Title of Rule: Quality Improvement Rule

Rule Number: MSB 03-10-16-A

Division / Contact / Phone: Health Benefits / Laurel Karabatsos / x2445

**STATEMENT OF BASIS AND PURPOSE**

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   To streamline and update the quality improvement rule and bring it into compliance with new federal managed care regulations.

2. An emergency rule-making is imperatively necessary

   ☒ to comply with state or federal regulation and/or

   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

   42 C.F.R. Sections 438.200-438.242

4. State Authority for the Rule:

   25.5-1-301 through 25.5-1-303, C.R.S. (2003);

Initial Review **04/09/04** Final Adoption **5/14/04**

Proposed Effective Date Emergency Adoption

**DOCUMENT #4**

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**REGULATORY ANALYSIS**

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   The Quality Improvement rule sets forth quality assessment and improvement standards for Medicaid Providers and does not create any fiscal impact.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   No fiscal impact.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   No fiscal impact.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   Inaction would mean that the Department is not fully compliant with federal regulation

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   The proposed rule does not change provider requirements.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   None.

# 8.079 QUALITY IMPROVEMENT

## 8.079.1 DEFINITIONS

Managed Care Entity means, for purposes of Section 8.079, any person, public or private institution, agency or business concern with which the Department does business pursuant to a capitated reimbursement contract.

Provider means any person, public or private institution, agency, or business concern providing medical or remedial care, services or goods authorized under Medicaid and holding, where applicable, a current valid license or certificate to provide such services or to dispense such goods, and enrolled under the State Medical Assistance Program. Provider does not include a Managed Care Entity.

## 8.079.2 EXTERNAL QUALITY REVIEW (EQR)

Providers and Managed Care Entities shall comply with annual EQR activities. EQR may include, but is not limited to the following activities:

1. Performance improvement projects.
2. Performance improvement project validation.
3. Performance improvement measurement.
4. Performance improvement measurement validation.
5. Consumer satisfaction survey.
6. Medical record review.
7. Review of individual cases.
8. PCPP credentialing and recredentialing.

## 8.079.3 MONITORING AND REVIEW

8.079.3.A. All Providers and Managed Care Entities shall comply with Department efforts to monitor performance through site visits, reviews, desk audits, emergency site visits, profiling, compliance reporting requirements and other quality and program integrity review activities. Monitoring activities shall be conducted for the purpose of determining compliance with state and federal requirements, contracts or Provider agreements, Medicaid service provision and billing procedures, and/or Medicaid Bulletins and Provider Manuals.

1. Managed Care Entities - The Managed Care Entity shall be subject to annual site visits to determine compliance with established standards. The annual site visit process shall consist of a desk audit component and an onsite visit. The Managed Care Entities and/or its subcontractors shall, upon request, provide

and make available staff to assist in the audit or inspection efforts and provide adequate space on the premises to reasonably accommodate review personnel.

2. Providers – the Department may conduct site reviews, desk audits, medical records review and/or claims review for Providers as it deems appropriate. The Provider shall submit or produce requested materials within twenty-one (21) calendar days, unless the review is based on quality of care concerns, in which case the materials shall be submitted within fourteen (14) calendar days of the request. Medical records requested for review shall be provided to the Department at the expense of the Provider.

   a. Records received by the Department after the twenty-one (21) calendar day deadline shall not be considered in the review, unless the Department has granted a written extension. The request for an extension must be received by the Department within ten~~seven~~ (10~~7~~) calendar days from the date of the Department's request, must specify the additional time requested, and reasons for requesting the extension.

   b. Any claims submitted for which documentation is not received within the time limits specified in this section shall be an overpayment subject to recovery regardless of whether or not services have been provided.

   c. The Department's post-review formal correspondence shall indicate areas of strength, suggestions for improvement and required actions, unless the review is conducted for the purpose of post-payment review. For all post payment reviews, the Provider shall receive a letter identifying the overpayment demand, or notice of no repayments.

   d. Duplication of Records - The Department staff, its designated representatives, or the Medicaid Fraud Control Unit may photocopy or otherwise duplicate any document, chart, policy, or other record relating to medical care or services provided, or goods dispensed for which a claim is submitted. The Department or its designee and the Medicaid Fraud Control Unit shall be allowed to use duplicating equipment on the Provider's premises to the extent that such use results in minimal disruption of the Provider's business. If such use of duplicating equipment will cause more than minimal disruption of business, the Provider will notify the Department, which will attempt to resolve the issue with the Provider or make other arrangements.

3. The Department reserves the right to deem other State agencies or private accreditation organizations approved reviews to constitute compliance with specific contractual obligations or regulatory requirements.

4. The Department may delegate monitoring activities.

5. The Department shall conduct unannounced or emergency site visits in instances where patient safety, quality of medical care, potential fraud or financial failure is imminent.

## 8.079 QUALITY ASSURANCE

This section of Staff Manual Volume 8 is reserved for the quality assurance of Medicaid programs. This section addresses, but is not limited to Managed Care Organizations (MCOs), the Primary Care Physician Program (PCPP), and the Unassigned Fee-For-Service system.

## 8.079.1 GENERAL PROVISIONS

The following section includes data collection and reporting requirements established by the Medical Services Board. Quality shall be measured by individuals and groups for satisfaction of service, and analyzed and compared to PCPP and other Medicaid fee-for-service populations when feasible. Quality shall focus on health status and maintenance of the individual's highest level of functioning, without adherence to strict statistical norms.

Copies of the federal regulations cited in the Quality Assurance regulation are available for public inspection or will be provided at cost by the Division of Managed Care Contracting at the Colorado Department of Health Care Policy and Financing, 1575 Sherman Street, Denver, Colorado 80203-1714; or may be examined at any State Publications Depository Library. No later amendments to or editions of the cited federal regulations are incorporated in this rule.

8.079.2 DEFINITIONS

For the purpose of this Section, the following definitions are used:

A. Client - means an individual who applied for and was determined eligible for Medicaid benefits.

B. Desk Audit – the review of materials submitted to Department or its agents upon request.

C. Fee-for-Service (FFS) - Care provided to Medicaid non-MCO clients by providers who submit billings for individual services directly to the Department's fiscal agent. This includes both services as provided under the PCPP and services for those who are Unassigned.

D. Managed Care – Delivery by a Managed Care Organization of a predefined set of services to clients or the delivery of services provided through the Primary Care Physician Program.

E. Managed Care Organization (MCO) – As defined in 26-4-114(2), C.R.S.: An entity contracting with the State Department that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services through the client's use of health care providers managed by, owned by, under contract with, or employed by the entity because the entity or the State Department either requires the client's use of those providers or creates incentives, including financial incentives, for the client's use of those providers.

F. Network - a group of participating providers that have a contractual arrangement or an agreement with an MCO to provide services to the MCO's enrollees. Any subdivision or subgrouping of a network is considered a network if covered individuals are restricted to the subdivision or subgrouping for covered benefits under the MCO.

G. Ombudsman - an independent intermediary who will assist the client and/or the designated client representative in understanding and navigating the process for complaint and grievance within the managed care system.

8.079.2 DEFINITIONS (Continued)

H. Participating Provider – When not capitalized means a provider that, under a contract with an MCO or with its contractor or subcontractor, has agreed to provide health care services to covered persons with an expectation of receiving payment directly or indirectly from the carrier.

I. Provider – When capitalized, is a non-MCO institution (e.g. hospital), agency (e.g., home health agency), or practitioner (e.g. physician) providing medical services.

J. Primary Care Physician Program (PCPP) – Medicaid clients may select a "primary care physician" in the Primary Care Physician Program to provide primary care and to make referrals to specialty services. That physician, physician group, or health clinic is responsible for coordinating, managing, and authorizing all health care services for the client. Medicaid pays for services on a fee-for-service basis. These providers receive an incentive payment to provide management for clients assigned to their care.

K. Site Review – The visit of Department staff or its agents to the site or the administrative office(s) of a Provider or an MCO and its participating providers for the purpose of review and monitoring.

L. Unassigned Fee-For-Service, or Unassigned – The Medicaid program for clients who are not enrolled in an HMO or in the Primary Care Physician Program.

8.079.3 QUALITY IMPROVEMENT COMMITTEE

The Department shall establish a quality improvement committee consisting of quality assurance leaders from each MCO and the fee-for-service arena. This committee shall meet at least quarterly to provide consultation on the design of reviews required by regulation and contract. This committee shall communicate decisions and resolutions with stakeholders.

## 8.079.4 MCO QUALITY ASSURANCE PROGRAMS

A. Each Medicaid Managed Care Organization (MCO) shall maintain an internal quality assurance program that complies with 42 C.F.R. 434 - CONTRACTS, most current edition, for all of its covered services.

B. The scope of the MCO's internal quality assurance program shall be comprehensive and include standards for quality, accessibility, and availability of services for clients; monitoring and evaluation of important aspects of care and services which shall include the maintenance of the highest level of functioning and normal daily activity; systematic measurement and improvement; and corrective action and follow-up by the MCO, its participating providers, and its subcontractors.

C. Each MCO's internal quality assurance program shall include all aspects required by the Medicaid contract, including but not limited to consumer outcomes based on statistics maintained on individual consumers as well as the total consumer populations served; consumer satisfaction; consumer utilization; and health status of consumers measured in a manner negotiated between the Department and the MCOs.

D. The MCO's internal quality assurance program shall include, but not be limited to, the routine review, analysis, and improvement of participating provider performance, appointment and wait times, utilization and quality indicators, enrollment and disenrollment patterns, complaints and grievances, anecdotal evidence, referrals, medical records, and client service.

E. The MCO shall make available information about its internal quality assurance program to clients, client advocates, advocacy organizations and the Department upon request. This information shall include but not be limited to:

1. An annual written summary of the quality assurance program;

2. Its accomplishments during the last contract year, if applicable;

3. Those activities planned during the upcoming contract year;

8.079.4 MCO QUALITY ASSURANCE PROGRAMS (Continued)

4. A description of quality improvement activities that address the special health care needs of clients to the extent the services are provided or arranged by the MCO. The quality assurance program shall include a comprehensive table of current activities, timelines, and expected outcomes that can be distributed to clients, the Department, and its agent upon request. Client requests for information that are received by the enrollment facilitator will be forwarded to the MCO.

F. The MCO shall comply with all applicable local, State, and Federal licensing and certification requirements and standards necessary in the performance of the contract. The MCO shall have effective written policies and procedures for provider credentialing and recredentialing. These policies and procedures shall ensure that all participating providers meet applicable State and Federal licensure requirements and are qualified to provide services to clients. The policies and procedures must provide for quality assessment of all subcontracting health delivery organizations, including but not limited to: hospitals, home health agencies, skilled nursing facilities, and freestanding surgical centers.

Rev. eff. 8/01/98

G. As to alleged quality of care concerns involving non-physician providers, the MCO shall investigate such concerns upon request of the Department. In response to a request from the Department, the MCO shall submit a letter to the Department that includes a brief but clear description of the issue, the efforts that the MCO took to investigate the issue, and the outcome of the review as determined by the MCO. The outcome shall include whether or not the issue was found to be a quality of care issue and what action the MCO intends to take with the provider(s) involved. The letter shall not include the names of the persons conducting the investigation. This complete letter shall be sent to the Department within fourteen (14) calendar days of the Department's request. Upon request, the Department may allow additional time to investigate and report.

~~8.079.4 MCO QUALITY ASSURANCE PROGRAMS (Continued)~~

Added eff. 8/01/98

~~As to alleged quality of care concerns involving physician providers, an MCO that has a professional review committee, established pursuant to §12-36.5-104, C.R.S., may utilize the process set forth at 12-36.5-104 C.R.S. when a quality of care concern involving a physician is brought to its attention. An MCO that does not have or chooses not to utilize such a professional review committee shall apply the above process to alleged quality of care concerns involving physicians.~~

~~Notwithstanding any other provision of this regulation, the MCO is not required to disclose any information which is confidential by law.~~

~~H. In a manner to be negotiated between MCOs and the Department, MCOs shall provide recognition for improved health status outcomes through the quality assurance program.~~

~~I. Each MCO shall submit an annual report to the Department that describes techniques used by the MCO to provide more efficient use of health care services, better health status for populations served, assistance for clients in order to maintain their highest level of functioning, and better health outcomes for individuals. Upon request, this information shall be made available to providers and clients at cost.~~

~~J. Each MCO shall impose practice guidelines for the following:~~

~~1.Perinatal, prenatal, and postpartum care for women,~~
~~2.Birthing and neonatal care for infants,~~
~~3.Conditions related to persons with disabilities or special needs, and~~
~~4.Well child care.~~

~~The standards and indicators shall be based on nationally approved guidelines, although modifications may be granted by the Department to address regional variations. These standards and guidelines must be available upon request of the Department and clients no later than July 1, 1998.~~

## 8.079.5 DELEGATED FUNCTIONS

The MCO shall maintain oversight of all delegated administrative activities, including but not limited to utilization management and provider performance monitoring. If the MCO delegates administrative activities to a subcontractor, the MCO shall prepare a written description of the delegated activities, accountability, frequency of reporting, and evaluation. The MCO must maintain direct responsibility of the activity, and must be able to show evidence of the subcontractor's compliance during reviews and audits.

## 8.079.6 MONITORING

The Department shall monitor the performance of MCO contracts and Provider agreements. Aspects of these reviews shall be coordinated with the Colorado State Department of Regulatory Agencies, Division of Insurance; the Colorado Department of Public Health and Environment; the Health Care Financing Administration, Office of Prepaid Health Care; the Medicaid Fraud Control Unit; private accreditation agencies; and private purchasing groups and coalitions. The amount of coordination and the aspects under coordination shall be at the discretion of the Department. The Department reserves the right to deem approved reviews from other State agencies or private accreditation organizations to constitute compliance with specific contractual obligations or regulatory requirements at its discretion. The aspects to be deemed shall be at the discretion of the Department after collaboration with MCOs. The Department may delegate any of the following activities to a qualified contractor or perform the functions with Department staff.

## 8.079.61 MCO SITE REVIEW PROCEDURE

A. Site Reviews shall be conducted at least annually or, on an emergency basis, more frequently as needed. Site Reviews shall be conducted by the Department for the purpose of determining compliance by the MCO with these regulations and Medicaid contractual requirements. In the event that right of access is requested under this section, the MCO and/or its subcontractors shall, upon request, provide and make available staff to assist in the audit or inspection effort, and provide adequate space on the premises to reasonably accommodate Department or Federal personnel conducting the audit or inspection effort. All inspections or audits shall be conducted in a manner that will not unduly interfere with the performance of the MCO's or a subcontractor's provision of care.

B. For non-emergency Site Reviews, MCOs shall participate in the preview of the monitoring instrument to be used as part of the assessment and shall be contacted for mutually agree-upon dates for a Site Review. Final notice of the Site Review schedule and a copy of the monitoring instrument will be mailed to the MCO at least three weeks prior to the visit.

C. The MCO shall submit copies of policies, procedures, manuals, handbooks, reports, and other requested materials to facilitate the Department's Desk Audit prior to the Site Review. The MCO shall have a minimum of thirty (30) calendar days to submit the required materials for non-emergency reviews. If a complete set of Desk Audit materials has not been received within forty-five (45) calendar days of the Department's request, the MCO may be subject to sanctions as specified in Section 8.079.86.

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| THIS REVISION: VIII-97-8 | LAST REVISION: New Material REVISION NUMBER |
| Adopted: 12/12/97 | Adopted: |
| Effective Date: 2/01/98 | Effective Date: |

8.079.61 MCO SITE REVIEW PROCEDURE (Continued)

D. Where policies, procedures, programs, and plans are required by contract or rule, MCOs shall maintain and provide internal documents that clearly demonstrate all such requirements. Such internal procedures must detail responsibilities of the MCO. Where the MCO is required to communicate to providers, documentation shall exist outside of the MCO's internal policies and procedures, generally in the form of direct provider correspondence or a provider manual. Exception can be made for a single source for provider and MCO documents if the MCO clearly specifies in the documents the role of the MCO and the role of the provider. Where the MCO is required to communicate to Clients, documentation shall exist outside the MCO's internal policies and procedures, generally in the form of direct Client correspondence or a member handbook.

E. The MCO shall make available to the Department and its agents for Site Review all records and documents related to the execution of the Medicaid contract, either on a scheduled basis as noted elsewhere in this section, or immediately on an emergency basis. Delays in the availability of such documents and records may cause the MCO to be subject to sanctions as specified in Section 8.079.86. These records and documents shall be maintained according to statutory or general accounting principles and shall be easily separable from other Contractor records and documents.

F. A written report of the site visit shall be transmitted to the MCO within thirty (30) calendar days of the Site Review. The report shall indicate areas of strength, suggestions for improvement, and required actions. A copy of the Site Review report and MCO response shall be transmitted to the Colorado Department of Regulatory Agencies, Division of Insurance.

G. The MCO shall respond to any required actions, if necessary, with a corrective action plan within thirty (30) calendar days of the final written report, specifying the action to be taken and time frames. The corrective action plan is subject to approval by the Department. Department review staff shall monitor progress on the corrective action plan until the MCO is found to be in complete compliance. Department staff shall notify the MCO in writing when the corrective actions have been completed, accepted, and the MCO is considered to be in compliance with the contract.

~~8.079.61 MCO SITE REVIEW PROCEDURE (Continued)~~

~~H. Any data submitted by MCOs after the last site visit day shall not be accepted towards compliance with the visit in the written report. This data shall apply toward the corrective action plan.~~

~~I. The Department review staff shall notify the Director of the Division of Managed Care Contracting if any MCO was found to be seriously out of compliance or uncooperative with the Site Review process or the corrective action plan.~~

~~J. An emergency or unannounced review may be required in instances where patient safety, quality of medical care, potential fraud, or financial viability is at risk. The Department reserves the right to determine when an emergency review is required.~~

~~K. The Site Review may include reviews of a sample of the MCO's participating providers to ensure that providers have been educated and monitored by the MCO about the requirements of the Medicaid contract.~~

~~8.079.62 PROVIDER SITE REVIEW PROCEDURE~~

~~A. Site Reviews and/or Desk Audits may be conducted for individual FFS Providers as deemed appropriate by the Department. Site Reviews shall be conducted by the Department for the purpose of determining compliance with Volume 8 regulations, the Provider agreement, and other criteria developed in consultation with provider representative groups. The Provider shall submit or produce policies, procedures, reports, and other materials to facilitate the Department's review. The Provider shall have a minimum of fourteen (14) calendar days to submit or prepare the required materials, unless the Department deems necessary an unannounced visit. If materials are not available within twenty (20) calendar days of the Department's request, termination of the Provider from the Medicaid program shall be considered, pursuant to Section 8.051.21 of this staff manual. If a Provider were chosen for site review, Department staff or its agent would visit the provider site to conduct a review according to a tool sent to the Provider at least fourteen (14) days prior unless an unannounced review is warranted.~~

8.079.62 PROVIDER SITE REVIEW PROCEDURE (Continued)

B. Providers subject to this review include any Fee-For-Service Provider of the Medicaid program, including but not limited to: Providers enrolled in the Primary Care Physician Program (PCPP), hospitals, home health agencies, nursing homes, Providers of Home and Community Based Services, transportation Providers, clinics, laboratories, dental care Providers, pharmacies, advanced nurse practitioners, podiatrists, optometrists, psychologists, psychiatrists, and Providers of durable medical equipment and supplies.

C. A written preliminary report of the review shall be transmitted to the Provider within thirty (30) calendar days of the Site Review. The final report, considering responses from the Provider received within thirty (30) days of the preliminary report, shall indicate areas of strength, suggestions for improvement, and required actions. The Department may submit a copy of the final Site Review report and the Provider's response to applicable regulatory and licensing agencies.

D. The Provider shall respond to any required action(s), if necessary, with a corrective action plan within thirty (30) calendar days of the final written report, specifying the action to be taken and time frames. The corrective action plan is subject to approval by the Department. Department review staff shall monitor progress on the corrective action plan. Department staff shall notify the Provider in writing when the corrective actions have been completed and accepted.

E. Any data submitted by Providers after the last site visit day shall not be accepted toward compliance with the visit in the written report. This data shall apply toward the corrective action plan.

F. The Department review staff shall notify applicable regulatory and licensing agencies if any Provider was found to be seriously out of compliance or uncooperative with the Site Review process or the corrective action plan.

G. The Department shall collaborate with the Colorado Department of Public Health and Environment and appropriate licensing boards on the status and review of individual Providers.

H. An unannounced review may be required in instances where patient safety, quality of medical care, potential fraud, or financial inviability is imminent. The Department and its agents reserve the right to determine when an unannounced review is required.

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## 8.079.63 EXTERNAL REVIEW

MCOs, Providers in the PCPP, and Providers for the Unassigned Fee-For-Service system shall comply with an annual external review. This review may involve a qualified Department contractor(s) to assure quality and accessibility of health care to Medicaid Clients.

A. The external review may include but not be limited to all or any of the following: medical record review, quality improvement studies, surveys, calculation and audit of quality and utilization indicators, administrative data analyses, and reviews of individual cases.

B. MCOs, Clients, and Providers shall participate in the development and design of studies to assess and assure quality of care. Final study specifications shall be at the discretion of the Department. The external review contractor shall be required to meet with MCOs and Providers to hear their concerns and take reasonable action in relation to external review issues.

C. The external review contractor shall prepare and submit reports that illustrate individual MCO performance and the performance of the PCPP and the Unassigned Fee-For-Service system, when individual review of those entities is included. Aggregate summary reports shall also be submitted for distribution to consumers and the interested public upon request at cost. Final reports shall incorporate response from the MCO should the MCO request such inclusion in a timely manner, as defined by the external review contract.

D. MCOs and Providers shall comply with requests for records and documents for external review within thirty (30) calendar days or longer, if indicated in writing by the Department or external review contractor. Should any required documents or records not be submitted within 30 days of the written deadline, the MCO or Provider may be subject to sanctions as specified in Section 8.079.86. If an emergency review is required, as determined by the Department, the MCO or Provider shall have five (5) working days from the date of the request to submit the record unless otherwise noted in the request. The same sanction may apply after that date.

~~8.079.7 CLIENT SATISFACTION, COMPLAINTS, AND DISENROLLMENTS~~

~~The Department shall monitor Client perceptions of accessibility and adequacy of services provided by the Medicaid program and any contractors or Providers of care. Quality improvement plans shall be implemented when:~~

~~1. Clients report statistically significant levels of dissatisfaction;~~
~~2. A pattern of complaints is detected; or~~
~~3. A serious single complaint is reported.~~

~~Tools shall include the use of Client surveys, anecdotal information, complaint and grievance data, and disenrollment information.~~

~~A. Annual surveys of randomly selected, statistically valid samples will be conducted. These surveys shall routinely report by 1) individual MCOs, 2) the PCPP, and 3) the Unassigned Fee-For-Service system, when allowed by availability of funds and population size. The surveys shall address Client satisfaction.~~

~~B. Surveys shall be professionally developed and the methodology shall be scientifically sound to support publication of results. Updated information about Client satisfaction, if found to be valid, shall be provided to Clients.~~

~~C. The Department shall track, trend, analyze and address complaints about the Medicaid program as they are received. Individual anecdotal complaints and Ombudsman activities may also be analyzed and investigated.~~

~~D. The Department shall analyze reports of complaints and grievances from MCOs to determine whether quality improvement plans necessitated by complaints and grievances have been implemented. The Department will require that MCOs take corrective action if such have not been implemented.~~

~~E. MCOs and the PCPP shall analyze disenrollment information provided by the enrollment facilitator.~~

## 8.079.8 QUALITY AND UTILIZATION MEASURES

A. MCOs shall accurately calculate and submit quality and utilization measures specified each year by the Department. The Department will notify the MCOs which measures must be reported at east six months before the measures are due. The Department will collaborate with the MCOs to determine the required measures which will address, at a minimum, women, infants and children. Efforts will be taken to develop measures for persons with disabilities and/or special needs. MCOs shall make improvements in care, access, administrative processes, and utilization, when indicated, in order to improve results.

B. The Department shall calculate quality and utilization measures for the PCPP and the Unassigned Fee-For-Service system each year, depending on volume. The measures will be determined by the Department. Whenever feasible, the measures for the PCPP will be the same as those required for MCOs.

C. MCOs shall routinely audit their quality and utilization measures according to guidelines and a timeline negotiated between the MCOs and the Department. The Department shall conduct similar audits for Unassigned Fee-For-Service and the PCPP. Audits support the publishing of measures, and allow the Department to determine compliance with the calculation of measures.

## 8. 079.81 PROGRAM INTEGRITY

A. MCOs shall provide for a program integrity officer to be responsible for detecting potential incidents of Medicaid fraud, and reporting such concurrently to the Medicaid Fraud Control Unit (MFCU) and the Director of the Managed Care Contracting Division. MCO responsibilities will also include:

1. Developing effective lines of communication for reporting of violations;
2. Clarification of Medicaid and MCO policy; and
3. Enforcement of MCO standards through notification of procedures, discipline and credentialing.

This position will respond appropriately and immediately to all detected program violations and prevent further offenses through systematic changes and corrective action initiatives. MCOs shall comply with requirements promulgated by the National Practitioner Data Bank and the Colorado State Board of Medical Examiners.

B. Upon becoming aware of Network exclusions, the MCO shall immediately report concurrently to the Department and the MFCU exclusions from the provider Network relating to quality of care, competence, or professional conduct. Should the MCO be found to knowingly withhold information or refuse to detect or report incidents of potential fraud, the MCO shall be referred to the Medicaid Fraud Control Unit for investigation.

C. The Department shall continue surveillance and utilization review of Fee-For-Service Providers conducted within the scope and authority of 42 C.F.R, 455 - Program Integrity and 456 - Utilization Control, October 1996 edition. Any suspicions of potential fraud shall be referred to the Medicaid Fraud Control Unit for investigation.

## 8.079.82 UTILIZATION MANAGEMENT

A. The MCO shall establish and maintain a comprehensive Utilization Management (UM) Program which is consistent with requirements for UM under the Division of Insurance regulation 3 C.C.R. 702-4 at 4-2-17, and can be used to monitor access to and appropriate utilization of covered services by Clients. The program shall be under the direction of an appropriately qualified clinician and shall include written policies and procedures that describe how the primary care physician and the MCO will evaluate medical necessity to ensure that all populations of Clients receive the most appropriate covered services as defined in 8.205.11 of the Medicaid Managed Care System rule.

B. The MCO shall ensure that the UM program incorporates mechanisms to continuously update guidelines, policies and procedures used in making determinations based on evaluation of new medical technologies and new application of established technologies, including medical procedures, drugs and devices.

C. Utilization determinations shall be based on written clinical criteria and guidelines developed or adopted with involvement from practicing physicians and other participating providers, or nationally recognized standards. These guidelines and criteria shall be periodically reviewed and updated and shall, with the exception of internal or proprietary quantitative thresholds for Utilization Management, be readily available, upon request, to affected participating providers, Clients, and advocates.

D. The Contractor shall maintain mechanisms to evaluate the effects of the UM program.

E. The UM program shall assure all medically necessary covered services and assure adequate access to covered services. The construction of the UM program shall in no way aim to impede Clients' timely access of services. The UM program shall include a review mechanism to ensure fair procedures and a process for prescribing physician requests to override restrictions to obtain medically necessary prescription drugs, supplies, equipment, or services for Clients.

8.079.82 UTILIZATION MANAGEMENT (Continued)

F. MCOs shall not interfere with appropriate medical care decisions rendered by the provider or penalize the provider for requesting medical services outside the standard treatment protocols developed by the MCO or its contractors.

G. MCOs shall offer an educational component that takes into consideration Client input and informs Clients as to the availability of the medical services system, appropriate preventive health care procedures, self-care, and appropriate health care utilization.

8.079.83 OTHER FEE-FOR-SERVICE QUALITY ASSURANCE AND UTILIZATION ACTIVITIES

A. Quality of care and medical necessity is reviewed routinely for non-institutional Fee-For-Service Providers, including those in the PCPP, through the Department's fraud and abuse program. Chims analyses and referrals indicate areas of concern for review. Providers found to provide inappropriate services, undocumented services, substandard care, and services that are not medically necessary are subject to Provider education, administrative recoupment, civil penalties, termination, and/or criminal prosecution. See 42 CFR section 455.16.

B. Quality of care and medical necessity is reviewed routinely for hospital services, including those provided through the PCPP, through the Department's peer review organization. Claims analyses and focused studies indicate areas of concern for review. Providers found to provide inappropriate services, undocumented services, substandard care, and services that are not medically necessary are subject to Provider education, administrative recoupment, civil penalties, termination, and/or criminal prosecution.

C. Utilization controls and medical necessity review for long-term care services are provided through contract with the Department's peer review organization. See Section 8.481 of this staff manual.

## 8.079.84 OTHER MCO QUALITY ASSURANCE ACTIVITIES

In consultation with the Department, the MCOs shall participate in and respond to other Department quality review activities including but not limited to:

A. Encounter data analysis,

B. Encounter data validation (the comparison of encounter against medical records),

C. Complaints and grievance analyses to identify trends in the Medicaid program and among MCOs,

D. Risk adjusted rates studies, and

E. Other reviews as determined by the Department. Reviews of significant administrative burden to MCOs, not hereto specified, will be negotiated with the MCOs.

F. Processes shall exist for measuring group and individual Client health outcomes, including but not limited to, use of tools or methods that:

1. Identify increased health status or maintenance of the individual's highest level of functioning,
2. Determine the degree of medical access, and
3. Reveal Client satisfaction and habits, at the discretion of the client.

~~8.079.85 PROFILING~~

~~The Department may use any and all valid collected MCO, PCPP, and other Fee-For-Service data for distribution to consumers, except to the extent that individual Clients and Providers could be identified. Validity shall be determined by the Department. The Department may engage in profiling activities or the development of a report card to provide Clients with descriptive information and assist Clients in making informed choices about the options provided under the Medicaid program. The Department shall consult with MCOs, Providers, and Clients in the design of related products. This process supports the assurance of informed choice and the ability of Clients to choose Managed Care delivery systems on the basis of quality and access. The Department will not compile descriptive information about individual providers.~~

~~8.079.86 REMEDIAL ACTIONS~~

~~A. All medical records shall be produced by the date specified in the Department's written request, which will allow a minimum of thirty (30) calendar days for the MCO to produce the records for non-emergency reviews and fourteen (14) calendar days for Fee-for-Service Provider reviews. If the said records are not produced within thirty (30) calendar days/fourteen (14) calendar days of the date specified in the Department's written request, a financial penalty may be imposed. The penalty for MCOs is defined in their contract, and for FFS Providers is the amount of the claims for which records are missing, or $300, whichever is greater. If an emergency review is required, as determined by the Department, the MCO or FFS Provider shall have three (3) working days from receipt of the request to submit the record by mail or immediately upon emergency MCO or Provider site visit.~~

~~A Provider may also be investigated under 8.075.01 or 42 C.F.R. 455 and 456, October 1996 edition, and the rules pursuant to Section 8.130.32 shall apply.~~

~~B. If an MCO or FFS Provider is out of compliance with a corrective action plan for thirty (30) calendar days after the corrective action plan indicates that compliance should have been achieved, or if they failed to submit an approved corrective action plan as specified in 8.079.61 and .62 within thirty (30) calendar days of the date it was due, a financial penalty may be imposed. For MCOs, the penalty will be pursuant to contract. For FFS Providers, a penalty may be imposed for up to ten percent of their Medicaid billings each month, or at the Department's discretion, $500 each month, until the Provider is in compliance.~~

8.079.86 REMEDIAL ACTIONS (Continued)

C. All requested documents, including but not limited to policies, procedures, reports, manuals, and handbooks, shall be produced by the date specified in the Department's written request, which will allow a minimum of thirty (30) calendar days for MCOs, and fourteen (14) calendar days for individual FFS Providers, to produce the documents. If the said documents are still not produced within thirty (30) calendar days/fourteen (14) calendar days of the date specified in the Department's written request, a financial penalty may be imposed for MCOs as defined by contract. For FFS Providers, a penalty may be imposed for up to ten percent of their Medicaid billings each month, or at the Department's discretion, $500 each month, until the Provider is in compliance. If the Department deems necessary an emergent or unannounced site visit, said documents shall be produced immediately or upon a timeline set by the Department. The same sanctions may apply after that date.

D. The MCO or FFS Provider may appeal any penalty imposed. The appeal rights are set forth in the Department's regulations at 8.050. The scope of the appeal is limited to:

1. A review of the factual finding that a penalty is warranted; and
2. A review of the penalty's severity.