Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Virginia Department of Health
VAC Chapter Number:	12VAC 5-408
Regulation Title:	Rules and Regulations for Certification of Quality Assurance for Managed Care Health Insurance Plan Licensees
Action Title:	Amendments to clarify the regulation
Date:	June 4, 2001

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The proposed amendments reflect the Department of Health's ("Department") enhanced understanding of the inherent differences within managed care health insurance plan (MCHIP) licensees. In order to promulgate a reasonable regulation, the Department sought to accommodate these differences. Rather than regulate MCHIP licensees in a homogenous manner, as does the extant regulation, the proposed regulation (a) make appropriate distinctions between preferred provider organizations ("PPOs") and health maintenance organizations ("HMOs"); (b) limits compliance in sections requiring clinical data to those MCHIP licensees that have access to clinical data; (c) allows PPOs that do not have clinical data to demonstrate quality assurance in administering care rather than delivering care; and (d) provides greater opportunities for voluntary compliance by eliminating unnecessarily prescriptive language.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

The source of legal authority to promulgate the regulation is found at section 32.1-137.3 of the Code of Virginia. The Department of Health ("Department") understands that the authority to amend the regulation is derived from its authority to promulgate the regulation. The statute states, in relevant part: "Consistent with its duties to protect the health, safety, and welfare of the public, the Board [of Health] shall promulgate regulations, . . . , governing the quality of care provided to covered persons by a managed care health insurance plan licensee through its managed care health insurance plans . . . ." Thus, the promulgation of the regulation was mandated by statute.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The current regulation assures MCHIP licensees have in place and comply with the quality systems and procedures outlined in section 32.1-137.2 of the Code of Virginia. Because there is an expanding number of persons enrolled in managed care health insurance plans, the aforementioned statute and regulation are essential to protect the health, safety, and welfare of Virginia citizens.

A number of MCHIP licensees expressed concern with the regulation because it: (a) did not provide notice of the Department's expectations and reasonable people had to guess at its meaning; (b) was internally inconsistent; (c) assumed organizational structures and capabilities for some MCHIP licensees that did not exist; and (d) was unreasonably prescriptive.

The proposed amendments seek to maximize compliance by the providing a regulation that is clearly written. The extant regulation contains language that permits the applicant to determine whether compliance with a particular section is appropriate given its organizational structure or capability. It does not offer guidance regarding the Department's expectations. The proposed regulation identifies specific sections with which certain MCHIP licensees need not comply. It

offers examples of acceptable activities for compliance. Finally, it permits the Department greater flexibility in allowing for variances provided patient care, safety, or the ability of an MCHIP licensee to provide or arrange for care will not be adversely affected.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The Department proposes to amend the regulation where necessary, including, but not limited to: (a) providing criteria to permit the granting of variances by the Department; (b) clarifying the exemptions regarding PPOs to better address the unique aspects of this type of managed care health insurance plan; (c) providing a clearer distinction between the MCHIP and the MCHIP licensees; and (d) eliminating internal inconsistencies regarding PPO responsibilities.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

There are no perceived disadvantages to the public or to the Commonwealth associated with the proposed regulatory action. The advantages of amending the MCHIP regulation are many.

The greatest advantage is that Virginia citizens enrolled in MCHIPs will be the beneficiaries of a regulation that assures these plans have appropriate standards for ensuring quality. The extant regulation, while detailed, does not contemplate the great variation in MCHIP organizational structure or abilities. Thus, while the regulation may have appropriate criteria for HMOs, PPOs may find compliance difficult. The cost of compliance by PPOs may be passed along to enrollees or to businesses in the form of higher premiums. Because the criteria are not appropriate for PPOs, their compliance efforts do not necessarily result in enhanced quality. The proposed regulations allow for meaningful quality activities.

There is also a great advantage to the Department in amending the regulation. Its ability to maintain effective regulatory programs during a period characterized by increasingly complex and dynamic health care change will be strengthened. The Department has worked hard in getting input from many stakeholders in the amendment process. It has convened an advisory committee comprised of members of the regulated industry, consumers, advocates and purchasers. The amendments represent a consensus by these groups and the good faith effort by the Department to incorporate the language evidencing consensus when possible. Thus, it is not only the substance of the proposed amended regulation that represents an improvement, but the

process of involving stakeholders in the regulatory process in a meaningful manner is likewise an improvement.

Finally, the regulation provides further evidence of the Governor's committment to creating a "level playing field" between HMOs and PPOs. The current regulation interprets that committment to mean HMOs and PPOs must be treated the same. Thus, it subjects PPOs to a regulation appropriate to HMOs, yet burdensome for PPOs given their organizational structure. The result is that PPOs are placed at a distinct disadvantage, thereby precluding the possibility of a true "level playing field." The proposed regulation recognizes the inherent differences within MCHIPs and encourages meaningful compliance by detailing a range of compliance possibilities and exempting PPOs when appropriate.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

The Bureau of Insurance (BOI), State Corporation Commission, administers the state licensure program for MCHIPs in Virginia. An MCHIP requires a Certificate of Quality Assurance from the Virginia Department of Health in order to obtain a license from the BOI to operate in Virginia. MCHIP staff conduct initial administrative reviews (desk reviews) of each applicant for a Certificate of Quality Assurance, process renewal packages, examine service area expansions, and investigate consumer complaints. An on-site examination is conducted once every three years at each of the approximately 100 MCHIP locations.

The program and subprogram for MCHIPs is 561-03-00. The program is staffed with four examiners and one supervisor. Funding consists of an annual appropriation of $170,000 in general funds and approximately $208,000 in special fund certification fees. The amount of the certification fee is based upon a percentage of gross premium income.

Since the proposed amendments will eliminate the unnecessarily prescriptive language associated with the extant regulations, the cost to the 100 MCHIP entities, to individuals, and to localities that will be affected should be minimal or none. It is estimated that the Department will incur a one time cost of $6,000 to promulgate the proposed regulations; however, the Department is not expected to experience any added cost to enforce the regulations.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This

statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The proposed substantive changes are as follows:

12 VAC5-408-10 Definitions. "Adverse decision" is proposed to be amended to mean a utilization review determination by the utilization review entity that a health service rendered or proposed to be rendered was or is not medically necessary, when such determination may result in noncoverage of the health service or health services. The current regulation does not appropriately describe an adverse decision as confined to utilization review determinations.

12 VAC5-408-10 Definitions. "Appeal" is proposed to be amended to be defined as "a formal request by a covered person or a provider on behalf of a covered person for reconsideration of a decision, such as a final adverse decision, a benefit payment, a denial of coverage, or a reimbursement for service." This change has been made to correctly identify which decisions covered persons may appeal.

12 VAC5-408-10 Definitions. "Complaint" is proposed to be amended to state "a written communication from a covered person primarily expressing a grievance. A complaint may pertain to the availability, delivery, or quality of health care services including claims payments, the handling of reimbursement for such services, or any other matter pertaining to the covered person's contractual relationship with the MCHIP." The language now reflects industry consensus concerning what is generally classified as a complaint. It eliminates adverse decisions as an example because these decisions are not typically complaints.

12 VAC5-408-10 Definitions. "Emergency services" is proposed to be determined from the perspective of a reasonable person, as opposed to a prudent layperson. This change was proposed because the Virginia Code governing insurance uses a prudent layperson standard to define emergency services for health maintenance organizations, but not for preferred provider organizations. As such, the definition promotes consistency for preferred provider organizations.

12 VAC5-408-10 Definitions. The term "material" is proposed to be added to this section and defined as "that which has an effective influence or bearing on, or is pertinent to, the issue in question." The definition is necessary as the term is used in a number of sections.

12 VAC5-408-10 Definitions. "Preferred provider organization" or "PPO" is proposed to be amended to be defined as "an arrangement in which a health carrier, as defined in 38.2-5800 of the Code of Virginia, undertakes to provide, arrange for, pay for, or reimburse any of the costs of health care services, on an insured basis, which creates incentives, including financial incentives, for a covered person to use health care providers directly or indirectly managed, owned, under contract with, or employed by the health carrier, but shall not include a health maintenance organization as defined in 38.2-4300 of the Code of Virginia." This amendment expands the definition to accommodate the many types of preferred provider organizations.

12 VAC5-408-10 Definitions. The term "Quality assurance program" is proposed to be added to the definition section and defined as "the systems, standards and processes including, but not limited to, reasonable and adequate systems to assess, measure, and improve the health status of covered persons, necessary to obtain a certificate of quality assurance from the Department in accordance with this regulation (12 VAC 5-408-10 et seq) and in accordance with 32.1-137.2, C. of the Code of Virginia." The addition of this term is necessary as the regulations refer to it often.

12 VAC5-408-20 Responsibility of Department. Because the Department does not intend to adopt interpretive guidelines, it proposes deleting subsection D which reads, "The Department will be guided by its own interpretive guidelines when determining compliance with this regulation."

12 VAC5-408-30 Certificate of quality assurance. The Department proposes adding a clause to allow the Commissioner to issue variances to regulatory requirements.

12 VAC5-408-40 Fees. The Department proposes to add a sentence to subsection "A" that reads, "MCHIP licensees wishing to submit separate applications for each plan must include the appropriate fee." This sentence gives notice to the regulated community of the Department's expectation that the fee should accompany the MCHIP certificate application.

12 VAC5-408-50 Preferred provider organizations. The Department believes a change in the name of this section to "Compliance provisions appropriate for type of plan" offers an improvement because the scope of exemptions is no longer limited to PPOs. In addition, the Department proposes to exempt PPOs from the requirement to have quality assurance plans that delineate the expected outcomes for the plan's performance expectations. The Department does not believe this expectation is warranted given the difficulty PPOs have in getting access to patient data. It likewise proposes to exempt PPOs from being required to have their quality assurance plan delineate strategies to evaluate the continuity of care that covered persons receive. This amendment is necessary to maintain internal consistency within the regulations as PPOs are exempt from the section on continuity of care pursuant to 12 VAC5-408-50.

12 VAC5-408-50 Preferred provider organizations. In addition to the changes proposed above, the Department proposes to amend subsection A, paragraph 3, to exempt PPOs from the covered person notification requirement of provider termination, the requirement that covered persons be given a preventive care appointment within sixty days, and that there be consultation for specialty services as required in section 38.2-2407.11:1 of the Code of Virginia. The exemptions recognize the reality that unlike HMOs, PPOs do not have access to the information that would enable them to fulfill these requirements.

12 VAC5-408-50. Preferred provider organizations. Subsection A is proposed to have an additional paragraph allowing PPOs the ability to satisfy certain regulatory requirements by achieving accreditation by a nationally recognized accrediting body.

12 VAC5-408-50. Preferred provider organizations. The Department proposes a new subsection that allows managed care health insurance plans other than PPOs to likewise satisfy a greater number of regulatory requirements by achieving national accreditation.

12 VAC5-408-50. Preferred provider organizations. The Department proposes to allow MCHIPs desiring exemption from the comprehensive onsite examination to be so exempt if they are accredited by a nationally recognized accrediting body.

12 VAC5-408-60. General examination process. The sentence requiring MCHIP licensees that operate outside of the geographic boundaries of Virginia to demonstrate a record of successfully implementing their quality improvement program to the benefit of covered persons that they serve is proposed to be deleted. The requirement may exceed the Department's statutory authority and may be overly burdensome for MCHIP licensees.

12 VAC5-408-70. Administrative review. The section describing the requirements for administrative review has been amended to include requirements for MCHIP licensees desiring to satisfy the regulation by nationally recognized accrediting body accreditation.

12 VAC5-408-70. Administrative review. The section is proposed to be expanded to notify MCHIP licensees with more than one MCHIP that they may file a separate certificate of quality assurance application for any of their MCHIPs.

12 VAC5-408-80. Renewal application. The subsection advising MCHIP licensees that failure to adequately document that the MCHIP's quality improvement program has measurably improved the quality of care received by their enrollees over time will be a factor in renewal of the certificate of quality assurance is proposed to be deleted. The requirement was difficult to document and may not have been a reliable indicator of a substandard quality improvement program.

12 VAC5-408-408-90. Comprehensive onsite examination. The requirement that the MCHIP licensee demonstrate it has systems that result in the improvement of enrollees' health outcomes and the delivery of their care is proposed to be deleted. Once again, the requirement was difficult to document and may not have been a reliable indicator of a substandard system.

12 VAC5-408-90. Comprehensive onsite examination. The time period in which the Department is to give the MCHIP licensee advance notice of the onsite examination and a description of the parameters is proposed to be changed from 60 days to 90 days.

12 VAC5-408-90. Comprehensive onsite examination. The requirement that the MCHIP licensee is to provide the Department with member mailing lists for Virginia covered persons to be used to select samples of the plan's membership for the surveys of public notice of the examination is proposed to be deleted. The proposed replacement language would allow the Department to review the results of the MCHIP licensee's member satisfaction survey or similar initiative. MCHIP licensees that did not conduct a survey would be responsible for publishing public notice of the examination and soliciting comments from their covered persons.

12 VAC5-408-100. Examination by a nationally recognized accreditation organization. The requirement that only full accreditation will be recognized as satisfying identified regulatory requirements is proposed to be amended. Because nationally recognized accreditation organizations allow MCHIP licensees 15 to 18 months to correct any noted deficiencies, and because those deficiencies may exist in areas not related to quality, the Department proposes to amend the language to allow for conditional or provisional accreditation provided a second examination results in full accreditation.

12 VAC5-408-100. Examination by a nationally recognized accreditation organization. The 90 day time period of notification by the MCHIP licensee to the Department of its accreditation examination is proposed to be deleted. Notification will still be required, but the time period will not be identified.

12 VAC5-408-120. Changes to geographic service areas. The language requesting notification by an MCHIP licensee of any change to its geographic service area is proposed to be changed because it is too vague and is likely to result in unnecessary notification. The amended language requests notification of information that results in material variation with the information the Department has on file.

12 VAC5-408-160. Management and administration. Rather than require MCHIP licensees to submit a description of their disease management program and quality improvement plan in the application, the Department suggests deletion of this language. The regulation requires a description of these areas in other sections.

12 VAC5-408-170. Provider credentialing and recredentialing. The proposed language authorizes MCHIPs to grant provisional credentialing for providers who have completed their residency or fellowship requirements for their specialty area within twelve months prior to the credentialing decision. It likewise identifies the supporting documentation necessary to provisionally credential a practitioner and limits this status to 60 days. This amendment recognizes the inherent difficulty of credentialing new practitioners. Finally, it changes the cylical time period in which practitioners are to be recredentialed from 2 years to 3 years.

12 VAC5-408-200. Data management. The Department proposes to amend this section to provide better notice to the regulated community of its expectations. It requires the data management system to be reasonable and adequate to assess, measure, and evaluate the functions of the quality assurance program. The system is to comply with the Virginia Health Records Privacy Act.

12 VAC5-408-220. Purpose. The section identifying the minimum standards for the quality improvement program is proposed to be deleted as it is redundant.

12 VAC5-408-230. Program requirements. The language specifying that the quality improvement activities have to be integrated into all other organizational units is proposed to be amended to appropriate organizational units. The Department proposes MCHIPs should no longer have to identify the resources necessary for the MCHIP to successfully pursue

improvement priorities because a successful quality assurance program will be evidence of an appropriate allocation of resources.

12 VAC5-408-230. Program requirements. Rather than dictate that every MCHIP licensee have a medical director, the Department proposes the language be amended to require a designated physician or clinical professional appropriate to the type of MCHIP licensee. This would accommodate specialty plans, such as dental plans, that may contract exclusively with dentists.

12 VAC5-408-230. Program requirements. The Department proposes to amend the language concerning descriptions of the responsibilities of the MCHIP licensee's operational units to include an organizational chart. It also proposes eliminating language requiring the designated physician or clinical professional to report directly to the MCHIP licensee's executive management.

12 VAC5-408-240. Program plan. The language requiring the quality assurance plan to examine the overutilization and underutilization of services and strategies to evaluate experimental treatment procedures is proposed to be deleted because not all plans have this capability. In addition, the Department proposes to add qualifying language to limit requirements involving the use of clinical data to those MCHIP licensees that have access to clinical data. Finally, the Department proposes adding language that informs the regulated community that it can demonstrate compliance with the language requiring after-hour coverage by evidence of contract language with providers stipulating after-hour care, customer satisfaction surveys, and complaint reviews.

12 VAC5-408-250. Continuity of care. The Department proposes to delete language requiring enrollees affected by a change or termination in benefits, services, or providers to be assisted in understanding how such developments impact them and the options available for dealing with them, as these concerns are addressed elsewhere.

12 VAC5-408-270. Travel and appointment waiting times. Rather than stipulate strict travel time measurements and appointment waiting times, the Department proposes to offer guidance concerning these areas. It proposes to allow MCHIP licensees to set reasonable and adequate standards for the number and geographic distribution of service sites as well as access to medical care. The MCHIP licensee is then required to collect and analyze data to measure its performance against the standards it has developed.

12 VAC5-408-280. Urgent care and emergency services. Because the regulations require MCHIP licensees to be in compliance with all federal laws, the Department proposes the deletion of the requirement that MCHIP licensees comply with the Emergency Medical Treatment and Active Labor Act. In addition, its provisions may not be applicable to MCHIP plans.

12 VAC5-408-290. Health promotion. The Department proposes amending the language requiring the MCHIP licensee to develop and implement two health prevention guidelines to requiring them to develop and implement one such guideline. The Department recognizes the resources necessary to satisfy this requirement may have been overly burdensome.

12 VAC5-408-310. Data collection and submission. The language requiring the data to allow for intra and intersystem comparisons for the purpose of improving patient health outcomes and improving clinical health delivery systems is proposed to be deleted as it is too prescriptive.

12 VAC5-408-320. Delegated services. The Department proposes deleting language that requires the MCHIP licensee to ensure that data held by the delegated service provider be required to be shared with the state's Health Care Data Reporting System. This requirement is found elsewhere in the regulations.

12 VAC5-408-340. Exchange of information. The Department proposes deleting language requiring the MCHIP licensee to inform its covered persons and providers which services they may need are delegated and how those services are accessed because this information may prove to be confusing to covered persons.

12 VAC5-408-350. Quality improvement integration. The Department proposes deleting the requirement that MCHIP licensees evaluate the delegated health service provider's quality improvement program, complaint and appeals processes, and provide the delegated health service with a report of its evaluation. The Department believes the requirement is too prescriptive and that there may be superior ways to achieve the same result.

12 VAC5-408-360. Utilization review and management. The Department proposes to add language informing the public that MCHIP licensees that are not accredited by a nationally recognized accrediting body accepted by the Department are subject to the triennial onsite examination.

Alternatives

Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

There are no relevant alternatives to the proposed regulatory action. The extant regulation satisfies the Department's statutory responsibility to certify the quality of health care services provided by MCHIP licensees. The revised regulation honors the mandate of Executive Order 25-98 that this statutory responsibility result in a regulation that is not overly burdensome.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

The Department received many comments before, during, and after the comment period from the MCHIP advisory committee. The committee is composed of consumer advocates, purchasers, and members of the regulated community. The Department had five meetings with them and

shared earlier versions of the proposed regulation. The committee provided insightful comments concerning the regulation.

In addition, the Department received two letters during the comment period. The first was sent from the National Association of Dental Plans ("NADP"). The letter expressed concern that there was no opportunity for dental plans to provide their perspective to members of the Department. The NADP criticizes the current regulation as relying too heavily on national accreditation systems. It points out that none of the national accreditation organizations has programs that include dental benefits plans.

It likewise expressed concern that the regulation relies on the standards of treatment and protocols that, while clearly utilized in the medical field, do not exist in dentistry. Finally, the NADP asserts dentistry does not utilize a recognized set of diagnostic codes. The letter underscores this point by stating that while the American Dental Association has been developing such codes, the codes have not been widely utilized by dentists in general and are therefore not useful for the dental benefits industry. The letter concludes by stating there are concerns that ongoing compliance and examinations by dental plans will be difficult.

The Department has considered these comments and believes that the concerns may result from a misunderstanding of the extant regulation as well as the regulatory process. It notes that the NADP, as well as other members of the public, have opportunities for participation in the regulatory process pursuant to the Virginia Administrative Procedure Act. The concern regarding the regulation's heavy reliance on national accreditation is unwarranted because the extant regulation, as well as its proposed revision, allow MCHIP licensees to satisfy regulatory requirements by securing national accreditation, but do not require the MCHIP licensees to do so. The choice remains with the MCHIP licensee. Finally, the concern that dentistry does not utilize a recognized set of diagnostic codes has been addressed in the revised regulation. MCHIP licensees that do not have access to clinical data may use other data, such as service data, in their quality improvement plan.

The second letter came from the Mennonite Mutual Aid Association (MMAA) and the MMA Insurance Company (MIC). It summarizes the overall problems with the current regulation as the lack of differentiation between regulatory requirements for HMOs and those for PPOs. It states, "The regulations need to clearly define the diffferent types of health plans available, and establish regulatory safeguards based directly upon the inherent risks involved in each type of licensed plan." Specific concerns concerning relevancy of certain provisions include the following:

a) provider credentialing is only necessary for closed panels and not for plans that allow members free access;
b) a complaint system is not relevant if the primary concern is provider access and quality of care issues;
c) covered person education is only relevant for plans that have a gatekeeper;
d) the data management section is only of concern if the focus is on promptness of claims payment pursuant to the Ethics and Fairness in Carrier Business Practices Act;

e) PPOs are limited in their ability to have an impact on a quality improvement program. Such a program is of questionable application because members may not be limited to a panel of practitioners;
f) regulatory provisions concerning coordination and continuity of care are of limited applicability if members are not limited to a list of practitioners;
g) data necessary to complete a clinical performance evaluation may be costly to collect and analyze;
h) the section concerning delegated services should have fewer number of services where oversight accountability is required;
i) the utilization review and management section requirements should be able to be satisfied by national accrediting body accreditation.

The Department has considered each comment, and its decision regarding each is as follows:
a) provider credentialing of the MCHIP's providers is necessary to assure quality of care and the ability of members to go outside of the panel does not negate its importance;
b) a complaint system is important for covered persons to have their concerns addressed;
c) covered person education may cover a variety of topics and is therefore relevant for plans with and without gatekeepers;
d) data management concerns may cover a multitude of issues, such as privacy, and is not limited to issues involving the Ethics and Fairness in Carrier Businesses Practices Act;
e) because it is the fastest growing type of MCHIP, it is important for PPOs to have a quality improvement plan whether or not they restrict members to a panel;
f) the proposed regulation limits coordination and continuity of care requirements to appropriate MCHIPs;
g) the proposed regulation requires clinical perfomance evaluation of MCHIP licensees with access to clinical data;
h) the oversight of the large number of delegated services is important so that MCHIP licensees understand the Department will hold them accountable for the quality of these services, regardless of their delegated status; and
i) the Department agrees that accrediting by a nationally recognized accrediting body is important and has expanded the number of requirements that may be satisfied by such accreditation.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The agency has drafted this regulation without the excessive use of technical terms and jargon so that its terms may be clearly understood.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The agency will review this regulation within three years of the date on which it becomes effective to determine if it should be continued, amended, or terminated.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The intended action should not have any direct effect on the institution of the family and its stability. The proposed amendments do not erode the authority and rights of parents in the education, nurturing, and supervision of their children; encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, one's children and/or parents; they do not strengthen or erode the marital committment nor do they increase or decrease a family's disposable income.