

CHAPTER 38A**HEALTH CARE QUALITY ACT APPLICATION TO INSURANCE COMPANIES, HEALTH SERVICE CORPORATIONS, HOSPITAL SERVICE CORPORATIONS, AND MEDICAL SERVICE CORPORATIONS****Authority**

N.J.S.A. 26:2J-21 and 26:2S-1 et seq.

Source and Effective Date

R.2000 d.183, effective May 1, 2000.
See: 31 N.J.R. 953(a), 32 N.J.R. 1544(a).

Executive Order No. 66(1978) Expiration Date

Chapter 38A, Health Care Quality Act Application to Insurance Companies, Health Service Corporations, Hospital Service Corporations, and Medical Service Corporations, expires on May 1, 2005.

Chapter Historical Note

Chapter 38A, Health Care Quality Act Application to Insurance Companies, Health Service Corporations, Hospital Service Corporations, and Medical Service Corporations, was adopted as R.2000 d.183, effective May 1, 2000. See: Source and Effective Date.

CHAPTER TABLE OF CONTENTS**SUBCHAPTER 1. GENERAL PROVISIONS**

- 8:38A-1.1 Scope and purpose
- 8:38A-1.2 Definitions
- 8:38A-1.3 Compliance time frames

SUBCHAPTER 2. PROVISIONS APPLICABLE TO ALL CARRIERS

- 8:38A-2.1 Scope and applicability
- 8:38A-2.2 HCQA Registration Form
- 8:38A-2.3 Disclosure requirements
- 8:38A-2.4 Submission of disclosure statements to the Department
- 8:38A-2.5 Other rights of covered persons
- 8:38A-2.6 Emergency and urgent care services
- 8:38A-2.7 Violations

SUBCHAPTER 3. UTILIZATION MANAGEMENT

- 8:38A-3.1 Scope and applicability
- 8:38A-3.2 Disclosure requirements
- 8:38A-3.3 Designation of a medical director
- 8:38A-3.4 Utilization management program
- 8:38A-3.5 Internal utilization management appeals process
- 8:38A-3.6 Independent health care appeals process
- 8:38A-3.7 Carrier action on the IURO recommendations
- 8:38A-3.8 Continuous quality improvement

SUBCHAPTER 4. PROVISIONS APPLICABLE TO CARRIERS OFFERING ONE OR MORE HEALTH BENEFITS PLANS THAT ARE MANAGED CARE PLANS

- 8:38A-4.1 Scope and applicability
- 8:38A-4.2 Disclosures to covered persons
- 8:38A-4.3 Disclosures to consumers
- 8:38A-4.4 Submission of disclosures
- 8:38A-4.5 Designation of a medical director

- 8:38A-4.6 Complaint system
- 8:38A-4.7 Provider application for participation
- 8:38A-4.8 Termination of providers from a network
- 8:38A-4.9 Hearings for provider terminations
- 8:38A-4.10 Network adequacy
- 8:38A-4.11 Utilization management program
- 8:38A-4.12 Internal utilization management appeal process
- 8:38A-4.13 Continuous quality improvement
- 8:38A-4.14 Provider input on protocols
- 8:38A-4.15 Minimum standards for provider contracts
- 8:38A-4.16 Reporting of quality outcome measures and compensation arrangements
- 8:38A-4.17 Requirement to offer a managed care plan without a gatekeeper system

SUBCHAPTER 5. INDEPENDENT HEALTH CARE APPEALS PROGRAM

- 8:38A-5.1 General requirements
- 8:38A-5.2 Department review of carrier actions on IURO recommendations

APPENDIX**SUBCHAPTER 1. GENERAL PROVISIONS****8:38A-1.1 Scope and purpose**

(a) The purpose of this chapter is to set forth the minimum standards which carriers, as defined at N.J.A.C. 8:38A-1.2, must meet in order to be in compliance with the requirements of the Health Care Quality Act, P.L. 1997, c.192, enacted August 8, 1997.

(b) A carrier shall comply with each of the subchapters of this chapter as appropriate to the types of health benefits plans delivered or issued for delivery by the carrier in this State.

(c) The provisions of this chapter shall apply to any services or functions of a carrier that the carrier may subcontract to another entity just as if the carrier were performing those services or functions itself, and no carrier shall be relieved of assuring full compliance with any applicable provision because one or more functions or services are subcontracted.

(d) A carrier that complies with this chapter shall not be relieved of its obligation to comply with all applicable Federal, State and local laws, rules and regulations.

8:38A-1.2 Definitions

For the purposes of this chapter, the words and terms set forth below shall have the following meanings, unless the word or term is further defined within a subchapter of this chapter, or the context clearly indicates otherwise.

“Act” means the Health Care Quality Act, P.L. 1997, c.192 (as codified: N.J.S.A. 26:2S-1 et seq.; 26:2J-4.16, 18.1

and 24; 17:48-6r, 17:48A-7p, 17:48E-35.15, 17B:26-2.1n, 17B:27-46.1q, 17B:27A-2.3 and 17B:27A-19.5; and 34:13A-31).

“Carrier” means a insurance company authorized to transact the business of insurance in this State and doing a health insurance business in accordance with N.J.S.A. 17B:17-1 et seq., a hospital service corporation authorized to do business pursuant to N.J.S.A. 17:48-1 et seq., a medical service corporation authorized to do business pursuant to N.J.S.A. 17:48A-1 et seq. or a health service corporation authorized to do business pursuant to N.J.S.A. 17:48E-1 et seq.

“Commissioner” means the Commissioner of the New Jersey Department of Health and Senior Services.

“Continuous quality improvement” or “CQI” means an on-going and systematic effort to measure, evaluate, and improve either a carrier’s process of providing quality health care services to covered persons with respect to managed care plans, or the carrier’s process of performing utilization management functions with respect to health benefits plans in which utilization management has been incorporated.

“Contract holder” means an employer or organization that purchases a contract or policy for the provision of health care services covered under the terms of the policy or contract or for the payment of benefits therefor.

“Covered person” means the person on whose behalf a carrier is obligated to pay benefits or provide health care services pursuant to the health benefits plan.

“Department” means the New Jersey Department of Health and Senior Services.

“Emergency” means a medical condition manifesting itself by acute symptoms of sufficient severity including, but not limited to, severe pain, psychiatric disturbances and/or symptoms of substance abuse such that a prudent lay person, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate attention to result in: placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of a bodily organ or part. With respect to a pregnant woman who is having contractions, an emergency exists where: there is inadequate time to effect a safe transfer to another hospital before delivery; or the transfer may pose a threat to the health or safety of the woman or the unborn child.

“Financial incentive arrangement” means a formal mechanism instituted by a carrier or a secondary contractor that exposes a provider, or group of providers, to risk or reward based upon meeting or failing to meet prescribed standards.

“Financial risk” means participation in financial gains or losses accruing pursuant to a contractual arrangement, based on aggregate measures of medical expenditures or utilization.

“Gatekeeper system” means a system in which a covered person’s level of benefits for all or a specified set of health care services under a policy or contract is dependent upon the covered person obtaining appropriate referrals for the services through a primary care provider or the carrier.

“Health benefits plan” means a policy or contract for the payment of benefits for hospital and medical expenses or the provision of hospital and medical services delivered or issued for delivery in this state by a carrier. The term “health benefits plan” specifically includes:

1. Medicare supplement coverage and risk contracts for the provision of health care services covered by Medicare to the extent that state regulation of such contracts or policies is not otherwise preempted by Federal law; and
2. Any other policy or contract not otherwise specifically excluded by statute or this definition.

The term “health benefits plan” specifically excludes:

1. Accident only policies;
2. Credit health policies;
3. Disability income policies;
4. Long-term care policies;
5. CHAMPUS supplement coverage;
6. Hospital confinement indemnity coverage;
7. Coverage arising out of a workers’ compensation law or similar such law;
8. Automobile medical payment insurance or personal injury protection insurance issued pursuant to N.J.S.A. 39:6A-1 et seq.; and
9. Coverage for medical expenses contained in a liability insurance policy.

“IHC Program” means the Individual Health Coverage Program set forth at N.J.S.A. 17B:27A-2 et seq., and any rules promulgated pursuant thereto.

“Independent Health Care Appeals Program” means the external appeals process for a covered person or provider on behalf of the covered person with the covered person’s consent, to appeal a decision of a carrier to deny, reduce or terminate services or payment of benefits resulting from a decision by a carrier with respect to the covered person which services are otherwise covered under the health benefits plan.

“Independent utilization review organization” or “IURO” means an independent organization with which the Department contracts to provide independent reviews through the Independent Health Care Appeals Program of carrier determinations regarding medical necessity or appropriateness of services which are contested by the covered person or a provider on behalf of the covered person.

“Managed care plan” means a health benefits plan that integrates the financing and delivery of appropriate health care services to covered persons by arrangement 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.

“Participating provider” means a provider which, under contract or other arrangement acceptable to the Department with the carrier, its contractor or subcontractor, has agreed to provide health care services or supplies to covered persons in the carrier’s managed care plan(s) for a predetermined fee or set of fees.

“Primary care provider” or “PCP” means an individual participating provider who supervises, coordinates and provides initial and basic care to members and maintains continuity of care for the members.

“Primary contractor” means a provider that agrees directly with a carrier to provide one or more services or supplies directly to a carrier’s covered persons.

“Provider” means any physician or other health care professional, hospital, facility or other person who is licensed or otherwise authorized to provide health care services or other services in the state or jurisdiction in which the services are furnished.

“Secondary contractor” means a person who agrees to arrange for the provision of one or more services or supplies for a carrier’s covered persons. A primary contractor also may be a secondary contractor when acting as a broker or administrator for the rendering of services or supplies that, in scope of licensure, type or quantity, the primary contractor (provider) alone could not offer directly to the carrier’s covered persons.

“SEH Program” means the Small Employer Health Benefits Program set forth at N.J.S.A. 17B:27A-17 et seq., and any rules promulgated pursuant thereto.

“Subscriber” means, in the case of a group policy or contract, an individual whose employment or other status, except family status, is the basis for eligibility for coverage under the policy or contract or, in the case of an individual policy or contract, the person in whose name the contract is issued.

“Utilization management” means a system for reviewing the appropriate and efficient allocation of health care services under a health benefits plan according to specified guidelines in order to recommend or determine whether, or to what extent, a health care service given or proposed to be given to a covered person should or will be reimbursed, covered, paid for, or otherwise provided under the health benefits plan. The system may include: preadmission certification, the application of practice guidelines, continued stay review, discharge planning, preauthorization of ambulatory care procedures and retrospective review.

8:38A-1.3 Compliance time frames

(a) For disclosures required to be made on or about the effective date of coverage (whether or not annual disclosure is required thereafter), carriers shall make the disclosure to new subscribers no later than July 30, 2000.

(b) For disclosures required to be made on or about the effective date of coverage (whether or not annual disclosure is required thereafter), carriers shall make the disclosures to current subscribers or covered persons no later than the anniversary date of the contract or policy under which they are covered first occurring on or after July 30, 2000.

(c) For disclosures required to be made upon request, carriers shall begin providing those disclosures no later than July 30, 2000.

(d) With respect to form filings required to be made for inforce policies and contracts, carriers shall make the required filings no later than July 30, 2000.

SUBCHAPTER 2. PROVISIONS APPLICABLE TO ALL CARRIERS

8:38A-2.1 Scope and applicability

(a) This subchapter shall apply to all carriers that have delivered and inforce, or are offering for delivery, health benefits plans in this State.

(b) This subchapter shall apply to all health benefits plans of a carrier that have been or will be delivered or offered for delivery in this State.

8:38A-2.2 HCQA Registration Form

(a) Carriers shall complete and submit to the Department and the Department of Banking and Insurance the HCQA Registration Form, available from the Department upon request, describing, if required, the carrier’s internal appeal process, by which covered persons, or a provider on behalf of a covered person (with the covered person’s consent), may appeal a carrier’s UM decision, and the carrier’s notice to covered persons of the right to appeal a carrier’s final

UM decision to the Independent Health Care Appeals Program.

1. Carriers shall file the HCQA Registration Form at least 30 days prior to the date that the carrier will begin to offer any health benefits plan issued under a policy or contract form for which an HCQA Registration Form has not previously been filed.

2. Completion of the HCQA Registration Form with respect to the description of the carrier's internal appeals mechanism and its notice of a covered person's right to appeal through the Independent Health Care Appeals Program shall be consistent with the requirements of N.J.A.C. 8:38A-3.5.

3. Carriers shall file a copy of the HCQA Registration Form with the Department and the Department of Banking and Insurance at the following addresses:

New Jersey State Department of Health and Senior Services
Office of Managed Care
PO Box 360
Trenton, NJ 08625-0360
and
New Jersey Department of Banking and Insurance
Managed Care Bureau
Division of Life and Health Division
PO Box 325
Trenton, NJ 08625-0325

(b) Carriers shall submit a revised HCQA Registration Form pursuant to (a)3 above no later than 10 business days following the date of any substantive change to the information contained in the prior HCQA Registration Form submission.

1. In lieu of resubmission of the entire HCQA Registration Form, carriers may submit an HCQA Registration Form indicating the revisions only, and specifying for unchanged sections "No change from the submission of (specify date)."

(c) The HCQA Registration Form shall include a request for the following information:

1. General information about the carrier, including the carrier's name and NAIC number, address, the name of the person completing the form and the means by which that person may be contacted, an explanation of what type of carrier the carrier is, a statement as to whether the carrier has health benefits plans in force in New Jersey, or the date the carrier intends to begin offering health benefits plans in New Jersey, and the name of the person responsible for the carrier's operations in New Jersey, with specification of how that person may be contacted;

2. A statement as to whether the carrier does or will administer any of its health benefits plans using utilization management features, and whether any of the carrier's health benefits plans are managed care plans;

3. If a carrier's health benefits plans incorporate utilization management features or are managed care plans, a statement identifying the carrier's medical director for those health benefits plans, and any other persons responsible for the carrier's utilization management program, along with a description of the appeal process that the carrier uses for its health benefits plans;

4. If a carrier's health benefits plans incorporate utilization management features or are managed care plans, a general description of the nature of each product, including its form number and market name; and

5. A certification that the answers contained in the form are accurate.

8:38A-2.3 Disclosure requirements

(a) Carriers shall provide to each subscriber within no more than 30 days following the effective date of coverage, and upon request thereafter, through a handbook, certificate or other evidence of coverage designed for covered persons, information describing the following:

1. The services or benefits therefor to which a covered person is entitled under the policy or contract, including:

i. All exclusions and limitations with respect to at least physical and occupational therapy, clinical laboratory tests, hospital and surgical procedures, prescription drugs and biologics, radiological examinations and behavioral health services;

ii. All restrictions on accessing covered services, such as the requirement to obtain prior authorization, preadmission certification, or periodic review of ongoing treatment;

iii. A full and clear description of the carrier's policies and procedures governing the provision of emergency and urgent care services or the payment of benefits therefor, including a statement that emergency or urgent care services are not covered, if that is the case; and

iv. All dollar, day, visit or procedure limitations applicable to at least those services set forth at (a)1i above, and the method for exchanging inpatient for outpatient services or vice versa, when such exchanges are permitted under the policy or contract;

2. The responsibility of the covered person to pay deductibles, coinsurance or copayments, as appropriate.

i. Carriers shall clearly distinguish any differences in the covered person's financial responsibility for accessing services within and outside of a carrier's network, when applicable;

i. The time period for correction of the violation, which shall be no less than 30 calendar days from the date of the written notice;

ii. The minimum actions that the carrier is required to take in order to determine at the end of the period whether the carrier has corrected the violation; and

iii. The effect of correction of the violation upon the levying of the civil penalty.

3. An order to cease and desist shall serve as a written notice of an intent to levy a penalty if followed within no more than five business days of the date of service of the order to cease and desist with a written notice including all of the statements required in (b)1 above, except that the effective date of the penalty may be the same as the date of the written notice.

(c) In accordance with the provisions of the act, the Commissioner may seek injunctive relief against a carrier.

SUBCHAPTER 3. UTILIZATION MANAGEMENT

8:38A-3.1 Scope and applicability

(a) This subchapter shall apply to all carriers that incorporate UM in the administration of one or more of their health benefits plans that have been or will be delivered or offered for delivery in this State.

(b) This subchapter shall apply to all health benefits plans in which UM is performed by or on behalf of the carrier in the administration of the health benefits plan.

8:38A-3.2 Disclosure requirements

(a) In addition to the requirements of N.J.A.C. 8:38A-2.3, carriers shall include in the disclosure statements a covered person's right to appeal to the carrier a denial, reduction or termination of health care services or the payment of benefits therefor resulting from a utilization management decision by or on behalf of a carrier, setting forth:

1. A description of the internal appeal procedure, including the address and toll-free telephone number through which the covered person may contact the carrier;

2. The amount of time for a final decision on the appeal; and

3. The process for expediting appeals in urgent or emergency situations.

(b) The statement that a covered person has a right to appeal a carrier's utilization management decision at the option of the covered person through the Independent Health Care Appeals Program, including:

1. The cost to the covered person of making such an appeal (that is, the cost of the application fee), and the right of the covered person to request a waiver from the Department for financial hardship;

2. A statement that the carrier shall bear the costs of the review by the Independent Health Care Appeals Program;

3. A statement that the covered person must file the application for review of the carrier's final decision within 60 days following the date the final decision was issued by the carrier; and

4. A statement that the decision of the Independent Health Care Appeals Program is not binding upon either the carrier or the covered person.

8:38A-3.3 Designation of a medical director

(a) The carrier shall designate a physician licensed to practice medicine in New Jersey to serve as the medical director for the carrier with respect to its contracts or policies delivered in this State to which a utilization management program applies.

(b) The medical director shall be responsible for at least the following:

1. Overseeing the continuing in-service education of professional staff;

2. Providing clinical direction and leadership to the continuous quality improvement and utilization management programs;

3. Establishing policies and procedures covering all utilization management determination criteria and protocols applicable to health care services for which benefits are payable under a carrier's health benefits plans; and

4. Establishing policies and procedures covering all health care services provided to covered persons when the carrier is authorized, and elects, to engage in the direct or indirect provision of health care services.

8:38A-3.4 Utilization management program

(a) A carrier's UM program shall be under the direction of the medical director, or his or her designee (who shall be a physician licensed to practice medicine in the State of New Jersey), and shall be based on a written plan, reviewed annually by the carrier, and available for review by the Department upon request, specifying at least:

1. The scope of the carrier's UM activities;

2. The procedures to evaluate clinical necessity, access, appropriateness, and efficiency of services;

3. The mechanisms to detect underutilization and over utilization of services;

4. The clinical review criteria and protocols used in decision-making;

5. The mechanisms to ensure consistent application of review criteria and uniform decisions;

6. The development of measures for evaluating the carrier's UM program, including outcome and process measures when the carrier utilizes a gatekeeper system or practice guidelines for its managed care product(s);

7. A system for covered persons, and providers on behalf of covered persons (with the covered person's consent) to appeal UM determinations in accordance with the procedures set forth at N.J.A.C. 8:38A-3.5; and

8. A mechanism to evaluate the satisfaction of covered persons with the appeals system, which mechanism shall coordinate with the carrier's CQI program required pursuant to N.J.A.C. 8:38A-3.8.

(b) Carriers shall ensure that UM determinations are based on written clinical criteria and protocols developed with involvement from practicing physicians and other licensed health care providers and based upon generally accepted medical standards.

1. The carrier shall periodically review (no less than annually) and update these criteria as necessary.

2. The carrier shall make the criteria readily available, upon request, to covered persons and interested providers except that internal or proprietary quantitative thresholds for UM is not required to be released to covered persons or providers pursuant to this subchapter.

i. When the request is related to specific treatment or services for which benefits are being sought, the information provided may be limited to all criteria and protocols by which the carrier performs UM relevant to only that treatment or services.

(c) The carrier shall provide access to UM services as follows:

1. For routine utilization-related inquiries, covered persons and providers shall have access to UM staff on, at a minimum, a five-day, 40 hours a week basis through a toll-free telephone number.

2. If the carrier requires preauthorization for use of emergency departments or for reimbursement of services rendered under an emergency or urgent situation, the carrier shall have a registered professional nurse or physician immediately available by phone seven days a week, 24 hours a day to render UM determinations to providers.

(d) The carrier shall have written policies and procedures, available for review by the Department upon request, that address the responsibilities and qualifications of staff who render determinations to authorize admissions, services, procedures or extensions of stay meeting the following:

1. All determinations to deny or limit an admission, service, procedure or extension of stay, or benefits therefor, shall be made in accordance with the clinical and medical necessity criteria developed in accordance with (b) above, and rendered by a physician under the clinical direction of the medical director required pursuant to N.J.A.C. 8:38A-3.3.

i. The physician shall communicate the determination directly to the provider or, if this is not possible, the physician shall supply his or her name, telephone number and where he or she may be reached so that the provider may contact the physician for further discussion.

ii. The physician rendering the determination shall be available immediately to the treating provider in urgent or emergency cases and on a timely basis for all other cases as required by the medical exigencies of the situation.

2. All determinations shall be made on a timely basis, as required by the exigencies of the situation.

(e) A carrier shall not deny reimbursement retroactively for a covered service provided to a covered person by a provider who relied upon the written or oral authorization of the carrier (or its agents) prior to providing the service to the covered person, except in cases where there is material misrepresentation or fraud.

(f) A carrier shall provide written notice within five days, or sooner if the medical exigencies dictate, upon request, of any determination to deny coverage or authorization of services or payment of benefits therefor otherwise covered under the contract or policy of the covered person, and shall include an explanation of the appeal process.

8:38A-3.5 Internal utilization management appeals process

(a) A carrier shall establish an appeal process whereby a covered person or a provider acting on behalf of the covered person, with the covered person's consent, may appeal any UM decision resulting in a denial, termination or limitation of services or the payment of benefits therefor covered under the contract or policy.

(b) Carriers shall detail the appeal process in a writing provided to covered persons at the time of coverage (and periodically as changes occur), upon the occurrence of a utilization management decision adverse to the request of the covered person, upon the conclusion of each stage of the appeal process, and upon request.

(c) Carriers shall provide a written description of the appeal process and the carrier's decision on an appeal to providers upon request, and upon the conclusion of each stage of the appeal process, when the provider is making the appeal on behalf of a covered person with the covered person's consent.

4. The covered person or provider acting on behalf of a covered person with the covered person's consent has provided all information required by the IURO and the Department to make a preliminary determination, including a copy of any information provided by the carrier regarding its decision to deny, reduce or terminate the covered service or payment of benefits therefor, and an executed release of necessary medical records from the carrier and any relevant provider.

(f) Upon completion of the preliminary review, the IURO immediately shall notify the member and/or provider in writing as to whether the application has been accepted for processing of the appeal, and if not, the reasons therefor.

(g) Upon acceptance of the application for processing of the appeal, the IURO shall conduct a full review to determine whether, as a result of the carrier's decision, the carrier inappropriately denied services, or the payment of benefits therefor, for the provision of medically necessary treatment or supplies that were/are covered under the contract or policy, taking into consideration the following:

1. All pertinent medical records, consulting physician reports and other documents submitted by the parties;
2. Applicable generally accepted practice guidelines developed by the Federal government, national or professional medical societies, boards and associations; and
3. Applicable clinical protocols and/or practice guidelines developed or used by the carrier, if any.

(h) The IURO shall conduct its initial full review through a registered professional nurse or physician licensed to practice in New Jersey, and, when necessary, shall refer all cases for review to a consultant physician in the specialty or area of practice that generally would manage the type of treatment that is the subject of the appeal, but shall not render a final recommendation except with the approval of the IURO's medical director.

(i) The IURO shall complete its review and issue its recommendation in writing as soon as possible consistent with the medical exigencies of the case, but in no instance later than 30 business days following the date of receipt of the appeal application, unless additional review time is necessitated by circumstances beyond the control of the IURO.

1. In the event that the IURO may not complete its review within 30 business days, the IURO shall provide written notice to the covered person and his or her provider, the Department and the carrier of this fact prior to the completion of the 30 business day review, but in no event shall the IURO render its decision later than 90 days following receipt of a complete application.

2. The IURO shall specify in the written notice the reasons for the delay, the status of the review, and the anticipated completion date of the full review.

(j) Notwithstanding (i) above, if the appeal involves care for an urgent or emergency case, the IURO shall complete its review within no more than 48 hours following its receipt of the appeal.

(k) The IURO shall set forth in its written recommendation whether the IURO has determined that the covered person was deprived of receipt of or benefits for medically necessary services otherwise covered under his or her contract or policy, and shall specify the services the covered person should receive or receive benefits therefor.

1. The IURO shall submit its recommendation to the covered person and his or her provider (if the provider assisted in filing the appeal with the covered person's consent), the carrier and the Department.

8:38A-3.7 Carrier action on the IURO recommendations

(a) A carrier shall submit a written report to the covered person and his or her provider (if the provider assisted in filing the appeal), the Department and the IURO of its intent to accept and implement or reject the IURO's recommendation(s) within 10 business days of the date that the carrier first receives the recommendation of the IURO.

1. The carrier shall specify its intentions sooner if the medical exigencies of the case warrant a more rapid response.
2. If the carrier rejects one or more of the recommendations of the IURO, the carrier shall specify in its written report every basis for which it has rejected a recommendation.

(b) A carrier that elects to accept and implement one or more of the recommendations of an IURO shall not be liable in any action for damages to any person for any action taken to implement a recommendation, notwithstanding that the carrier may elect to implement only a portion of the IURO's recommendations.

8:38A-3.8 Continuous quality improvement

(a) Carriers shall have or employ a CQI program to monitor the quality of their UM program under the direction of the carrier's medical director.

(b) No later than June 30, 2000, a carrier shall set forth its system for its CQI program in a plan reviewable upon request by the Department specifying the following:

1. The scope and purpose of the program;
2. The organizational structure of quality improvement activities;
3. The duties and responsibilities of the medical director (or designee);

4. Contractual arrangements, if any, for delegation of quality improvement activities;
5. Confidentiality policies and procedures;
6. Specifications of standards for the assessment of the adequacy and appropriateness of health care resources utilized;
7. A system of on-going evaluation activities;
8. A system of monitoring satisfaction of covered persons; and
9. A system for evaluation of the effectiveness of the CQI program.

(c) The carrier shall establish a multidisciplinary CQI committee to be responsible for the implementation and operation of the CQI program, which shall be composed of representatives of the carrier's medical, nursing and administrative staff, with substantial involvement of the carrier's medical director.

1. The committee shall maintain minutes of its meetings, and such minutes shall be reviewable, upon request, by the Department.

2. The committee shall monitor provider and member access to utilization management services including waiting times to respond to phone requests for service authorization, member urgent care inquiries, and other services required for the carrier's UM program.

3. The committee shall prepare an annual report on the carrier's CQI activities, which shall be available for review upon request by the Department and the Department of Banking and Insurance, delineating quality improvements, performance measures used and their results, and demonstrated improvements in service quality, corrective action recommendations, including corrections to policies and procedures of the carrier, and educational activities for covered persons.

(d) The carrier shall follow-up on the findings of its CQI committee to assure that recommendations made are implemented effectively, and shall document the corrective actions taken and the results of their outcome, which documentation shall be reviewable upon request by the Department or the Department of Banking and Insurance.

(e) The carrier shall coordinate its CQI activities with other performance monitoring activities it may have, if any.

(f) The Department's review of a carrier's health benefits plan that has been approved as a selective contracting arrangement is not intended to be duplicative of, but complementary to, the review of the carrier's utilization review program and quality assurance program made pursuant to N.J.A.C. 11:4-37.4(c)11, 12 and 13.

SUBCHAPTER 4. PROVISIONS APPLICABLE TO CARRIERS OFFERING ONE OR MORE HEALTH BENEFITS PLANS THAT ARE MANAGED CARE PLANS

8:38A-4.1 Scope and applicability

(a) This subchapter shall apply to all carriers that have delivered, will deliver or offer for delivery in this State a health benefits plan that is a managed care plan.

(b) This subchapter shall apply to the health benefits plans that have been or will be delivered or offered for delivery in this State by a carrier that are managed care plans.

8:38A-4.2 Disclosures to covered persons

(a) Carriers shall provide to a covered person no later than the effective date of coverage, and at least annually thereafter a current directory of participating providers.

1. The directory shall include all of the medical providers and hospital providers participating in the carrier's network, and may contain other participating providers at the discretion of the carrier.

2. The directory shall distinguish participating providers by provider category or specialty and by county.

3. For participating providers who provide primary care (which may include providers other than providers practicing family or internal medicine, if so designated by the carrier), the directory also shall include:
 - i. The office address of the participating provider;
 - ii. The participating provider's hospital affiliation(s); and
 - iii. An indication of which participating providers have the capacity to communicate in languages other than English.

4. The directory shall include a statement providing the approximate percentage of the carrier's participating physicians that are board certified, and the date on which that percentage was last calculated.

5. If a carrier does not include all of its participating providers within its directory of medical and hospital providers, the carrier shall include a statement in its directory of medical and hospital providers setting forth the categories of other participating providers in the carrier's network, and the means by which a covered person may obtain a written list or lists of such participating providers, distinguished by category and county, free of charge.

3. In the case of oncological treatment, coverage of services by the terminated health care professional shall continue for a period up to one year.

4. In the case of psychiatric treatment, coverage of services by the terminated health care professional shall continue for a period of up to one year.

5. The carrier is not required to continue coverage in those instances in which the health care professional has been terminated based upon: the opinion of the carrier's medical director that the provider is an imminent danger to one or more covered persons or the public health, safety and welfare, a determination of fraud, or a breach of contract by the provider or the health care professional is the subject of disciplinary action by the State Board of Medical Examiners.

6. The determination as to the medical necessity of a covered person's continued treatment with a terminated health care professional shall be subject to the appeal procedures set forth at N.J.A.C. 8:38A-4.12.

7. Notwithstanding (d) above, when termination is by the health care professional, the contract shall include a provision requiring the health care professional to continue to provide services at the contracted price to covered persons who are patients of the health care professional immediately prior to the date of termination for 30 days following the date of termination, but for the remainder of the four-month period only in cases where it is medically necessary for the covered person to continue treatment with the terminated health care professional, except as (d)1 through 4 above may apply.

(e) The carrier shall establish policies regarding the termination of providers other than health care professionals.

(f) The carrier shall establish a policy and procedure, reviewable upon request by the Department or the Department of Banking and Insurance, addressing the following:

1. Methods by which the termination policy shall be made known to providers upon initial participation and on renewal; and

2. Methods by which the termination policy regarding providers shall be made known to covered persons at the time of enrollment and on a periodic basis.

8:38A-4.9 Hearings for provider terminations

(a) A health care professional shall have the right to request a hearing in writing with respect to termination of the health care professional from a carrier's network within 10 business days following the date of the notice.

1. A contract shall be deemed to have terminated, creating the right to a hearing, whenever a contract terminates on any date other than a designated renewal or anniversary date of the contract, except that no such

right shall exist with respect to terminations described at N.J.A.C. 8:38A-4.8(b).

2. If no renewal or anniversary date is specified in the contract, then the renewal or anniversary date shall be deemed to be the month and day in each calendar year on which the contract was originally signed by both parties, or became effective, whichever date is latest.

(b) The carrier shall hold a hearing within 30 days following receipt of a written request for a hearing by a terminated health care professional before a panel appointed by the carrier.

1. The panel shall consist of no less than three people.

2. At least one person on the panel shall be a clinical peer in the same or substantially similar discipline and specialty as the provider requesting the hearing.

3. The carrier shall not preclude the provider from being present at the hearing, nor shall the carrier preclude the provider from being represented by counsel at the hearing.

(c) The panel shall render a decision on the matter in writing within 30 days of the close of the hearing unless the panel provides notice of a need for an extension for rendering its decision, and provides the notice to both the carrier and the health care professional prior to the date the panel's decision would otherwise be due.

1. The panel's decision shall set forth the relevant contract provisions and the facts upon which the carrier and the provider have relied at the hearing.

2. The panel shall recommend that the provider be terminated, reinstated or provisionally reinstated.

3. The panel shall specify its reasons for its recommendations, including the reasons for any conditions for provisional reinstatement.

4. The panel shall specify the conditions for provisional reinstatement, the duration of the conditions, and the consequences of a failure to meet the conditions.

5. In the event of reinstatement or provisional reinstatement, the panel shall specify the impact of the reinstatement upon the terms of duration of the contract at issue.

(d) In the event that the panel recommends that the health care professional be terminated, the carrier shall then provide notice of the termination to covered persons in accordance with N.J.A.C. 8:38A-4.8(c), as necessary.

8:38A-4.10 Network adequacy

(a) Except with respect to any selective contracting arrangement approved on or before May 1, 2000 pursuant to N.J.A.C. 11:4-37, a carrier shall maintain an adequate network, as set forth in (b) below, of PCPs, specialists and other ancillary providers to assure that covered persons are

able to access services in-network and take full advantage of the in-network benefits levels when the policy or contract specifies that there is a differential between the in-network and out-of-network benefits levels for one or more covered services, or the policy or contract is subject to a gatekeeper system.

1. The requirement that the network meet the adequacy standards of (b) below shall apply only to those services for which there is an in-network benefit, and if no in-network benefit exists for a specific service, the carrier is not required to meet the network adequacy standards with respect to the type of provider who typically renders that service.

2. Notwithstanding that a contract or policy may not be subject to a gatekeeper system, if the contract or policy requires that each covered person select or have a PCP, the carrier shall comply with (b) below with respect to the offering of that policy or contract.

(b) The carrier shall meet the following requirements for network adequacy:

1. The carrier shall have a sufficient number of physicians to assure that at least two physicians eligible as PCPs are within 10 miles or 30 minutes driving time or public transit time (if available), whichever is less, of 90 percent of the carrier's covered persons.

i. The carrier shall demonstrate sufficiency of network PCPs to meet the adult, pediatric and primary ob/gyn needs of the current and/or projected number of covered persons by assuming:

(1) Four primary care visits per year per member, averaging one hour per year per member; and

(2) Four patient visits per hour per PCP.

ii. To demonstrate PCP availability, a carrier shall verify that the PCP has committed to providing a specific number of hours for new patients that cumulatively add up to projected clinic hour needs of the projected number of covered persons by county or service area.

iii. The carrier shall demonstrate that the network of PCPs is sufficient to ensure that:

(1) If the carrier provides benefits for emergency services:

(A) Emergencies shall be triaged immediately through the PCP or by a hospital emergency department through medical screening or evaluation;

(B) Urgent care shall be provided within 24 hours of notification of the PCP or carrier; and

(C) In both emergent and urgent care, PCPs shall be required to provide seven day, 24 hour access to triage services;

(2) Routine appointments can be scheduled within at least two weeks; and

(3) Routine physical exams can be scheduled within at least four months.

2. The carrier shall have a sufficient number of the medical specialists, as applicable to the services covered in-network, to assure access within 45 miles or one hour driving time, whichever is less, of 90 percent of covered persons within each county or approved sub-county service area.

i. The carrier shall contract with a sufficient number of optometrists to assure access to an optometrist consistent with the requirements of (b)2 above, and the carrier shall not require that covered persons use the services of an ophthalmologist rather than an optometrist in order to obtain benefits, unless referral by a PCP is determined to be medically required, and the care needed outside the scope of practice of an optometrist.

3. For institutional providers, the carrier shall maintain contracts or other arrangements acceptable to the Department sufficient to meet the medical needs of covered persons, and maintain geographic accessibility of the services provided through institutional providers, subject to no less than the following:

i. The carrier shall have a contract or arrangement with at least one licensed acute care hospital with licensed medical-surgical, pediatric, obstetrical and critical care services in any county or service area that is no greater than 20 miles or 30 minutes driving time, whichever is less, from 90 percent of covered persons within the county or service area.

ii. The carrier shall have a contract or arrangement with surgical facilities, including acute care hospitals, licensed ambulatory surgical facilities, and/or Medicare-certified physician surgical practices available in each county or service area that are no greater than 20 miles or 30 minutes driving time, whichever is less, from 90 percent of covered persons within the county or service area.

iii. The carrier shall have a contract or otherwise agree to cover medically necessary trauma services at a reasonable cost with all Level I or II trauma centers designated by the Department pursuant to N.J.A.C. 8:33P, with the provision of benefits at the in-network level.

iv. The carrier shall have contracts or arrangements for the provision of the following specialized services at in-network benefit levels (if covered by one or more of the carrier's health benefits plans in network, and determined to be medically necessary), so that services will be available within 45 miles or 60 minutes average driving time, whichever is less, of 90 percent of covered persons within each county or service area:

- (1) At least one hospital providing regional perinatal services;
- (2) A hospital offering tertiary pediatric services;
- (3) In-patient psychiatric services for adults, adolescents and children;
- (4) Residential substance abuse treatment centers;
- (5) Diagnostic cardiac catheterization services in a hospital;
- (6) Specialty out-patient centers for HIV/AIDS, sickle cell disease, hemophilia, and cranio-facial and congenital anomalies; and
- (7) Comprehensive rehabilitation services.

v. The carrier shall have a contract or arrangement so that the following specialized services may be provided at in-network benefit levels (if covered by one or more of the carrier's health benefits plans in network, and determined to be medically necessary), so that services will be available within 20 miles or 30 minutes average driving time, whichever is less, of 90 percent of covered persons within each county or service area:

- (1) A licensed long-term care facility with Medicare-certified skilled nursing beds;
- (2) Therapeutic radiation;
- (3) Magnetic resonance imaging center;
- (4) Diagnostic radiology, including x-ray, ultrasound, and CAT scan;
- (5) Emergency mental health service, including a short term care facility for involuntary psychiatric admissions;
- (6) Outpatient therapy for mental health and substance abuse conditions; and
- (7) Licensed renal dialysis.

vi. The carrier shall have a contract or arrangement with at least one home health agency licensed by the Department to serve each county where 1,000 or more covered persons reside.

vii. The carrier shall have a contract or arrangement with at least one hospice program certified by Medicare in any county where 1,000 or more covered persons reside, if hospice care is covered under the health benefits plan in-network.

(c) With respect to the provider specifications of (b)4 above, the carrier may request, and will receive, relief from the mileage requirements where the carrier can document to the satisfaction of the Department that appropriate access to alternative sites is available, but documentation shall address travel accommodations and travel times, financial hardship placed on families and other logistical details as

requested by the Department from the carrier in order to be a valid request.

(d) In any county or approved service area in which 20 percent or more of a carrier's projected or actual number of covered persons must rely upon public transportation to access health care services, as documented by U.S. Census Data, the driving times set forth in the specifications of (b) above shall be based upon average transit time using public transportation, and the carrier shall demonstrate how it will meet the requirements in its application.

(e) The carrier shall not deny any registered pharmacy or pharmacist the right to participate as a preferred provider if the carrier provides pharmacy services, prescription drugs, or a prescription drug plan and the pharmacy meets the carrier's standards for participation.

1. Carriers shall comply with rules, if any, promulgated by the Department of Banking and Insurance applicable to the type of carrier.

(f) Those providers qualified to function as PCPs may include:

1. A licensed physician who has successfully completed a residency program accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association in family practice, internal medicine, general practice, obstetrics and gynecology or pediatrics;

2. A licensed physician who does not meet the standards of (e)1 above, but who has been evaluated by the carrier's committee charged with setting standards for and reviewing provider credentialing under the direction of the carrier's medical director, and is found by that committee to demonstrate through training, education and experience, equivalent expertise in primary care;

3. Nurse practitioners/clinical nurse specialists certified by the State Board of Nursing in accordance with N.J.S.A. 45:11-45 et seq. in advance practice categories comparable to family practice, internal medicine, general practice, obstetrics and gynecology or pediatrics, and in hospitals or other facilities;

4. Physician assistants licensed by the New Jersey Board of Medical Examiners;

5. Certified nurse midwives registered by the New Jersey Board of Medical Examiners; and

6. At the discretion of the carrier, appropriate, licensed medical specialists for specified individual covered persons or patient groups who, due to health status or chronic illness, would benefit from medical care management by such a medical specialist.

8:38A-4.11 Utilization management program

(a) A carrier shall comply with N.J.A.C. 8:38A-3.4.

(b) In addition to (a) above, the carrier shall comply with the following:

1. The carrier shall develop its UM criteria and protocols with involvement from its participating providers in accordance with N.J.A.C. 8:38A-4.14; and
2. For contracts or policies in which emergency and/or urgent care services are covered, and preauthorization may be required, the carrier shall establish a mechanism to ensure that covered persons have immediate access to their PCP or his or her authorized on-call back-up provider, and that all covered persons have access to a registered nurse or physician on the UM staff to respond to inquiries concerning emergency or urgent care seven days per week, 24 hours per day.

8:38A-4.12 Internal utilization management appeal process

(a) A carrier shall establish an internal appeal mechanism whereby a covered person or a provider acting on behalf of a covered person, with the covered person's consent, may appeal any decision to deny, reduce or terminate services or the payment of benefits therefor covered under the contract or policy, in compliance with N.J.A.C. 8:38A-3.5.

(b) In addition to the requirements set forth in (a) above, a carrier shall provide a written explanation of the appeal process to all of its network providers, and to other providers upon request, as well as at the conclusion of each stage of the appeal process.

(c) In addition to (a) and (b) above the carrier shall not establish or maintain policies, procedures or set forth anything in provider agreements that prohibit or discourage a covered person or provider from discussing or exercising the right to an appeal available under this subchapter, or the right to an external appeal through the Independent Health Care Appeals Program at N.J.A.C. 8:38A-3.6.

8:38A-4.13 Continuous quality improvement

(a) In addition to complying with N.J.A.C. 8:38A-3.8, carriers shall comply with the requirements of N.J.A.C. 8:38-7.1 not otherwise included in N.J.A.C. 8:38A-3.8.

(b) A carrier shall have performed and shall submit to the Department, by May 1, 2002 or entrance of the carrier into the managed care plan market, and every 36 months thereafter, documentation of its most recent external quality audit performed by an external quality audit review organization approved by the Department.

1. The carrier shall submit the documentation to the Department within 60 days of its receipt in final form by the external quality review organization.
2. The carrier shall make such documentation available to the Department of Banking and Insurance upon request.

(c) The documentation shall describe in detail the carrier's conformance to the standards of the external quality review organization, other standard-setting bodies for carriers of the category to which the carrier belongs, and/or the rules of this State applicable to the carrier and its managed care plans.

1. The documentation also shall describe any recommended corrective actions for the carrier, and whether or not the corrective actions have been undertaken by the carrier and approved, in whole or in part, by the external quality review organization.

(d) The Department shall grant a deferral to a carrier, upon its request, of the requirements of (c) above for up to a 12-month period if it is the initial three years of start-up of the carrier's operations in New Jersey, and it demonstrates a financial or operational hardship.

(e) The Department shall establish a Healthcare Data Committee (HeDaC) to assist the Department in developing a performance measurement and assessment system for monitoring the quality of care provided to covered persons as described in N.J.A.C. 8:38A-3.8, the quality of care provided to the covered persons of carriers subject to this subchapter, and the quality of care provided to members of HMOs.

1. The HeDaC shall include no more than 15 and no less than 12 members who shall be appointed by, and serve at the pleasure of, the Commissioner. The members shall include providers, consumers, at least four insurer representatives, no more than two HMO representatives, and two other persons representing the interests of carriers. In addition to the above, a representative of the New Jersey State Health Benefits Commission and the Departments of Banking and Insurance and Human Services shall serve as additional ex-officio members. The HeDaC shall be chaired by the Commissioner or his or her designee. Additional experts may be invited to participate on an invitational ad hoc basis as needed.

2. The HeDaC shall advise the Commissioner on the development of a uniform data reporting system to obtain reliable, standardized and comparable information from all carriers subject to this subchapter, and HMOs. In the process of developing this system, the HeDaC shall address the following:

- i. The relevance, validity and reliability of each measure selected to be an indicator of performance;
- ii. The protection of confidentiality of patient-specific information;
- iii. The cost and difficulty of data collection;
- iv. The measures to reduce duplicative reporting of information to state agencies; and
- v. The public release of data in formats useful to purchasers and/or consumers.

3. The HeDaC shall advise the Commissioner as to the data reporting established pursuant to (e)2 above that should be applicable to carriers that are subject to N.J.A.C. 8:38A-3.8, if any, and shall advise the Commissioner as to the appropriate data reporting to obtain from such carriers.

8:38A-4.14 Provider input on protocols

(a) A carrier shall develop written clinical criteria and protocols and shall base its UM determinations upon such clinical criteria and protocols.

1. The carrier shall develop its clinical criteria and protocols with the input of practicing physicians and other health care providers within the carrier's network.

2. The carrier's clinical criteria and protocols shall be based upon generally accepted medical standards.

(b) A carrier shall periodically review and update its clinical criteria and protocols, and maintain evidence of such periodic reviews.

(c) A carrier's clinical criteria and protocols, as well as evidence of its most recent review and updating (if appropriate) of its clinical criteria and protocols, shall be made available, upon request, to covered persons and participating providers in relevant practice areas, as well as the Department.

(d) Notwithstanding (c) above, a carrier's internal or proprietary quantitative thresholds for UM shall be confidential, and shall not be required to be released pursuant to (c) above.

8:38A-4.15 Minimum standards for provider contracts

(a) Both primary contractor and secondary contractor agreements shall be consistent with laws regarding confidentiality of information and shall not be so worded that compliance with the terms of the contract would cause any health care provider to violate his or her professional licensing standards, including, but not limited to, N.J.S.A. 45:14B-31 et seq., and shall comply with the standards of (b) through (e) below.

(b) In addition to complying with N.J.A.C. 11:4-37, all provider contracts shall specify:

1. The term of the contract and reasons for which the contract may be terminated by one or more parties to the contract, including the procedures for notice and effectuation of such termination, and opportunities, if any to cure any deficiencies prior to termination, subject to the following:

i. Provisions regarding notice of termination shall specify that if the contract is terminated prior to the contract's renewal date, the carrier shall give the provider at least 90 days prior written notice; and, that in the event of such a termination, the provider has a right

to request a hearing following such notice except in enumerated circumstances consistent with N.J.A.C. 8:38A-4.9;

ii. Provisions regarding contents of the notice of termination to be provided shall specify that the notice shall contain a statement as to the right of the provider to obtain a reason for the termination in writing from the carrier if the reason is not otherwise stated in the notice; the right of the provider to request a hearing, and any exceptions to that right; and, the procedures for exercising either right;

iii. Provisions regarding the hearing shall set forth the procedures for requesting a hearing, and otherwise shall be consistent with the standards set forth at N.J.A.C. 8:38A-4.9;

iv. Provisions regarding the hearing shall include a statement that a provider's participation in the hearing process shall not be deemed to be an abrogation of the provider's legal rights; and

v. Provisions regarding the right of the provider to request from the carrier the reasons for the termination shall specify the procedure for the provider to make the request, and that the carrier's reason in response to the request shall be in writing;

2. That no provider may be terminated or penalized because of filing a complaint or appeal as permitted by these rules;

3. That no provider may be terminated or penalized for acting as an advocate for the patient in seeking appropriate, medically necessary health services;

4. That a provider shall continue to provide services to covered persons at the contract price following termination of the contract, in accordance with N.J.A.C. 8:38A-4.8;

5. The method of reimbursement, including the method, events and timing of application of any penalties, bonuses or other types of compensation arrangements, subject to the following:

i. The contract shall not provide financial incentives to the provider for the withholding of covered health care services that are medically necessary, but this shall not prohibit or limit the use of capitation arrangements between the carrier and provider;

ii. To the extent that some portion of the provider compensation is tied to the occurrence of a pre-determined event, or the nonoccurrence of a pre-determined event, the event shall be clearly specified, and the carrier shall include in its contracts a right of each provider to receive a periodic accounting (no less frequently than annually) of the funds held;

iii. The contract shall include a process whereby a provider may appeal a decision denying the provider

additional compensation, in whole or in part, in accordance with any compensation arrangement tied to the occurrence or nonoccurrence of a pre-determined event; and

iv. Notwithstanding (a)5i above, capitation shall not be used as the sole method of reimbursement to providers who primarily provide supplies (for instance, prescription drugs or durable medical equipment) rather than services;

6. The services and/or supplies to be provided by the provider and for which benefits will be paid by the carrier;

7. That providers shall not discriminate in their treatment of the carrier's covered persons;

8. That providers shall comply with the carrier's utilization review program, and quality assurance program as applicable to the provider;

9. That patient information shall be kept confidential, but that the carrier and the provider shall engage in timely and appropriate communication of patient information, so that both the providers and the carrier may perform their respective duties efficiently and effectively for the benefit of the covered person;

10. The process for an internal provider complaint and grievance procedure to be used by participating providers, pursuant to N.J.A.C. 8:38A-4.6(b); and

11. That the provider shall have the right to communicate openly with a patient about all diagnostic testing and treatment options.

(c) In addition to (b) above, all primary care provider contracts and contracts with specialists shall specify:

1. The responsibility, if any, of the provider with respect to acquiring and maintaining hospital admission privileges; and

2. The mutual responsibility of the provider and carrier to assure 24 hour, seven-day a week emergency and urgent care services and benefits therefor to covered persons, as appropriate to the carrier's managed care plans, and the procedures to assure proper utilization of such coverage.

(d) In addition to (b) above, all health care facility contracts shall specify:

1. The responsibility of the health care facility to follow clear procedures for granting of admitting and attending privileges to physicians, and to notify the carrier when such procedures are no longer appropriate;

2. The admission authorization procedures for covered persons;

3. The procedures for notifying the carrier when covered persons present at emergency departments, if notice is necessary to assure payment of benefits (other than a screening fee); and

4. The procedures for billing and payment, schedules, and any negotiated arrangements.

(e) No contract with any provider shall impose obligations or responsibilities upon a provider which require the provider to violate the statutes or rules governing licensure of that provider if the provider is to comply with the terms of the contract.

(f) The form(s) of the provider agreements, and any amendments thereto, shall be submitted to the Department for prior approval.

(g) Provider agreements in effect on May 1, 2000 that are not in compliance with the requirements of this subchapter shall be deemed withdrawn on May 1, 2001.

8:38A-4.16 Reporting of quality outcome measures and compensation arrangements

(a) Carriers shall comply with the reporting requirements established by the HeDaC, which shall be promulgated by the Department in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., which shall include independent consumer satisfaction survey results and an analysis of quality outcomes of health care services.

1. The Department may use the information collected to:

i. Assist carriers and their providers in quality improvement efforts;

ii. Obtain information on the performance of carriers for regulatory oversight;

iii. Support efforts to inform consumers about carrier performance with respect to managed care health benefits plans;

iv. Promote the standardization of data reporting by carriers and providers; and

v. Any other purpose consistent with this chapter and N.J.S.A. 26:2S-1 et seq.

2. The performance and outcome measures shall include population-based and patient-centered indicators of quality of care, appropriateness, access, utilization, and satisfaction.

3. When possible, the performance measures shall be designed to incorporate data routinely collected or available to the Department from other sources.

4. When appropriate, the Department shall make statistically valid adjustments to account for demographic variations among carriers.

5. Carriers shall have an opportunity to comment on the compilation and interpretation of the data before its release to consumers.

6. Each carrier shall provide the Department with a mailing list of covered persons, upon request, so that the Department may conduct or arrange for periodic member satisfaction surveys using a select sample of the carrier's covered persons.

7. Carriers shall submit data established by the HeDaC and other information required by this subsection as the Department may request from time to time.

8. The Department shall ensure the confidentiality of patient-specific information, and shall make every attempt to reduce duplicative reporting of information to agencies in New Jersey.

(b) Carriers shall comply with the requirements of N.J.A.C. 8:38-11.7, submitting the information in conjunction with their financial statements required to be filed annually on March 1.

1. For purposes of complying with this requirement, carriers shall submit information for all of its managed care plan business by line, separated by Medicaid (if any), Medicare (if any), Medicare supplement (if any) and non-Medicare business if the carrier has different compensation arrangements for these lines of business.

2. A carrier with an HMO affiliate shall submit its data for its HMO and non-HMO affiliates separately.

8:38A-4.17 Requirement to offer a managed care plan without a gatekeeper system

(a) A carrier may offer a managed care plan with a gatekeeper system, but a managed care plan with a gatekeeper system shall not be the only type of managed care plan that the carrier offers in this State, except as (b) below may apply to the carrier.

(b) A carrier that offers a managed care plan with a gatekeeper system shall be deemed to be in compliance with (a) above if:

1. The carrier also offers a selective contracting arrangement approved in accordance with N.J.A.C. 11:4-37;

2. The approved policy or contract allows a covered person to receive services covered under the policy or contract or receive payment of benefits therefor from providers not in the carrier's network of participating providers without obtaining a referral or prior authorization from the carrier; and

3. The carrier provides subscribers under all group health plans in which the contractholder offers one of the carrier's contracts or policies provided in conjunction with an approved selective contracting arrangement an opportunity to elect coverage under the contract(s) or policy(ies) provided in conjunction with a selective contract-

ing arrangement on at least an annual basis following a written notice to the subscribers setting forth the details of the contract(s) and policy(ies) provided in conjunction with the selective contracting arrangement.

SUBCHAPTER 5. INDEPENDENT HEALTH CARE APPEALS PROGRAM

8:38A-5.1 General requirements

(a) The Department shall be responsible for the operation of the Independent Health Care Appeals Program.

1. The Department shall combine the Independent Health Care Appeals Program with the External Appeals program set forth under N.J.A.C. 8:38-8-7, but, in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., may amend the standards set forth at N.J.A.C. 8:38-8.7 as necessary to make the appeal process more effective for covered persons insured through contracts or policies of carriers that are not HMOs.

2. The general qualifications of and standards of practice for IUROs participating in the Independent Health Care Appeals Program are set forth at N.J.A.C. 8:38-8.8.

3. The Department shall establish a per case reimbursement schedule for all IUROs that participate in the Independent Health Care Appeals Program, based on the bids obtained by IUROs.

(b) Carriers who are the subject of an appeal through the Independent Health Care Appeals Program shall be responsible for paying the cost of the appeal.

1. The carrier shall be responsible to pay the per case cost that is applicable on the date that the preliminary review of the appeal is completed by the IURO.

2. The carrier shall submit payment to the IURO for the appeal no later than 30 days following the date that the IURO renders its final recommendation in writing to the Department.

8:38A-5.2 Department review of carrier actions on IURO recommendations

(a) The Department shall periodically review records of carrier reports submitted pursuant to N.J.A.C. 8:38A-3.7 to determine whether a carrier exhibits a pattern of noncompliance with the recommendations of an IURO as well as possible violations of patient rights or other applicable laws.

(b) If the Department determines that a carrier exhibits a pattern of noncompliance with the recommendations of an IURO, the Department shall review:

1. Whether the carrier's noncompliance is with a specific set of recommendations;

2. Whether the carrier's noncompliance is with a specific IURO (in the event more than one IURO participates in the Independent Health Care Appeals Program); and

3. The carrier's utilization management program, if any.

(c) If the Department determines that the carrier's utilization management program is not in compliance with the utilization management standards set forth at N.J.A.C. 8:38A-3.4 and 4.11, as applicable, or other relevant laws, the Department shall:

1. Notify the Department of Banking and Insurance of the violation; and

2. Take action(s) as deemed appropriate, in the discretion of the Commissioner, if any, pursuant to N.J.A.C. 8:38A-2.7.

(d) If the Department determines that the carrier is in violation of patient rights or other applicable regulations, the Department shall:

1. Notify the Department of Banking and Insurance of the violation; and

2. Take action(s) as deemed appropriate, in the discretion of the Commissioner, if any, pursuant to N.J.A.C. 8:38A-2.7.

(e) A pattern of noncompliance shall mean the occurrence of multiple incidents of refusal to follow the recommendations of the IURO, in whole or in part, within a 12 month period, when such recommendations require the carrier to provide services or benefits therefor to a covered person.

APPENDIX

Exhibit 1

New Jersey Department of Health and Senior Services

Office of Managed Care

PO Box 360

Trenton, NJ 08625-0360

AN EXPLANATION OF THE INDEPENDENT HEALTH CARE APPEAL PROCESS

A covered person, and any provider acting on behalf of a covered person with the covered person's consent, who is dissatisfied with the results of a carrier's internal appeal process shall have the right to pursue his or her appeal to an Independent Utilization Review Organization (IURO).

A covered person, or a provider acting on behalf of a covered person, **MUST** comply with the carrier's internal appeal process **BEFORE** an appeal can be made to an IURO.

An appeal to the IURO must be made within 60 days of the date a final decision was issued by the carrier. An IURO designated by the New Jersey Department of Health and Senior Services will determine whether the covered person was deprived of a medically necessary covered service, as a result of the carrier's utilization management determination. The Department shall assign appeal requests to an approved IURO.

Preliminary Review:

Upon receipt of the request for appeal from the Department, the IURO will conduct a preliminary review of the appeal and accept it for processing if it determines that:

1. The individual was a covered person of the carrier at the time of the action on which the appeal is based;
2. The service which is the subject of the complaint or appeal reasonably appears to be a covered service under the benefits provided by contract to the covered person;
3. The covered person, or provider acting on behalf of the covered person, has completed the carrier's internal appeals process; and
4. The covered person, or provider acting on behalf of the covered person with the covered person's consent, has provided all information required by the IURO and Department to make the preliminary determination. This information includes the appeal form, a copy of any information provided by the carrier regarding its decision to deny, reduce or terminate the covered service, and a fully executed release to obtain any necessary medical records from the carrier and any other relevant health care provider.

The IURO will complete the preliminary review and notify the covered person and/or provider in writing as to whether the appeal has been accepted for processing and if not so accepted, the reasons therefor within 5 business days of receipt of the request.

Full Review of Appeal:

Upon acceptance of the appeal for processing, the IURO shall conduct a full review to determine whether, as a result of the carrier's utilization management determination, the covered person was deprived of medically necessary covered services. In reaching this determination the IURO shall take into consideration all information submitted by the parties and information deemed appropriate in the opinion of the IURO including: pertinent medical records, consulting physician reports and other documents submitted by the parties, any applicable, generally accepted practice guidelines developed by the Federal government, national or professional medical societies, boards and associations, and any applicable clinical protocols and/or practice guidelines developed by the carrier.

1. The IURO shall complete its review and issue its recommended decision as soon as possible in accordance with the medical exigencies of the case which, except as provided for herein, in no event shall exceed 30 business days from receipt of all documentation necessary to complete the review.