

**INSURANCE
DEPARTMENT OF BANKING AND INSURANCE
DIVISION OF INSURANCE**

Health Maintenance Organizations

Readoption with Amendments: N.J.A.C. 11:24

Proposed: August 20, 2007 at 39 N.J.R. 3466(a)

Adopted: February 15, 2008 by Steven M. Goldman, Commissioner, Department of Banking and Insurance.

Filed: February 15, 2008 as R, 2008 d.60, **without change**.

Authority: N.J.S.A. 17:1-8.1, 17:1-15e, 26:2J-21, 26:2S-18 and 17B:30-54.

Effective Date: February 15, 2008, Readoption;
March 17, 2008, Amendments.

Expiration Date: February 15, 2013

Summary of Public Comments and Agency Responses:

The Department received comments from the New Jersey Association of Mental Health Agencies, Inc. (NJAMHA), Medical Society of New Jersey (MSNJ), New Jersey Academy of Family Physicians (NJAFP), CARES Foundation, Inc., New Jersey Chapter of the March of Dimes Foundation, New Jersey Association of Long Term Care Pharmacy Providers (NJALTCPP), Carrier Clinic, Raritan Bay Medical Center (RBMC), and New Jersey Hospital Association (NJHA).

COMMENT: Several comments concerned the proposed readoption of N.J.A.C. 11:24-18, Drug Formularies. One commenter stated that many children with special health care needs rely upon state health care assistance programs like Medicaid and NJ Family Care, and utilization of a drug formulary by HMOs would threaten patients' ability to access the medicines

that they need. The commenter urged the Department to reconsider the inclusion of a drug formulary in the HMO regulations.

RESPONSE: While the Department understands the commenters' concerns, the Department reiterates its position at the time the drug formulary rules were proposed. As stated in the rule proposal Summary (see 32 N.J.R. 211(a)), the goal in adopting the rules was to see that reasonably priced drug coverage was provided while ensuring that quality of care was not jeopardized. The Department believes that goal was accomplished in that the rules set standards for formulary usage that require the provision of benefits for nonformulary drugs, require formularies to include at least one drug for each covered disease state, provide for expedited appeals, and mandate distribution of the formulary. The commenters are reminded that these rules were promulgated in response to concerns raised by providers that there were no standards governing an HMO's use of drug formularies and that without these rules, there would be no standards governing an HMO's use of drug formularies.

COMMENT: Five commenters expressed their concern with HMOs using a process whereby physician prescribed medications are routinely denied and patients are forced to try and fail a number of less effective drugs before being treated with a clinically proven appropriate agent. This process is known as "step edits," "step therapy," "precertification," "try and fail" requirements, or "first fail" requirements. The commenters further stated that in many instances the HMO recommended prerequisite choices are not FDA approved for the treatment indication requested for a given patient. The commenters urged the Department to include language in the drug formularies subchapter proposed for readoption stating that a formulary shall not include step edits or a requirement to try and fail other formulary drugs first.

Four comments concerned proposed N.J.A.C. 11:24-18.2, Nonformulary medications. The commenters stated that physicians and pharmacists have seen a significant increase in the number of prior authorization denials for medications used for clinically appropriate indications. More specifically, the commenters stated that HMOs have violated the original intent of the regulation by denying medications not based on clinical reasons but on an attempt to enforce step edit designs, by directing physicians to try and fail non-FDA approved medications for a specific diagnosis before approving the physician's clinically recommended medication, by continuing to change approval criteria, and by denying patients who have a history of being well maintained on a particular drug. The commenters requested that N.J.A.C. 11:24-18.2(c)2, which describes instances when a nonformulary medication shall be considered medically necessary, be amended to read as follows: "The prescribing health care provider states that the patient is currently well managed on a therapy, or the physician states the drug is 'medically necessary,' or all formulary medications used to treat a disease state have been ineffective in the treatment of the covered person's disease or condition, or all such medications have caused or are reasonably expected to cause adverse or harmful reactions, or would be less effective, in the covered person."

RESPONSE: The commenters' suggested changes are substantive in nature, and would require the Department to give separate and additional public notice and an opportunity for public comment if the Department wished to pursue the suggestions at this time. The Department is currently in the process of formulating rulemaking proposals intended to address several issues related to the operations of HMOs including network adequacy, provider agreements, the content of network directories and preauthorization requirements. It is anticipated that these deliberations will result in several proposals which may not necessarily be published simultaneously. In the interim, the Department has concluded that at this time it is

necessary and appropriate for all of N.J.A.C. 11:24 to remain in effect without interruption. However, the Department will consider these comments in the course of its formulation of the proposals referenced above and will specifically address the points raised concerning the precertification process and preauthorization denials when it proposes a rule directed to those practices.

COMMENT: One commenter expressed its support for the proposed addition of N.J.A.C. 11:24-5.3(c) making the section consistent with language included in the Health Claims Authorization, Processing and Payment Act (HCAPPA) regarding hospital and physician reimbursement for covered emergency and urgent care services provided in a Level I or II trauma center or hospital. Two commenters expressed their concern that the proposed amendment could be open to interpretation and may have the unintended result of increasing the number of denied claims for emergency room screening services, even more than reflected in current practices.

RESPONSE: As noted by one of the commenters, the proposed language is consistent with language contained in the HCAPPA (P.L. 2005, c. 352, §7, now codified at N.J.S.A. 17B:30-54). Regarding the second commenters' concern, the rules of the Department of Health and Senior Services addressing emergency department and trauma services define "medical screening examination" at N.J.A.C. 8:43G-12.6 as "an examination and evaluation within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, performed by qualified medical personnel (as defined below and specified by hospital by-laws or policies and procedures) to determine whether or not an emergency medical condition exists." Accordingly, this definition requiring coverage of tests

to determine whether a person's condition is emergent even when the test results indicate that no emergency existed, would prohibit an HMO from denying an emergency room claim with respect to such tests on medical necessity grounds.

COMMENT: Three commenters referenced the Department's acknowledgment in the proposal Summary that following the adoption of the HCAPPA, substantive changes are needed to the HMO rules. The commenters agreed with the Department, especially since the rules have not been updated since the Department of Health and Senior Services readopted them in 2002, despite recent changes in healthcare delivery that would be appropriate for inclusion (such as the availability of long-term acute care hospitals for network services). The commenters suggested that several amendments be proposed:

The commenters' first suggestion concerned the proposed replacement of the current language at N.J.A.C. 11:24-5.3(b)5 with HCAPPA-compliant language, stating that carriers shall reimburse hospitals and physicians for "all medically necessary emergency and urgent health care services covered under the health benefits plan, including all tests necessary to determine the nature of an illness or injury." According to the commenters, the current language has been misinterpreted to mean that if testing and treating emergent symptoms ultimately results in a more benign diagnosis, an emergent medical condition did not exist and the tests were not medically necessary. The intent of the prudent layperson standard, which allows a reasonable person who believes that immediate medical care is warranted to access care at the emergency department, has been eroded over the years. Today, carriers often deny such claims simply because the patient responded to medical treatment and was stabilized (such as during acute asthma episodes). In such cases, the carrier deems the visit non-emergent. The commenters are

concerned that the proposed language may have the same effect as the current language, and requested that the Department exercise its discretion to re-draft the amendment to reflect the intent of the HCAPPA provision despite the restrictions inherent in the statutory language. For example, stating that reimbursement must be made for medically necessary tests allows carriers to decide after the patient has been stabilized and released that the tests conducted to ensure the patient was clinically ready for discharge were not medically necessary. Decisions regarding what constitutes an emergency are based upon the symptoms presented and not the ultimate diagnosis. Moreover, the commenters noted that the suggestion that hospitals must first determine whether a test is covered under the health benefits plan before providing it in the emergency department is misleading. Hospitals that do so could be violating Federal law, and it is not in the best interest of the patient to withhold treatment until coverage can be determined. The commenters requested that the Department specify that the carrier must cover tests even if in the end the purpose of the visit is determined by the HMO to be non-emergent. They further state that if a carrier determines the service was not medically necessary, or could have been provided in an urgent care setting rather than the emergency department, the hospital should not be prohibited from billing the patient for the service.

RESPONSE: The commenters' suggested changes are substantive in nature, and would require the Department to provide separate and additional public notice and an opportunity for public comment if the Department wished to pursue the suggestions at this time. As was noted in the Summary of the notice of the proposed readoption of these rules, the Department intends to propose certain new rules, repeals and amendments to these rules in the future. The Department will take the comments and suggestions under advisement when proposing rules

implementing the HCAPPA to the extent that the suggestions are consistent with HCAPPA. In the interim, the current rules will remain in effect as a result of their readoption.

As previously stated, the Department believes that the definition of “medical screening examination” at N.J.A.C. 8:43G-12.6 requires coverage of all tests performed during an examination in an emergency room to determine whether an urgent/emergency medical condition exists regardless of whether it is ultimately determined that the patient’s emergency room visit was non-emergent. However, the Department understands the commenters’ concerns and will take their comments into consideration in proposing regulations implementing the HCAPPA.

COMMENT: Three commenters requested that the Department propose regulations without delay to implement Sections 5 and 6 of the HCAPPA, which address utilization management and the obligation of HMOs to pay claims pursuant to an authorization. The requirement at Section 5a that HMOs provide a denial or authorization in writing is new, and it is essential that it be codified in regulation because many payers still do not comply with this provision despite its being in effect for more than a year. Also, Section 6a(3) of the HCAPPA states that a carrier may not deny a claim based on medical necessity if the provider received authorization but the patient is no longer eligible to receive coverage from that payer and instead is covered under another benefits plan. The commenters note that this provision does not address the situation where a payer authorizes a service and later denies it because the member was no longer eligible for coverage, and there is no subsequent payer under which the patient is insured. Providers who in good faith render services pursuant to a payer’s authorization should not be financially penalized later because of an error made by the payer. The commenters requested

that the Department draft amendments clarifying that if a provider receives authorization from a payer and later the member is found to be not eligible under the benefits plan and has no other coverage, the payer remains liable for paying the claim.

RESPONSE: The Department agrees with the commenters that it is necessary for the Department to propose rules implementing Sections 5 and 6 of the HCAPPA. The commenters' suggested changes are substantive in nature, and would require the Department to provide separate and additional public notice and an opportunity for public comment if the Department wished to pursue the suggestions at this time. The Department intends to separately propose amendments to the rules at N.J.A.C. 11:24 as well as N.J.A.C. 11:24A, along with new rules to both chapters in the near future implementing, among other things, the provisions of sections 5 and 6 of the HCAPPA (as codified, N.J.S.A. 17B:30-52 and 53). The Department will take the comments and suggestions under advisement when it proposes these amendments and new rules.

COMMENT: Three commenters requested that the Department establish time frames for the filing of a utilization management (UM) appeal under N.J.A.C. 11:24-8.5 and 8.6. The absence of deadlines in regulations has resulted in a patchwork of requirements among carriers, with some requiring submission of Stage 1 and Stage 2 appeals within 60 days, and others allowing 90 days. The commenters stated that the Department has indicated previously that it intends to make New Jersey's rules consistent across all health benefit plans subject to state law, and prefers a 180-day deadline for the submission of UM appeals. However, the commenters note that there has been a lack of consistency on the Department's website in providing guidance with respect to the filing of UM appeals (see <http://www.state.nj.us/dobi/umappeal.htm> and <http://www.state.nj.us/dobi/chap352/352umappealsqanda.html>). Therefore, it is essential that

the Department codify its intent in regulations as soon as practicable. The lack of regulated deadlines and clear guidance has already had an impact on providers. One hospital that relied on the deadline indicated on the Department's website found its appeal denied by the HMO because it was not filed within the HMO proprietary deadline.

RESPONSE: The Department has recently revised its website to clarify the information therein regarding the timeframes for the filing of UM appeals. The Department intends to propose rules addressing this issue by way of a separate proposal and will consider establishing uniform timeframes for the initiation of Stage 1 and Stage 2 appeals. In the interim, however, the Department reminds readers that health plans (including self-funded health plans which are not within the Department's regulatory jurisdiction) should be complying with applicable Federal law with respect to appeals of adverse utilization management determinations. (State law applies to group health plans subject to State jurisdiction to the extent that compliance with the State law will not prohibit the group health plan from being in compliance with the Federal regulations. See 29 CFR 2560.503-1(k).) Among other things, Federal regulations at 29 CFR 2560.503-1(h)3 establish that beneficiaries covered by group health plans must have a minimum 180-day period in which to appeal adverse benefit determinations, at least with respect to Stage 1 appeals. However, health care providers (and covered persons) should be aware that filing deadlines for adverse utilization management appeals may vary among carriers.

COMMENT: Two commenters expressed their concern about the disconnect between the network that HMOs state on paper vs. the reality of the availability of the network it maintains. While N.J.A.C. 11:24-6.1 requires an HMO to have an adequate number of primary care providers and specialists available to service all of its members, it appears that the

regulations do not provide a mechanism for the ongoing evaluation of the network. Instead, the network's adequacy is determined only at the time of the carrier's initial application for a certificate of authority. Feedback received by the commenters from hospitals throughout the State indicates that networks are grossly inadequate despite the number of physicians listed in carriers' "books." [The Department construes this to be a reference to carriers' directories of network providers.] The commenters recommended that the Department include language in its rules to strengthen the network adequacy standards applicable to primary care physicians, specialists, hospitals and other health care facility providers. Specifically, HMOs must be required to submit a formal verification that an adequate number of network providers have capacity to take on new patients, that they are actually accepting new patients, that provider offices have office hours to see patients, and that provider offices are not merely administrative facilities. Following HMOs' submission of such information, the Department must monitor the efficacy of the network to ensure that it is maintained by requiring the submission of quarterly reports. Also, to further reduce the reliance on emergency departments as the after-hours provider for all services, the commenters requested that the Department promulgate regulations that would provide more guidance on access by covered persons to physician services after office hours so that primary care providers may satisfy the emergency care access requirement within a network setting while discouraging inappropriate utilization of emergency department services at hospitals. Such a requirement would help to make carriers more accountable with respect to both their covered persons' use of emergency departments at hospitals and the appropriate referral of covered persons to an emergency department by a physician or triage service after hours.

RESPONSE: The commenters' suggested changes are substantive in nature, and will require the Department to provide separate and additional public notice and an opportunity for

public comment if the Department determines to pursue the suggestions. The Department understands and shares the commenters' concerns. The Department previously proposed rules addressing several of these issues that were never adopted. As was noted in the Summary of the notice of the proposed readoption of these rules and in response to a prior Comment, the Department intends to propose new rules, repeals and amendments in the future that will address a number of issues, including network adequacy and the accuracy of network directories. When it does so, the Department will consider these comments in the course of its formulation of the proposals and will specifically address the points raised in this comment in the proposal directed to network adequacy and the accuracy of network directories. In the interim, the Department does monitor the adequacy of HMO networks through reviews and analysis of each HMO's annual supplement. Further, if a complaint regarding network adequacy were received by the Department, the HMO's network adequacy would be examined as part of the complaint investigation process.

COMMENT: Two commenters requested that the Department consider adding language to the rules governing network services to state that not only must HMOs ensure that covered persons have access to participating providers, but that HMOs must identify a contracted facility or provider that can accept a patient if the plan determines that medically necessary care can be provided in a non-acute care setting. Two commenters stated that if a health plan will only authorize the utilization of post-acute services with their in-network facilities and agencies, then it must be responsible for ensuring the availability and provision of such services. The commenters recommended that the Department propose language clarifying that carriers have a responsibility to manage all aspects of a patient's care along the continuum, including identifying

a network or non-network provider to take the patient when the carrier determines the patient no longer needs inpatient care. Also, the identification and authorization for alternate services should occur within 24 hours. The commenters further recommended that the Department specifically require that carriers transfer stabilized patients from non-participating hospitals to one with which the carrier is contracted. By not doing so, the originating non-participating hospital is subjected to utilization management protocols and reimbursement that it has not agreed to. If a carrier fails to identify a contracted provider that can and will accept a patient, non-contracted providers must retain the right to negotiate the carrier's reimbursement for these services on a case-by-case basis. Non-contracted providers should not be financially penalized for the carrier's failure to transfer its plan member to a facility that has chosen to participate with the carrier.

RESPONSE: The commenters' suggested changes are substantive in nature, and would require the Department to provide separate and additional public notice and an opportunity for public comment before being pursued by the Department. As was noted in the summary of the notice of the proposed readoption of these rules and in the response to the previous comment, the Department intends to propose certain new rules, repeals and amendments to these rules in the future that will address issues of network adequacy. When it does so, the Department will consider these comments in the course of its formulation of that proposal and will specifically address the points raised in this comment regarding the availability of post-acute services from in-network providers. It should be noted that as part of the current general network adequacy standards HMOs are required to have contracted facilities or providers that can accept members if the plan determines that medically necessary care can be provided in a non-acute care setting. However, they are not required to guaranty the availability of a provider or of a room in a facility

that is geographically convenient to the member on any given date upon which the member's need for care or treatment in an acute-care facility might terminate. In addition, non-contracted providers do retain the right to negotiate reimbursement for acceptance of a patient from an inpatient facility.

COMMENT: Three commenters stated that many of the issues that continue to be contentious between payers and providers in New Jersey cannot be resolved through contracts alone. In fact, problems continue to exist because hospitals have little ability to ensure better HMO business practices through their contracts. With growing consolidation of payers, hospitals' ability to actually negotiate contracts with payers has diminished. The current approach to contracting is weighted in the payers' favor, with payers presenting completed contracts to providers and allowing little room for hospital-initiated changes to what is essentially the payer's contract. When hospitals attempt to insert their own language into the contract, payers claim that because it has already been reviewed by the Department, it is deemed compliant with State requirements and there is no need to negotiate. The commenters requested that the Department establish specific requirements that would govern the contracting process, including a clear process and time frames for reviewing contracts and amendments within the Department. Amendments that would delineate specific terms that must be included or prohibited in contracts should also be included. Although legislation has been introduced that would establish contracting standards, the commenters believe that the Department can achieve the same result by amending the HMO regulations at the first opportunity. The issues that the commenters recommend be addressed in regulations include the following:

(1) Unilateral contract amendments: The commenters recommended that regulations be drafted that would require either party seeking to amend the contract to submit the amendment request in writing to the other party, allowing 45 days to respond with acceptance or rejection of the amendment;

(2) Amending contracts through the provider manual: Many payers use “side agreements” or other means of communication to make changes to the contract. Most often, payers circumvent the contracting process by changing key policies and procedures through the provider manual. Most contracts include a provision stating that the provider agrees to abide by the policies in the manual or other documents, which the payer, “at its sole discretion, may amend from time to time.” The commenters believe that if hospitals are contractually required to comply with the policies spelled out in additional documents, these documents are virtually an extension of the contract and must be treated as such, subject to the same amendment procedures that would be required for amending the contract text itself. The commenters stated that the Department must codify its position regarding the use of side agreements that it set forth in Bulletin 07-13. The commenters also requested that the Department clarify whether amendments must be reviewed prior to being shared with providers for negotiation, or whether payers may first negotiate an amendment and then share the completed amendment with the Department;

(3) Regulatory amendments: Payers often submit amendments during the term of the contract and present them as regulatory requirements not subject to negotiation. The commenters’ review of several payer contracts found, however, that the language of such amendments did not accurately reflect state law requirements. Providers cannot be expected to adopt such amendments wholesale despite their presentation as “required” amendments. The

commenters expressed their concern that payers are misrepresenting the process by which their contract templates are “approved” by the Department, as well as circumventing the review process by submitting amendments and appendices to providers when only the main body of the contract has been examined by the Department. The commenters requested that the Department ensure that unilateral amendments are not allowed.

The commenters further recommended that several specific provisions should be included in regulations governing payer/provider contracts. The commenters urged that the following be designated as required contract terms: (1) New forms and amendments to previously approved forms of provider agreements that are initiated by the payer shall be submitted to the Department for review and approval prior to presentation to the provider. New forms and amendments to previously approved forms that are initiated by the provider shall be submitted to the Department for review, which shall be completed within 15 business days; (2) The compensation methodology, including the fee schedule, between the carrier and the provider; (3) The provider may limit the carrier’s products for which the provider will be considered a participating provider so long as the standards for the limitations are set forth clearly in the provider agreement (that is, providers need not agree to participate in all products); (4) The right of the provider to submit complaints and grievances to the Department or the Department of Human Services (Division of Medical and Health Services), depending on the issue, if not satisfied with the resolution of the complaint or grievance through the internal provider complaint mechanism.

The following were urged to be designated as prohibited contract terms: (1) An indication that the compensation terms will be determined subsequent to the execution of the contract; (2) A provision that states or can be interpreted to mean that the provider cannot dispute a reassignment or bundling of codes on a claim, or that the provider must accept any or all

adjustments to a claim as payment in full when the adjustment is made as a result of the quality assurance, continuous quality improvement, utilization management, provider incentive, or similar such program; (3) A provision that states that payment to a provider with respect to a medically necessary health care service or supply will be denied if the service was not precertified or preauthorized; and (4) A provision that requires the provider to assure that it never charges the carrier a rate that is greater than the least amount charged to another entity with which the provider contracts for similar services, or any other “most-favored-nation” type of clause.

RESPONSE: The commenters’ suggested changes are substantive in nature, and would require the Department to provide separate and additional public notice and an opportunity for public comment before being pursued by the Department. The Department understands the commenters’ concerns, and notes that many of the commenters’ issues are addressed at N.J.A.C. 11:24B, regarding organized delivery systems. As was noted in the response to a prior comment, the Department intends to propose new rules, amendments and/or repeals to these rules in the future that will address provider agreements and amendments to such agreements and compensation methodology and fee schedules. When it does so, the Department will consider these comments and will specifically address the points raised concerning provider agreements and provider compensation practices in the proposal directed to those practices.

Federal Standards Statement

Certain aspects of an HMO’s operation would be regulated by Federal law if an HMO elects to become Federally qualified, serves as a carrier for Medicare programs, provides services to the Federal Employee Health Benefits Plan, or provides administrative services only

for self-funded arrangements. Federal law preempts application of State law in some instances (for example, with respect to the covered services or benefits, required health care providers, and some aspects of grievance and appeals handling for Medicare products). In those instances where there may be an overlap between Federal and State law, but there is no preemption of State law (for example, time frames for responding to member complaints for certain types of products offered by HMOs), the rules being readopted are neither inconsistent with, nor more stringent than, any Federal statutes or rules, including 29 CFR 2510, 2520, 2560 and 2590; 42 CFR 417, 422, 438 and 457; and 45 CFR 144, 146 and 148. These rules were promulgated by the Federal government in accordance with various amendments to Sections 1102 and 1871 of the Social Security Act (42 U.S.C. §§1302 and 1395hh), or are based on provisions within the Employee Retirement Income Security Act of 1974 (ERISA) (29 U.S.C. §§1002 et seq.) and subsequent amendments thereto, including the Health Insurance Portability and Accountability Act (HIPAA) (Pub. Law 104-191) and its subsequent amendments. Thus, no analysis is required. The rules being readopted do not apply to administrative services provided to self-funded arrangements, and, thus, no analysis of the Federal standards is required.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 11:24.

Full text of the adopted amendments follows:

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