and requirements. MA recipients must request transportation from the CAO in such cases, including all trips involving air travel.

The county or the prime contractor does not need to provide all MATP transportation services directly or through subcontractors. It may issue public transit vouchers or passes and reimburse volunteers for out-of-pocket expenses or recipients for private vehicle mileage. The DPW expects the MATP to be a payer of last resort. It must integrate its services with programs funded through the Departments of Aging and Transportation.

The MATP does not provide adequate service for MA recipients, according to the Consumer Subcommittee of the Medical Assistance Advisory Committee (MAAC). The need for transportation services has increased in southeastern Pennsylvania since managed care became mandatory for MA recipients, and the expansion of HealthChoices to the ten-county southwestern region will create greater needs. Such demands on an already inadequate system call for basic changes, the subcommittee contends.

Relative local autonomy and inflexible MATP rules have created a fragmented system incapable of meeting MA recipients' needs, according to the Consumer Subcommittee. Recipients do not always know whether the MATP or the CAO will cover a particular trip, even if they know about both programs. They might end up applying to both programs and rescheduling appointments more than once.

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[32]The federal government provides a 50-percent subsidy for administrative services under the Social Security Act. It subsidizes medical services at more than 50 percent.

MATP providers may prioritize scheduled trips during peak hours, as stated in the instructions and requirements. MA recipients must schedule their appointments well in advance to accommodate the transportation service and might experience long waits before and after appointments.

Counties have inconsistent policies regarding sanctions. Recipients have received warnings about being late for return trips even though their doctors have kept them waiting past their scheduled appointment times. Many recipients do not receive service because they do not fill out the request forms correctly or completely, the MATP providers in southeastern Pennsylvania reported. Transportation providers do not always inform recipients of the reasons for denying services or their rights to appeal such decisions. Not all MATP providers have Spanish-speaking personnel available to answer questions.

MATP policies also conflict with the HealthChoices approach to delivering medical care. Regional managed care systems might require MA plan members to travel beyond the boundaries of their MATP service areas, particularly to reach specialists in the Pittsburgh metropolitan area, and the primary care provider of their choice might not be in the service area. Such circumstances might result in the denial of transportation services. In some situations, emergency room care might be the only alternative if plan members must schedule their transportation days in advance.

The plans in southwestern Pennsylvania will have to become familiar with ten different MATP systems if their special needs units are going to help members resolve their transportation problems. The MATP providers will have to know not only which services have MA coverage but also which providers belong to which managed care network to validate a recipient's eligibility.

In response to the problems identified by the MAAC subcommittee, DPW has developed a brochure for beneficiaries in HealthChoices Southwest counties. As of March 1999, the Department reported it was formatting the brochure for distribution. The draft brochure advised Medical Assistance beneficiaries on how to access MATP services. It also indicates that HealthChoices managed care plans are available to assist beneficiaries in arranging transportation and seeking reimbursement from MATP if they need to go to a medical provider quickly or during hours when the MATP does not operate.

2. External Reviews Have Consistently Reported Problems With the Quality Assurance Efforts of Pennsylvania's Medicaid HMOs Over the Past Ten Years

DPW has selected managed care organizations to implement HealthChoices that, for the most part, have had difficulty implementing an effective quality assurance programs. Past and recent reviews have documented similar and recurring

quality assurance problems. Past research also underscores the significant problems encountered in attempting to assure quality of care for a population that is not continuously eligible for Medical Assistance services and may be unfamiliar with the benefits of preventive health care.

General Accounting Office 1987. HealthPASS was DPW's initial mandatory managed care demonstration. It operated in parts of Philadelphia (and was incorporated into HealthChoices with the inclusions of HMA, or Health Management Alternatives, as one of the four southeast HealthChoices plans). The GAO reported that the quality assurance program required by HCFA for the HealthPASS waiver was only partially implemented.[33]

Duke University and Solon Consulting Groups. In 1990, Duke and Solon Consulting Group completed the external evaluation of HealthPASS. The final report included an assessment of care provided to specific sub-populations. The report considered rates of mortality for sub-populations in HealthPASS and the fee-for-service system. The analyses were adjusted for patient severity.

The independent researchers reported significantly greater mortality for women over 40 and under 65 served in HealthPASS with cervical cancer and heart disease than for women in the fee-for-service system.[34] Their findings were statistically significant. With respect to this finding, the researchers concluded:

> This kind of finding does not indicate that there is a systematic problem with the [HealthPASS] concept; but, instead reflects the absence of a targeted outcome-based quality assurance process integral [emphasis in the original] to the operation of the [HealthPASS] itself.

University of Pennsylvania. In 1991, researchers[35] from the University of Pennsylvania reported there were no significant differences in pregnancy outcomes for Medical Assistance beneficiaries enrolled in Medicaid fee-for-service and those enrolled in HealthPASS. They also reported on issues identified with the implementation of HealthPASS. The Hospital of the University of Pennsylvania (HUP) acted as a primary care provider, because it was already a major source of health

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[33]HealthPASS did not adhere to the required sampling methodology in conducting reviews of outpatient and inpatient cases, outpatient reviews at the case management sites were not random, and the sample sizes were smaller than required. The completed reviews, moreover, did not focus on the quality of care provided as required by HCFA for the waiver. There were, moreover, no valid standards used to assess potential patterns of under use or other quality problems. DPW reported to HCFA in 1987, it was developing quality standards to assess performance and to assess quality problems.

[34]The sample included 23,226 women who were under age 64. Thirty-three percent of the sample was enrolled in HealthPASS, and the remainder in Medicaid fee-for-service.

[35]Hillman, Alan L., Neil Goldfarb, John M. Eisenberg, and Mark A. Kelley, "An Academic Medical Center's Experience with Mandatory Managed Care for Medicaid Recipients," *Academic Medicine*, Vol. 66 No. 3, March 1991, 134-138, Goldfarb, N. and others "Impact of a Mandatory Medicaid Case Management Program on Prenatal Care and Birth Outcomes" *Medical Care*, January 1991, Vol. 29. No. 1.

care services for Medicaid recipients who were living in HealthPASS areas. The HUP had approximately 5,000 HealthPASS patients, making it the largest adult primary care site and referral center in the program.

The study reported that enrollees sought medical care when they needed it but that continuity of care was a largely unattained goal. The HealthPASS contractor estimated that three to four percent of the covered population was involuntarily turning over every month during the first year. Medicaid recipients, a highly mobile population, moved into and out of the geographic area or lost their coverage because of other changes in their eligibility. Only 2,000 of 6,000 HUP patients in the program had been enrolled for a full year as of October 1987.[36] Such turnover rates undermine not only continuity of care but also outreach, prevention, and other elements of a comprehensive program. Providers and administrators had difficulty maintaining accurate lists of eligible patients, many of whom were already confused about how to get the services they needed.

Voluntary changes added to the turnover problem. Concerns about limiting freedom of choice had prompted the Commonwealth to give HealthPASS enrollees the option of changing primary care providers once a month. The monthly option increased the risk of adverse selection for large practices such as the HUP, which tended to attract severely ill patients or enrollees who anticipated a need for medical care. The capitation rate for the HUP did not take its patient mix into account.

General Accounting Office–1993. The GAO reported that Health Management Alternative's (HMA) physician credentialling program did not identify all physicians who have had sanctions taken against them or their licenses or malpractice claims paid on their behalf. This occurred even though HMA required providers to respond to specific questions concerning these matters. The GAO identified three physicians with sanctions against their licenses. One had his licenses suspended because of hospital concerns about the care provided. Another resigned his practice after issues were raised about the quality of the physician's care. The Pennsylvania State Board of Osteopathic Medicine placed a third on probation.

State Treasury—1995. In September 1995, the State Treasurer completed a field audit of Keystone Mercy Health Plan. The auditors reported the results of a random sample of physician credentialling files. Only 44 percent of the sample had current physician licenses in the files. Subsequently, the auditors drew a second random sample and found that only 6 percent of the sample had current licenses in the physician credentialling files.

[36]The Department indicated in its HealthChoices Southeast RFP that about half of the MA population loses eligibility in the course of six to eight months.

HealthPro External Quality Reviews.[37] The Social Security Act requires state Medical Assistance Programs to require quality control peer review organizations (designated by the Secretary of DHHS) to annually conduct independent, external reviews of the quality of services of HMOs and HIOs.[38] DPW contracted with HealthPro to conduct such reviews from 1994 to 1997.

HealthPro reviewed the quality assurance plans and medical records of 8 to 11 unduplicated fully[39] capitated risk-based managed care plans serving Medical Assistance recipients. As shown in Appendix K, the 11 plans include the 4 plans participating in the HealthChoices demonstration in Southeastern Pennsylvania. The 11 plans also include 3 plans that were eventually selected to participate in HealthChoices in the southwestern region of the state.

Review of Quality Assurance Plans and Their Implementation. HealthPro reviewed each plan's quality assurance programs for compliance with DPW's contractual requirements. It reported to the Department that quality assurance studies were not conducted consistently by the plans. When managed care organizations completed internal quality assurance studies, they were not all developing corrective action plans and completing follow-up assessments to assure that quality of care problems were corrected.

HealthPro reviewed each plan's member satisfaction surveys. The quality and usefulness of the member satisfaction studies varied greatly among the plans, according to HealthPro. Some were not based on reasonable statistical samples. Some plans did not follow up when members did not return their questionnaires. Plan surveys, therefore, could not provide reliable information to assess plan performance from the enrollees' perspective.

The Department had required its managed care organizations to conduct specific quality assurance focused studies to assess their performance in providing certain health services. These studies, however, were not completed by the plans, according to HealthPro.

In 1994 and 1995, HealthPro reported that several managed care organizations were not properly credentialling providers. In other words, they were not verifying that providers were licensed by the appropriate state licensing body, carried medical malpractice insurance, and had not been subject to discipline procedures.

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[37]The LB&FC staff requested any reviews completed by the Keystone Peer Review Organization, DPW's current contractor. The Department's response did not include any Keystone Peer Review organization reports in its response to our request.

[38]42 U.S.C.A. §1396a.

[39]The number of plans involved in the review varied at different points during the review period. Moreover, HealthPartners and Mercy Health Plan that were separate IDSs of Keystone Health Plan East were not reported on separately in some of the HealthPro reviews. With the exception of HealthPASS/HMA, enrollee participation was totally voluntary during the time of the HealthPro reviews.

Medical Record Audits. The Department directed HealthPro to conduct medical records audits of managed care organizations serving Medical Assistance recipients to determine if medical care was provided to plan enrollees. HealthPro, therefore, reviewed medical records for well child-care, adult preventive care and prenatal care.

- Preventive Health Care for Children: Because of the importance of preventative care for children, the federal Medical Assistance program has established requirements for states to provide Early and Periodic Screenings Diagnosis and Treatment (EPSDT) services for eligible children.[40] The EPSDT program requires that "immunizations shall be updated and recorded during EPSDT screening. The physician's records shall show as much immunization history as can be provided by the physician and the parents."

HealthPro did not find immunization records in all of the children's medical records it reviewed in 1994 and 1996. Twenty percent or more of the records did not contain immunization information for two of five plans eventually selected for HealthChoices in 1994 and for two such plans in 1996. (See Appendix L for information for each plan.)

HealthPro reviewed managed care organization well-child medical records to determine how many were completing comprehensive examinations as required by EPSDT guidelines. Between 1 and 3 percent had complete examinations at the plans subsequently selected for HealthChoices. (See Appendix M for information for each plan.)

- Prenatal Care: HealthPro reviewed medical records to assess prenatal care provided to Medical Assistance recipients enrolled in managed care organizations. More than one-half of the medical records did not include complete prenatal care histories at four of the five plans subsequently selected for HealthChoices in both 1994 and 1996. (See Appendix N for information on individual plans.)

HealthPro also examined medical records to determine if women who delivered received complete regular prenatal visits. HealthPro found that less than 80 percent of the women who delivered had received complete, regular prenatal visits in 1994 at each of the plans eventually selected to participate in HealthChoices. In 1996, less than 80 percent of women who delivered had received complete, regular,

[40]In addition, the Department of Public Welfare has agreed to meet certain performance standards for well-child care. Plaintiff's filed a lawsuit in federal court in November 1991 alleging that the Department of Public Welfare had not implemented the provisions of the Social Security Act and the 1989 and 1990 amendments concerning the EPSDT program. This suit ultimately resulted in a settlement agreement known as the "Scott Settlement Agreement." In the Scott Settlement agreement the Department of Public Welfare agreed to certain performance standards and measures.

prenatal care at four of five such plans. (See Appendix O for information on each plan.)

- Adult Preventive Care: HealthPro conducted medical record audits for adult preventative care. HealthPro found that the percent of adults who had routine history and physical exams within the last three years declined over time at the five plans selected to participate in HealthChoices. (See Appendix P for information on each plan.)

Special Studies. HealthPro reviewed managed care organization medical records to determine if the care provided was consistent with the National Institute of Health's National Heart, Lung and Blood Institute's guidelines for care of children over age six with asthma.[41] These guidelines can be used to assess the quality of care available to such children.

The results of the study indicate that many DPW managed care plans were not providing care consistent with the Institute's practice guidelines. Twenty percent or more of the children with asthma were hospitalized or had to visit the emergency room[42] at four of the four plans eventually selected to participate in HealthChoices. (One such plan did not provide a reliable sample for the HealthPro analysis.) Only 5 percent to 19 percent of the children received any type of objective assessment of lung functioning at these plans. At least half of the children and their caregivers did not receive any asthma-related education at three of five plans eventually selected for HealthChoices.

More than 20 percent of the children received inappropriate prescribing on at least one occasion and during 50 percent or more office visits at each of the plans eventually selected for HealthChoices. Inappropriate prescribing of asthma medication was quite high at most plans. HealthPro also compared the treatment regimen and degree of disease severity for children with asthma. It concluded that the majority of patients were under-treated. (See Appendices Q through T for information for each plan.)

Corrective Action Plans. The DPW requested the managed care organizations to provide corrective action plans based on the findings of HealthPro's reviews on two separate occasions. Not all DPW managed care organizations provided

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[41]Asthma is a disease that makes the airways in the lung inflamed. Persons with asthma have swollen and sensitive airways all of the time even when they feel fine. Asthma cannot be cured. The swelling, however, can be controlled with oral and inhaled medication and by staying away from irritants that cause swelling of the airways. Asthma attacks occur when airways in the lung narrow. They result in progressively worsening shortness of breath, cough, wheezing, chest tightness, or some combination of these symptoms. Such episodes can result in sleep disruption, missed school, and need for emergency department visits or hospitalizations. Proper treatment, moreover, is essential to prevent death of those with severe asthma.

[42]Hospitalization and emergency room visits are sentinel events suggesting treatment for asthma is not adequate.

corrective action plans to the Department in response to each of these requests. When plans were submitted, they were not all acceptable to the Department.

Three of the five plans eventually selected for HealthChoices did not provide a corrective action plan to the Department on all occasions as requested, according to the documentation provided by the Department to the LB&FC. Moreover, all five plans submitted corrective action plans that were not accepted by the Department on one or more occasions.

DPW's 1998 On-Site Clinical Reviews. At least some of the problems found during the HealthPro' reviews appear to have continued. When DPW conducted its onsite clinical review at the HealthChoices plan with the largest enrollment in early 1998, it reported:

> The Department was unable to obtain information detailing how the Quality Management Program (QMP) was implemented during 1997. This included:
>
> - how or if the approved workplan was implemented,
> - findings and subsequent actions from investigations of quality of care concerns,
> - routine quality assurance activities such as medical record audits,
> - results of planned focused studies,
> - success in meeting previously identified goals, and
> - measurable evidence that any activities designed to improve upon the quality of care provided to recipients were undertaken.
>
> The Department found little evidence to support a planned program of quality assurance and quality improvement. In addition, the Department was unable to substantiate that [the plan] implemented corrective actions as requested. Therefore, the Department finds that [the plan] continues to be out of compliance with requirements of the RFP.

Earlier the Department had to threaten fiscal sanctions of up to $4,000 per day against the plan before it submitted an acceptable quality assurance plan.

During its onsite clinical reviews DPW staff considered HealthChoices plans' compliance with its quality assurance requirements. The Department considered plan quality assurance program structure and organization, credentialing and recredentialing, inpatient quality management, outpatient quality management, provider profiling and analysis, health education and outreach, medical record keeping and quality improvement programs.

The Department staff identified many of the same problems found by other reviewers. DPW staff found the four HealthChoices southeast plans were not auditing medical records as required. The four plans did not meet established benchmarks for EPSDT documentation. The four plans did not meet the Southeast RFP requirements that physicians be board eligible or board certified to participate in the plan networks. Moreover, recredentialing of providers in the plan networks was not occurring within required time frames.

DPW reports that all of the HealthChoices plans currently have approved quality assurance and quality improvement plans and programs in place at this time. DPW staff indicates plans have implemented corrective actions in response to the problems identified during the onsite clinical reviews. The Department, however, has not prepared a public report documenting the actions that have been taken and the corrective action steps in progress.

NCQA Reviews as of November 1998. The four Southeast HealthChoices plans and the three Southwest plans have all undergone some form of NCQA review as required by the Department of Health. Only one of the seven HealthChoices plans (Gateway Health Plan) had full accreditation as of November 1998.

Status of the Four Southeastern HealthChoices Plans: Health Partners, Inc., had full accreditation from 1993 to 1996 but was given only provisional accreditation after its NCQA external review in October 1996.[43] Revisions to the final report delayed its release until November 1997.

In December 1997 Health Partners advised the Department of Health that it had restructured its quality improvement program following the NCQA review and had changed its scope to focus on population-based performance measurement instead of provider audits. Three issues remained outstanding after a March 1998 meeting between the Department and Health Partners. The HMO resolved one of them by agreeing to survey its membership before its next NCQA site visit in October 1998.

A second issue involved grievance procedures. A subcontractor, Partnership Health Plan, was coordinating the grievance process and its medical director was signing letters of denial, which Health Partners was reviewing to monitor compliance. The Health Partners medical director and the grievance coordinator attended hearings for plan members. The HMO revised its grievance policy in June 1998 to prohibit subcontractors from processing grievances. The Department approved the revised policy.

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[43]The provisional accreditation will remain in effect until the NCQA makes a determination based on its October 1998 resurvey.

A third issue was still being addressed in June 1998. Primary care physicians at Philadelphia City Health Centers were treating plan members even though such physicians did not have admitting privileges at participating hospitals. The HMO was still working to obtain admitting privileges for some of the City Health District physicians as of June 1998.

Healthcare Management Alternatives (HMA), Inc. received provisional accreditation based on a December 1997 NCQA review. The survey team identified a credentialing issue during their review. The Department requested information about the extent of the credentialing problem two weeks after the site visit, and HMA spent almost nine months attempting to resolve the issue (see page 48).

The Oxford Health Plan of Pennsylvania had an NCQA preaccreditation review in July 1997. The Department received a copy of the final report in November 1997 and requested a response to the opportunities for improvement identified in the report. They included coordinating quality improvement with other programs, documenting clinical data and utilization management denials, monitoring the utilization management process and member satisfaction, and resolving complaints and appeals in a timely manner.

Keystone Mercy Health Plan, an IDS under contract with Keystone Health Plan East, had voluntarily undergone an external review[44] in 1992 and the NCQA had awarded it full accreditation. Keystone Mercy had its next NCQA survey in 1995 but received only one-year accreditation. Resurveys in the next two years resulted in two more periods of one-year accreditation.

The last year of accreditation for Keystone Mercy expired in May 1998. The IDS did not seek to renew its accreditation, but it needed an external review in keeping with Department of Health policy because resurveys focus only on specific issues. Although the NCQA generally does not do preaccreditation reviews of managed care plans that have had previous accreditation surveys, it agreed to do such a review of Keystone Mercy in September 1998.[45]

A credentialing issue resurfaced during the external review. Although Keystone East had proposed taking responsibility for the Keystone Mercy recredentialing program in May 1997, most of the files in a small sample had not been updated in more than 26 months, as determined during the resurvey. The Department expressed concern over the apparent noncompliance and requested specific information about the magnitude of the problem and any contributing factors. The request noted the accountability of Keystone East and its need to be involved in resolving

[44]The Department of Health has a policy of considering such voluntary reviews, if they have the prior approval of the Department, as evidence that the IDS and its contracting HMO have fulfilled their obligations to maintain quality assurance oversight.

[45]The NCQA has developed new policies and procedures to accommodate managed care plans that need external reviews for purposes other than accreditation (see Appendix B).

the issue. A meeting was scheduled for November 1998 to discuss a corrective action plan.

Status of the Three Southwestern HealthChoices Plans: Gateway Health Plan was given full accreditation after an NCQA external review it underwent voluntarily as a Highmark-owned IDS in December 1996. It achieved HMO status by acquiring a certificate of authority in December 1997, when it purchased Coventry Health Plans of Western Pennsylvania, Inc.

Three Rivers Health Plans, Inc., had an NCQA pre-accreditation review in August 1997. The Department of Health requested a response to the key recommendations in the final report two weeks after receiving a copy in November 1997. Three Rivers submitted a response proposing 23 quality improvement projects in February 1998. Eleven of the projects addressed not only NCQA standards but also HealthChoices standards, including the accessibility of providers, a need for internal quality improvement plans, and the coordination of physical and behavioral health care.

Representatives from the Department and Three Rivers met in April 1998 to discuss the response and the proposed work plan. The Department sent the HMO a follow-up letter advising it of plans for a site visit. The plan had not yet clearly demonstrated the ability to measure the clinical quality of its members' care or to take rigorous interventions clearly related to improvements in the quality of care and service to its members, the letter stated.

The UPMC Health Plan, doing business as Best Health Care of Western Pennsylvania, had also undergone an NCQA pre-accreditation review in August 1997. The Department expressed concern the following month about issues identified during the site visit. Discussions with plan representatives focused not only on the need to develop a corrective action plan but also on the need to clarify the relationship between the health plan and its provider network, the Tri-State Health System.

3. The HealthChoices Program Provides Relatively Little Opportunity for Public Input and Has Not Been Independently Assessed

HealthChoices Policy Development and Communication. DPW provides opportunity for public comment in the development of its HealthChoices RFP but has not incorporated the HealthChoices program into MA regulations or bulletins. It also has not consistently used the regulation or bulletin development processes when modifying or interpreting substantive policies set forth in the RFP. Many states incorporate their Medicaid waivers into state regulations, thus providing for consumer, provider, and legislative input when the waiver is developed and whenever substantive changes are to be introduced. In the past consumers and

providers had opportunity to comment and be informed of DPW Medical Assistance program policies and changes through the regulatory, bulletin, or public notice process (depending on the content of the policy). With HealthChoices, DPW has taken the position that it can communicate its interpretation of contract language to plans without public notice.

For example, in the HealthChoices Southeast and Southwest RFPs, DPW uses a definition of medical necessity tailored to the needs of disabled individuals with extraordinary health care needs. In the Southwest RFP, the Department included guidelines for interpreting the definition which essentially altered the intent of the original definition, according to the Hospital and Healthsystem Association of Pennsylvania. For example, DPW's interpretive guidelines require that substantial benefit would be expected as a result of the service. Such a criteria will adversely effect special needs individuals in particular as it precludes possible treatment that may do no more than allow the patient to maintain the treatment gains that have been made, according to HAP.

Initially, DPW rescinded its guidelines for interpreting medical necessity from the Southwest RFP. In its final 1999 contracts for HealthChoices Southwest plans, however, it requires plans to comply with DPW's interpretative guidelines should the Department decide to institute the medical necessity criteria it previously rescinded. The Department has not indicated that it plans to institute the revised medical necessity criteria at this time. It has indicated, however, that should such a decision be made it could be communicated to the plans through a policy clarification letter without public notice.

The problems resulting from DPW interpreting the HealthChoices RFP and contracts through communications with plans are further complicated by the absence of a central source for providers and consumers to learn of DPW's policies. Absent Medical Assistance Bulletins, standard plan provider manuals could serve as such a source, at least for plan providers. HealthChoices provider manuals, however, are not standard (each plan has its own), and provider manuals were not distributed for nearly a year after the program began in the southeast.

The Hospital and Healthsystem Association of Pennsylvania has stated:

> There needs to be an ongoing, formal mechanism to assure that there is public notice of program changes, opportunity for comment, and receipt of notification of program changes . . . . It is difficult for providers and consumers to be fully informed about changes to provide input to make changes more effective. In addition, affected parties--including consumers and provider--need the ability to seek redress regarding failures of managed care organizations in either physical health or behavior health programs to adhere to contract provisions. The latter

has not occurred effectively in implementing HealthChoices-SE. Such redress needs to be timely and provide all parties with policy clarification and program changes.

Independent Evaluation of HealthChoices. The DPW is expanding the HealthChoices program into southwestern Pennsylvania and has plans to expand the program statewide. It plans to have the results of an independent assessment of HealthChoices to present to the DHHS November 1, 2000, at which time, most of the state will have been incorporated into HealthChoices.

In July 1998, the Office of Medical Assistance released results from a client satisfaction survey it had conducted of HealthChoices enrollees. This study was not designed in such a way as to assure that medically fragile and disabled children's and adults' responses were included in the survey. The Department had limited information about the population sampled and, therefore, cannot compare respondents to the population surveyed. The results of the study, therefore, cannot be generalized to the HealthChoices population overall. The Department mailed 5,723 surveys to HealthChoices enrollees in October 1997 and had a 22 percent response rate. Of the 1,263 total respondents, 685 indicated they were very satisfied with the health plan in general. DPW indicated it is pleased with the responses it received to its survey. It is concerned, however, that only 462 respondents indicated they knew how to file a complaint through their health plan, and 310 indicated they knew how to file a grievance. Only 385 respondents, moreover, indicated they knew how to access the plan's special needs unit.

In September 1998, the Office of Medical Assistance issued *HealthChoices; the First Year, February 1, 1997—January 31, 1998.* This 20-page report provides descriptive information about the program.[46] In October 1998, the Office of Medical Assistance issued *HealthChoices Southeast: Clinical Review Findings from the On-Site Review of the Physical Health Managed Care Organizations, January-April 1998.*[47] This 26-six-page report summarizes the findings from DPW onsite clinical reviews. The Department attributes the problems its staff identified during these onsite reviews to the "rapid implementation time frame."

The federal DHHS' December 31, 1996 letter granting DPW a waiver to operate HealthChoices in the southeast region indicates:

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[46]The Department has included basic descriptive information in the report tables and exhibits. They include, for example, information on the number of persons enrolled in each plan, enrollee categories of financial eligibility, and demographic characteristic. The report also includes information on the number of plan providers reported by each plan as of February 1998, reasons enrollees give for requesting changes to health plans, and the number of enrollee complaints and grievances reported by the plans as of December 1997.

[47]In late November 1998, the Department also released individual reports for each plan outlining the result of DPW staff reviews.

> Finally, approval of the renewal of the HealthChoices waiver is contingent upon the Commonwealth of Pennsylvania's arranging for an independent, comprehensive evaluation of the waiver program, to be submitted three-months prior to the end of the waiver period, with special emphasis on beneficiary access to quality health care . . . .

In November 1998, the Department made its submission to DHHS. The Division of Program Evaluation in the Department's Office of Policy Development prepared the assessment. The Division acknowledges that its report is not based on independent data and analysis, and is based largely on the previously described work of Office of Medical Assistance staff.[48]

The report submitted to DHHS did not include information gathered from HealthChoices providers. It indicates that:

> Departmental staff also visited providers, such as PCPs, dentists, pharmacies, specialists and Durable Medical Equipment providers to monitor access to health care. This review included the following areas: (1) receipt of policies, procedures and member lists from the MCOs; (2) referral process, including Behavioral Health Services; (3) prior authorization process; (4) billing issues; (5) language or transportation barriers; and (6) physical, visual and hearing access. Findings from these site visits are being compiled, and were not available for inclusion in this independent assessment.

The Division attributed its reliance on reports prepared by Office of Medical Assistance staff to the absence of reliable and valid encounter data for an independent analysis of access and quality of care. DPW in its contracts with the four southeast HealthChoices plans requires submission of encounter data to the Department. However, it has not received reliable encounter data from these plans. The Department advised LB&FC staff that it has developed stronger contract standards for plans involved in the expansion of the HealthChoices program into southwestern Pennsylvania.

DPW also requires the HealthChoices plans to provide HEDIS[49] data to allow the Department and the public to reliably compare plan performance on a standardized set of measures. Such information is based on information for members who have been continuously enrolled in a plan for one year.

DPW originally planned to publish 1997 HEDIS data for the four southeast plans. The Department, however, reported that plan-specific results using data from 1997 on effectiveness of care and access/availability of care were "...erratic, in-

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[48]The portion of the report dealing with cost effectiveness was prepared by the Comptroller's Office.
[49]Health Plan Employer Data and Information Set.

ternally inconsistent and susceptible to misinterpretation." Based on consultation with NCQA, DPW has decided not to attempt to analyze or publish the 1997 HEDIS data. It intends to publicly report actual 1998 HEDIS data in late 1999. It has entered into a $400,000 multi-year contract with Island Peer Review Organization, an NCQA certified HEDIS auditor, to perform concurrent reviews of HEDIS '99 data for the four Southeast HMOs, audit the data, and provide other assistance for the HealthChoices plans. Island Peer Review was engaged by the Medicare program when it encountered similar problems with HEDIS data reported by Medicare plans.

The information released to date by the DPW is limited. It does not include any of the information such as that being gathered by Mathematica Policy Research in its survey of individuals with disabilities participating in Tennessee's managed care waiver (see Appendix U).[50] It does not include most basic program information such as: the number of Medical Assistance beneficiaries who have seen a PCP at least once during the year, the number of plan enrollees who have never seen their PCPs, the number of children who are up-to-date on their immunization, or the unduplicated number of PCPs and specialists participating in HealthChoices.

Researchers from Cornell University and Commonwealth of Virginia University, with support from the Pew Charitable Trusts and the Center for Health Care Strategies in Princeton, are conducting the only independent research to date on HealthChoices. Drs. Kuder and Hurley are conducting a focused study to determine why participants change HealthChoices doctors and health plans. Their survey includes HealthChoices participants who are disabled, and they plan to report results separately for this group. Their survey results will be available in 1999.

The Hospital and Healthsystem Association of Pennsylvania had recommended to the General Assembly that an outcome evaluation of HealthChoices be performed to provide information to be used to improve the overall structure of the program. Specifically, HAP urged "the development of a series of performance measures, and the convening of an interagency work group, supplemented by outside experts, to develop a series of normative benchmarks that the department can use for evaluating Health Choices—SE prior to statewide expansion."

4. Pennsylvania Has Been More Aggressive Than Most States in Requiring Special Needs Individuals to Enroll in Risk-Based Managed Care

Pennsylvania has been more aggressive than other states when it comes to enrolling special needs individuals in mandatory risk-based managed care. Most states do not require disabled individuals or children in substitute care to enroll in

[50]Mathematica's study is part of a larger independent evaluation of states with section 1115 waivers sponsored by the Department of Health and Human Services. For more information on the initial findings from this multi-year study, see Appendix V.

fully capitated risk-based managed care plans, such as HMOs, to receive medical assistance services.

Individuals Eligible for SSI. Only 11 states, including Pennsylvania, mandate the enrollment of SSI[51] eligibles in fully capitated risk-based managed care plans. Five of the 11 states have Section 1915 (b) waivers and six have Section 1115 waivers.

Disabled individuals are required to receive medical assistance benefits through fully capitated risk-based managed care plans under Section 1915 (b) waivers in selected counties in California,[52] Virginia, Utah, and Pennsylvania, and statewide in New Mexico.

SSI eligible individuals are mandated to enroll in HMOs in one county in Alabama and Vermont, and in parts of Oregon under Section 1115 Research and Demonstration waivers. Delaware, Kentucky, and Tennessee operate, or are starting to operate, statewide programs with such requirements.

Pennsylvania is different from the other states that require SSI eligibles to receive medical assistance through HMOs. Its population, for example, is much larger. California is the only state with a population larger than Pennsylvania's. California, however, has only 363,356 Medicaid enrollees in counties where disabled individuals must enroll in managed care organizations. Pennsylvania has over 475,000 individuals enrolled in managed care organizations in the five southeastern counties of Pennsylvania, and it plans to enroll an additional 300,000 by July 1999.

Pennsylvania differs not only in population size but also in important population characteristics. The incidence of AIDS, for example, is much greater in Pennsylvania than the other states. Philadelphia's AIDS rate is roughly twice as great as the rate in Orange County, CA; Salt Lake City; Mobile; Portland; and Albuquerque according to federal Center for Disease Control and Prevention data. Philadelphia's rate is also much greater than that of Memphis, Nashville, Norfolk, and Louisville.

Pennsylvania had 32 new pediatric AIDS cases reported in 1997. This compares with 24 in California, 10 in Virginia, 4 in Alabama, 2 in Delaware, Oregon, Kentucky, and Tennessee, 1 in Utah, and none in New Mexico or Vermont.

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[51]SSI refers to the federal Supplemental Security Income program for the aged, blind, and disabled. Individuals who receive SSI payments and those who meet the disability requirements for SSI typically qualify for Medical Assistance.

[52]California has three managed care models (Geographic Managed Care, Two-Plan Model, and the County Organized Health Systems). In one of the three models—the County Organized Health System (COHS) model-SSI eligible individuals are required to participate in a managed care program unless authorized by the COHS. COHS are Health Insuring Organizations (HIOs) and not HMOs. They are, however, risk-based managed care plans.

Pennsylvania's HealthChoices program also differs from programs in other states. Nine of the other ten states requiring SSI individuals to enroll in HMOs either do not require individuals served through home and community service waivers (such as Michael Dallas and AIDS waivers) to enroll in managed care or they exclude such waiver services from capitation.

HealthChoices does not have explicit processes to exempt medically fragile individuals from participation. In the past this has occurred only when ventilator dependent individuals were hospitalized for more than 30 days, or admitted to a state ICF/MR facility. Four of the other ten states with mandatory programs for disabled individuals have processes to exempt medically fragile individuals.

HealthChoices includes costly services such as major organ transplants and personal care services within its capitation rates. Eight of the other ten states requiring the disabled to enroll in HMOs exclude such exceptionally costly services from capitation.

Several states also operate state ombudsman programs, especially for the disabled. Some also make, or are in the process of making, payments to plans based on enrollee health status. For more information on programs in other states see Appendix W.

Children in Substitute Care. Only ten states, including Pennsylvania, require children in substitute care to enroll in risk-based managed care plans to obtain medical assistance services. They include three states with county-administered child welfare programs and seven with state administered programs.

Pennsylvania is one of three states with county-based child welfare systems mandating the inclusion of children in substitute care in fully capitated risk-based managed care plans. In California's County Organized Health Systems (COHS) (Santa Barbara, San Mateo, Solano, Napa, Orange, and Santa Cruz counties), children in substitute care must be enrolled in managed care. Maryland also mandates enrollment of children in foster care.

Seven states where the state maintains custody of the child in substitute care mandate enrollment of children in substitute care in managed care. Connecticut, Delaware, Hawaii, Kentucky, Missouri, New Mexico, and Utah have such a mandate.

California initially had included all children in substitute care in its three managed care program models, including models in areas of the state such as San Francisco and Los Angeles. In 1996, the California legislature directed that children in foster care not be included in mandatory managed care enrollment. The

state legislature directed that such children be enrolled only on a voluntary basis if two conditions are met. The county director of social services, or his or her delegated representative, determines voluntary enrollment is in the best interest of the child and the child's caretaker agrees to the enrollment. Moreover, if a child is enrolled and the child's caseworker or other responsible party determines that disenrollment from a managed care plan is in the best interest of the child, such a child must be disenrolled immediately from a plan (no later than 48 hours).[53] Michigan and West Virginia reported they attempted to enroll children in substitute care in mandatory managed care and ceased such enrollment.

Pennsylvania's HealthChoices program for children in substitute care differs from that in other states. For example, HealthChoices plans operate in specific geographic areas and are not statewide. Several states mandating enrollment of children in substitute care utilize managed care plans with statewide networks. Appendix X provides additional information on other state programs requiring children in substitute care to enroll in mandatory risk-based managed care.

Maryland's Programs for Persons with Special Needs. Traditional methods of assuring quality of care in managed care are not designed to assess the care of children and adults with complex medical needs.[54] States, moreover, have had difficulty holding plans accountable for the quality of care they provide, especially for individuals with special needs. In 1997, the US General Accounting Office (GAO) examined the efforts of several states, including Pennsylvania,[55] to hold managed care organizations accountable for providing Medicaid beneficiaries enrolled in capitated managed care plans with the care they need. The GAO concluded that the ways in which states typically hold plans accountable are not useful for assessing the quality of care of enrollees with special needs.

In view of these problems, several states are attempting to design hybrid managed care programs for persons with special needs. Maryland currently has one such program in place.

Maryland's Primary Care Case Management Alternative to HMOs for Medically Fragile Individuals: Individuals with rare and expensive medical conditions have the option of enrolling in an HMO or in a primary care case management program (PCCM) operated by a major teaching and training hospital. Individuals enrolled in this program have their care coordinated by primary care case managers. Their services, however, are paid on a fee-for-service basis. Exhibit 14 lists the con-

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[53]State of California Health and Welfare Agency, MMCD letter No 97-06, May 5, 1997 and California's 1996-97 Budget Act. The 48-hour provision is intended to apply to weekends. The state has in its contracts provisions for recovery of capitation payments it has made to plans when the state determines that a plan member should have been disenrolled.

[54]Neff, J. and Anderson, G., "Protecting Children With Chronic Illness in A Competitive Market Place," *Journal of the American Medical Association*, December 20, 1995, Vol. 274. No. 23., pp.1866—1869.

[55]This study considered information for Pennsylvania covering periods prior to the implementation of HealthChoices.

ditions, diagnosis and age groups that qualify for Maryland's primary care case management program. All ventilator dependent individuals up to age 64, for example, qualify for this program. Maryland had almost 1,500 individuals participating in its PCCM program as of June 30, 1998.

Other Innovative Features of Maryland's Mandatory Managed Care Demonstration: Children with disabilities without exceptional medical needs may be enrolled in HMOs. Maryland permits such children to have direct access to specialty care such as physical therapy, occupational therapy, and speech therapy from out-of-network providers. If the child is a new enrollee to a plan and has been receiving these services, the child can continue to receive the services from an out-of-network provider if the provider submits a plan of care to the managed care organization within 30 days of the child's enrollment. If the child is already enrolled and has need for these services, the child or their representative may request them from an out-of-network provider.

Maryland does not allow its managed care organizations discretion in approving such requests. It requires them to approve such requests unless they have a local in-network specialty provider with the same professional training and expertise who is reasonably available and provides the same services and service modalities. In both situations there is an appeal right if the managed care organization denies, reduces, or terminates the service. Moreover, the HMO must reimburse services provided while it reviews the case or any appeals are pending.

Maryland permits adults with HIV/AIDS to enroll in a special risk-based program. This program consists of a network of experienced HIV/AIDS providers. AIDS specialists serve as the primary care provider and coordinator of all specialty care needed by the patient. Services essential to care of HIV/AIDS patients are provided, including outpatient primary and specialty care, home health care, hospice care, preventive dental and vision care. Participants in the program are also offered access to clinical trials.

Maryland, moreover, pays capitation rates that are adjusted for health status and take into account adverse selection. During the upcoming year, an HMO providing care to an AIDS recipient in Baltimore will receive over $2,100 per member per month. (This rate excludes certain AIDS drugs and testing.) In 1997, Pennsylvania's average per member per month capitation rates in the southeast ranged from $103.20 to $354.34. (Pennsylvania's rate also excludes certain AIDS drugs in HealthChoices Southeast.)

Maryland also operates a state enrollee hotline, a provider hotline, and a complaint resolution and special services unit. This unit is staffed by 32 full time equivalent positions. It intervenes in individual cases, tracks all enrollee and provider complaints and grievances, and analyzes data monthly and quarterly to determine if specific intervention with a particular plan is required or changes in State policies and procedures are necessary.

The state unit operates in conjunction with the state ombudsman program. This program operates through local government units. Its purpose is to investigate disputes between enrollees and managed care organizations referred by the Department's complaint unit. In all cases the local ombudsman files a report with the state within 30 days. If the local ombudsman cannot resolve a dispute, it is referred back to the state unit for a decision.

The state dispute resolution unit makes a determination based on the information provided by the local ombudsman. In the case where the state disagrees with the managed care organization's determination to deny a benefit or service, it may order the HMO to provide the benefit or service immediately (including reimbursing out-of-pocket costs incurred in obtaining services). The state issues a written notice to the HMO regarding its decision. The HMO may appeal the state's decision. The HMO, however, must provide a disputed benefit or service or reimburse the recipient while the appeal is pending. The state reimburses the managed care organization for the disputed benefit or service if the state does not win on appeal.

If the state dispute resolution unit does not agree with the enrollee, it notifies the enrollee of its determination. The enrollee can then exercise his/her appeal rights.

Maryland also has procedures to assure that providers understand the state's Medicaid managed care program's covered services and procedures. The state issues a single provider manual to all physicians and hospitals participating in its managed care program to help ensure they are aware of state and federal policies and the responsibilities of the managed care organization.

Rare and Expensive Conditions Not Subject to Mandatory HMO Enrollment

Condition Type	Diagnosis	ICD9 Codes	Age Group
HIV Disease	Symptomatic HIV/AIDS (Pediatric)	042. x all	0-20
	Asymptomatic HIV Status (Pediatric)	V08	0-20
	Inconclusive HIV Result (Infant)	795.71	0-12 Mo.
Metabolic	Disturbances of Amino-Acid Transport	270.0	0-20
	PKU, MSUD, Other Amino Acid Metabolism	270.1 thru 270.4	0-20
	Disturbances of Histidine Metabolism	270.5	0-20
	Disorders of Urea Cycle Metabolism	270.6	0-20
	Amino Acid Metabolism Disorders	270.7, 270.8	0-20
	Glycogenesis, Galactosemia, Fructose Intolerance	271.0, 271.1, 271.2	0-20
	Lipidoses	272.7	0-20
	Cystic Fibrosis	277.0, .00, .01	0-64
	Purine/Pyrimidine Disorders	277.2	0-64
	Mucopolysaccharidosis	277.5	0-64
	Histiocytosis	277.8	0-64
Blood	Aplastic Anemia, Constitutional	284.0	0-20
	Hemophilia	286.0 thru 286.4	0-64
Degenerative Diseases	Cerebral Degen. Disease of Childhood	330. x all 4th digits	0-20
	Communicating and Obstructive Hydrocephalus	331.3, 331.4	0-20
	Extrapyramidal Degen.--Myoclonus	333.2	0-5
	Idiopathic Torsion Dystonia	333.6	0-64
	Symptomatic Torsion Dystonia	333.7	0-64
	Unspec Extrapyramidal Disease	333.90	0-20
	Spinocerebellar Degenerative Disease	334. x all	0-20
	Anterior Horn Cell Disease	335. x all	0-20
Nervous System	Schilder's Disease	341.1	0-64
	Diplegic Infantile Cerebral Palsy	343.0	0-20
	Quadriplegic Infantile Cerebral Palsy	343.2	0-64
	Quadriplegia and Quadriparesis	344.0	0-64
Muscular Dystrophies	Congenital Hereditary MD	359.0	0-64
	Hereditary Progressive MD	359.1	0-64
	Congenital Myotonic Dystrophy (Steinert's Only)	359.2	0-64
Cerebrovascular	Moyamoya Disease	437.5	0-64
Digestive Disease	Short Gut Syndrome	579.3	0-20
Genitourinary Disease	Chronic Glomerulonephritis Conditions	582, 582.0, 582.1, 582.2, 582.4, 582.8, 582.81, 582.89, 582.9	0-20

Exhibit 14 (Continued)

Condition Type	Diagnosis	ICD9 Codes	Age Group
Genitourinary Disease (Cont.)	Chronic Renal Failure Diagnosed by a Pediatric Nephrologist	585	0-20
	Chronic Renal Failure With Dialysis and Documented Rejection from Medicare	585 V45.1	21-64
Congenital Anomalies	Spina Bifida	741. x all	0-64
	Encephalocele, Microcephalus, Hydrocephalus	742.0, 742.1, 742.3	0-20
	Other Brain Anomalies	742.4	0-20
	Spinal Cord Anomalies	742.5, 742.59	0-64
	Nose: Cleft or Absent Nose Only	748.1	0-5
	Web Larynx	748.2	0-20
	Only Atresia or Agenesis of Larynx, Trachea, or Bronchus	748.3	0-20
	Congenital Cystic Lung	748.4	0-20
	Agenesis, Hypoplasia, and Dysplasia	748.5	0-20
	Cleft Palate	749 Except 749.1x	0-20
	Tracheoesophageal Fistula	750.3	0-3
	Atresia Large Intestine	751.2	0-5
	Hirschsprung's, Other Colon	751.3	0-15
	Biliary Atresia, Cystic Disease of Liver	751.61 and 751.62	0-20
	Pancreas	751.7	0-5
	Other Digestive (Specified)	751.8	0-10
	Urinary System Anomalies (Only if Bilateral)	753.0	0-20
	Cystic Kidney Disease (Only if Bilateral)	753.1	0-20
	Polycystic Kidney, Unspecified Type (Only if Bilateral)	753.12	0-20
	Polycystic Kidney, Autosomal Dominant (Only if Bilateral)	753.13	0-20
	Polycystic Kidney, Autosomal Recessive (Only if Bilateral)	753.14	0-20
	Renal Dysplasia (Only if Bilateral)	753.15	0-20
	Medullary Cystic Kidney (Only if Bilateral)	753.16	0-20
	Medullary Sponge Kidney (Only if Bilateral)	753.17	0-20
	Exstrophy of Urinary Bladder	753.5	0-20
	Musculoskeletal--Skull and Face Bones	756.0	0-20
	Chondrodystrophy	756.4	0-1
	Osteodystrophy, Unspecified	756.50	0-1
	Osteogenesis Imperfecta	756.51	0-20
	Osteopetrosis	756.52	0-1
	Osteopoikilosis	756.53	0-1
	Polyostotic Fibrous Dysplasia of Bone	756.54	0-1
	Chondroectodermal Dysplasia	756.55	0-1
	Multiple Epiphyseal Dysplasia	756.56	0-1
	Other Osteodystrophies	756.59	0-1
	Anomalies of Diaphragm	756.6	0-1
	Anomalies of Abdominal Wall	756.7	0-1
	Multiple Congenital Anomalies	759.7	0-10
Other	Ventilator Dependent (Non-Neonate)	V46.1 and V46.9	1-64

Source: Maryland Department of Health and Mental Hygiene.

V. Appendices

APPENDIX A

PRINTER'S NO. 1861

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 185 Session of 1997

INTRODUCED BY O'BRIEN AND OLIVER, JUNE 2, 1997

REFERRED TO COMMITTEE ON RULES, JUNE 2, 1997

A RESOLUTION

Directing the Legislative Budget and Finance Committee to examine the effectiveness of Commonwealth programs and efforts to ensure the quality of health care services provided in this Commonwealth.

WHEREAS, Fundamental changes are occurring in the health care delivery system in this Commonwealth; and

WHEREAS, There has been a dramatic increase in the growth of managed care, an increase in the number of persons without health insurance, an increase in the number of hospital mergers and consolidations, a shift from acute inpatient care services to outpatient care services and a change in the mix of health care practitioners; and

WHEREAS, The Department of Health is revising its rules and regulations on quality assurance as a result of the sunset of the certificate of need program; therefore be it

RESOLVED, That the House of Representatives direct the Legislative Budget and Finance Committee to examine existing Commonwealth programs and efforts to monitor changes in the

delivery and reimbursement practices of health care services and to ensure that these changes do not negatively impact on the quality of health care in this Commonwealth; and be it further

RESOLVED, That the Legislative Budget and Finance Committee:

(1) Review the adequacy of Federal and State laws, regulations and standards relating to the assurance of quality care, including the associated licensure and certification of health care facilities, health care practitioners and health plans.

(2) Review the use of nationally recognized voluntary accreditation standards and practices for assuring quality in health care delivery in this Commonwealth and other states.

(3) Identify the effective methods, policies and practices used in this Commonwealth and other states to promote and achieve quality standards of care.

(4) Identify current efforts being made in this Commonwealth and other states to improve public accountability of health care providers and health plans in the delivery of quality services.

(5) Identify those special concerns in providing the above-referenced quality assurance processes and practices to address the needs of children, persons with mental illness, substance abusers, persons with disabilities and person with chronic illness; and be it further

RESOLVED, That the Department of Health, the appropriate State professional licensure boards, the Department of Public Welfare, the Insurance Department, the Department of Aging, the Health Care Cost Containment Council, the Health and Human Services Committee and all other Commonwealth agencies shall provide assistance upon request as the Legislative Budget and

Finance Committee may deem appropriate; and be it further

RESOLVED, That the Legislative Budget and Finance Committee may hold hearings, take testimony and make its investigations at such places as it deems necessary in this Commonwealth. Each member of the committee shall have power to administer oaths and affirmations to witnesses appearing before the committee; and be it further

RESOLVED, That the committee shall report to the House of Representatives on its activities, findings and recommendations by June 30, 1998, and shall issue interim reports to the House of Representatives as the committee deems necessary.

APPENDIX B

The National Committee for Quality Assurance Managed Care Accreditation Surveys

The National Committee for Quality Assurance (NCQA) awards accreditation for varying periods, depending on the status of a managed care plan as determined during a three-to-five-day site visit. Full accreditation is awarded for three years if a plan fully or substantially complies with the standards the NCQA has set for each of the six categories[a] it surveys. Substantial compliance means the NCQA has not found any issue significant enough to warrant additional action by the plan.

The NCQA awards full accreditation with recommendations if it finds action warranted and the managed care plan can take such action to produce the intended effect within 90 days. The plan must document the successful implementation of the action within the 90-day period to retain its full accreditation. Otherwise, the NCQA will change it to a lesser status or issue a denial.

One-year accreditation is awarded if a plan shows significant compliance for each category but needs to take further action, requiring evaluation over a period not exceeding one year, to achieve full compliance. One-year accreditation may remain in effect for 15 months. The NCQA will conduct a resurvey within 12 months to determine whether full compliance has been achieved or a change in accreditation status is warranted.

Provisional accreditation is awarded if a plan partially complies in each category and does not have any deficiencies posing a potentially significant risk to the quality of care. Provisional accreditation has the same duration as one-year accreditation. Similar resurvey provisions apply, including the use of standards in effect during the original survey even though such standards might have changed.

Although managed care plans must generally wait at least one year to reapply after being denied accreditation, the NCQA has the discretion to expedite its surveys. Circumstances such as the need for accreditation to achieve licensure may justify an expedited survey.[b] The NCQA also has a reconsideration committee to hear requests for the modification of accreditation decisions. Such requests must be based on conditions existing at the time of the survey, not on subsequent actions to achieve compliance.

Practicing professionals with managed care experience participate not only in designing standards and review procedures but also in performing the surveys. An NCQA survey team includes at least one physician surveyor and one administrative

surveyor. Surveyors must complete a training program, which is updated annually, and must have the following:

- An appropriate health profession;
- Good standing in the health care community and a license if applicable;
- An in-depth understanding of quality improvement and managed care;
- No direct financial relationship with the organization under review.

The NCQA Review Oversight Committee makes the final determinations on compliance status and accreditation. The Committee reviews the documented recommendations of its surveyors, who assess the compliance status for each standard and assign a score. Assigned weights reflect the relative importance of each standard within its category. The NCQA also weights the total scores for each category to determine the overall score the managed care plan has achieved. The weights of specific categories may vary from year to year, but quality improvement generally has the highest weight.

The weighted approach to determining an overall score is one of the guidelines the NCQA uses to focus the surveyors' attention on the issues the Committee considers most important. Other guidelines are the total score for the quality improvement category, compliance with the effectiveness standard for quality improvement, and evidence of major deficiencies in any category.

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[a]The six categories are quality improvement, credentialing, utilization management, members' rights and responsibilities, preventive health services, and medical records.

[b]The NCQA has developed an alternative survey to accommodate managed care plans that need external reviews for purposes other than accreditation. The 1999 Standards for Managed Care Organizations will contain the policies and procedures for state and federal agency regulatory surveys.

Source: Developed by LB&FC staff.

APPENDIX C

Summary of Selected Health Care Cost Containment Council Reports

Coronary Artery Bypass Graft Surgery (CABGS) Reports. The HCCCC has issued five CABGS reports with profiling information for individual physicians and hospitals, and most recently some insurers. In these reports, HCCCC identifies statistical ratings for in-hospital deaths from the procedure. The reports typically provide ratings for individual surgeons for each facility at which they practice and ratings for individual facilities. The data reported by the HCCCC is risk-adjusted to account for certain patient differences.[a]

In its fourth CABGS report, the HCCCC reported that in Pennsylvania the quality of care for this procedure was improving.

- The overall mortality rate for patients undergoing this procedure decreased even though the percentage of patients with significant risk factors was consistent.
- Five of the seven Pennsylvania hospitals that had significantly more deaths than expected in 1990 had moved up to the average category.

In May 1998, the HCCCC issued its fifth report using data from 1994-95. This report included information for hospitals, physicians, and for the first time certain health insurers and health maintenance organization. The HCCCC reported that statewide four hospitals had significantly more deaths than expect in 1994-1995 and that 90 percent of the surgeons had risk-adjusted patient mortality rates that were well within what was expected or better after accounting for patient risk.

In May 1998, the HCCCC also reported the surgeon's volume of open heart surgery cases was an important determinant of in-hospital survival. Higher volume was associated with increased survival.

Focus on Heart Attack Reports. The HCCCC has issued reports which compare actual to expected in-hospital mortality from heart attacks for physician groups with 30 or more cases. Mortality rates are not reported for groups without 30 or more cases because the numbers are too small for statistical reliability. They are also not reported for solo practitioners.[b]

According to the HCCCC's 1993 data:

- 93.7 percent of hospitals and 98.2 percent of reportable physician practice groups had risk-adjusted patient mortality rates well within what was expected or better given significant patient risk factors.
- Residents in rural counties had significantly higher rates of in-hospital mortality compared to the state rate.

Appendix C (Continued)

- Residents of rural areas were also less likely to receive advanced cardiac services (such as cardiac catheterizations, balloon angioplasties, and cardiac surgery) than residents of urban areas.
- Cardiologists had fewer patient deaths than expected and shorter lengths of stay than expected across all hospitals.
- Patients treated by physicians specializing in internal medicine had longer lengths of stay in hospitals.
- Family medicine physicians practicing in hospitals without advanced cardiac services had more patient deaths than expected.
- Physicians practicing internal medicine in hospitals with advanced cardiac services had more deaths than expected.

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[a]Because methods used to adjust for important differences inpatient characteristics and patient risk factors are not perfect, the HCCCC publishes along with the outcome data a separate volume in which the practitioner or facility can provide additional information or comments relevant to the data. Moreover, practitioners and facilities verify all data used by HCCCC in its reports.

[b]The names of such practitioners and group practices with 30 or fewer cases and their number of cases are, however, included in the report.

Source: Developed by LB&FC staff from Health Care Cost Containment reports.

APPENDIX D

Medical Assistance Fair Hearing Timeliness Requirements

Every person applying for or receiving medical assistance has the right to appeal a departmental action involving the following:

- a denial, suspension or discontinuance, in whole or in part;
- a denial, discontinuance, reduction or exclusion from a service or program.

Notice Requirements

An agency must inform every applicant or recipient in writing of the right to a hearing; of the method for requesting a hearing; and of the right to be represented by counsel. This information must be provided when the individual applies for Medicaid or at the time of any action affecting a claim. The state or local agency must mail such a notice at least ten days before the date of action.[a]

Requirements for Continued Provision and Reinstatement of Services

An agency must continue and reinstate services until a decision is rendered after a fair hearing if:

- the recipient requests a hearing within ten days of the mailing of the notice terminating, suspending, or reducing service.
- services are terminated, suspended, or reduced without notice.
- the termination, suspension, or reduction of service resulted from other than the application of federal or state law or policy.

Time Limitation on the Right to Appeal

An applicant or recipient must exercise his right of appeal within the following time limits. Appeals which do not meet the following time limitations will be dismissed without a hearing:

1. Thirty days from the date of written notice of a decision or action by a county assistance office, administering agency, or service provider.

2. Sixty days from the date of a decision or action by a county assistance office, administering agency, or service provider when they did not send written notice because the notice was not required; or 60 days from their failure to act.

3. When the county office, administering agency, or service provider fails to send written notice which was required of the action and of the right of appeal or because of administrative error, ongoing delay or failure to take corrective action that should have been taken, the time limit in paragraph (2) will not apply. For a period of six months from the date of the action or failure to act, the client shall have the right of appeal and shall exercise that right in writing. After six months from the date of the county office, administering agency, or service provider action or failure to act, a written appeal may be filed with the agency provided that the client signs an affidavit stating the following:

   - the client did not know of his right of appeal or believed the problem was being resolved administratively.
   - the client actually believes the county office erred in its actions.
   - the appeal is being made in good faith.

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[a]Action means a termination, suspension, or reduction of Medicaid eligibility or covered services.

Source: Developed by LB&FC staff from a review of 55 Pa. Code Ch. 275 and federal regulations at 42 CFR §431.200 et seq.

APPENDIX E

The Relationship Between Volume and Mortality Outcome in Coronary Artery Bypass Surgery

Research in peer review journals clearly demonstrates higher than expected mortality rates for those facilities that perform less than 100 procedures per year. The articles reviewed included those that examined the relationship by individual surgeon volume, by hospital volume and by physician practice volume. These articles show that, generally, a minimum threshold of 100 cases per year is necessary.

Clark, Richard, et. al. "Outcome as a Function of Annual Coronary Artery Bypass Graft Volume", **Annals of Thoracic Surgery,** ***1996; 61:21-26.***

Time of Study and Sample Size: This research was performed in September 1994 on CABG patients from 1991 through 1993, numbering 124,793. Practice group data yielded 180 practices with 120,377 patients.

Results: The data show that the observed mortality ranged form 2 percent to 3.6 percent for practices of more than 100 cases through practices with more than 900 cases per year. Those practices with less than 100 cases (18 in all) had a mean mortality rate of 5 percent. There was no clinically relevant correlation of volume to outcome *except* at extremely low annual volume (less than 100 cases per year).

Crawford, Fred A. et. al. "Volume Requirements for Cardiac Surgery Credentialing: A Critical Examination," **Annals of Thoracic Surgery,** ***1996; 61, 12-16.***

This review of previously published research examines the volume-quality relationship in CABG surgery concluded that there is no conclusive basis for requiring minimum individual surgeon volumes and, if this relationship were to be proven. The authors found, however, agree that previous research does demonstrate a significant relationship between hospital volume and outcome.

Hannan, et. al. "CABG Surgery: The Relationship Between Inhospital Mortality Rate and Surgical Volume After Controlling for Clinical Risk Factors," **Medical Care,** ***November 1991, Vol. 29, No. 11.***

Time of Study and Sample Size: The source of data for this research was the Cardiac Surgery Reporting System of New York State, and includes all 1989 data for coronary artery bypass grafts performed without other open heart procedures. This total number was 12,448, 458 hospital admissions.

Results and Conclusions: "This study demonstrates that the surgical volume measures remain significantly related to mortality even when clinical risk factors are used as controls." In-hospital mortality rates from this study are as follows:

Risk adjusted mortality rates:	7.25 percent for hospitals with volumes from 1-199. 2.85 percent for hospitals with volumes of 890 and above.
Risk adjusted mortality rates:	8.14 percent for hospitals with volumes under 55. 2.43 percent for hospitals with volumes of 360 and above.

Hannan et al. "Investigation of the Relationship Between Volume and Mortality for Surgical Procedures Performed in New York State Hospitals", JAMA (* Journal of the American Medical Association), *July 28, 1989, Vol.262, No. 4, pp. 503-510.

General: This research uses measures of physician volumes to test the combined relationship of hospital and physician volume with in-hospital mortality rates.

Time of study and sample size: Data for the study was individual patient discharge data abstracts for 1986 obtained from the Statewide Planning and Research Cooperative System maintained by the New York State Department of Health.

Results and Conclusions: Physician volume was found to have a significant impact on mortality rate by contrasting standardized mortality rates for the two volume ranges. For low volume (less than or equal to 116 procedures): 4.92 percent mortality. For high volume (greater than 116 procedures): 4.04 percent mortality. High volume doctors have no statistically significant hospital volume cuts among the ranges presented. Hospitals performing 650 or fewer procedures had a standardized mortality rate of 5.28 percent, those with over 650 procedures, 3.82 percent. For both high and low volume doctors, rates continue to decrease at the higher levels of hospital volume.

Kirkin et al. "American College of Cardiology/American Heart Association Task Force Report: Guidelines and Indications for CABG Surgery,"* Journal of the American College of Cardiology, *Vol. 17, No. 3, pp. 545-589.

This task force report recommends a minimum of 200-300 open heart operations should be performed in hospitals with open heart programs. The majority of these should be CABG surgeries. The authors point out, however, that different, specifically derived recommendations might be necessary for either highly or sparsely populated areas. The recommendation for individual surgeons is 100-150 open heart surgeries per year, again, the majority being CABG operations. With individuals populations must also be taken into consideration. The report also points out that "these recommendations are general and should be applied with the knowledge that several reports attest that it is possible for a particular low volume hospital or surgical group to have good results."

Appendix E (Continued)

Pennsylvania Health Care Cost Containment Council, "Pennsylvania's Guide to Coronary Artery Bypass Graft Surgery 1994-1995," May, 1998.

Under its section of Physician Characteristics, HCCC states that "the surgeon's volume of open heart surgery cases was an important determinant of in-hospital survival." Higher volume was associated with *increased* survival. The number of open-heart surgeries performed, on average, by a Pennsylvania cardiac surgeon in 1994-95 was 127 per year.

Showstack et al. "Association of Volume with Outcome of CABG Surgery: Scheduled vs. Non-Scheduled Operations", JAMA, February 13, 1987, Vol. 257, No. 6, pp. 785-789.

Time and Size of Study: The source of data for the research was individual patient discharge data abstracts for 1983 obtained from the California Health Facilities Commission.

Results and Conclusions: In combining both scheduled and non-scheduled operations, the study found a strong association between volume and adjusted death rate. In hospitals performing 20-100 procedures, the rate was .052. The rate for hospitals performing 101-200 procedures was .039, for 201-350, .041 and for over 350 procedures, the rate was .031. There was a strong volume/outcome relationship for those undergoing scheduled surgery and a trend toward this relationship for non-scheduled patients. There was also a strong volume/outcome relationship in assessing poor outcomes. The likelihood of a poor outcome in a high volume hospital is two-thirds that in the lowest volume hospitals.

Shroyer, A. Laurie et. al. "No Continuous Relationship Between Veterans Affairs Hospital CABG Volume and Operative Mortality",* Annals of Thoracic Surgery, *1996; 61: 17-20.

General: This research was undertaken to determine whether risk-adjusted CABG mortality rates are significantly related to volume within the Department of Veterans Affairs hospital system.

Time and Size of Study: Patient data for clinical risk factors and 30 day operative mortality were obtained from the VA Continuous Improvement in Cardiac Surgery Study for 23,986 CABG patients. The time frame was from April 1987 to September 1992. Patients were from 44 different hospitals.

Results: This study found a statistically significant relationship between annual hospital CABG volume and observed 30 day operative mortality rates with no adjustment for clinical or with age adjustment only. Although, when risk factors were taken into account, a facility's CABG volume was found not to be a statistically significant predictor of operative mortality. However, the research also showed that hospitals with 100 or less cases per year have higher observed to expected mortality ratios than hospitals performing more that 100 cases per year.

APPENDIX F

Healthcare Cost and Utilization Project (HCUP)-3: Quality Access to Primary Care Indicators

Quality Access to Primary Care Indicator	Pennsylvania's Rate	Comparison to Other States[a]
Obstetrical		
Low Birthweight[b]	5.43 per 100 newborns	PA's rate is lower than AZ, CO, FL, IL, NJ, & NY
Very Low Birthweight[c]	1.309 per 100 newborns	PA's rate is lower than FL, IL, NJ, & NY
Pediatric		
Pediatric Asthma Discharges[d]	9.846 discharges per 100 pediatric discharges	PA's rate is lower than AZ, CA, CO, FL, IL, MA, NJ, NY, & WI
Prevention		
Immunization-Preventable Pneumonia and Influenza Among the Elderly[e]	0.406 discharges with pneumonia or flu per 100 discharges	PA's rate is lower than AZ, CA, CO, IL, IA, MA, WA, & WI and the same as NY
Cerebrovascular Disease Among Non-Elderly Adults[f]	2.568 discharges with TIA or CVA per 100 discharges	PA's rate is lower than CA & FL
Internal Medicine		
Diabetes Short-Term Complications[g]	2.494 discharges with complications per 100 discharges	PA's rate is lower than AZ, CA, CO, FL, IL, IA, NY, WA, & WI
Diabetes Long-Term Complications[h]	33.793 discharges with complications per 100 discharges	PA's rate is the lowest of the 12 reporting states
Surgical		
Perforated Appendix[i]	31.941 perforations/abscesses per 100 appendectomies	PA's rate is lower than CA, FL, NJ, & NY

Please see footnotes on next page.

Appendix F (Continued)

[a] Twelve states participated in the HCUP-3: Arizona, California, Colorado, Florida, Illinois, Iowa, Massachusetts, New Jersey, New York, Pennsylvania, Washington, and Wisconsin.

[b] Low birthweight is a major determinant of infant mortality. Maternal factors that influence birthweight are smoking cessation, reduced maternal weight gain, and initiation of early prenatal care. The Year 2000 target is to reduce low birthweights to no more than 5 per 100 live births.

[c] The Year 2000 target is for no more than 1 per 100 live birth.

d According to AHCPR, adequate ambulatory care can prevent hospitalizations for asthma. Studies have shown that hospitalization for asthma is a particular problem among poor children and adolescents. Hospitals with high rates of pediatric asthma may reveal a problem in access to primary care in the community.

[e] According to AHCPR, pneumococcal pneumonia and influenza are significant causes of morbidity and morality, especially among the elderly. Low vaccination rates among the elderly contribute to continued high mortality from these conditions. Hospitals with high rates of preventable pneumonia may reveal a problem in access to preventive care in the community.

[f] Reduction of high blood pressure, cholesterol, and smoking can result in lower stroke-related morbidity and mortality. Hospitals with high rates of cerebrovascular disease among the non-elderly may reveal a need for targeted risk reduction in the community.

[g] According to AHCPR, some acute complications of diabetes require emergency treatment. Such complications are more likely to occur in patients who are inadequately monitored or poorly educated about the management of diabetes. Hospitals with high rates of diabetic complications may reveal a problem in access to diabetes services in the community.

[h] Long term complications of diabetes include blindness, renal failure, and vascular disease leading to amputation. Onset of these complications can be postponed or prevented if patients control their blood glucose to near normal levels and receive early medical care for complications. Hospitals with high rates of diabetic complications may reveal a problem in access to diabetes services in the community.

[i] According to AHCPR, appendectomy performed early rarely results in perforation and associated peritonitis or apppendiceal abscess. Although some patients will present too late to prevent perforated appendix, hospitals with high rates may reveal a problem in access to medical care in the community.

Source: Agency for Health Care Policy and Research, *Healthcare Cost and Utilization Project (HCUP)--3 Quality Indicators Benchmarks from Twelve States With Detail From Pennsylvania*, February 1996.

APPENDIX G

Healthcare Cost and Utilization Project (HCUP)-3: Quality/Outcome Indicators Benchmarks for Pennsylvania

Quality Outcome Indicator	Pennsylvania's Rate	Comparison to Other States[a]
Mortality Following Common Elective Procedures:[b]		
Hysterectomy	0.084 in-hospital deaths per 100 procedures	PA's rate was lower than CA, FL, IL, IA, MA, NJ, & NY
Laminectomy/Spinal Fusion	0.036 in-hospital deaths per 100 procedures	PA's rate was lower than AZ, CA, CO, IL, IA, MA, NJ, & NY[c]
Cholecystectomy	0.575 in-hospital deaths per 100 procedures	PA's rate was lower than CA, CO, FL, IL, IA, NJ, NY
Transurethral Prostatectomy	0.385 in-hospital deaths per 100 procedures	PA's rate was lower than IA, NJ, & NY
Hip Replacement	0.574 in-hospital deaths per 100 procedures	PA's rate was lower than FL & NJ
Knee Replacement	0.421 in-hospital deaths per 100 procedures	PA's rate was lower than FL & NJ
Coded Complications:		
Obstetrical Complication[d]	6.494 complications per 100 deliveries	PA's rate was lower than CO, IA, MA, NJ, WA, & WI
Wound Infection[e]	0.27 complications per 100 discharges	PA's rate was lower than CA, CO, FL, IA, MA, NJ, NY, WA, & WI
Adverse Effects and Iatrogenic Complications[f]	2.596 complications per 100 discharges	PA's rate was lower than AZ, CA, CO, FL, IA, MA, NJ, WA, & WI
Complications Among Surgical Patients:		
Pulmonary Compromise After Major Surgery[g]	0.517 complications per 100 procedures	PA's rate was lower than CA, CO, FL, MA, NJ, & NY[h]
Acute Myocardial Infarction After Major Surgery[i]	0.243 complications per 100 procedures	PA's rate was lower than FL, MA, NJ, & NY[j]
Gastrointestinal Hemorrhage or Ulceration After Major Surgery[k]	0.205 complications per 100 procedures	PA's rate was lower than CA, FL, MA, NJ, & NY[l]
Venous Thrombosis or Pulmonary Embolism After Major Surgery/ Invasive Vascular Procedures[m]	0.507 complications per 100 procedures	PA's rate was lower than NJ and NY[n]
Mechanical Complications Due to Device, Implant, or Graft (Excluding Organ Transplant)	0.641 complications per 100 procedures	PA's rate was lower than all reporting states
Urinary Tract Infection After Major Surgery[o]	3.311 complications per 100 procedures	PA's rate is lower than FL, MA, NJ, & NY[p]

Appendix G (Continued)

Quality Outcome Indicator	Pennsylvania's Rate	Comparison to Other States[a]
Pneumonia After Major Surgery/ Invasive Vascular Procedure[q]	0.549 complications per 100 procedures	PA's rate was lower than CA, CO, FL, MA, NJ, & NY[r]

[a] Twelve states participated in the HCUP-3: Arizona, California, Colorado, Florida, Illinois, Iowa, Massachusetts, New Jersey, New York, Pennsylvania, Washington, and Wisconsin.

[b] AHCPR selected these measures because mortality following surgery for uncomplicated diagnoses and elective procedures should rarely occur. It is important to note that according to AHCPR the right rate for these measures is unknown. Moreover, while the hospital is the unit of analysis, the hospital's inpatient data may reflect hospital care, physician practice patterns, physician-patient decision making, and availability of care in the community.

[c] Data were not reported for Wisconsin.

[d] AHCPR selected this indicator because obstetrical complications may contribute to maternal, fetal, and neonatal morbidity and mortality. Such complications are largely preventable through routine prenatal care and appropriate obstetrical care. HHS has established a year 2000 target of reducing obstetrical complications to no more than 15 complications per 100 deliveries.

[e] Surgical and traumatic wounds are often contaminated with bacteria, however, strict surgical aseptic technique can minimize the incidence of wound infections.

[f] According to AHCPR, this indicator combines a range of conditions and procedures that denote potentially substandard care and poor outcomes.

[g] According to AHCPR, patients who receive general anesthesia are at risk of pulmonary complications; however, meticulous post-operative care should prevent most such occurrences.

[h] Data were not reported for Arizona, Illinois, Iowa, and Washington.

[i] According to AHCPR, risk of surgery-related myocardial infarction (MI) increases for patients with existing cardiac conditions, age greater than 70 years, and poor medical condition. MI after surgery may indicate that patients were inadequately screened prior to surgery or that they experienced substandard care during or following surgery.

[j] Data were not reported for Arizona, Illinois, Iowa, and Washington.

[k] According to AHCPR irritation of the stomach or duodenum can occur in surgical patients as a result of excessive secretion of gastric acid, medications, and other factors. GI hemorrhage or ulceration can be prevented under most circumstances through prophylactic use of medication that coats the stomach lining or that inhibits the secretion of gastric acid.

[l] Data were not reported for Arizona, Illinois, Iowa, and Washington.

[m] According to AHCPR, blood clots in the deep veins (venous thrombosis) can dislodge and travel to the lung causing blockage of the pulmonary circulation (pulmonary embolism). Although patients who receive general hospital anesthesia are at risk for such complications, meticulous post-operative care should prevent most such occurrences.

[n] Data were not reported for Arizona, Illinois, Iowa, and Washington.

[o] According to the AHCPR, an infection of the urinary tract can result from Foley catheterization of the urinary bladder to monitor surgical patients' output of fluids. Although patients who receive general anesthesia and catheterization are at risk for subsequent urinary tract infection, meticulous post-operative care should prevent most such occurrences.

[p] Data were not reported for Arizona, Illinois, Iowa, Washington.

[q] Surgical patients are at particular risk of post-operative pneumonia. Pneumonia usually results from immobility, inadequately treated atelectasis (partial collapse of lung tissue), or contamination of the airway through aspiration. Although patients who receive general anesthesia are at risk for pneumonia, meticulous post-operative care should prevent most such occurrences.

[r] Data were not reported for Arizona, Illinois, Iowa, and Washington.

APPENDIX H

Healthcare Cost and Utilization Project (HCUP)-3: Quality Utilization Indicators

Quality Utilization Indicator	Pennsylvania's Rate	Comparison to Other States[a]
Obstetrical		
Cesarean Section Delivery[b]	21.947 C-sections per 100 deliveries	PA's rate is lower than FL, MA, NJ, & NY
Successful Vaginal Birth After Cesarean Section[c]	28.328 vaginal births per 100 deliveries with prior C-section	PA's rate is lower than AZ, CA, CO, WA, & WI
Other Procedures		
Incidental Appendectomy Among Elderly[d]	1.603 incidental appendectomies per 100 intra-abdominal procedures	PA's rate is lower than CA, CO, FL, IL, IA, NJ, NY, WA, & WI
Hysterectomy[e]	5.415 procedures per 100 discharges	PA's rate is lower than AZ, CA, CO, FL, IL, IA, WA, & WI
Laminectomy and/or Spinal Fusion[f]	1.6 procedures per 100 discharges	PA's rate is lower than AZ, CA, CO, FL, IA, WA, & WI
Transurethral Prostatectomy[g]	3.362 procedures per 100 discharges	PA's rate is lower than AZ, CA, CO, FL, IL, MA, NJ, NY, WA, & WI
Radical Prostatectomy[h]	0.591 procedures per 100 discharges	PA's rate is lowest of the 12 reporting states
Laparoscopic Cholecystectomy[i]	72.525 procedures per 100 cholecystectomies	PA's rate is greater than AZ, CA, FL, IL, IA, NY, & WA
Coronary Artery Bypass Graft[j]	1.033 procedures per 100 discharges	PA's rate is lower than AZ, CA, CO, FL, IL, IA, WA, and WI

Please see footnotes on next page.

Appendix H (Continued)

[a] Twelve states participated in the HCUP-3: Arizona, California, Colorado, Florida, Illinois, Iowa, Massachusetts, New Jersey, New York, Pennsylvania, Washington, and Wisconsin.

[b] Maternal complications such as hemorrhage, infection, and mortality are more common in women who have a C-section than in women who deliver vaginally. Although the overall C-section delivery rate cannot determine inappropriate use, it may identify areas where C-section rates can be reduced. The Year 2000 target for C-sections is no more than 15 C-sections per 100 deliveries.

[c] According to AHCPR, vaginal birth after C-section (VBAC) is safe and beneficial for women with a prior Cesarean section. Repeat C-sections account for a large percentage of C-section births in the U.S. Although a low VBAC rate cannot determine inappropriate use of C-section, it may identify areas where VBAC rates can be increased. The Year 2000 targets for VBAC is 35 per 100 deliveries.

[d] According to AHCPR incidental appendectomy is often performed during an unrelated intra-abdominal procedure to prevent future appendicitis. While the risk of appendicitis decreases with age, the risk of complications from incidental appendectomy outweighs the potential preventive effect in the elderly. Therefore, incidental appendectomy should not be performed on elderly patients.

[e] According to AHCPR, it is widely recognized that the rate of hysterectomy (surgical removal of the uterus) in the U.S. is too high and that hysterectomies are performed for inappropriate reasons. Although the overall hysterectomy rate cannot determine inappropriate use, it may identify areas where hysterectomy rates can be reduced.

[f] According to AHCPR, studies suggest that laminectomy (removal of a portion of a vertebra) and spinal fusion (joining two or more vertebrae for stabilization) are not superior to non-surgical therapies for back pain and may in fact be inferior. Although the overall laminectomy rate cannot determine inappropriate use, it may identify areas where laminectomy rates can be reduced.

[g] According to AHCPR, the most common treatment for benign prostatic hypertrophy is transurethral resection of the prostate (TURP), which can result in urinary leakage and impotence. Recent guidelines have recommended TURP only for men with serious symptoms, such as urinary retention and kidney problems. Although the overall rate of TURPs cannot determine inappropriate use, it may identify areas where TURP rates can be reduced.

[h] Radical prostatectomy (removal of the prostate through an open incision) is a common therapy for localized prostate cancer, a very slow-growing tumor in elderly men. The probability for medical complications following surgery is high, and there is no evidence that prostatectomy is superior to less invasive therapy. Although the overall radical prostatectomy rate cannot determine inappropriate use, it may identify areas where radical prostatectomy can be reduced.

[i] Cholecystectomy (surgical removal of the gallbladder) performed using a laparoscope has significantly lower morbidity and mortality than open cholecystectomy. According to AHCPR, this indicator demonstrates the extent to which this new, less invasive technology has been adopted.

[j] Coronary Artery Bypass Graft (CABG) (surgical restoration of blood flow to the coronary arteries) is a common therapy for coronary artery disease, according to AHCPR. It is known that outcomes from CABG are better at institutions that perform more CABGs. But it is also known that many CABGs may be unnecessary. Although the overall CABG rate cannot determine inappropriate use, it may identify areas where CABG rates can be reduced or where too few procedures are performed.

Source: Agency for Health Care Policy and Research, *Healthcare Cost and Utilization Project (HCUP)--3 Quality Indicators Benchmarks from Twelve States With Detail From Pennsylvania*, February 1996.

APPENDIX I

Selected DPW Critical Action Steps and Recommendations for HealthChoices Southeast

HealthCare Management Alternatives, Inc.

Access to Care

- HMA must expand their existing network of specialists, where choice of specialists is less than two, specifically in the area of dentistry.
- HMA must institute a policy to notify members on a monthly basis who do not have a record of encounter in the last six months.
- HMA must implement a process to ensure that SSI members have an initial visit within 45 days of enrollment.
- HMA must ensure that any new enrollee under the age of 21 is scheduled for EPSDT screens within 45 days of enrollment, unless the child is already under the care of a PCP and the child is current with screens and immunizations.
- HMA should continue to expand their effort to increase the network of HIV specialists to those counties that are currently underserved.
- HMA should expand their network for hospice providers. They reported only one hospice provider in Philadelphia County, two hospice providers in Montgomery County and no hospice providers in Delaware, Chester, or Bucks County.
- HMA should monitor night time and weekend phone calls to access PCP availability.
- HMA should expand the existing network of providers that treat special needs (in addition to HIV providers).

Special Needs

- HMA must monitor services provided by the community-based HIV/AIDS case managers to ensure compliance with RFP requirements.
- HMA must actively monitor the case management services provided by their subcontractor for technology-dependent members under 21 years of age to ensure compliance with RFP requirements.
- HMA must increase their efforts for PCP training relating to members with special needs to ensure compliance with the RFP.
- HMA must follow the specialist/PCP protocol approved last fall. Members requesting a specialist to serve as their PCP must be provided decisions regarding their request.
- HMA must submit a copy of the current contract with the social service agency which provides home assessments for members. In addition, HMA must submit a copy of any other contracts for community-based services not previously approved by the Department in order to be in compliance with the RFP.
- HMA should revise the procedure entitled "Behavioral Health/Mental Retardation Program Coordination" to more accurately reflect the procedure for ensuring communication and coordination of treatment between the PCP and BH provider.

Appendix I (Continued)

- To comply with RFP requirements, the procedure entitled "Coordination of Healthcare Services for the Aging" should be revised. The revision should more adequately reflect how HMA ensures that a referral for an OPTIONS Assessment has occurred.
- According to the RFP, HMA should continue to meet with BH-MCOs, the other plans, and necessary program offices to work out various problems with coordination of care. This includes issues around confidentiality.
- HMA should submit to the Department a plan of improvement indicating how they intend to be more proactive in year two of the HealthChoices SE Program.
- HMA should clarify information related to case management activities both in-house and contracted to the community. In addition, HMA should provide the Department with procedures that accurately reflect current HMA activities.

Complaints, Grievances, and Appeals

- HMA must make revisions to its established policies and procedures to support the HealthChoices SE Program, the RFP requirements, and the HMA Denial Letters.
- HMA must submit its revised policies and procedures, prior to implementation, for advance written approval.
- HMA must include documentation in their grievance procedures that state a subcontractor may not process a grievance.
- HMA must document in the grievance policies and procedures that services continue to members pending Grievance Committee, the Department Fair Hearings and/or Second Level appeals to DOH decisions.
- HMA must establish an independent provider appeals system and grievance policy and procedure for adjudication of disputed decisions where the party against which a judgement is made bears the independent adjudication costs. This policy and procedure must be submitted for advance written approval prior to implementation.
- HMA must make revisions to their established policies and procedures to support RFP requirements.
  - HMA should document in the grievance procedures that the Second Level Grievance committee contains members who were not initially involved in the denial of service or claim.
  - HMA should change the wording in the Second Level Grievance policy and procedure that the Grievance Committee is comprised of one HMA member to one-third HealthChoices SE members.
- HMA should revise their member Expedited Grievance policy and procedure to establish a specific time frame for the Medical Director to provide written notification to the member.
- HMA should develop and implement policies and procedures to support the Department Fair Hearing process.
- HMA should provide explicit documentation of the member complaint and grievance process in the Provider Manual.

Appendix I (Continued)

Quality Management

- HMA must take immediate steps to ensure full compliance with credentialing/ recredentialing requirements.
- HMA must take immediate steps to ensure that all potential quality of care concerns are investigated in accordance with accepted principles and practices of peer review.
- HMA must have sufficient staff available to perform all quality assurance review activities.
- HMA must perform routine medical audits of all PCP sites at least every two years.
- HMA should provide for systematic data collection of performance and patient results consistent with Medicaid HEDIS requirements including separate data for individuals with disabilities and chronic illnesses.
- A provider directory should be available to HMA's members to include all PCPs and all specialists available to them.

Health Partners

Access to Care

- HP must expand their existing network of specialists, where the choice of specialists is less than two in a given county specifically in the area of dentistry.
- HP must implement a process to ensure that SSI members schedule an initial visit within 45 days of enrollment.
- HP must ensure that any new enrollee under the age of 21 is scheduled for EPSDT screenings within 45 days of enrollment, unless the child is already under the care of a PCP and the child has had the appropriate screenings and immunizations.
- HP should take immediate steps to remedy being out of compliance with large hospital clinic sites exceeding their 5,000 member enrollment limit.
- HP should expand their network of hospice providers in Buck County.
- HP should monitor nighttime and weekend phone calls (at various hours throughout a 24-hour period) to access PCP availability. They should also send providers who are unavailable a letter requesting an explanation for their unavailability, place a follow-up phone call to the provider within 30 days, and document the results. HP should also follow up with phone calls in three months to those who were unavailable.

Special Needs

- HP must submit a plan of improvement indicating how they will comply with the [Department of Human Services] Program Document [concerning special needs services].
- A policy to audit HIV/AIDS community-based case management subcontractors must be implemented. Also HP must evaluate the need to expand this provider network. In addition, monitoring of the case management services provided at the [Centers of Excellence] COEs must be conducted to assure compliance with applicable MA Bulletins and the RFP.

Appendix I (Continued)

- HP must track services provided to maternity members to ensure accurate reporting from their maternity providers. In addition, HP must ensure that registered nurse care coordinators are used for evaluating maternity members on a face-to-face basis.
- HP should revise or make corrections to the following policies:
  - Revise the PCP assignment policy to more accurately comply with the RFP requirement.
  - Correct the revised transplant policy to provide coverage for all transplant procedures available under MA.
  - Revise the current nursing home placement policy to address those who request the OPTIONS Assessment.
  - The letters of agreement between HP and the BH-MCOs must be revisited to make necessary revisions to enhance HP's ability to provide better coordination of services.

Complaints, Grievances, and Appeals

- HP must make revisions to its established [Complaints, Grievances, and Appeals] policies and procedures to support the RFP requirements.
- Prior to implementation, HP must submit its revised policies and procedures to the Department for advance written approval.
- HP must include documentation in its grievance procedures that states that a subcontractor may not process a grievance.
- In the grievance policies and procedures, HP must indicate that services will continue to members pending Grievance Committee, Second Level Appeals and/or the Department Fair Hearing decisions.
- When a grievance is filed, HP must continue with the formal grievance process. HP may not downgrade a grievance to a complaint status.
- HP should make revisions to its established policies and procedures to support the HealthChoices SE Program, the RFP requirements, and the HP Denial Letters.
  - HP should initiate an internal audit process for assessing the appropriateness of member complaint resolutions.
  - In the grievance procedures, HP should indicate that the member is allowed 30 days to appeal the ruling, and 60 days if extenuating circumstances exist.
  - In the grievance procedures, HP should indicate that the plan will issue a written response to the member within 10 days of the First Level Grievance process.
  - In the grievance procedures, HP should indicate that the member is given at least 15 days notification prior to the Second Level Grievance process.
  - HP should include documentation in the "Rights and Duties as a Member" brochure that addresses the member's responsibility to provide, to the extent possible, information that professional staff need in order to care for the member.
  - HP should include documentation of all provider complaints and provider appeals in the quarterly reports.

  - In the grievance policies, HP should indicate that the member is insured confidentiality of specified patient information and records.
- HP should take steps to ensure that all required information files including medical records, member correspondence, or provider correspondence is included with the MCR form.
- HP should develop and implement a policy and procedure to support the Department Fair Hearing process.
- HP should develop and implement a policy and procedure to support the Member Denial Letters.

Quality Management

- HP must take immediate steps to ensure all credentialing/recredentialing RFP requirements are met.
- HP must promptly address the potential quality of care concerns raised in the results of HP's Fourth Quarter population based Member Satisfaction Surveys.
- HP must ensure sufficient and appropriate staff to perform all quality management and utilization management review activities.
- HP must take immediate steps to ensure that all potential quality of care concerns are investigated in accordance with accepted principles and practices of peer review.

Keystone Mercy Health Plan

Access to Care

- KMHP must expand their existing network of specialists where choice of specialists is less than two.
- KMHP must implement a process to follow up with providers found to be noncompliant during the After Hours PCP Accessibility Audits.
- KMHP must implement a process to follow up with providers found to be noncompliant during the PCP Access to Care Surveys.
- KMHP should educate providers of their process to notify PCP of members who have not had a record of an encounter during the previous six months.
- KMHP should place nighttime and weekend phone calls to providers (at various hours throughout the 24-hour period) to assess PCP availability.

Special Needs

- In order for KMHP to be in compliance with RFP requirements, KMHP is required to meet the HBP [Healthy Beginnings Plus] standards currently being used by established HBP providers. KMHP must assure that HBP providers have care coordinator ratios of no more than 1:75.
- In order for KMHP to be in compliance with RFP requirements, KMHP will be responsible to pay for organ transplants covered by the FFS Program. KHMP must review the Office of Medical Assistance's list of approved organ transplants and bring KMHP's list into compliance.

Appendix I (Continued)

- In order for KMHP to be in compliance with RFP requirement, a policy to audit subcontractors on a regular basis must be applied to monitor contract performance standards. The policy would also assure that only MA enrolled targeted case managers are providing community-based targeted case management services. KMHP must examine their contracts with community-based organizations to assure compliance.
- KMHP should clarify the following:
  - The member's role in relaying information to his or her PCP about medical necessity letter(s) to be submitted to KMHP.
  - The appearance that members or other agencies must initiate requests for waiver services instead of interventions made proactively by KMHP to offer waiver services.
  - Members with HIV/AIDS being responsible for follow up with community agencies for case management services.

KMHP should clarify the coordination and linkages between the general case management services and the SNU. In addition, KMHP should clarify the case or care management components of the disease management programs and the SNU.

- KMHP should submit the development and implementation plan timelines for the disease-specific care management programs currently in development: CHF, Sickle Cell, and HIV/AIDS.
- KMHP should provide a plan to demonstrate its provider education efforts which focus on populations with special needs.
- KMHP has submitted member handbook translations to the Department. The Department returned the member handbook translations to KMHP with additional recommendations for revision. A time frame and plan for distribution upon final approval should be in place.
- KMHP should develop and implement a dental provider recruitment plan, policy and procedure, and submit the same to the Department for advance written approval.
- KMHP should improve consistency in documenting the closure/resolution in member records for the following:
  - Problems that have been solved to the member's satisfaction.
  - Services that have been authorized.

Complaints, Grievances, and Appeals

- KHPE/KMHP must make revisions to its established policies and procedures to support the RFP requirements.
- KHPE/KMHP must include documentation in its grievance procedures that states that a subcontractor may not process a grievance. KHPE must submit its member and provider complaint, grievance, and appeal policies and procedures to the Department for advance written approval. Under no circumstances shall a HealthChoices SE contractor PH-MCO delegate the processing of HealthChoices SE member grievances to a subcontractor; this includes, but is not limited to, a subcontractor integrated delivery system, physician-hospital organization, physician organization, or individual practice association.

Appendix I (Continued)

- KHPE/KMHP must inform all members presenting a grievance of their right to have a staff member appointed to assist them. Each HealthChoices SE contractor shall be required to initially designate a minimum of two staff persons who will undertake this role of assisting HealthChoices SE members in utilizing the grievance process. This number must be appropriately increased as the volume of grievances increases. These staff members are expected to be effective and articulate advocates of HealthChoices SE members as they utilize the grievance process.
- KHPE/KMHP must make revisions to their established policies and procedures to support the HealthChoices SE Program, the RFP requirements, and the KHPE/KMHP Denial Letters.
  - There must be clarification in the grievance policies and procedures that KHPE/KMHP must offer assistance to and/or representation of the member during the grievance process.
  - The specifics of the member's right to request a Department Fair Hearing at any time during the complaint and grievance process must be explicitly addressed in the member complaint and grievance policies and procedures.
  - KHPE/MHMP must document in the grievance policies and procedures that services continue to members pending Grievance Committee, Department Fair Hearings, and/or Second Level appeals to DOH decisions.
  - There must be clarification in the member complaint and grievance policies and procedures that reports encompassing complaint and grievance data should be submitted to the QM department for tracking and trending purposes.
  - There must be documentation in the Grievance Procedure for Members, First Level Review, in the case of an upheld denial that the member has the right to request a Second Level Grievance.
  - There must be documentation in the Grievance Procedures for Members that the member may appeal to the Second Level Grievance Committee in the case of an upheld denial.
  - The documentation in the Grievance Procedure for Members, Expedited Review, under the "Policy" heading must be changed to "The decision must be rendered within 48 hours."
  - Regarding current documentation in the Grievance Procedure for Members, First Level Review, KHPE may not automatically overturn an appeal if information regarding the grievance is not received within 30 days. KHPE must make an informed decision based on the information at hand.
- KHPE/KMHP should develop and implement policies and procedures to support the Department Fair Hearing process.
- KMHP should implement a quality improvement process to ensure that there is documentation in the complaint files of an actual resolution date after interdepartmental KMHP referrals and that the member is notified of the complaint resolution.

Quality Management

- KMHP must take immediate steps to ensure full compliance with all QM requirements of the HealthChoices SE RFP.

- KMHP must take immediate steps to ensure the availability of its provider network.
- KMHP must take immediate steps to ensure that all potential quality of care concerns are investigated in accordance with accepted principles and practices of peer review.

Oxford Health Plan

Access to Care

- OHP must expand its existing network of endocrinologists in Bucks County where choice of specialists is less than two.
- OHP must expand their network of dentists with experience in treating the special needs population in Bucks and Chester Counties where there are none.
- OHP should educate providers of their process to notify PCPs of members who have not had a record of an encounter during the previous six months.
- OHP should monitor nighttime and weekend phone calls (at various hours throughout the 24-hour period) to assess PCP availability.
- OHP should institute a policy to ensure that new SSI members are scheduled for an appointment with the PCP/specialist within 45 days of enrollment.
- OHP should institute a policy to ensure that new members under the age of 21 are scheduled for EPSDT screens within 45 days of enrollment, unless the child is already under the care of a PCP and is current with screens and immunizations.
- OHP should expand its network of hospice providers.
- OHP should provide training to its providers and their staff regarding the contents and requirements of the provider manuals in addition to orientation and provider-driven contacts.

Special Needs

- OHP must fulfill the RFP requirement for a special dedicated unit to deal with issues relating to MA members with special needs. To do this OHP must provide the Department with a current organizational chart and program description outlining the functions of OHP's SNU.
- OHP must cover all transplants covered under the FFS Program. OHP submitted a document entitled the "Department of Public Welfare External Clinical Review Clarifications," dated June 9, 1998, which only stated that they cover all transplants listed under Pennsylvania's FFS Program. This document had no staff signature, therefore the validity remains questionable.
- OHP must provide evidence that its SNU is assisting members in accessing services and benefits of the HMO. In addition, evidence must be provided to ensure that the SNU acts as liaison with various government offices, providers, public entities, and county entities including county mental health agencies. OHP must also coordinate EPSDT services with other health, education, and human services systems. In addition, OHP must assist in the development of a comprehensive individual/family service plan.
- OHP must implement processes for ensuring that members under 21 years of age receive an initial EPSDT screen.

Appendix I (Continued)

- OHP should provide evidence to demonstrate that they conduct training to assist providers in service delivery to diverse populations, specifically special needs populations.
- OHP should clarify the following:
  - Coordination and linkage between the Case Management Program(s) and the SNU.
  - Composition and function of the Special Needs Committee.
  - Current operational policy regarding the PCP auto-assignment process.
  - Methods for how members can self-identify as having special needs. Information provided by the SNU Coordinator verbally on the visit seems to contradict the intent of the RFP that an individual be considered a special needs member based on a non-categorical or generic perspective.
- OHP describes social case management as a function of the SNU; however, documentation was not submitted to support this. The Department is requesting examples documenting social case management activities.
- OHP should develop a process for using enrollment information from Benova to identify all children placed in substitute care.
- OHP should remove references to specific county or city limitations in policies or procedures. OHP is to be covering a five-county zone.
- OHP should establish a procedure for proactively identifying and outreaching to potential special needs members prior to auto-assigning a PCP.

Complaints, Grievances, and Appeals

- OHP must make revisions to its established policies and procedures to support the RFP requirements.
- OHP must submit its revised policies and procedures, prior to implementation, for advance written approval by the Department.
- OHP must include documentation in its revised grievance procedures that indicates that a subcontractor may not process a grievance. OHP must maintain responsibility for processing all member grievances.
- OHP must establish and implement an independent provider appeals system for adjudication of disputed decisions where the party against which a judgement is made bears the independent adjudication costs.
- OHP should make revisions to its established policies and procedures to support the RFP requirements.
  - The specifics of the member's right to request a Department Fair Hearing at any time during the complaint and grievance process should be explicitly addressed in the member complaint and grievance policies and procedures.
  - OHP should document in the member complaint and grievance policies and procedures that services continue to members, when a grievance is filed within 10 days of the initial denial, pending Grievance Committee, Department Fair Hearings, and/or Second Level appeals to DOH decisions.
  - OHP should document in the First Level grievance procedures that the member is allowed 30 days, or 60 days in extenuating circumstances, to appeal the ruling.

Appendix I (Continued)

  - OHP should document in the First Level Grievance procedures that the First Level Grievance Committee members were not initially involved in the denial of the claim or service.
  - OHP should include documentation in the First Level grievance procedures that a record of those persons participating in the First Level grievance decision must be maintained.
  - OHP should change the wording in the Second Level grievance procedure from "one-third of which will be subscriber members of the Oak Tree/Oxford Health Plan's Board of Directors" to "one-third subscriber members of OHP, one of which must be a HealthChoices SE member."
  - OHP should have written minutes or a tape recorded record of the second level hearing.

- OHP should complete all elements of the quarterly reports and submit these reports to the Department on or before the due dates as specified by the RFP.
- OHP should develop and implement policies and procedures to support the Department Fair Hearing process.
- OHP should implement a member complaint and grievance satisfaction survey to determine why members are dissatisfied with its complaint resolutions.

Quality Management

- OHP must take immediate steps to ensure that all credentialing and recredentialing processes meet the HealthChoices SE RFP requirements, specifically provider networks, and provider enrollment procedures.
- OHP's revised credentialing and recredentialing policies and procedures must be submitted to the Department for review and approval before implementation by OHP.
- OHP must ensure that physician profiling is performed as required by the HealthChoices SE RFP.
- Benchmarks and performance goals should be established for OHP's quality improvement activities. This will enable OHP to effectively monitor and measure quality improvements.
- OHP should take organization-wide steps to ensure that information systems provide reliable and accurate data that can be accessed by end users for decision analysis support.

Source: Developed by LB&FC staff from DPW's *Results From the On-Site Clinical Reviews for the HealthChoices Southeast Physical Health Managed Care Organizations.*

APPENDIX J

HealthChoices-1999 Southeast and Southwest Contracts PH-MCO Recipient Coverage Policy Document

This document includes descriptions of policies supported by the Department's data systems and processes. In cases in which policy expressed in this document conflicts with another provision of the PH-MCO's contract, the contract will take precedence.

A PH-MCO is responsible for a member if coverage is determined by applying the general rules found in any of paragraphs A, B, or C below, subject to exceptions and clarifications found in paragraphs D, E, F, and G.

A. Unless otherwise specified, the PH-MCO is responsible to provide Medical Assistance (MA) benefits to members in accordance with eligibility information included on the monthly membership file and/or the daily membership file, which is provided by the Department to each PH-MCO.

B. Monthly membership files containing information on members are created on the next to the last Saturday of each month and are provided to the PH-MCO no later than the following Monday. Information on the file includes retroactive, current or prospective eligibility periods, PH-MCO coverage periods and demographic data. For each PH-MCO member identified on the monthly membership file, the PH-MCO is responsible to provide services from the beginning date of the month or from the PH-MCO coverage start date, whichever is later. PH-MCO coverage will continue from the start date through the last day of the calendar month. PH-MCO coverage dates beyond the last day of the month in which the monthly membership file is created are preliminary information that is subject to change.

   Daily files are provided to each PH-MCO with changes that have been applied to their enrolled population. In the example that follows, assume that the only information provided by the Department is on the monthly eligibility file created in October. If an eligibility period of October 21 through November 18 is indicated, the PH-MCO is responsible from October 21 through November 30, assuming no subsequent daily file changes occur prior to November 1 to end coverage in October. If two eligibility periods are provided, one from October 10 through October 25 and one from October 29 on with no end date, the PH-MCO is responsible from October 10 through at least November 30, subject to a daily file change prior to November 1. Coverage after October 31 is preliminary based on daily file changes.

   If a recipient is shown on the Department's Client Information System (CIS) as covered by a PH-MCO (coverage by a PH-MCO is indicated by an open eligibility record and an open PH-MCO record), the PH-MCO is responsible for that recipient from the first day of coverage shown through at least the last day of that month or the PH-MCO end date, if any. The Department will pay the PH-MCO from the first day of coverage in a month through the last calendar day of the month. Information on CIS for any future month should be viewed as preliminary.

   Members who become ineligible for MA will retain their PH-MCO selection for six months. These members will become the responsibility of the same PH-MCO if they regain MA eligibility during that six-month period, as long as their category of assistance and geographic location are valid for that PH-MCO. Upon regaining eligibility, their PH-MCO effective date will be their eligibility begin date or the date CIS is updated with their coverage, whichever is later. EXCEPTION: Members may voluntarily disenroll from their PH-MCO during the ineligibility period.

Appendix J (Continued)

C. The Department has established benefit packages based on category of assistance, program status code, age, and, for some packages, the existence of Medicare coverage or a Deprivation Qualifying Code. In cases where the member benefits are determined by the benefit package, the most comprehensive package is to be honored. For example, if a member has the most comprehensive package on the first of the month but changes to a lesser level package during the month, they should receive the higher level of benefits for the entire month. If a member has a lesser level benefit package at the beginning of the month but changes to higher level during the month, they should receive the higher level benefits effective the first day of coverage under the higher level. The daily and monthly membership files can be used for determining increased benefits during a month.

D. Exceptions and Clarification:

1. The PH-MCO will not be responsible and will not be paid when the Department sends the PH-MCO correspondence specifying member months for which they are not responsible. The Department will recover capitation payments made for members for whom it has been determined that the PH-MCO was not responsible to provide services.

2. If CIS shows Fee-For-Service (FFS) coverage that coincides with PH-MCO coverage, the member may use either coverage and there will be no monetary adjustment between the Department and the PH-MCO. (This is subordinate to #7 below.)

3. If a member is deceased and shows on the member file as active, the PH-MCO should notify the County Assistance Office (CAO) and the Department. For up to two years after payment is made, the Department will recover capitation payments made after the month of death.

4. If it is determined that the member was not MA eligible on the begin date of coverage during a month, and the PH-MCO was paid, the Department will recover or adjust payments.

5. If a member is placed in a setting that results in the termination of coverage by the PH-MCO, the Department will take back capitation payments made for months after the month in which the termination occurred.

6. A newborn is the responsibility of the PH-MCO that covered the mother on the date of birth. Where CIS does not reflect this, if the PH-MCO notifies the Department, they will coordinate adjustment of coverage. Limitations in Sections E-2 and E-3 applicable to the mother will apply to the newborn.

7. Movement out of a PH-MCO's service area does not negate a PH-MCO's responsibility to provide MA benefits. If a PH-MCO is aware that a member is residing outside its service area, it is the PH-MCO's responsibility to inform the CAO of the address change.

8. If the rules to determine PH-MCO responsibility to provide benefits that are outlined in this document indicate that a PH-MCO is responsible to provide benefits on a certain date, a lack of MA eligibility indicated on CIS for that date does not negate this responsibility.

9. Errors in coverage must be reported to the Department within 45 days of receipt of the monthly eligibility file in order for retroactive changes to be considered. The PH-MCOs will be responsible to cover members, even when coverage assignment resulted from errors, if not reported to the Department within 45 days, unless the error results in duplicate payment or coverage.

10. If CIS shows an exemption code or a placement code that precludes PH-MCO coverage, the recipient may not be enrolled in a PH-MCO.

E. When a MA consumer has managed care coverage during part of an inpatient/residential stay or long-term care stay, responsibility is as follows: For purposes of the attachment, an inpatient/residential stay shall include those in the following facilities: General Hospital, and Rehabilitation Hospital. For the purposes of the attachment, long-term care stay includes nursing facility admissions. (MA provider types 35 and 36.)

1. If a recipient is covered by FFS when admitted to a hospital and assumes PH-MCO coverage while still in the hospital, the Department's FFS Program is responsible for the stay. Starting with the PH-MCO begin date, the PH-MCO is responsible for physician, DME or other bills not included in the hospital bill.

   EXCEPTION #1: If the FFS recipient is still in the hospital on the PH-MCO coverage begin date, and the recipient's PH-MCO coverage begin date is the first day of the month, FFS will be financially responsible for the stay through the last day of that month. The PH-MCO will be financially responsible for the stay beginning on the first day of the next month. For example, if a recipient covered by FFS is admitted to a hospital on June 21, and the PH-MCO coverage begin date is July 1, the PH-MCO will assume payment responsibility for the stay on August 1. The FFS program will remain financially responsible for the stay through July 31.

   EXCEPTION #2: If the FFS recipient is still in the hospital on the PH-MCO coverage begin date, and the recipient's PH-MCO coverage begin date is any day other than the first day of the month, FFS will be financially responsible for the stay through the last day of the following month. The PH-MCO will be financially responsible for the stay beginning on the first day of the next month. For example, if a recipient covered by FFS is admitted to a hospital on June 21 and the PH-MCO coverage begin date is July 15, the PH-MCO will assume payment responsibility for the stay on September 1. The FFS program will remain financially responsible for the stay through August 31.

2. If a recipient is covered by a PH-MCO when admitted to a hospital and the recipient loses PH-MCO coverage and assumes FFS coverage while still in the hospital, the PHMCO is responsible for the stay.

   EXCEPTION #1: If the recipient is still in the hospital on the FFS coverage begin date, and the recipient's FFS coverage begin date is the first day of the month, the PH-MCO will be financially responsible for the stay through the last day of that month. The FFS program will be financially responsible for the stay beginning on the first day of the next month. For example, if a recipient covered by the PH-MCO is admitted to a hospital on June 21 and the FFS program coverage begin date is July 1, the FFS program will assume payment responsibility for the stay on August 1. The PH-MCO will remain financially responsible for the stay through July 31.

   EXCEPTION #2: If the recipient is still in the hospital on the FFS program coverage begin date, and the recipient's FFS program coverage begin date is any day other than the first day of the month, the PH-MCO will be financially responsible for the stay through the last day of the following month. The FFS program will be financially responsible for the stay beginning on the first day of the next month. For example, if a recipient covered by a PH-MCO is admitted to a hospital on June 21 and the FFS program coverage begin date is July 15, the FFS program will assume payment responsibility for the stay on September 1. The PH-MCO program will remain financially responsible for the stay through August 31.

3. If a recipient is covered by a PH-MCO when admitted to a hospital and transfers to another PH-MCO while still in the hospital, the losing PH-MCO is responsible for that stay.

   EXCEPTION #1: If the recipient is still in the hospital on the gaining PH-MCO coverage begin date, and the recipient's gaining PH-MCO coverage begin date is the first day of the month, the losing PH-MCO will be financially responsible for the stay through the last day of that month. The gaining PH-MCO will be financially responsible for the stay beginning on the first day of the next month. For example, if a recipient is admitted to a hospital on June 21 and the gaining PH-MCO coverage begin date is July 1, the gaining PH-MCO will assume payment responsibility for the stay on August 1. The losing PH-MCO will remain financially responsible for the stay through July 31.

   EXCEPTION #2: If the recipient is still in the hospital on the gaining PH-MCO coverage begin date, and the recipient's gaining PH-MCO coverage begin date is any day other than the first day of the month, the losing PH-MCO will be financially responsible for the stay beginning on the first day of the following month. The gaining PH-MCO will be financially responsible for the stay beginning on the first day of the next month. For example, if a recipient is admitted to a hospital on June 21 and the gaining PH-MCO coverage begin date is July 15, the gaining PH-MCO will assume payment responsibility for the stay on September 1. The losing PH-MCO will remain financially responsible for the stay through August 31.

4. If a recipient is covered by a MCO and is admitted to a nursing facility and, during that stay, transfers to another MCO or FFS, the MCO responsible at the time of the admission is responsible for 30 consecutive days of nursing home care.

F. Other Causes for Coverage Termination: If a condition described below occurs, the PH-MCO can request that the Department take action by completing a "Request for Involuntary Disenrollment of PH-MCO Recipient" form and faxing it to the Division of Managed Care Systems Support at 717-772-6290.

1. Nursing Facilities (MA Provider Types 35 and 36) - Members are disenrolled after 30 consecutive days of placement in a nursing facility. EXCEPTION: Placement in an ICF/MR facility will not result in the disenrollment of the member from the plan. The residential/treatment facility payments will be made by the FFS program.

2. Pennsylvania Department of Aging (PDA) Waiver - Members covered by the PDA Waiver are disenrolled after 30 days of service.

3. Admission to a State Facility (MA Provider Types 14 and 34) - PH-MCOs are not responsible for members in a state facility. The member will be disenrolled from the PH-MCO and become effective in FFS on the admission date. The Department will recover capitation payments made for each month following the month of placement.

   EXCEPTION: A member placed in a state ICF/MR facility will continue to be enrolled in the PH-MCO, and the PH-MCO will continue to be responsible for all covered medical services, except the residential/treatment costs.

4. Admission to a Correctional Facility -A member who becomes an inmate of a penal or correctional institution will be disenrolled from the PH-MCO effective the day before placement in the institution. The PH-MCO is responsible for notifying the CAO and the Department to initiate disenrollment.

Appendix J (Continued)

5. Ventilator Dependent Members - A member in an acute or rehabilitation hospital for more than 30 consecutive days will be disenrolled effective on the 31st day. All services will be covered under FFS for the remainder of the stay.

6. Placement in a Juvenile Detention Center (JDC) - A member who is placed in a juvenile detention center is disenrolled from his/her PH-MCO after 35 days and covered through FFS.

7. Health Insurance Premium Payment Program (HIPP) - Members determined to be HIPP eligible will be disenrolled from the HC-SW Program. Additionally, HIPP eligible MA consumers are prevented from enrolling in PH-MCOs.

G. Other Facility Placement Coverage

1. ICF-MR/ICF-ORC (PT 24 and 25) - Members placed in an ICF-MR or an ICF-ORC facility will continue to be covered by their selected PH-MCO for all medical services. The residential/treatment costs will not be the responsibility of the PH-MCO.

2. Residential Treatment Facilities (PT 53) - Members placed in RTFs will continue to be covered by their selected PH-MCO for all medical services. The residential/treatment costs will not be the responsibility of the PH-MCO.

3. Extended Acute Psychiatric Care Hospital (PT 53) - Members admitted to an extended acute psychiatric hospital will continue to be covered by their selected PH-MCO for all medical services. The residential/treatment costs will not be the responsibility of the PH-MCO.

HC-SW PH-MCO
Revised April 1, 1998
(BDCM)

Source: Developed by LB&FC staff from the HealthChoices Southwest and Southeast contracts.

APPENDIX K

DPW Managed Care Plans

Managed Care Plans	Date of HMO Certificate of Authority Issuance or Acquisition	HealthChoices Participation	Comments
Plan 1: Aetna Health Plans of Central and Eastern PA - Mercy	1/1/93	No	Services to Medicaid recipients enrolled with this HMO were provided through an Integrated Delivery System (IDS). The IDS was the Mercy Health Plan.
Plan 2: Aetna Health Plans of Western PA, Inc., Name Changed to Coventry Health[a]	2/20/91 5/30/96	No	Services to Medicaid recipients were provided through the HMO's IDS for Medicaid recipients. The IDS was Care Plus.
Plan 3: Best Healthcare Western PA, Inc., Name Changed to Best Health Care of Western PA, Inc., Name Changed to UPMC Health Plan, Inc.	2/8/96 6/12/97 10/3/97	Yes - Southwest	
Plan 4: Greater Atlantic Health Services, Inc., Name Changed to QualMed Plans for Health, Inc.	10/27/89 5/3/96	No	
Plan 5: Hamilton Health Center/Healthmate		No	Not a state-approved HMO.
Plan 6: HealthPass/ Healthcare Management Alternatives, Inc.	9/21/95	Yes - Southeast	HealthPass was developed in 1983 by the Department of Public Welfare as a Medicaid alternative in parts of Philadelphia. The original HealthPASS administrator filed for bankruptcy in March 1989 forcing the state to pick a new administrator. Healthcare Management Alternatives (HMA), Inc., administered HealthPASS, from July 1989 through September 1995 as a Health Insuring Organization (HIO) that coordinates but does not deliver health care services directly. In 1995, HMA obtained a certificate of authority as an HMO. HMA had 68,955 Health Choice-Southeast enrollees as of 2/6/98. It accounted for about 14 percent of the total number of Health Choices-Southeast enrollees.

Appendix K (Continued)

Managed Care Plans	Date of HMO Certificate of Authority Issuance or Acquisition	HealthChoices Participation	Comments
Plan 7: Keystone Health Plan East – Mercy[b]	1/6/87	Yes - Southeastern	Services to Medicaid recipients enrolled with this HMO were provided through an IDS. The IDS was the Mercy Health Plan. Keystone Mercy Health Plan had 235,440 Health Choices-Southeast enrollees as of 2/6/98. It accounted for about 49 percent of the total number of Health Choices-Southeast enrollees.
Plan 8: Health Partners of Philadelphia.[b, c]	11/22/94	Yes - Southeastern	Health Partners had 108,853 Health Choices-Southeast enrollees as of 2/6/98. It accounted for about 23 percent of the total number of Health Choices-Southeast enrollees.
Plan 9: Keystone Health Plan West – Gateway	12/31/86	Yes - Southwestern	Gateway was an IDS of KHPW. On 2/18/98, Gateway became a state approved HMO when it purchased the Certificate of Authority previously held by Plan 2 in this exhibit--AHPW and Coventry Health Plan of Western PA.
Plan 10: Oak Tree Health Plan of Pennsylvania Name Changed to Oxford Health Plans (PA), Inc.[d]	5/13/93 8/4/95	Yes - Southeastern	Oxford Health Plan had 64,791 Health Choices-Southeast enrollees as of 2/6/98. It accounted for about 14 percent of the total number of Health Choices-Southeast enrollees.
Plan 11: Three Rivers Health Plan, Inc.	1/2/96	Yes - Southwestern	

[a]Name changed to Gateway Health Plan, Inc., 2/18/98. Gateway Health Plan is owned by a limited partnership consisting of Highmark, Allegheny General Hospital, and Philadelphia's Mercy Health System.

[b]Before November 22, 1994, Keystone Mercy and Health Partners were separate and distinct IDSs of the Keystone Health Plan East. HealthPro data prior to 1995 collapsed the data for the two plans together. After 1994 HealthPro reported on the two plans separately.

[c]Health Partners of Philadelphia is owned by Albert Einstein Medical Center, Episcopal Hospital, Frankford Hospital, Allegheny Health Education and Research Foundation (which was recently acquired by Tenet, a for-profit entity), Temple University Hospital, and Hospital of the University of Pennsylvania.

[d]Health Risk Management, Inc., of Minneapolis, MN, has filed an application for the acquisition of Oxford Health Plans (PA), Inc., which was noted in the *Pennsylvania Bulletin*, Volume 28, Number 46, Saturday, November 14, 1998, p. 5732. The Department of Insurance approved the acquisition that had not occurred as of January 11, 1999.

Source: Developed by LB&FC staff from information provided by the Department of Health and the Department of Insurance.

APPENDIX L

Percent of Medical Records With No Immunization Information by Managed Care Organization

(1994 and 1996 HealthPro Reports)

Managed Care Organization	Percent of Medical Records With No Immunization Information - 1994 Report	Percent of Medical Records With No Immunization Information - 1996 Report[a]
Aetna Health Plan of Central & Eastern PA--Mercy	14% (150 Records Reviewed)	24 % (123 Records Reviewed)
Aetna Health Plan of Western PA. Inc.	28% (94)	21% (108)
Greater Atlantic Health Service	6 % (143)	23 % (119)
Hamilton Health Center (Healthmate)	5% (98)	4% (122)
Keystone Health Plan East—Mercy and Health Partners	8% (301)	NA
Keystone Health Plan East--Mercy	NA	36% (168)
Health Partners	NA	15% (163)
HealthPASS/Health Management Alternatives	13% (245)	12% (223)
Keystone Health Plan West--Gateway	21% (151)	29% (150)
Oak Tree/Oxford	35% (101)	5% (111)

[a] Seventy-five percent of the medical records were for children 0 through 12 and the remaining 25 percent for children ages 13 through 20.

Source: Developed by LB&FC staff from *HealthPro's Evaluation of the Quality Assurance Program Implementation* for Commonwealth of Pennsylvania, Department of Public Welfare, September 1994; and *HealthPro's Quality Assurance Audit--Year 2/Phase 1,* for Commonwealth of Pennsylvania, Department of Public Welfare, March 1996.

APPENDIX M

Selected Results From Health Pro's Medical Record Reviews – September 1994
Well Child Care Records
Percent of Children With Well Child Visits With Complete, Partially Complete, or Incomplete Comprehensive Examinations as Defined by EPSDT Guidelines*

HMO	Number of Records	Percent Complete Exam[a]	Percent Partially Complete[a]	Percent Incomplete[a]
Aetna Health Plan of Central and Eastern PA, Inc.	113	0%	4%	98%
Aetna Health Plan of Western PA, Inc.	56	0	14	91
Greater AtlanticHealth Service	130	2	30	90
Hamilton HealthCenter (Healthmate)	89	10	39	94
Keystone Health Plan East – Mercy – Health Partners	274	1	20	94
Healthcare Management Alternatives, Inc. (HealthPASS)	217	3	30	89
Keystone Health Plan West – Gateway	104	2	16	91
Oak Tree Health Plan Oxford Health Plan...	65	1	5	95

*The nine measures normally present in a comprehensive EPSDT screening which were recorded were: General Health Assessment, Developmental (Cognitive) Exam, Health History Documented, Nutritional Status Documented, Unclothed Physical Exam, Vision Screening, Hearing Screening, Dental Exam, and Appropriate Health Education. These guidelines were created to ensure adequate health monitoring for children who are at risk for negative health outcomes.

[a]The comprehensive screening was rated as complete if all of the 9 standard measures were documented in the record, as partially complete if 7-8 measures were recorded, and as incomplete if less than 7 measures were recorded.

Source: Developed by LB&FC staff from *HealthPro's Evaluation of the Quality Assurance Program Implementation* for Commonwealth of Pennsylvania, Department of Public Welfare, September 1994.

APPENDIX N

Percent of Women Who Delivered During 1993 With Complete Prenatal Care Histories by Managed Care Organization*

(1994 and 1996 HealthPro Reports)

Managed Care Organization	1994 Percent With Complete Prenatal Care History	1996 Percent With Complete Prenatal Care History
Aetna Health Plan Central & Eastern Pa--Mercy	57% (21 records reviewed)	30% (33 Records Reviewed))
Aetna Health Plan of Western PA	45% (20)	0% (4)
Greater Atlantic Health Service	42% (26)	6% (86)
Hamilton Health Center/Healthmate	11% (19)	0% (7)
Health Management Alternatives/HealthPass	58% (50)	30%(64)
Keystone Health Plan East—Mercy and Health Partners	13% (61)	NA
Keystone Health Plan East—Mercy		12% (136)
Health Partners.....		19% (85)
Keystone Health Plan West—Gateway	27% (34)	68% (63)
Oak Tree/Oxford.....	5% (19)	11% (57)

*A complete initial prenatal history was operationally defined to include the following 26 items: documentation that pregnancies were discussed--(1) previous, (2) number; type--(3) live, (4) still born, (5) abortion, (6) C-section, (7) preterm deliveries, (8) congenital anomalies; documentation that medical history of patient was discussed--(9) sexually transmitted disease (STD), (10) menstrual history, (11) date of last menstrual period, (12) diabetes, (13) other chronic illness, (14) alcohol use, (15) cocaine use, (16) tobacco use, (17) other addictive substances; documentation that medical history of family was discussed--(18) hypertension, (19) diabetes mellitus, (20) heart disease, (21) surgeries; documentation that personal history was discussed--(22) health habits, (23) sexual history, (24) domestic violence, (25) sexual abuse; and (26) week of pregnancy at initial visit entered.

Source: Developed by LB&FC staff from HealthPro's Evaluation of the Quality Assurance Program Implementation for Commonwealth of Pennsylvania, Department of Public Welfare, September 1994, and HealthPro's Quality Assurance Audit, Year 2/Phase 1 for Commonwealth of Pennsylvania, Department of Public Welfare, March 1996.

APPENDIX O

Percent of Women Who Deliver With Complete Regular Prenatal Visits by Managed Care Organization*

(As Reported in 1994 and 1996)

Managed Care Oreganization	1994 Percent of Women Who Deliver With Complete Regular Prenatal Visits	1996 Percent of Women Who Deliver With Complete Regular Prenatal Visits
Aetna Health Plan Central & Eastern PA--Mercy..	65% (21 Records Reviewed)	58% (33 Records Reviewed)
Aetna Health Plan Western PA.	84% (20)	75% (4)
Greater Atlantic Health Service	80% (26)	58% (86)
Hamilton Health Center/Healthmate	32% (19)	0% (7)
Health Management Alternatives/HealthPASS	51% (50)	80% (64)
Keystone Health Plan East—Mercy and Health Partners	60% (61)	NA
Keystone Health Plan East--Mercy	NA	56% (136)
Health Partners	NA	75% (85)
Keystone Health Plan West--Gateway	73% (34)	68% (63)
Oak Tree Health Plan/ Oxford	53% (19)	78% (57)

*Complete regular prenatal visits are defined as the nine after the first visit in which weight, blood pressure, fundus size, and urinalysis or dip stick are recorded.

Source: Developed by LB&FC staff from *HealthPro's Evaluation of the Quality Assurance Program Implementation* for Commonwealth of Pennsylvania, Department of Public Welfare, September 1994; and *HealthPro's Quality Assurance Audit--Year 2/Phase 1* for Commonwealth of Pennsylvania, Department of Public Welfare, March 1996.

APPENDIX P

Percent of Adults Who Had a Routine History and Physical Exam Within the Last Three Years*

(As Reported in 1995, 1996, and 1997)

Managed Care Organization	1995 Percent of Adults With Routine History And Physical Exam Last Three Years	1996 Percent of Adults With Routine History And Physical Exam Last Three Years	1997 Percent of Adults With Routine History And Physical Exam Last Three Years
Aetna Health Plan Central and Eastern Pa/Mercy	38% (123)	37% (75)	6% (99)
Aetna Health Plan Western Pa./Care Plus	43% (80)	26 % (53)	43% (74)
Greater Atlantic Health Service/QualMed Plans for Health	45% (120)	36% (103)	16% (132)
Hamilton Health Center/Healthmate)	88% (80)	44% (54)	73% (63)
Healthcare Management Alternatives/ Health-PASS	50% (201)	35% (139)	12% (178)
Keystone Health Plan East—Mercy	70% (119)	31% (140)	12% (186)
Health Partners	61% (122)	35% (134)	9% (185)
Keystone Health Plan West/ Gateway	71% (120)	68% (118)	67% (133)
Oak Tree/Oxford	60% (80)	48% (104)	23% (147)

*Routine history and physical exam were operationally defined to include: (1) past medical history, (2) family history, (3) social history, (4) immunization history, and (5) addictive substances history (alcohol use, cocaine use, tobacco use, other substance use). The following 20 standard items comprising a comprehensive physical exam were assessed: (1) height, (2) weight, (3) blood pressure, (4) temperature, (5) pulse, (6) respiration, (7) HEENT, (8) neck, (9) skin, (10) chest, (11) breast (females only), (12) cardiac, (13) vascular, (14) abdomen, (15) neurologic, (16) muscular skeletal, (17) genital (males only), (18) rectal, (19) appropriate follow-up of abnormal findings, and (20) summary statement.

Source: Developed by LB&FC staff from *HealthPro's Quality Assurance Audit-Phase II,* for Commonwealth of Pennsylvania, Department of Public Welfare, April 1995; *HealthPro's Quality Assurance Audit-Year 2/Phase 1,* for Commonwealth of Pennsylvania, Department of Public Welfare, March 1996; and *HealthPro's Quality Assurance Audit--Year 2/Phase 2,* for Commonwealth of Pennsylvania, Department of Public Welfare, January 1997.

APPENDIX Q

Percent of Children With Asthma With Hospitalizations or Emergency Room Visits by Plan

Managed Care Organization	Number of Children With Asthma With Records Reviewed	Percent With Hospitalizations	Percent With Emergency Room Visits	Percent With Hospitalization or Emergency Room Visits
Aetna Health Plan Central and Eastern/Mercy...	[a]	[a]	[a]	[a]
Aetna Health Plan of Western Pa/Care Plus.....	20	15%	25%	25%
Greater Atlantic/QualMed Plans for Health	51	24%	35%	41%
Hamilton Health Center/Healthmate.....	57	14%	49%	51%
Health Partners.....	46	13%	7%	20%
Health Management Alternative/HealthPASS	33	27%	42%	52%
Keystone Health Plan East--Mercy	[a]	[a]	[a]	[a]
Keystone Health Plan West--Gateway	51	16%	45%	51%
Oak Tree/Oxford.....	53	25%	68%	77%

[a] According to HealthPro, this plan did not provide encounter files with members' hospitalizations and emergency room visits as requested.

Source: Developed by LB&FC staff from *HealthPro's Medical Care Evaluation: Asthma,* for Commonwealth of Pennsylvania, Department of Public Welfare, February 1997.

APPENDIX R

Percent of Children Age 6 and Older With an Objective Assessment of Lung Function by Managed Care Organization

Managed Care Organization	Number of Records Reviewed	Percent With Any of the Three Possible Objective Assessments	Percent With Peak Expiratory Flow Rate (PERF) Assessment	Percent With Spirometry Assessment	Percent With Home Use of PERF Assessment
Aetna Health Plan of Central and Eastern PA--Mercy	28	25%	21%	0%	7%
Aetna Health Plan of Western PA—Care Plus	15	7	7	0	7
QualMed Plans for Health (Formerly Greater Atlantic)	30	27	23	3	10
Hamilton Health/ Healthmate	48	58	56	2	25
Health Partners	30	17	13	3	7
Health Management Alternatives/HealthPass	19	16	11	0	11
Keystone Health Plan East Mercy	19	5	5	0	0
Keystone Health Plan West Gateway	27	19	7	0	15
Oxford Health Plan/Oak Tree	31	19	10	7	13

Source: Developed by LB&FC staff from HealthPro's Medical Care Evaluation: Asthma, for Commonwealth of Pennsylvania, Department of Public Welfare, February 1997.

APPENDIX S

Percent of Members Who Received Any Asthma Related Education at Least Once During an Office Visit by Managed Care Organization

Managed Care Organization	Number of Records Reviewed	Percent of Members Who Received Any Education
Aetna Health Plan of Central and Eastern PA--Mercy. ...	42	48%
Aetna Health Plan of Western PA.--Care Plus	20	70
QualMed Plans for Health (formerly Greater Atlantic Health Service)	51	31
Hamilton Health Center/Healthmate	57	95
Health Partners	46	39
Health Management Alternatives/HealthPASS	33	49
Keystone Health Plan East--Mercy	35	66
Keystone Health Plan West--Gateway	51	80
Oxford Health Plan (formerly Oak Tree)	53	42

Source: Developed by LB&FC staff from HealthPro's Medical Care Evaluation: Asthma, for Commonwealth of Pennsylvania, Department of Public Welfare, February 1997.

APPENDIX T

Percent of Children With Asthma With Inappropriate Prescribing of Asthma Medication

Managed Care Organization	Number of Records Reviewed	Percent of Members With Any Inappropriate Prescribing of Asthma Medication	Percent of Members With Inappropriate Prescribing of Asthma Medication on 50 Percent or More Office Visits
Aetna Health Plan Central--Mercy	33	55%	49%
Aetna Health Plan West/Care Plus	16	81	69
Greater Atlantic/QualMed Plans for Health	47	58	49
Hamilton Health Center/Healthmate	50	72	46
Health Partners	41	51	39
Health Management Alternatives/HealthPASS	27	56	52
Keystone Health Plan East--Mercy	33	39	24
Keystone Health Plan West	40	78	73
Oak Tree/Oxford	42	48	36

Source: Developed by LB&FC staff from HealthPro's Medical Care Evaluation: Asthma, for Commonwealth of Pennsylvania, Department of Public Welfare, February 1997.

APPENDIX U

Survey of Disabled SSI Beneficiaries
Mathematica Policy Research, Inc.'s, Analytic Survey Measures

Selected Analytical Measures

Plan Choice: Percent of SSI beneficiaries who were assigned to an MCO, percent of SSI beneficiaries (or their proxy) who chose their MCO, most important reasons for choosing their current MCO, other reasons for choosing their current MCO, reasons for not choosing their MCO, percent who changed plans, and reasons they did change or may change plans.

Access to Care: Percent with a usual place of care, type of place, percent who changed usual place in the last year, percent who see the same person at their usual place of care most of the time or always, type of provider (doctor or nurse), reasons for no usual source of care, percent who were assigned to a provider (reason they did not choose), percent who are reminded about the time of their appointments, percent who are reminded when they are due to come in for a check-up, percent who usually schedule appointments in advance, mean waiting time between scheduling an appointment and the day of the visit, mean waiting time in the office, mean travel time from home to place of care, percent whose transportation to the appointment is provided by the clinic or MCO, percent with difficulty communicating with medical staff because of a language problem, percent with unmet needs for hospital care (reason for unmet need), percent with unmet needs for dental care (reason for unmet need), percent with unmet needs for doctors (reason for unmet need), percent with unmet needs for special medical equipment (reason for unmet need, type of equipment), percent with unmet needs for prescription medicines, (reason for unmet need, percent who tried to make prescription medicines last longer by taking less or less frequently, percent who waited for plan approval for care (percent whose wait caused trouble, type of care delayed for which there was trouble, consequences of the delays), percent of those with referrals who said getting a referral to a specialist or therapist was very difficult, percent who were not referred to specialist or therapist they thought they needed (type of specialist/therapist, went without referral, who paid), and consequences of not getting specialty care or therapy.

Service Use: Percent with visits to doctors or clinics not in MCO in the last three months, mean number of visits to doctors or clinics not in MCO, types of services received from out-of-plan doctors, reasons for not using MCO doctor or clinic, percent who paid for out-of-plan visits, percent with hospital stays for other treatment in the last year, mean number of hospital stays for other treatment in the last year, mean number of nights in the hospital, mean number of doctor visits in the last three months, and mean number of specialist visits in the last three months.

Expenditures: Percent with out-of-pocket expenditures in the last three months, out-of-pocket expenditures, and services purchased out-of-pocket.

Satisfaction: Percent rating each of the following either poor, fair, good, very good, and excellent--the amount of time it takes to travel to the doctor or other medical care, the amount of time you have to wait between making an appointment and the day of the visit, the length of time spent waiting at the office to see the doctor, the amount of time you have with doctors and staff during a visit, the explanations of medical procedures and tests, the ease of getting medical care in an emergency, the friendliness and courtesy of the doctors, getting care from a specialist when you need it, the services available for getting prescriptions filled, the number of doctors you have to choose from, the freedom to change doctors, percent rating each of the following either poor, fair, good, very good, and excellent--how well [usual source of care] understands the way your disability affects day-to-day life, how

Appendix U (Continued)

much [usual source of care] knows about treating your disability, how well the staff gives you information to help you manage your health problem, the ease with which you can get in and around [usual source of care], percent rating each of the following either poor, fair, good, very good, and excellent--the amount you or your family pay for providers and services not covered by MCO, and the overall quality of health care you get as a member of MCO, percent who would recommend usual place for care to family or friends, percent who would recommend MCO to family or friends, percent who would recommend MCO to family or friends who have a chronic or serious health problem, percent who have ever reported a problem about health care received in MCO in the last 12 months (who they complained to, percent filing written complaints, percent complaining by phone, topic of complaint), and percent satisfied with how the complaint was handled.

Quality: Percent with a primary preventive care visit in the last three months, mean number of secondary preventive care visits in the last three months, percent who had blood pressure checked in the past year, preventive dental visit in the past year, percent of women age 40+ who had a mammogram in the past year, percent of women age 21 to 64 who had a Pap smear in the last year, percent who have received recommended check-ups, percent whose plan helped them keep track of their vaccinations, percent with a preventive dental visit in the past year, percent with emergency room visits for primary care (for upper respiratory infections; influenza; acute bronchitis; urinary-tract infection; gastroenteritis; dehydration; vomiting), percent with emergency room visits for primary care for management of chronic conditions (hypertension, asthma, diabetes, headache, low back pain), percent with emergency room visits for primary care (for upper respiratory infections, influenza, acute bronchitis, dehydration, vomiting, ear infection or ear ache, stomach ache), percent with emergency room visits for primary care for management of chronic conditions: asthma and diabetes, percent of those with multiple providers who feel their doctors and therapists talk to each other about their care.(percent for whom this is a problem, results of doctors not talking), percent who have someone who helps with arranging non-medical care (who helps), satisfaction with how well the coordinator(s) understand disability, and unmet needs for care coordination.

Characteristics of Beneficiaries: Percent whose health is excellent, very good, fair, poor, percent whose health is better or worse than a year ago, percent of children with a lot of pain or distress health status and functioning, percent with various chronic conditions, mean number of ADL limitations, mean number of ADL limitations, percent who need special help at home, percent who need special medical equipment for eating or toileting, percent who have difficulty chewing, swallowing, or digesting, percent who need constant supervision, percent who can be left only with a person trained to handle medical emergencies, mean number of IADL limitations, percent limited to crawling, walking, running, or playing, percent with cognitive delays, percent with language delays, days absent from school because of health, percent with paid help with ADLs and IADLs, percent of sample members with proxy interviews who have serious difficulty communicating, and percent of sample members with proxy interviews who have serious difficulty understanding.

Note: MCO = managed care organization; ADL = Activities of Daily Living; IADL = Independent Activities of Daily Living

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[a]Emergency room visits for primary care are one indicator of discontinuities in care. The questions ask about the symptoms causing the visit, rather than the diagnosis.

Source: Mathematica Policy Research, Inc., Survey of Disabled SSI Beneficiaries Enrolled in TennCare Survey Questionnaire, October 1998.

APPENDIX V

Independent Evaluation of Medicaid Managed Care Demonstrations

Mathematica Policy Research and the Urban Institute are evaluating Medicaid managed care demonstrations in five states (Hawaii, Maryland, Oklahoma, Rhode Island, and Tennessee) with Section 1115 waivers.[a] The Health Care Financing Administration is sponsoring these evaluations.

Mathematica Policy Research, Inc. issued the first annual report for the five-year study in January 1997. This report focused on the three states (Hawaii, Tennessee, and Rhode Island) that had implemented their projects in 1994. The three states in the study experienced situations and problems similar to what Pennsylvania has encountered with its HealthChoices demonstration.

Mathematica reported that each state moved quickly to design its program and submit its waiver application. Although providers and consumers were given opportunities to express their opinions in some cases, they generally had little input regarding basic program elements.

Implementation problems arose almost immediately. Consumers were confused about how to enroll or select a managed care organization (MCO) and a physician. Enrollments were delayed after applications were submitted. The MCOs could not reconcile discrepancies between their records and state information, and physicians were not always sure which MCO had enrolled their patients. Physicians in Hawaii were particularly concerned about disruptions in the continuity of care.

Providers in all three states complained about a lack of consumer education. Their patients did not understand the primary care gatekeeper's role or the limitations on emergency room use. Physicians in Tennessee and Hawaii had problems making referrals. Specialist participation was low there, because the urgency to initiate the programs had forced newer MCOs to develop their networks rapidly.

Although consumers in focus groups expressed overall satisfaction with their state programs, a result supported by relatively low rates of plan switching (10 percent or less), specific problems were identified. Physician choice was a source of complaints in Tennessee and Hawaii. Tennessee patients also had problems with prescription coverage, and consumers in Rhode Island were uncertain about the definition of an emergency.

Disabled and chronically ill patients seemed less satisfied. They expressed concern about access to specialists and emergency care, issues that already might have been problems when they were receiving fee-for-service care, the report noted.

All initial MCOs were still operating at least one year after the programs started. The MCOs in Rhode Island reported losing money the first year but were not facing insolvency, and Tennessee reported mixed results after 18 months. Tennessee increased its capitation rates more than it had originally planned and stiffened the penalties for failing to report accurate encounter data.

Hawaii negotiated slight reductions in its capitation rates after the first year, because all of its MCOs seemed to be making money. It capped enrollments for the largest plan to ensure the viability of the others.

Although Rhode Island had well-developed standards for quality improvement, its ability to monitor MCO performance was hampered by a lack of first-year encounter data 18 months after startup. Tennessee and Hawaii lagged further behind. They had concentrated on basic operational problems during the first year and had not yet developed monitoring processes.

The three states lacked the necessary administrative resources to start their programs, the report concluded. Their fee-for-service focus had not prepared them for the transition to managed care. The failure to monitor performance highlighted a need for sophisticated data systems to track MCO enrollment, and staff shortages had contributed to problems in consumer relations and enrollment.

In addition to the overall evaluation of state managed care programs, Mathematica Policy Research is currently surveying non-elderly disabled SSI beneficiaries who are enrolled in Tennessee's mandatory managed program in the Memphis area. Mathematica will have interviewed a total of 2,060 beneficiaries by the end of the 1998.

Mathematica has designed the survey to help identify differences in the experiences of non-elderly SSI recipients in four managed care organizations in the Memphis area. The design also allows Mathematica to compare results for urban and rural SSI recipients and children and adult SSI recipients with different types of disabilities. Because the study is focused on a specific managed care plans and health care market, Mathematica will be able to link survey results to information about the plans and their structures.

The Mathematica survey provides detailed information about disabled individuals plan choices, access to care, service use, out-of-pocket expenditures, satisfaction, and quality. It also provides detailed information about individual's health status and functioning and other characteristics relevant to analyze the data.

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[a] These states do not necessarily mandate the inclusion of disabled individuals and/or children in substitute care in fully capitated risk-based managed care organizations.

Source: Developed by LB&FC staff from Mathematica Policy Research, Inc., reports.

APPENDIX W

HealthChoices and Other State Mandatory HMO Programs for Disabled Individuals

DPW's HealthChoices program does not include safeguards present in many of the other ten states mandating the enrollment of SSI eligible individuals into fully capitated risk-based managed care plans.

Home and Community Based Waiver Participants from HMOs and/or Waiver Services: DPW requires HealthChoices managed care plans to serve medically fragile individuals previously served through special waiver programs and it pays for waiver services by including their costs within its capitation rates.[a]

DPW requires Michael Dallas and AIDS waiver participants to enroll in HealthChoices. The Michael Dallas Waiver provides essential home care services, beyond the scope of traditional Medical Assistance services, to technology-dependent children under age 21. It provides for private duty nursing (up to 16 hours per day), specialized life support equipment and disposable supplies, and case management services by trained personnel. The Department's AIDS waiver programs provide for prolonged and intensive skilled nursing care, prolonged home health aide services, homemaker services, specialized medical equipment and supplies, and other services such as nutritional supplements and nutritional consultation.

Nine of the other ten states mandating inclusion of SSI individuals in fully capitated risk-based managed care plans treat waiver participants and waiver services differently than Pennsylvania. Five of the other ten states exempt waiver participants from enrollment in such plans. Delaware, Kentucky and Vermont exempt all participants in waivers from mandatory enrollment in managed care organizations. Alabama and Virginia exempt individuals with AIDS from mandatory enrollment in managed care.

Five states (Alabama, California, Oregon, New Mexico, and Utah) do not exempt all waiver participants from mandatory enrollment. However, they do not include waiver services within their capitation rates. Waiver services provided to waiver participants enrolled in managed care organizations are paid for through the state Medicaid fee-for-services system.

Medically Fragile Individuals: DPW does not have explicit processes to exempt medically fragile individuals from enrolling in managed care organizations when their needs cannot be met by the organizations. According to the Department, "generally we do not disenroll our consumers into fee-for-service." In the past this has occurred, only when ventilator dependent individuals were hospitalized for more than 30 days, or admitted to a state ICF/MR facility.

Four of the ten states with mandatory programs including disabled individuals have processes to exempt medically fragile individuals from mandatory managed care enrollment. Oregon and Utah have explicit processes in place to permanently exempt medically fragile individuals from enrollment in fully capitated managed care organizations.

The Oregon Health Plan Administrative Rules provide for several exemptions to mandatory enrollment in fully capitated managed care plans. The exemptions include children accepted by a special state program known as the Medically Fragile Children's Unit and individuals with End State Renal Disease. They also include those for whom enrollment in managed care would pose a serious health risk.

Oregon also has continuity of care exemptions. It exempts individuals from enrollment in fully capitated risk based plans when it would be detrimental to the health of the client to change practitioners. Such exemptions can be granted for twelve-month periods, and can be extended. They are granted when a client has established a relationship with a practitioner who is not a member of the provider panel of an Oregon fully capitated plan and the plan cannot negotiate a treatment plan or reimbursement arrangement consistent with its contracting practices. Temporary exemptions are also available for individuals in the final trimester of pregnancy. California, Vermont and Utah also have similar continuity of care exemptions.

Appendix W (Continued)

Exceptionally Costly Services Excluded from Capitation Rates: DPW includes certain exceptionally costly services within its capitation rates. DPW requires plans to pay for major organ transplants previously paid for by the Department. Currently, kidney, cornea, heart, heart/lung, single lung, double lung, liver, bone marrow, pancreas transplants, and liver-bowel transplants for children are covered by the Medical Assistance Program. The Department also includes within it capitation rate federally reimbursable services identified as part of an EPSDT screen and not covered in the state's Medicaid plan.

In California and Alabama transplant services are excluded from the state's capitation rate. Such services are paid for on a fee-for-services basis. Oregon, Vermont, and Virginia do not include any EPSDT special services in their capitation rates. Kentucky excludes all school-based services from its rates. Delaware, Oregon, Vermont, California, Virginia, and New Mexico do not include private duty nursing and personal care in their managed care organizations' capitation rates.

Excluding Those with Other Health Insurance From Mandatory Enrollment in HMOs: At times those with special needs (including elderly and disabled individuals who are eligible for both Medicare and Medicaid) rely on Medical Assistance to pay for only a portion of their health care. They or their family have other major insurance coverage. DPW requires such individuals to enroll in HealthChoices managed care organizations to receive care funded by Medical Assistance.

California, Kentucky and Vermont totally exempt individuals with other insurance coverage from their mandatory managed care programs. Oregon exempts individuals covered under a major medical insurance policy from enrolling in fully capitated plans. Such individuals, however, are required to enroll with a Primary Care Case Manager (PCCM) for coordination of care paid for on a fee-for-service basis.

State Ombudsman Programs: DPW has not established a state ombudsman program consumers and providers can contact when they have a problem with one of the HealthChoices plans. California, Oregon, Vermont, and Utah have established such programs.

In Oregon, the program serves only persons with disabilities. Oregon's state ombudsmen intervene with the plans to resolve all problems encountered by those with special needs and the agencies involved in serving them. In Oregon, state ombudsmen advocate on behalf of the disabled individual whenever the individual, their representative, a physician or other medical personnel, or other personal advocate is reasonably concerned about access to, quality of, or limitations of care being provided. They also respond to complaints about plan systems. Oregon statute also requires each disabled individual to have a medical case manager within the plan available to assist the individual with the coordination of the patient's health care services at the request of the patient, a physician, or other medical personnel.[b]

Capitation Rates Based on Health Status: Some states help assure quality of care for medically fragile individuals by adjusting their capitation payments to take into account the enrollee's health status.[c] Several systems are available, however, for state Medicaid programs to risk adjust payments based on a plan enrollee's health status.

DPW does not base its capitation rates on the health status of the individual Medical Assistance recipient. It makes payments based on an individual's category of financial eligibility and certain demographic characteristics.[d]

Utah currently pays capitation rates based on a Medicaid recipient's health status. It is also moving to develop centers of excellence for persons with exceptional medical needs.

California has special capitation rates for individuals with AIDS. In California, moreover, individuals with AIDS are permitted direct access to HIV specialists in managed care networks without the need for referral from a primary care physicians.

California also has a legislatively established Medical Assistance Commission.[e] Under the direction of the Commission, staff develops capitation rates for Medicaid managed care contracts and plans, develop, and negotiate contract services.

Appendix W (Continued)

Twice a year the Commission reports to the legislature. The reports include information such as the number of type of health service contracts, persons served, cost per service, and other relevant statistical information, including the total number of hospitals receiving a net increase or decrease in their contract rates during the preceding 12 months. The Commission's reports must also include a discussion of the effects of selective contracting on access and quality of services. In preparing this later portion of the report, the Commission is required to solicit the comments of beneficiaries and providers. Through the Commission, the California legislature is regularly and frequently kept informed about California's Medicaid managed care waivers and has a direct role in assuring the adequacy of the capitation rates.

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[a]The Department of Public Welfare's Office of Social Programs operates a Home and Community Based Service Waiver. This waiver program provides attendant care to mentally alert adults eighteen (18) through (59) years of age with physical disabilities who require nursing facility level of care but who choose to remain in their own home or community living arrangement. These waiver participants in HealthChoices zones are enrolled in HealthChoices. The attendant care waiver services, however, are not included in the capitation rate and are not the responsibility of the physical health managed care organization. Participants enrolled in the Department of Aging's home and community-based waiver are enrolled in HealthChoices for 30 consecutive days and are then disenrolled from HealthChoices.

[b]Oregon as part of its waiver was permitted to make capitation payments to contractors that exceed payment costs to Medicaid on a fee-for-service basis, to an actuarially equivalent non-enrolled population group. It used the state's requirement that health care provider organizations provide medical case management services for members who are elderly and disabled to justify such a waiver.

[c]Several researchers have demonstrated that the cost to care for persons with disabilities who receive Medical Assistance are significantly greater than the cost of caring for low income families enrolled in Medical Assistance program. For this reason they stress the need to adjust Medical Assistance capitation payments and base them on an individual enrollee's health status. See for example, Kronick, R., Dreyfus, T. et al. "Diagnostic Risk Adjustment for Medicaid: The Disability Payment System," *Health Care Financing Review*, Spring 1996, Volume 17, Number 3, pp. 7—33.

[d]For more detailed information on the Department of Public Welfare's capitation rates and problems with such rates refer to the February 1998 Report on an *Actuarial Review of the HealthChoices Program in Southeastern Pennsylvania* prepared by the LB&FC through contract with Arthur Andersen LLP.

[e]This seven member commission consists of persons with experience in management of hospital services, risk management insurance, prepaid health programs, the delivery of health services, the management of county health systems, and representatives of recipients of services. The Directors of the Department of Health Services and the Department of Finance also serve on the Commission. The governor and the state legislature each select and appoint Commission members.

Source: Developed by LB&FC staff from information provided by states.

APPENDIX X

HealthChoices and Other Mandatory Programs for Children in Substitute Care

DPW's HealthChoices program differs substantively from the managed care programs in the nine other states (selected counties in California, New Mexico, Maryland, Delaware, Connecticut, Hawaii, Kentucky, Missouri, and Utah) mandating enrollment of children in substitute care in fully capitated risk-based plans.

Pennsylvania HealthChoices HMOs do not have statewide provider networks. They serve only specific counties. In Delaware and Maryland the HMOs tend to have statewide provider networks. As a result, children who move from one region of the state to another do not have to change plans to access care. In Maryland, moreover, the initial medical examination for a child in substitute care is a self-referred service. As a result it does not need to be provided by a managed care organization network provider and it does not require prior authorization.

Pharmacy services are one of the most frequently used medical services. Pennsylvania's HealthChoices program includes pharmacy benefits within its HMO capitation rates. In Delaware and Utah pharmacy benefits are not included in the HMO capitation rate. Problems in accessing network pharmacy providers, therefore, do not occur as children move from one HMO coverage area to another. Connecticut includes pharmacy benefits within the HMO capitation rate. However, it requires its HMOs to provide additional prescriptions needed when children are placed or change placements. It also requires HMOs to cover "home visit medications." As a result, children in substitute care can readily obtain essential medications when they are taken into placement or go on home visits.

Connecticut requires its managed care organizations to pay for a comprehensive multidisciplinary examination for children entering placement within 30 days of placement. The evaluation must consist of a through assessment of the child's functional, medical, developmental, educational and other needs. It must also identify any specialized diagnostic and therapeutic needs. Each examination must occur at a single location and all components must be performed on the same day. Connecticut also has detailed contract provisions requiring the HMO to pay for care which is not medically necessary when alternative placements are not available. Connecticut goes so far as to detail in its managed care contracts situations in which the managed care plan is responsible for paying for hospital care which is not medically necessary.

Missouri and Utah report they have mandatory enrollment in HMOs for children in substitute care. They, however, disenroll children who are not in stable placements, or with special needs.

In Kentucky there are "special rules" which apply to children in substitute care. Before a child in substitute care can be enrolled in an HMO in Kentucky, state regulations require an individual plan of care must be developed and agreed to by the state agency holding custody of the child and the foster parents. Kentucky postponed the enrollment of children in substitute care until automated system changes were made to permit the HMO to include in its automated systems the child's placement address rather than the address of the agency holding custody of the child. Plan materials are forwarded directly to the foster parent according to the agreed upon service plan. The state children and youth agency has assigned each foster parent a unique number. Such numbers are used to identify themselves with the HMO and avoid any issues related to confidentiality.

The Kentucky HMO involved in the initial implementation of HMO enrollment has decided not to assign children in substitute care to PCPs after much discussion with the state, foster parents, and other caregivers. Rather, the HMO plans to use the providers that currently work with foster parents and others caring for children in substitute care.

In Kentucky, the HMO is responsible for the child in substitute care even if the placement is outside of the area covered by the HMO. Moreover, the HMO is responsible for the cost of care from the date the child is eligible for medical assistance, even if the child has not been formally enrolled in the HMO.

Source: Developed by LB&FC staff from information provided by states.

APPENDIX Y

Responses to This Report