

BANKING AND INSURANCE
DIVISION OF INSURANCE

Health Care Quality Act: General Implementation

Readoption with Amendments: N.J.A.C. 8:38A

Proposed: June 20, 2005 at 37 N.J.R. 2174(a)

Filed: October 27, 2005 as R. 2005 d. 418, with technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3) and with the proposed amendments, repeals and new rules not adopted.

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

Effective Date: October 27, 2005 Readoption;
November 21, 2005 Amendments

Expiration Date: October 27, 2010

Summary of Public Comments And Agency Responses:

The Department of Health and Senior Services (DHSS) proposed this readoption with amendments, and proposed new rules and repeals of certain existing rules in accordance with the authority established by P.L. 1997, c. 192 (as codified, N.J.S.A. 26:2S-1 et seq.), then-residing in the Commissioner of DHSS upon the date that the proposal was filed with the Office of Administrative Law. On June 30, 2005, Acting Governor Codey filed Reorganization Plan 005-2005 with the Senate and Assembly to provide for the transfer, consolidation and reorganization of the Office of Managed Care from the DHSS to the Department of Banking and Insurance (DOBI). Public Notice of Reorganization Plan 005-2005 was published in the New Jersey Register on August 1, 2005, at 37 N.J.R. 2737(a). Reorganization Plan 005-2005 became effective on August 29, 2005.

Among other things, Reorganization Plan 005-2005 transferred from the Commissioner of DHSS to the Commissioner of DOBI the authority to interpret, implement, administer and enforce numerous laws, including P.L. 1997, c. 192, generally known as the Health Care Quality Act (HCQA), and laws subsequently enacted that directly amend or supplement the HCQA. Consequently, authority to readopt rules promulgated pursuant to the HCQA and to adopt proposed amendments thereto and new rules no longer resides with DHSS, but rests with DOBI. Accordingly, it is the Commissioner of DOBI that is readopting the rules at N.J.A.C. 8:38A, which interpret and implement the provisions of N.J.S.A. 26:2S-1 et seq. At this time, DOBI's primary goal is to assure that the existing rules at N.J.A.C. 8:38A do not expire. DOBI is electing not to adopt the proposed amendments, new rules and repeals published on June 20, 2005 at 37 N.J.R. 2174(a).

In light of DOBI's new regulatory authority with respect to the administration of the HCQA, DOBI will need additional time to consider the previously proposed amendments, new rules and repeals as well as the comments received. Because DOBI has no specific position at this time on these proposed amendments, new rules and repeals, DOBI is taking the comments under advisement without further action. However, DOBI anticipates further substantive rulemaking activity regarding these rules at a future date. All but three of the comments received addressed the proposed amendments and new rules, rather than the rules proposed for readoption, per se. Because DOBI's response to them is the same, the comments on the proposed amendments, new

rules and repeal have been grouped together, and a single response is provided. The three comments regarding the readoption of the existing rules are treated separately. The grouped comments are ordered from general to specific, and follow the numbering of the rules as proposed. The three comments on the readoption of the existing rules appear first.

DHSS received timely comments from 11 commenters as follows:

1. Julie Haywood, Senior Counsel, on behalf of AmeriHealth HMO, Inc. (comments from the commenter are hereinafter referred to as comments from AmeriHealth).

2. Kerry A. Stevenson, Director of Managed Care and Compliance, on behalf of Carrier Clinic (comments from the commenter are hereinafter referred to as comments from Carrier Clinic).

3. Robert P. Morris, Jr., Political Relations Analyst, on behalf of Health Net of New Jersey, Inc., and Health Net of the Northeast, Inc. (comments from the commenter are hereinafter referred to as comments from Health Net).

4. Joseph Privitera, Assistant Vice President for Managed Care, on behalf of Holy Name Hospital (comments from the commenter are hereinafter referred to as comments from Holy Name).

5. Neil M. Sullivan, Assistant General Counsel, on behalf of Horizon Blue Cross Blue Shield of New Jersey (comments from the commenter are hereinafter referred to as comments from Horizon).

6. Dawn B. Crawford, Associate Counsel, on behalf of Magellan Health Services (comments from the commenter are hereinafter referred to as

comments from Magellan).

7. Raymond E. Cantor, Director of Governmental Affairs, on behalf of the Medical Society of New Jersey (comments from the commenter are hereinafter referred to as comments from MSNJ).

8. Michele K. Guhl, President, on behalf of the New Jersey Association of Health Plans (comments from the commenter are hereinafter referred to as comments from NJAHP).

9. Valerie Sellers, Senior Vice President, and Jill Squiers, Assistant Vice President, on behalf of the New Jersey Hospital Association (comments from the commenters are hereinafter referred to as comments from NJHA).

10. Carmel Colica, Vice President of Legal and Regulatory Affairs, on behalf of Oxford Health Plans of New Jersey, Inc. (comments from the commenter are hereinafter referred to as comments from Oxford).

11. Kristen L. Silberstein, Director of Managed Care, on behalf of The Valley Hospital (comments from the commenter are hereinafter referred to as comments from Valley Hospital).

DHSS also received comments from Kris Hathaway, Director of Government Relations, on behalf of the National Association of Dental Plans (NADP). The comments received were not timely, and, thus, are not addressed below, but because of the nature of this particular adoption, DOBI will keep the comments under consideration. It may be noted that a number of the comments submitted by other commenters are representative of the comments submitted on behalf of the NADP.

Comments on the Proposed Readoption

COMMENT: Horizon noted that N.J.A.C. 8:38A-3.6(g) was proposed for readoption without amendment, but stated a belief that an addition to the rules may be helpful. Horizon stated that the rule describes what the Independent Utilization Review Organization (IURO) should take into consideration in deciding a given case subject to review, but contained no clear statement that the reviewer should consider the specific language that is within the coverage document relevant to the case being considered, such as the carrier's definitions of medical necessity, experimental/investigational treatment or the language in relevant coverage provisions or exclusions, which may address, for instance, what the carrier considers to be cosmetic services (either in the form of an exclusion or a specific definition). The commenter said that, in addition, there is no requirement that the written medical necessity clinical criteria and protocols that a carrier may utilize in reaching its decision (such as Milliman and Robinson, Interqual, or internally developed coverage policy documentation or criteria, etc.), be considered by the IURO. The commenter said its experience with the external review process has shown that in some cases, the clear language of the health benefits plan is ignored, or the carrier's legitimate and thoughtfully developed written clinical coverage criteria and protocol documentation is not considered or reviewed, or both, with coverage ordered by the IURO despite clear exclusory language being present or legitimate clinical criteria or protocols not having been met. Based on this, the commenter requested that N.J.A.C. 8:38A-3.6(g) be amended to include new subsections with language essentially

as follows requiring the IURO to consider: "All relevant and applicable definitions, terms and provisions that are present within the covered persons health benefits plan documentation that describes what services are covered under the health benefits plan" and "All relevant and applicable written clinical coverage criteria and protocols either developed by outside organizations with generally recognized expertise in utilization management or the carrier, that the carrier has used or applied in reaching its previous decision regarding the medical necessity of the services requested." The commenter stated that this is an opportunity for DHSS to remind IURO review agents that their analysis of the facts and circumstances of a given case sent for their review must be decided within the context of the provisions of coverage present in the relevant health benefits plan documentation as well as the utilization management criteria that carriers may reasonably and legitimately apply in reviewing the medical necessity of services.

RESPONSE: DOBI questions the necessity for such language. N.J.S.A. 26:2S-12c states that the IURO is to base its review on "applicable, generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards or associations and any applicable clinical protocols or practice guidelines developed by the carrier." (emphasis supplied) Further, N.J.S.A. 26:2S-11 states that the "appeal review shall not include any decisions regarding benefits not covered by the covered person's health benefits plan." N.J.A.C. 8:38A-3.6(g) includes language similar to the statute, including a

statement that the IURO shall consider applicable clinical protocols and/or practice guidelines developed or used by the carrier. It is not apparent what the language offered by the commenter would add. DHSS has heretofore made every effort to assure that the review process has been performed in an appropriate manner, and DHSS monitored the IUROs closely. DOBI intends to continue to operate the IHCAP similarly. No revision to the rule as suggested by the commenter has been made upon adoption.

COMMENT: Health Net objected to both the existing language and proposed amendments to N.J.A.C. 8:38A-4.10(b)3i, which sets forth standards of network adequacy with respect to general hospitals. Health Net stated that DHSS is proposing to add the word “beds” to the standards for adequacy regarding critical care language; however, Health Net contracts with hospitals based on services, not beds. Health Net explained that a hospital may use a bed today for one service and tomorrow use that same bed for another service, and this is not under a carrier’s control. In addition, Health Net stated that a carrier might not be able to meet the requirement to contract with an acute care hospital in each county, because there may not be an acute care hospital in each county. Health Net suggested the current requirement of 20 miles and 30 minutes driving time allows members greater access, as they may be closer to an acute care hospital in a county other than the one in which they reside.

RESPONSE: It should be noted that DOBI has not adopted the proposed

language. DOBI disagrees with the commenter's assessment of the existing requirements. In addition, DOBI disagrees with the commenter regarding the inability of carriers to comply with the requirement to contract with a hospital in every county because there might not be an acute care hospital available in every county. Currently, there are acute care hospitals in each county.

COMMENT: Horizon objected to language at N.J.A.C. 8:38A-4.10(b)3iii, stating that DHSS proposed new language requiring carriers to contract with Level I or II trauma centers "at a reasonable cost." Horizon argued that reimbursement levels are and should continue to be determined by the contract with the provider and/or subscriber, and that such a term as "reasonable" only invites disputes over whether the amount is subject to regulation.

RESPONSE: The commenter is in error regarding the proposed amendment to N.J.A.C. 8:38A-4.10(b)3iii. The phrase "at a reasonable cost" has been in the rules since they were first adopted in May of 2000. DHSS proposed an amendment to the rule to remove a cross-reference to N.J.A.C. 8:33P, which is currently a reserved subchapter, and to add requirements regarding transfer of patients. Neither DHSS nor DOBI regulate the reimbursement levels between carriers offering managed care products and their contracted health care providers.

Consolidated comments to the proposed amendments, new rules and repeals

COMMENT: The MSNJ expressed general support of DHSS' efforts to bring additional clarity to the rules and strengthen their terms to ensure compliance by the carrier community. The commenter also supports attempts to bring consistency between federal and state law in order to avoid conflicts or duplicative requirements. However, the commenter stated that, as with all regulatory efforts, there is a distinction between what the law requires and the actual compliance with that law. The commenter noted that, too often, carriers have not been in compliance with the rules and statutes and both DHSS and DOBI have been ineffectual in enforcing the law. The commenter stated a hope that these new requirements will also result in enhanced enforcement.

Oxford and NJAHP generally objected to the proposed amendments and new rules, stating that a number of the proposed changes are also found in proposed legislation that is being considered by the State legislature. The commenter's noted that the proposed items include, but are not limited to, N.J.A.C. 8:38A-1.2 (definitions of "medical necessity" and "service agreements"); 8:38A-4.15C(a)4 (disclosure of compensation methodologies and fee schedules); 8:38A-4.15C(a)18ii (addressing the ability to limit patient panels); 8:38A-4.15C(c)2 (unilateral right to amend contracts); 8:38A-4.15C(c)4 (regarding bundling and adjustments to claims); and 8:38A-4.15C(c)7 (most favored nation clauses). Oxford stated that, based on the legislative activity, it believed many of the proposed rules are outside the scope of existing statutory authority and

mandates and, therefore, require legislative, not regulatory, enactment. Oxford urged that, at a minimum, DHSS withdraw these items from the proposed rules and allow the legislature to continue its deliberations. NJAHP stated that it was concerned that the proposal significantly over-reaches Executive Branch authority and that, in fact, DHSS is attempting to legislate through the rulemaking process. The commenter said excesses appear throughout the proposal and far exceed enabling statute(s).

NJAHP stated that the proposed new rules are entirely too expansive in at least two respects: they initiate government oversight in several areas (e.g., management agreements) for which authority is not apparent and, secondly, they empower providers to exercise judgment and control of areas that, by law and contract, should be, and always have been the responsibility of insurers and HMOs. NJAHP stated that, if implemented, these proposed rules would create large new areas of responsibility, work and cost for the government, and new opportunities for dispute between payers and providers for which there is neither precedent nor ground rules. NJAHP questioned the public good to be gained by this intrusiveness and micromanagement, and stated that one could easily argue public harm insofar as many of these requirements would add significant administrative burden and costs to carriers and, ultimately, to members. NJAHP stated that efforts to control health care costs are increasingly believed to be a worthy goal for public policy-makers.

NJAHP stated that the proposed rules create a set of rules for insurance products related to a wide variety of managed care practices and noted that, at

the same time, New Jersey has another set of rules that are arguably less stringent for similar or identical products issued by HMOs. NJAHP opined that promulgation of two sets of standards is inherently unfair. The commenter noted that most health care payers and providers (certainly, the larger ones), have integrated managed care functions for products issued on insurance and HMO paper, and that two sets of rules would create impossible and unnecessary administrative burdens. The commenter urged that the rules be withdrawn and a set of unified managed care regulations considered.

Oxford and NJAHP expressed concern about the process for promulgation of the proposal, given the transfer of regulatory oversight for managed care from DHSS to DOBI. The commenters stated that the notion that regulators are writing rules for which they will not be accountable - or conversely, that regulators will be forced to administer rules that they did not write - is totally contrary to practice or logic. The commenters suggested that the proposed rules be withdrawn until DOBI can determine whether they are even necessary to DOBI's administration of the law.

Seven commenters objected to the definition of "adverse determination" as proposed at N.J.A.C. 8:38A-1.2. AmeriHealth noted that the definition of adverse determination includes situations in which a service is redesignated as "dental" instead of "medical," but that redesignation of a service consistent with the member's benefits is not prohibited and should not be considered an adverse determination. AmeriHealth stated that the proposed change is not supported by the HCQA or its implementing regulations and should be deleted. Health Net,

Horizon, Oxford and NJAHP all noted that the definition differs significantly from the federal definition, particularly with the inclusion of denials made on the basis that a service is cosmetic and of denials of requests for the provision of in-network benefits for a covered person's use of a non-participating provider, when a participating provider is available. (For sake of brevity, DOBI is referring to the latter scenario as requests for "in-plan exceptions," while acknowledging that all carriers may not use this term or may use it differently than as described.) Health Net noted that decisions regarding requests for in-plan exceptions are very rarely medical necessity decisions and are not appropriately included in the definition of adverse determination. Oxford characterized the issue of requests for in-plan exceptions as a network adequacy issue, and stated that network adequacy standards are set forth elsewhere in the rules and should not be included in the definition of an adverse determination.

Magellan argued that adding the definition of adverse determination identical to 29 CFR 2560.503 would unnecessarily encroach on contractual issues and expand the state's external appeal process, unreasonably expanding the scope of the state's authority in reviewing Magellan's contractual requirements. The commenter provided the following example: if a member has HMO only coverage and wants to see a nonparticipating provider based on medical necessity, Magellan reviews the request for medical necessity, but if Magellan determines that there are no valid medical necessity reasons for the member to see an out of network or other specific provider, then the denial issued is contractual in nature and not subject to the state's external appeal

process; however, under the proposed language, the denial would be reviewable under the state's external appeal process and the decision is binding on the carrier. Magellan stated that it believes this is an impermissible expansion into contractual issues and requested a clarification prohibiting this.

Horizon stated that requests for in-plan exceptions are not easily characterized solely as questions of medical necessity, as many factors contribute to such requests, often having no bearing on network access, including preference (based on recommendations from others with experience with the provider, for instance), and convenience. Horizon opined that adding the latter portion of the language to the definition of adverse determination will result in virtually any denied request to use an out-of-network provider being deemed an adverse determination, and thus require all such requests to be reviewed by a clinician and eligible for appeal in the IHCAP process. Horizon stated that only when there is an identified issue that the medical knowledge and expertise does not exist in the carrier's network should a denial of such a request be considered an adverse utilization management (UM) determination subject to review through the Independent Health Care Appeals Program (IHCAP). Horizon suggested that, if it is desirable to incorporate the intent of the past bulletin (OMC Bulletin 2000-04, addressing questions about the types of decisions that are subject to appeal) into these regulations, the regulations could be revised to include some of the second sentence's language in the appropriate places within the rules that describe the right to an appeal through the internal and external UM appeals processes set forth at N.J.A.C. 8:38A-3.5 and 3.6. Horizon objected further to

the language regarding in-plan exceptions because the proposed language includes the phrase “because the covered person believes it is medically necessary to do so” as the rationale for using a non-participating provider at the in-network benefit level, which Horizon believes suggests that this choice to go out-of-network may be based on the subjective viewpoint of the layperson, rather than an objective determination of medical necessity. Horizon suggested that the language, wherever it is employed in the rules, should be revised to clarify that the only instances in which use of an out-of-network provider at the in-network level of benefits is justifiable is after a clear and objective showing of medical necessity because the necessary expertise is not available within the carrier’s participating network. Horizon suggested that if DHSS wishes to establish a definition for the term “adverse determination” it limit the definition to the proposed first sentence, and again stated that the second proposed sentence is best addressed through the detailed descriptions present in Bulletin 2000-04 as previously published, and should not be included in the definition.

On a different point regarding the definition of adverse determination, Horizon noted that, while it supports consistency between the federal and state rules, consistency probably is not achievable in this instance, because the federal definition applies to all benefit denials under ERISA plans whether based on eligibility, plan design, or clinical criteria, whereas the HCQA is concerned with that subset of benefit denials attributable to determinations of a clinical nature. Horizon suggested that it is counterproductive to use the term “adverse determination” in this case because it invites confusion between UM

determinations under the HCQA and benefit denials under ERISA plans. Further, Horizon stated that, to the extent that DHSS intends to incorporate positions previously published in DHSS bulletins regarding carrier UM and appeals programs, DHSS would do better to insert the language currently included in the proposed definition of adverse determination in the appropriate places within the rules where the full scope a UM determination in the context of the state laws will be better understood. In the alternative, Horizon suggested the Department revise the term to something like “adverse utilization management determination” to distinguish it from the term adverse determination as used in the federal regulations. Horizon stated that, in addition, the rules should be reviewed in their entirety to insert the defined term in all places it is applicable to assure consistency and avoid misunderstanding.

Valley Hospital requested that the term “adverse determination” be further clarified to include decisions as to whether care should be provided in an alternate care setting. Valley Hospital stated that often hospitals receive notice that the carrier is deeming a patient’s stay to be at an “alternate level of care” and payment is unilaterally reduced from an acute care rate to a subacute or skilled nursing facility rate. In these instances, it is not the patient’s benefits that are being reduced but rather, the hospital’s payment. Valley hospital stated that it believes DHSS intended for the revised definition to include these types of situations, but that, because hospitals can only appeal UM decisions on behalf of patients with the patient’s consent, the clarification should be made so that there could be no misinterpretation as to the definition’s intent. Valley stated that any

decision by a carrier to limit or change its payment obligations should be considered an “adverse determination” and communicated accordingly.

AmeriHealth, Health Net, and NJAHP objected to the definition of “continuity of care period” at N.J.A.C. 8:38A-1.2, stating that the definition may be misleading when it says that the term might also be referred to as the four month extension period because, in certain circumstances, the period is longer than four months (for example, the extension period is up to a year for psychiatric and oncological care, up to six months for post-operative care, and up to six weeks post partum). The commenters suggested the statement that the term may also be referred to as the “four month extension period” should be removed.

Health Net, Horizon and NJAHP expressed some concerns about the proposed amendments to the definition of “Independent Health Care Appeals Program,” set forth at N.J.A.C. 8:38A-1.2. Health Net and Horizon primarily noted technical concerns inasmuch as the insertion of the defined term “adverse determination” and other language in the proposal are largely redundant in their content, yet may possibly be inconsistent with other proposed language in other rule sections. NJAHP reiterated its objection to the inclusion of language regarding cosmetic surgery that might suggest that denials of cosmetic surgery requests are always appealable, because NJAHP was concerned that such appeals will flood the UM appeal process.

AmeriHealth expressed concerns regarding the proposed definition of “health care professional” at N.J.A.C. 8:38A-1.2, which includes nurses and pharmacists, noting that these health care providers are not the types of

providers that AmeriHealth contracts with. AmeriHealth stated that inclusion of these types of providers expands access to the UM and other requirements of the rules not previously contemplated, and suggested that, at a minimum, the reference to nurses and pharmacists should be removed upon adoption.

AmeriHealth, Health Net, Horizon, Oxford, NJAHP and MSNJ all objected to the proposed new definition of “medical necessity” at N.J.A.C. 8:38A-1.2. AmeriHealth objected to DHSS defining the term at all and, in particular, including the standard that “the treatment or service cannot be omitted without adversely affecting the patient’s condition or the quality of care,” suggesting that inclusion of a definition in the rules would hamper a carrier’s ability to define the term and is inconsistent with existing definitions of medical necessity in member benefits materials approved by DHSS. AmeriHealth expressed a concern that carriers denying a service or procedure on the grounds that the service or procedure is not covered by the benefits package (whether medically necessary or not) would face a significant challenge by a member who is denied such services. Health Net, Horizon, Oxford and NJAHP’s concerns were similar, but Health Net also noted that the proposed definition does not address the level of care that is appropriate for a treatment or service. Horizon added that the definition creates an irreconcilable conflict between the rules and the underlying health benefits plans, because virtually all such plans set forth their own definitions of the term, which have been approved by DOBI. Horizon suggested that this will leave covered persons, carriers, providers, regulatory authorities and the IUROs in a position of not being able to determine which definition should

govern. Horizon opined that the concept of medical necessity is well understood in the industry, the provider community and even among the insured population and does not require definition in this regulation but, rather, the rules should rely on the definition as set forth in each health benefits plan for guidance when necessary in each individual case.

On the other hand, MSNJ agreed that a definition of “medical necessity” is important for the reasons stated by DHSS in its Summary of the proposal. However, MSNJ opined that it is also important for the internal clinical guidelines of carriers used for determining what is medically necessary to be divulged to health care professionals and DHSS. In addition, MSNJ stated that, while helpful, the proposed definition does not go far enough in describing the term, especially for diagnostic procedures. MSNJ suggested that carriers should be required to approve all covered services if they find them to be medically necessary and they should be required to justify in writing any adverse determination to the contrary. MSNJ offered the following proposed definition of medical necessity that it believed would better achieve DHSS’ stated goals, as follows:

“medical necessity” means health care services that a health care professional exercising prudent clinical judgment, would provide to a patient for the purpose of evaluating, diagnosing or treating an illness, injury, disease or its symptoms and that are a) in accordance with generally accepted standards of medical practice; b) clinically appropriate in terms of type, frequency, extent, site and duration, and considered

effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient or health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease. For the purposes of this section, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed literature generally recognized by the relevant medical community, physician specialty society recommendations, the views of physicians practicing in relevant clinical areas, and any other relevant factors.

MSNJ stated that the definition it offered was taken from settlement agreements to lawsuits between the nation's physician community and several of the largest carriers in New Jersey, which means that, to a large extent, the proffered definition is in current usage.

Health Net, Horizon, Oxford and NJAHP objected to the proposed addition of the term "service agreement," and its definition. In general, the commenters stated that the definition was overly broad, while both Health Net and Horizon stated that definition would bring aspects of a carrier's business under regulatory oversight that is beyond the scope of the HCQA, or the Organized Delivery System (ODS) Act, N.J.S.A. 17:48H-1 et seq. Health Net stated that the HCQA does not seem to speak to these types of contracts by any name, and indeed, the proposed definition includes "case management" and "disease management"

contracts despite the fact that the ODS Act specifically and expressly excludes them from the purview of that law. Health Net stated that it is unclear how DHSS can, in accordance with N.J.A.C. 8:38A-4.15A, require that these types of contracts abide by its rules implementing the ODS Act without directly contravening legislative intent, if there are no express statutory provisions. Health Net goes on to state that such micromanagement of a carrier's business arrangements with vendors/consultants for other than the provision of health care services, which the Legislature deemed necessary to regulate via the ODS law, could very well discourage vendors and carriers from doing business in New Jersey and could be a disservice to the carrier's New Jersey covered persons. Health Net provided as an example disease management services, which Health Net explained are not mandated health care services but, rather, are services offered to a covered person to coordinate his or her care and help the person navigate the health care delivery system effectively and efficiently. Health Net stated that the services are definitely value-added services for the covered person but that, because many of these companies are national and many carriers offer health benefits plans nationwide, New Jersey will very likely be left out of these national contracts between carriers and disease management vendors because of the proposed stringent regulatory requirements governing the structure of the agreement that do not exist elsewhere. Health Net suggested that DHSS suspend its initiative to regulate the defined service agreements of carriers until the pros and cons of doing so are debated in the legislative arena.

Horizon also noted that the requirement that service agreements be approved prior to use is not consistent with standards set forth in the existing ODS rules, and has the practical effect of imposing certain requirements of the ODS rules on agreements that are not governed by the ODS regulations. Horizon stated that N.J.S.A. 17:48H-1 defines an ODS as an entity that is organized for the purpose of and has the capability of contracting with a carrier to provide, or arrange to provide, under its own management substantially all or a substantial portion of the comprehensive health care services or benefits under the carrier's benefits plan on behalf of the carrier, and that N.J.A.C. 8:38B-3.2 further clarifies that a management agreement between a carrier and an ODS is not subject to the ODS rules when a carrier contracts with an entity to perform less than a majority of the duties specified for a particular function. Horizon stated that under the ODS rules, a carrier is not considered to have delegated a particular function if the contracted entity is only performing a portion of the function, but that the proposed rules at N.J.A.C. 8:38A-4.15A do not include limitations similar to those set forth in the ODS legislation and corresponding rules. Horizon opined that the definition of a service agreement contemplates agreements that "address" functions such as complaints handling, appeals handling and member services, but that the word "address" is too vague in this context, and the proposed definition does not contemplate whether or not a carrier has effectively delegated a regulated function. Horizon suggested that the proposed definition could be construed to incorporate virtually any activity a carrier uses a vendor to perform. Horizon noted that the stated goal of DHSS is

to harmonize the HCQA regulations and the ODS regulations and to make the older rules consistent with the newer ones, and that DHSS appears to have been successful in that attempt with respect to “management agreements,” but that the creation of a new category of agreements called service agreements is overreaching and unnecessary. Horizon went on to state that the intent of the HCQA as described at N.J.S.A. 26:2S-18 is to establish consumer protection and quality standards governing carriers that offer managed care plans or use UM systems that are consistent with standards governing HMOs in New Jersey, but that the proposed definition of service agreement expands the standards for governing HMOs by including reference to the following types of agreements: member services, medical management, case management, disease management and health care services by a secondary contractor. Horizon noted that the new definition expands the scope of existing law by failing to incorporate the limitations set forth in the ODS Act and corresponding regulations, which specifically exclude certain entities, including entities that provide credentialing or recredentialing, UM development, UM management application, UM management appeals, member complaints, provider complaints, and/or continuous quality improvement, but do not also perform or arrange for the performance of one or more types of health care services or provide network management, including recruitment and retention. Horizon urged DHSS to eliminate or substantially reduce the scope of the definition of service agreement and corresponding requirements regarding approval of service agreements set forth in the proposed rules at N.J.A.C. 8:38A-4.15A and 4.15B in a manner

consistent with the enabling legislation and the finalized rules regarding ODSs.

NJAHP suggested, with respect to the concept of service agreements, that requiring carriers to notify DHSS about their various service agreements so DHSS can keep a record of them would be more than sufficient.

Health Net, Horizon, Oxford and NJAHP all expressed concerns regarding the proposed language of N.J.A.C. 8:38A-1.3(e), which essentially specifies that form filings of provider agreements and management agreements currently in existence will be considered withdrawn as of January 1, 2006 if the forms were not in compliance within one year following the effective date of readoption. Health Net stated that one year following adoption to be in compliance sounds reasonable, but the specific date of January 1, 2006 for withdrawal of noncompliant forms is in conflict with the one year standard. Horizon stated that one year to amend in-force provider and management agreements that are not in compliance with the new rules does not provide enough time for the comprehensive changes required to be drafted, filed and implemented, and suggested two years, which is the time period that DHSS adopted for in-force agreements in the final ODS rules. Horizon also noted that the proposed rule does not mention any time frame for service agreements, which the proposed rules at N.J.A.C. 8:38A-4.15B indicate need to be approved by DHSS prior to use. Oxford suggested that the date for withdrawal should be changed to January 1, 2007, which Oxford indicated would allow carriers time to implement any changes required under these rules and provide the necessary training to staff. NJAHP opined that the specific effective date (one year after readoption)

cannot be in the text since we do not know when the regulation will become effective.

Horizon suggested that the requirement at N.J.A.C. 8:38A-2.3(a)4 for carriers to include 911 information on ID cards should not apply to dental-only ID cards. Horizon suggested that individuals would be unlikely to reference their dental ID cards in the event of a life-threatening condition.

Carrier Clinic, Holy Name, NJHA, Horizon, Oxford and NJAHP all objected to the wording of proposed N.J.A.C. 8:38A-2.6(a)2, which essentially would require carriers to consider a covered person for purposes of benefits as being at an in-network hospital if the carrier fails to request a transfer of the person from a non-network hospital upon notice that the covered person is at a non-network hospital and is medically stable. Carrier, Holy Name, and NJHA all stated that, absent any incentive to transfer, carriers have historically left the patient in the originating hospital, subjecting the provider to UM protocols and reimbursement that the hospital has not agreed to, and suggested that DHSS should specifically require that carriers transfer stabilized patients from nonpar to par hospitals, rather than allowing carrier's the option. The commenters went on to say that, although the rule specifies the patient's cost-sharing must be assessed at the in-network level, nonpar providers must retain the right to negotiate the carrier's reimbursement for services on a case-by-case basis, and should not be financially penalized for the carrier's failure to transfer its member to a facility that has chosen to participate with the carrier.

Horizon suggested that proposed N.J.A.C. 8:38A-2.6(a)2 should be

stricken, stating that carriers do not request transfers of covered persons, but rather, make determinations as to the necessity of care and appropriateness of setting. Horizon also noted that carriers offering out-of-network benefits would provide coverage for covered out of network services, so it would be inappropriate (or at least unnecessary) to request such a transfer. Oxford and NJAHP concurred that the provision should be stricken, taking the stance that the covered person should assume the responsibility of knowing when he or she is accessing out-of-network care. These commenters stated that when a patient is medically stable, the patient should notify the carrier and make arrangements to move to a participating facility, or assume responsibility of reimbursement at their out-of-network cost share.

Carrier Clinic, Holy Name, NJHA, Valley Hospital, Health Net and Horizon all had comments regarding the proposed language of N.J.A.C. 8:38A-2.6(b), which would clarify the requirement for carriers to pay for the coverage of a medical screening examination when a covered person presents in a hospital's emergency department (ED). Carrier Clinic, Holy Name, NJHA and Valley Hospital stated that language requiring reimbursement for the cost of diagnostic testing in the ED is a good first step, but that current language requiring reimbursement for the cost of diagnostic tests "to determine whether a person has an emergency medical condition" has been wrongly interpreted to mean that if an emergency medical condition does not exist, the tests were not medically necessary. The commenters stated that the intent of the prudent layperson standard (allowing a reasonable person who believes immediate medical care is

warranted to access the ED) has been eroded over the years, and that today carriers often deny ED claims simply because the patient responded to medical treatment and was stabilized (such as during acute asthma episodes), because in such cases, the carrier deems the visit non-emergent. The commenters argued that, because hospitals must conduct tests and procedures to determine the nature of the patient's illness, they must receive reimbursement from carriers for those tests and procedures, and that if a carrier determines the service was not medically necessary, the hospital should not be prohibited from billing the patient for the non-covered service. The commenters suggested that DHSS should further specify that the carrier must cover tests even if in the end the patient is stabilized or the carrier determines that the patient could have been treated in an urgent care setting rather than an ED.

Horizon stated that the proposed change, particularly the language of N.J.A.C. 8:38A-2.6(b)2, appears to require coverage of diagnostic tests, and payment for a medical screening examination without regard to the prudent layperson definition. Horizon opined that, because only a cursory examination would be required to determine whether a prudent layperson would believe they were suffering an emergency and all services would already be covered if that test were passed, the effect of these changes would be to require carriers to pick up the cost of diagnostic tests for persons making imprudent use of the emergency room. This would encourage unnecessary visits to the emergency room and pass the cost of those unnecessary services on to all purchasers of insurance. Horizon suggested these changes not be made.

Health Net stated that carriers will need time to come into compliance with N.J.A.C. 8:38A-2.6(b)2 because they may need to renegotiate the rates for the inclusion of all diagnostic testing in the medical screening examination in a hospital's ED.

Health Net, Oxford, Horizon and NJAHP each had technical comments or criticisms regarding N.J.A.C. 8:38A-3.4(a)7, which essentially requires that carriers include, as part of their UM program, a system for covered persons to appeal utilization management (UM) determinations. Health Net, Oxford and NJAHP suggested that the word "adverse" should be substituted for "UM" to correspond to the new definition of adverse determination. Horizon noted that this was a rule in which DHSS had not used the newly defined term adverse determination within the text, thus creating the potential for misunderstanding and unintended misinterpretation.

In addition, Horizon suggested that DHSS make clear at N.J.A.C. 8:38A-3.4(a)7 that authorized representatives of the covered person, as well as providers acting on behalf of the covered person with consent, may appeal a carrier's UM determination, consistent with Federal law, and existing State practice.

Horizon and MSNJ expressed concerns about the proposed amendment to N.J.A.C. 8:38A-3.4(b)2, which would require carriers to make their clinical criteria available upon request to covered persons, participating providers and providers treating a covered person, and which would eliminate the exception from disclosure of materials that are internal or proprietary quantitative thresholds

for UM. Horizon stated that, while carriers are willing to be forthcoming with the criteria they use to reach UM conclusions, there is a concern regarding the deletion of the phrase “except that internal and proprietary quantitative thresholds for UM is not required to be released to covered persons or providers pursuant to this subchapter” which had previously qualified the carrier’s disclosure obligation. Horizon said that, because the remaining language simply uses the broad term “criteria,” there may be some elements of a carrier’s criteria that the carrier or a vendor considers proprietary that would preclude disclosure to all of the entities to whom the rule suggests disclosure should be made. Horizon added that there may still be some internal and proprietary quantitative thresholds that are employed by carriers that serve some purpose in the UM review process that do not really rise to the level of a UM criteria upon which the carrier bases its decision regarding medical necessity and, as such, should not be subject to disclosure. Horizon suggested that if, for example, a carrier uses an internal quantitative threshold that states the carrier will not perform UM review on any outpatient facility charge that is less than \$1,000, that is not a UM criteria or other criteria that should be required to be disclosed upon request to an outpatient facility, or otherwise, but N.J.A.C. 8:38A-3.4(b)2 as proposed is broad enough to suggest that the information should be disclosed. Horizon suggested that the section be revised to maintain the exception from the disclosure requirement as it currently exists.

MSNJ stated that, while agreeing with the strengthening of the disclosure requirements of proposed N.J.A.C. 8:38A-3.4(b)2, it believed that the UM criteria

should be made available to participating providers, or potentially participating providers, on the carrier's web page without the necessity of having to make a specific request – something the proposed rules did not address.

MSNJ, AmeriHealth, Health Net, Horizon, Oxford and NJAHP all had comments to the proposed amendments to N.J.A.C. 8:38A-3.4(c), which establishes standards for access to UM services. MSNJ expressed general support of the enhanced carrier responsibilities to respond to inquiries. However, AmeriHealth stated that, by exceeding the current standards for access at N.J.A.C. 8:38A-3.4(c)2, carriers would likely have to incur the added expense of hiring staff to render routine UM determinations around the clock, rather than just during core business hours. AmeriHealth suggested retaining the current language requiring 24/7 staff with a dedicated phone line to render UM determinations in urgent/emergent situations only. Health Net suggested that the rules should clarify that the phrase “all other utilization-related inquiries” refers to emergency situations only. Horizon concurred in the suggested clarification, but also suggested that the rule not apply to dental business. Oxford suggested that the phrase “dedicated phone line” be deleted, because the requirement is an added expense that does not improve quality of service to customers in non-urgent situations. NJAHP noted that emergency situations would not require preauthorization, and thus, the sentence relates to non-emergency situations and should be so clarified, with the concept of “other” situations deleted. NJAHP suggested that dedicated phone lines are an excessive request for non-emergency situations. NJAHP suggested the following replacement wording:

Payers and providers shall have appropriate staff available between the hours of 9:00 A.M. and 5:00 P.M., seven days a week, to respond to authorization requests.

Horizon, Health Net, and NJAHP suggested revisions to N.J.A.C. 8:38A-3.4(d). Horizon, Health Net and NJAHP noted that DHSS did not use the newly defined term “adverse determination,” and suggested changes that would make the rule consistent with the new definition, and make it clear that only UM determinations were at issue.

Oxford suggested revising N.J.A.C. 8:38A-3.4(d)2, setting forth the health care professionals authorized to make adverse determinations (that is, denials of or limitations upon requested services), to permit a clinical peer to render an adverse determination, i.e., a chiropractor, if applicable.

Carrier Clinic, Holy Name, NJHA and Valley Hospital all objected to the proposed language to N.J.A.C. 8:38A-3.4(d)3, establishing timeframes for rendering initial UM determinations by cross-referencing to Federal regulation. The commenters stated that the proposed timeframes are far too long and do not reflect the way healthcare is provided today, and suggested that DHSS should not adopt the Federal timeframes just because they exist. The commenters opined that the intent in requiring a response within a reasonable amount of time is to allow providers to take the carrier’s UM determination into account when rendering services, but that the ERISA timeframes would allow lengthy wait times before providers receive approval for providing services.

The commenters stated specifically that, while the proposal establishes

timeframes for concurrent care decisions within 24 hours, the ERISA definition of concurrent care means an ongoing course of treatment has been approved and the carrier is determining to reduce or terminate the treatment, which the commenters do not believe would apply in most inpatient stays because inpatient days more typically are determined on a daily basis, rather than upfront for a specific length of time. Thus, the commenters conclude that determinations regarding inpatient days would be subject to the urgent care timeframe of 72 hours under the Federal law. Meanwhile, the commenters explained, the hospital must continue to care for the patient while waiting for the determination from the carrier, and would most likely provide the medically necessary service rather than make the patient wait. The commenters noted that hospitals that experience a delay in providing a service due to equipment or technician unavailability often receive denials from carriers for the days in which the service is not provided, so it is likely carriers would deny payment for the three-day wait if services were not rendered specifically because the patient wasn't receiving any services. The commenters stated that denials issued well after services have been rendered result in numerous appeals to overturn the decision and, in the meantime, providers assume financial risk for all services rendered while awaiting a response to the appeal. The commenters continued by saying that, if payers want the opportunity to approve or deny care, then it is not unreasonable for them to act within a timeframe that does not place the providers at financial risk - a response by close of business notifying hospitals whether a requested service has been approved is not unreasonable and would allow providers to

obtain the patient's consent to an appeal while the patient is still at the hospital. The commenters suggested that carriers should be given no more than 24 hours to respond, and that if payers are truly managing care, then they should work in collaboration with the physician and render determinations in an accelerated timeframe for inpatient care.

Carrier Clinic, Holy Name, NJHA, and Valley Hospital applauded the requirement at proposed N.J.A.C. 8:38A-3.4(f) that all UM determinations be in writing, but requested that the provision require that written notices be provided to both the covered person and the provider. The commenters opined that the provider must receive the notice in order to initiate an appeal of any denied service or payment, and the covered person must receive the notice so that they are involved in their healthcare and know what procedures their insurance company is covering or denying. The commenters stated that, unfortunately, the timeframes for delivering the written notice guarantees that an inpatient hospital service will have already been provided by the time the carrier determines and notifies the provider that it will not be approved and suggested that requiring notices to be delivered by close of business on the date of the request, or within 24 hours following the authorization request, would better serve the patient. Valley Hospital suggested that all determinations should be delivered by 4:30 P.M. on the date a request was made.

Health Net, Horizon, Oxford and NJAHP all expressed concerns regarding proposed N.J.A.C. 8:38A-3.4(f)2, requiring carriers to provide an explanation of the appeal process in all communications regarding a UM determination. Health

Net suggested that requiring such information in all means of communication is excessive and, thus, removal of the phrase “including verbal communications” would be appropriate. Horizon suggested that the requirement should be limited to communications of an adverse UM determination. Oxford and NJAHP took the position that requiring appeal information with verbal communications was excessive, especially given that medical directors may contact a member’s physician on multiple occasions outside the formal review process and suggested that appeal language should only be required at each stage of review required by statute.

Health Net, Horizon and NJAHP suggested that the second use of the term “determination” at N.J.A.C. 8:38A-3.4(f)2 should be replaced by the word “appeal” to more appropriately convey DHSS’ intent.

Health Net commented that at N.J.A.C. 8:38A-3.4(f)2 and throughout the proposed rules, DHSS suggests that a covered person or provider can initiate an appeal by telephone, but stated that this avenue should be limited to situations where the covered person or provider determines that all necessary and relevant documentation has already been submitted and does not intend to submit anything further. Health Net opined that, in this way, the carrier can proceed to determine the appeal pursuant to regulatory timeframes and avoid having to issue a denial because of incomplete information in order to stay compliant with regulatory timeframes. The commenter stated that, conversely, if the covered person or provider desires to submit additional documentation in support of the appeal, then the rules should require the appeal to be initiated in writing.

AmeriHealth noted that N.J.A.C. 8:38A-3.4(f)4 appears to require a carrier to include in notices of adverse determinations the right of the covered person to bring a civil action except for covered persons not covered under a group health plan. AmeriHealth stated that providing such a notice would be a departure from the current process. The commenter opined that a member's right to bring a civil action should arise after the member has exhausted the carrier's internal appeal process, and N.J.A.C. 8:38A-3.4(f)4 should be revised to reflect that.

Carrier Clinic, Holy Name, NJHA and Valley Hospital objected to the proposed language of N.J.A.C. 8:38A-3.4(f)4, which, among other things, requires carriers to set forth the specific clinical criteria on which the adverse determination is based. The commenters stated that the Federal rules only require the carrier to state on a denial notice that an internal rule or guideline was used in making an adverse determination, and that providers must then request a copy of the guideline. The commenters opined that the process of delivering care in accordance with a carrier's clinical protocols is better achieved if the provider actually knows what the carrier's rules and protocols are. The commenters suggested that DHSS clarify the rules to require carriers to supply providers with the exact internal rules, guidelines, protocols or other criterion used in making the determination, rather than requiring providers to request it upon receiving the denial. Providers should not have the administrative burden of having to research why a carrier issued a denial.

Horizon suggested that, rather than using the term "adverse determination" at the end of N.J.A.C. 8:38A-3.5(a), which requires carriers to establish an

appeal process regarding UM determinations, this is a rule where the Department can clearly describe the various types of UM decisions made by carriers that are subject to the appeal process, including denials, reductions, terminations or limitations of covered health care services, cosmetic versus medical necessity cases, dental vs. medical cases, investigational/experimental cases, or situations where out-of-network providers are sought as medical necessity alternatives to participating providers versus the carrier's view that the expertise exists in-network and that such providers are being sought for the covered person's convenience or preference. Horizon also opined that this rule is a place for the Department to make it clear that authorized representatives of the covered person may appeal a carrier's UM determinations, in addition to providers acting on behalf of the covered person with the covered person's consent to bring an appeal.

Carrier Clinic, Holy Name, NJHA, Valley and MSNJ objected to proposed N.J.A.C. 8:38A-3.5(c)1, which specifies that the carrier's explanation of the appeal process must include a statement that specific consent is required for a provider to appeal on behalf of a covered person (except in limited circumstances). Carrier Clinic, Holy Name, NJHA and Valley stated there is no sound reason to insist that a consent form be obtained following the issuance of a denial, and noted that providers are most often the party that initiates an appeal (with the patient's consent). The commenters opined that allowing providers to obtain a patient's consent at the time of admission would enable providers to initiate appeals when a denial is issued rather than delaying an appeal for weeks,

if not months, while notifying and seeking the patient's consent. The commenters further noted that, unfortunately, in almost all cases, the patient is held financially harmless (by law and regulation) and has no vested interest in resolving medical necessity or payment determinations between providers and payers. The commenters stated that concerns have been expressed that allowing providers to appeal using a patient's consent obtained at admission would mean the member would not know that a denial has been made or an appeal initiated, particularly if the patient has been discharged prior to the denial, but argued that hospitals should be allowed to obtain consent at the time of admission and should be required to notify the member whenever the hospital initiates an appeal, as well as at each stage of the appeal, with members being allowed to revoke their consent to the appeal at any time. The commenters stated that another concern raised is whether a member's signature on a consent obtained at admission is actually indicative of a member's contest to the final decision of a carrier, but responded that requiring the hospital to notify the member of a denial and intent to initiate an appeal and allowing the member to revoke consent would provide evidence that a member that continues to allow consent indeed contests the carrier's decision. MSNJ argued that the requirement for specific consent merely creates an additional burden, and does not consider the unnecessary burden it places on both health care providers and patients.

Horizon suggested that the language of proposed N.J.A.C. 8:38A-3.5(c)1 and (d)1 be revised by expanding the parenthetical phrase referencing 29 CFR

2560.503-1(b)(4) to add clarity to the intended exception by including language allowing appeals to be made by a physician with knowledge of the claimant's medical condition in urgent care situations as described in the Federal rules.

MSNJ objected to proposed N.J.A.C. 8:38A-3.5(d)1, addressing the right of the carrier to establish policies and procedures within limitations and which, among other things, requires carriers to look for specific consent from covered persons before accepting an appeal submitted by a health care provider. MSNJ argued that the requirement for specific consent merely creates an additional burden, and does not consider the unnecessary burden it places on both health care providers and patients.

AmeriHealth, Health Net, Horizon, Oxford and NJAHP objected to proposed N.J.A.C. 8:38A-3.5(d)1i, regarding appeal processing, because it would prohibit a carrier from postponing processing of an appeal initiated by a provider pending receipt of written evidence of the member's consent (although allowing the carrier to withhold dissemination of the decision until written consent is received). The commenters argued that the right to appeal belongs to a member, and to permit the appeal to proceed in the absence of receipt of the member's consent flies in the face of existing regulation, and would result in an inordinate waste of UM staff resources in the event that a carrier never receives the member's consent. Health Net stated that N.J.A.C. 8:38A-3.5(d)1 and (d)1i are confusing and will result in the logging of an indeterminate number of appeals and innumerable hours of work on cases for which consent may never be received, and suggested that this would result in skewed reporting and waste a

large number of appeals and medical management hours, in addition to failing to consider the member's rights. Horizon noted that, even if consent is received, it is entirely possible that the consent is ultimately supplied in an untimely manner. Horizon also argued that, in urgent cases, the Federal rules and the proposed State rules provide adequate provisions for providers to act on behalf of covered persons without the need to document their authorization to act, providing adequate guidance to carriers, providers and covered persons in this area.

AmeriHealth commented favorably with respect to proposed N.J.A.C. 8:38A-3.5(d)1ii, which, at sub-subparagraph (d)1ii(1) would require a carrier to provide a copy of a carrier-generated consent form (if any) with each initial written adverse determination. AmeriHealth stated that this was a positive change that would make the appeal process more accessible to members without having to obtain consent at a later time. However, NJAHP objected to the requirements of proposed N.J.A.C. 8:38A-3.5(d)1ii(1), stating that there is no need for this onerous requirement because all providers have carrier-generated forms on file, and if there are providers that do not, carriers will be happy to provide the forms upon request.

Horizon objected to the requirements of proposed N.J.A.C. 8:38A-3.5(d)1ii, regarding standards for carrier-generated consent forms. Horizon stated that the requirements setting forth specific standards for carrier-generated consent forms at sub-subparagraph (d)1ii(2) through (5) are unnecessary and should be deleted because they create more formality around this process than a carrier may wish to impose. Horizon suggested that the Federal rules set forth

adequate guidelines for the manner in which a carrier may reasonably establish procedures for the designation of authorized representatives.

Carrier Clinic and Valley Hospital both voiced support for proposed N.J.A.C. 8:38A-3.5(d)1ii(5), prohibiting requirements for different or additional consents to be submitted for different stages of the appeal process, stating that the practice has been used to delay processing of appeals, and appreciating DHSS' recognition that any obstacle to an appeal does not serve the best interests of the patient.

Valley Hospital expressed support for proposed N.J.A.C. 8:38A-3.5(e)1, stating that, as long as providers are required to obtain a patient's consent to appeal after a denial is issued, requiring carriers to allow a minimum of 180 days for an appeal makes sense.

Health Net, Horizon, Oxford and NJAHP objected to certain provisions of proposed N.J.A.C. 8:38A-3.5(e)1i and 2i, which specify that, with respect to the time period for appeals to be filed, the count of the 180-day period does not start until five days after the date the adverse determination is issued. The commenters stated that the required 180 days is sufficient time for an appeal to be filed and that there is no need to extend the timeframe further. Horizon noted that it assumed DHSS was trying to reconcile the lack of verifiability of the commencement of the period under the Federal rules, but argued that the proposal does not resolve the issue unambiguously.

AmeriHealth suggested that DHSS should delete proposed N.J.A.C. 8:38A-3.5(e)1ii, which would permit a provider acting on behalf of the covered

person to initiate an appeal telephonically upon notice of an adverse determination, because it appears contrary to N.J.A.C. 8:38A-3.5(d)1ii, which suggests the carrier may require receipt of the member's consent. NJAHP stated that, in order to protect the patient and the carrier, carriers need to receive written consent first because they need assurance that a patient gave the doctor consent to appeal on behalf of the patient. NJAHP suggested that carriers would be irresponsible to accept the provider's verbal indication that the provider has been given the authority to act on the behalf of the covered person.

NJAHP also noted that if N.J.A.C. 8:38A-3.5(e)1ii is not deleted, then the phrase "carrier or" should be deleted, as carriers do not initiate the appeal.

MSNJ expressed support of proposed N.J.A.C. 8:38A-3.5(f), which requires a review upon appeal by a physician who did not consider the case for purposes of the prior determination, and who is not a subordinate of the prior reviewer. However, AmeriHealth objected to proposed N.J.A.C. 8:38A-3.5(f). AmeriHealth argued that if a carrier had a senior medical director render (or sign) the initial adverse determination, then the carrier would be curtailed from proceeding with a Stage 1 appeal if all other physicians on staff were subordinate to the senior medical director, which is impractical and may thwart a member being able to pursue a Stage 1 appeal. AmeriHealth requested that DHSS remove the text: "and who is not subordinate to the physician who rendered the initial adverse determination."

MSNJ indicated support of the proposed requirements at N.J.A.C. 8:38A-3.5(f)1 enhancing the standards of expertise of the person handling the appeal

as well as the timeframes for decision-making.

AmeriHealth, Health Net, Oxford and NJAHP expressed concern about proposed N.J.A.C. 8:38A-3.5(f)2, which would place an affirmative obligation upon the Stage 1 reviewer to try to obtain more information from the appellant prior to rendering an adverse determination if the reviewer believes the additional information is necessary. The commenters argued that such an obligation places an additional burden on carriers, given the timeframe for Stage 1, and is unwieldy. AmeriHealth questioned whether the member would be able to request dismissal of the Stage 1 appeal if an appellant believes that the reviewer should have obtained additional information before rendering the adverse determination. The commenter noted that the member always has the right to a Stage 2 appeal if unhappy with the Stage 1 outcome. Health Net requested that the phrase “an affirmative obligation to try to obtain” be replaced with “request additional” to make it clear what the carrier must reasonably do to assist the covered person, or provider, to perfect the appeal. Health Net also stated that the regulatory time in which the carrier must render a decision on an appeal should toll pending the receipt of additional information, and suggested that it may be advisable to include language that a carrier shall request any additional information it deems necessary to determine an appeal, and allow the covered person, or provider, ten days to submit such additional information, unless the carrier and covered person (or provider) agree to an extended timeframe, with the time in which the carrier must decide the appeal suspended pending receipt of the additional information or the time period for production of the additional

information has passed. Oxford stated that N.J.A.C. 8:38A-3.5(f)2 is not consistent with the Federal rules, and suggested that members should be required to provide all necessary information for a review initiated by them.

Oxford and NJAHP disagreed with proposed language at N.J.A.C. 8:38A-3.5(f)4i, stating that the Federal rules allow carriers with two levels of appeals to respond to non-urgent pre-service appeals within 15 days of the carrier's receipt of each request for review. The commenters argued that five days is too short a timeframe for the first level and may not add any benefit to the member in a non-urgent or concurrent situation.

Horizon stated that proposed N.J.A.C. 8:38A-3.5(f)5i appears to address the manner and content of communicating Stage 1 appeal determinations, but uses the newly defined term "adverse determination," which would include an initial UM denial, as defined.

AmeriHealth noted that proposed N.J.A.C. 8:38A-3.5(f)5ii appears to require a carrier to include in notices of adverse determinations the right of the covered person to bring a civil action except for covered persons not covered under a group health plan. AmeriHealth stated that providing such a notice would be a departure from the current process. The commenter opined that a member's right to bring a civil action should arise after the member has exhausted the carrier's internal appeal process, and N.J.A.C. 8:38A-3.5(f)5ii should be revised to reflect that.

Horizon stated that proposed N.J.A.C. 8:38A-3.5(g)2, which requires the carrier to have available and use additional consultant experts at the Stage 2

level appeal, goes well beyond the requirements set forth in Federal regulations. Horizon suggested that this provision be revised to reflect the Federal standard so that the decision-making panel includes a “health care professional who has appropriate training and experience in the field of medicine involved,” and incorporate the existing State requirement that the panel “have available consultant providers who are trained or who practice in the same specialty as would typically manage the case at issue.”

AmeriHealth, Health Net, Horizon, Oxford and NJAHP objected to aspects of proposed N.J.A.C. 8:38A-3.5(g)2ii, which requires the carrier to allow a consulting practitioner to participate in the second level panel if requested by the member or member’s representative or when the carrier does not have panel members available with appropriate training, or the member disputes the training of the carrier’s panel provider, or if there are multiple practitioners that can deliver a particular service. AmeriHealth noted that this represented a significant departure from current rules, and suggested that the requirement would mean carriers needed to have a crystal ball to determine whether the panel contains all licensed health care professionals that would provide the service/procedures at issue, especially if the member has multiple diagnoses. AmeriHealth stated that, although probably not contemplated, the provision could be used to challenge a carrier’s adverse determination and potentially delay the appeal process. Health Net opined that the rules are terribly confusing, ripe for abuse and susceptible of producing long delays in the processing of second level appeals. Health Net suggested it would be preferable to leave the standards as they currently exist,

and allow the covered person to argue the question of whether the Stage 2 appeal panel was appropriately constituted at the Stage 3 external appeal. Horizon added that it was worth noting that relevant industry accreditation standards address the issue of the composition and expertise of internal appellate panels, and do not go as far as the proposed rules. Horizon stated that the National Committee for Quality Assurance (NCQA) requires at least one person to review pre- or post-service appeals “who is a practitioner in the same or similar specialty who typically treats the medical condition, performs the procedure, or provides the treatment.” Horizon continued by saying that URAC (doing business as the American Accreditation Healthcare Commission, Inc.) requires that appeals be considered by health professionals who “are in the same profession and in a similar specialty as typically managed the medical condition, procedure, or treatment.” However, neither NCQA nor URAC requires any specific person with such expertise to actually participate in deciding the appeal or the hearing of the case if a hearing occurs. Horizon suggested DHSS revise the rules to better conform with the Federal standards, and revert to the previous language of N.J.A.C. 8:38A-3.5(g)2.

Oxford objected to proposed N.J.A.C. 8:38A-3.5(g)2ii stating that permitting members, or the members’ providers, to select the specialists for consultation at Stage 2 adds yet another layer to the review process and is duplicative of the existing process. Oxford stated that if the member disagrees with the carrier’s determination, he or she can always appeal the decision to the IHCAP, where it will be reviewed by an IURO, which has no affiliation with the

carrier, and suggested that the proposed rules offer no additional rights for the member, and would drive up costs as carriers would be required to have access to multiple specialists that may not be clinically required to review the case. NJAHP stated that allowing members to choose the type of consulting provider results in delays, increases inefficiency and drives up costs (for example, when multiple providers might handle the case, such as in the instance of Lyme disease, where a board-certified neurologist, infectious disease specialist or a rheumatologist might all be appropriate consultants).

Horizon noted that N.J.A.C. 8:38A-3.5(g)4 formerly allowed the carrier to request additional time to perform the Stage 2 review in certain instances, but the proposed amendment to N.J.A.C. 8:38A-3.5(g)4 removes this option, and no similar mechanism has been added back in. Horizon stated that Federal rules generally provide for the carrier to avail itself of an extension of the time frame if special circumstances exist, and suggested that the mechanism allowing carriers to extend their review time be continued in a manner that is consistent with the federal rules, so that thorough reviews can be performed under all circumstances.

Valley Hospital expressed concern regarding proposed language at N.J.A.C. 8:38A-3.6 (d)1 through 3, which sets forth reasons why DHSS would not forward a request for review through the IHCAP to an IURO. Valley Hospital stated it was concerned that the distinction the Department is making with regard to self-insured groups could be construed to mean that only the provisions of this section of the rules are not applicable to these plan types, and asked that DHSS

clarify in the definitions that these plans are specifically excluded from these rules as they are governed separately by ERISA. The commenter stated that it has experienced many carriers broadly interpreting the provisions of N.J.A.C. 8:38A to apply to all of their lines of business, both fully-insured and self-insured.

AmeriHealth and NJAHP questioned the proposed language at N.J.A.C. 8:38A-3.6(e)1, which would require the IURO to accept an appeal if the IURO determined that the individual was a covered person of the carrier on the date of service or on the date the service request was made. The commenters stated that the standard does not take into consideration eligibility, and noted that a covered person may not necessarily be eligible for a particular service either on the date that a service request was made, or on the date that a service was rendered. The commenters continued by saying that carriers are not required to pay for services provided to persons who are ineligible on the date of service, and that whether the member is eligible on the date the service was requested is irrelevant. The commenters suggested that to permit the IURO to accept an appeal based on whether the member was covered on the date the service request was made is inconsistent with the adverse determination that gave rise to the IURO appeal and inconsistent with member benefits, and that the provision should be deleted or revised.

AmeriHealth, Health Net, Horizon, Oxford and NJAHP disagreed with the proposed amendment to N.J.A.C. 8:38A-3.7(a), which would require the carrier to provide a written report to the member/member representative, Department and IURO in five business days, rather than 10 business days, following receipt of the

IURO's decision, describing the process for implementation of the decision. AmeriHealth opined there may be exigent circumstances that may require a longer period to implement the IURO decision, and suggested adding "or such longer timeframe depending on the exigencies of implementing the IURO's decision/recommendation." Health Net said that, in light of all of the administrative tasks carriers are required to complete and the desirability of informing the covered person of the correct implementation at the onset, allowing the carrier ten days to do so is necessary. Horizon stated that, if DHSS believes carriers should react to the IURO decisions more expeditiously, DHSS could accomplish the same intent without reducing the time frame in all cases to five business days. Horizon suggested instead that DHSS could rewrite the provision to read that the carrier's action should occur "as soon as possible given the exigencies of the case, but in no event longer than ten business days," arguing this would assure covered persons that carriers will implement the IURO's decisions within a time frame most appropriate to the circumstances of the case, and that this would also be consistent conceptually with the approach taken in the Federal regulations.

AmeriHealth and MSNJ both commented on proposed N.J.A.C. 8:38A-3.8(b)10, which would require a carrier to include a description of the criteria and methods used in utilization control, including the criteria for determining over and under utilization. AmeriHealth stated that it is unclear what the Department is seeking with this proposed change. MSNJ expressed support of the requirement for carriers to have a method to measure under- and over-utilization, stating that

MSNJ has long believed that these decisions and the process employed by carriers have been intended to reduce costs by discouraging appropriate utilization and without regard to medical necessity.

MSNJ expressed general support of the additional proposed disclosures required to be made to covered persons pursuant to proposed amendments to N.J.A.C. 8:38A-4.2, particularly with respect to utilization of out-of-network physicians. MSNJ stated that often the covered person's health benefits plan provides for out-of-network benefits and indicates that all or a certain percentage of the physician's usual and customary charges will be paid; however, often what a carrier considers usual and customary bears no relationship to the actual bill. The commenter said that, while the physician may balance bill the patient in these circumstances, the patient is often angry and confused, believing that he/she would have much less liability. The commenter suggested that these situations indicate that the language of their contracts or policies should be clarified, but also, the carrier information should clearly state that payments to the covered person for out-of-network providers needs to be given to the providers and not kept by the covered person. The commenter stated that too often, carriers do not honor an assignment of benefit agreement between the patient and the provider.

Horizon, Oxford and NJAHP objected to N.J.A.C. 8:38A-4.2(e) which would require carriers to provide handbooks or certificates to covered persons no later than the effective date of coverage, saying that the requirement is not practical. The commenters also stated that certificates by their terms certify to

the existence of coverage, so they really should not be delivered prior to the effective date of coverage. The commenters recommend delivery within 30 days following the effective date of coverage, consistent with the ERISA standards for summary plan descriptions.

Health Net questioned the difference between proposed N.J.A.C. 8:38A-4.2(e)1 and 2 (regarding the right of the covered person to select a primary care provider and to choose appropriate specialists) and the existing disclosure requirements at N.J.A.C. 8:38A-2.3 (specifying that carriers provide information about covered services and how to access such services). The commenter stated that it seems that the content of the proposed rules would already be covered in substance and that the commenter does not want to have to repeat much of the same information for another form at an increased cost in the administration of health care delivery.

AmeriHealth, Health Net, Horizon, and NJAHP expressed concerns about N.J.A.C. 8:38A-4.2(e)3, which essentially requires that the carrier assist a covered person in obtaining a referral to specialists within the carrier's network, or allow the covered person to obtain the services outside of the network at in-network benefit levels. AmeriHealth objected because it believed the proposed change appears to encourage members to seek referrals for out of network providers for chronic conditions which are typically not covered by carriers. Health Net stated that the language is far too ambiguous (and a little confusing) to be helpful and said it seems the language would encourage covered persons to seek in-network benefits when they receive services out of network as a

matter of preference, ultimately increasing the costs of health care coverage for all. Horizon objected on the basis that carriers do not practice medicine, and are not in the business of making referrals to specific providers. Horizon noted it would be appropriate for carriers to provide information to members about network providers and their areas of practice, and suggested changing the requirement so carriers had to provide such information. Horizon also considered the requirement that carriers refer to out-of-network providers when in-network providers are not available “within a reasonable period of time” was problematic because the reasonableness standard is ambiguous, would be impossible to administer, and carriers do not make referrals. Horizon suggested the issue is best addressed through the access standards carriers are required to adhere to in maintaining their network. NJAHP opined that requiring a carrier to refer a covered person to an out-of-network provider under the circumstances delineated is subject to wide interpretation and can easily lead to an abuse of the out-of-network benefits due to wrong interpretation of what reasonable waiting time for the appointment is.

Carrier Clinic, Holy Name, NJHA and Valley Hospital requested that DHSS revise proposed N.J.A.C. 8:38A-4.2(e)3 so that, in addition to specifying the financial responsibility of members referred out-of-network by the carrier, the rule would also specify that non-participating providers may continue to negotiate their reimbursement on a case-by-case basis and not be penalized for a carrier’s shortfall of network providers to which patients should be referred.

Carrier Clinic, Holy Name and NJHA stated that, while supporting

proposed N.J.A.C. 8:38A-4.2(e)3, DHSS should also address the oft-occurring case of a carrier approving less-than-acute-care services when there is not a skilled nursing facility or home health agency in the carrier's network that can or will take the patient. The commenters said in such cases the patient continues to reside in the acute care hospital, the carrier provides no assistance in locating an alternate provider, and denies the inpatient claim because the carrier states that the patient did not require acute care. The commenters strongly urged DHSS to clarify 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, within no more than 24 hours following identification of a need for an alternate level of care.

Oxford stated that the proposed language of N.J.A.C. 8:38A-4.2(e)4, regarding the right of the covered person to be held harmless on in-network services, is ambiguous. Oxford stated it agreed that the carrier may not balance bill for services authorized on an in-network basis. The phrase "or covered by the carrier" is confusing and should be deleted.

NJAHP expressed concerns about certain proposed amendments to N.J.A.C. 8:38A-4.5, which addresses the requirement to designate a medical director, and the medical director's responsibilities. NJAHP noted that the scope of functions for which the designated medical director is directly responsible has been expanded, and stated that having the medical director oversee credentialing is one thing, but actually having the medical director participating on

the committee is very difficult to implement.

Horizon suggested that the language of N.J.A.C. 8:38A-4.6(b)3, requiring carriers to have policies and procedures for handling provider complaints, be revised to insert the word “provider” in front of the word “complaints” for clarity.

Carrier Clinic and Valley Hospital expressed support for proposed N.J.A.C. 8:38A-4.6(b)3i, which establishes a turnaround time for carriers to respond to provider complaints. The commenters stated that providers have traditionally used the member’s appeal process (with consent) because there was no structure in place for carriers to respond to provider complaints. Requiring resolution of provider complaints within a specific timeframe may encourage providers to explore this as an avenue for resolving disputes.

Horizon suggested that proposed N.J.A.C. 8:38A-4.6(b)3ii, which would require the carrier’s provider complaint process to include a mechanism for notifying providers of the resolution of the complaint, be revised to clarify that the carrier’s mechanism for such notice can be satisfied by either oral or written notice, so long as the carrier’s records document the provision of such notice to the complainant.

AmeriHealth, Health Net, Horizon, Oxford and NJAHP suggested revisions to proposed N.J.A.C. 8:38A-4.6(f), which would require carriers to be responsive to Department inquiries regarding member complaints within 15 days following receipt of the complaint from the Department, or any greater or shorter period of time as specified by the Department’s request. AmeriHealth objected to the possibility that DHSS might shorten the turnaround time. AmeriHealth stated that

depending upon the issue raised, it may take a significant amount of time and coordination among various departments within the company to respond to an inquiry, and thus, abbreviating a carrier's response time may circumvent a thorough review of the issue raised. AmeriHealth suggested deletion of the phrase "or any...shorter period as specified in the Department's request." Oxford stated that a turnaround time for the resolution of a complaint is too burdensome for carriers, and fails to consider the time it takes to receive additional information which may be needed to resolve the matter. Oxford noted that these types of complaints are non-clinical and generally non-urgent matters which frequently require a lengthy investigation, and recommended revising the rules to permit a period of no less than 20 business days. Health Net and Horizon suggested modifying the 15-day requirement by adding "if the exigencies of the case require," which Horizon stated would be consistent conceptually with the approach taken by the Federal rules. NJAHP stated that a 15-day turnaround timeframe for complaints without any opportunity to request an extension is inconsistent with the U. S. Department of Labor rules at 29 CFR 2560.503-1, and suggested that carriers should be allowed some flexibility with respect to the medical exigencies of the case and they should be allowed to request an extension.

Health Net, Horizon, Oxford and NJAHP questioned the proposed amendments to N.J.A.C. 8:38A-4.8(a)2, which would require notices of termination to health care professionals be sent by certified mail to each address of record of the health care professional, if there is more than one address. The

commenters noted that participation agreements contain a notice provision in which the provider indicates the address of choice for receipt of notices from the carrier. The commenters stated that there does not seem to be a counterbalancing benefit to the costs that carriers would incur for the administrative task of sending multiple certified mailings. Horizon suggested the rules specify notice by certified mail, return receipt requested, with mailings being sent to only one address of record for each physician initially, but mailings to alternate addresses for a physician being required in the event that the address of record produces no return receipt. Horizon also suggested that in such circumstances, once mailings have been sent to all addresses of record by certified mail, return receipt requested, notice should be deemed to have been provided, regardless of whether any or all of the notices sent are signed for and hence received. Horizon opined that this would prevent a provider from evading notice of termination by refusing to sign for certified mail directed to their various office addresses of record.

Horizon objected to the proposed amendment to N.J.A.C. 8:38A-4.8(c), which would require carriers to give notice to covered persons regarding terminating primary care physicians (PCPs) as well as specialists whenever a covered person is currently receiving a course of treatment from a participating provider. Horizon stated that this adds an onerous requirement on carriers without taking into consideration how a carrier would gain the knowledge concerning which covered persons it should notify. Horizon stated carriers are not generally privy to provider plans for duration of treatment, so consequently, it

is the terminating provider that is in the best position to advise his or her patients regarding his or her participation status with a given carrier, and therefore, such notice obligation should not be shifted to the carriers via regulation.

NJAHP objected to the proposed language of N.J.A.C. 8:38A-4.8(c)4, which would require the notice of termination to provide information about the continuity of care period, and the covered person's rights during that period, because such information is already included in members' handbooks.

Health Net, Horizon, Oxford and NJAHP objected to the proposed language of N.J.A.C. 8:38A-4.8(c)4ii, which would require the carrier to include in the notice to covered persons the right of the health care professional to seek medically necessary hospital services for the covered person from hospitals without regard to whether the hospital is in the network of the covered person's carrier. The commenters argued that the proposed language would allow the health care professional to deviate from the participating provider's contract and as such contradicts existing law on continuation after termination. The commenters stated that during the continuation period, both the carrier and the provider are to abide by the terms of the terminated contract. The commenters pointed out that participating providers must have privileges at participating hospitals and are required to perform their services at such hospitals, absent a knowing exercise by the covered person of his or her out of network benefits with increased financial liability. Horizon added that the suggestion that health care professionals may disregard the participation status of the hospital goes beyond the statutory requirements for continuity of care, which would not prohibit the

rules from requiring the health care professional to make efforts to use in-network hospitals during the transition period. Horizon opined this would be a reasonable approach, and the rules should be amended accordingly. The commenters suggested that, if referral to a non-participating hospital is made and an admission or ambulatory stay occurs, coverage will still be provided (assuming preauthorization or precertification has occurred), consistent with available out of network benefits and current regulatory requirements.

AmeriHealth, Health Net, Magellan, Horizon, Oxford and NJAHP all objected to the proposed language of N.J.A.C. 8:38A-4.8(e), which would require carriers to send notices to terminated providers 30 days prior to the effective date of the termination, reminding them of their continuity of care period obligations under contract and law. The commenters stated that the notice appears to be superfluous given other information available to the health care professional (including their contracts), and results in an unnecessary administrative burden for carriers.

MSNJ stated that, while supporting the proposed changes to the rules at N.J.A.C. 8:38A-4.10 to help ensure network adequacy, the organization had concerns that DHSS may lack sufficient resources to verify carrier certifications and submissions concerning their networks. The commenter stated there needs to be enhanced checks of networks by carriers, perhaps by an outside source, as well as greater scrutiny by DHSS. The commenter said that, given recent trends of specialists dropping managed care plans, the organization was particularly concerned with network adequacy for specialized services.

Health Net, Horizon, Oxford and NJAHP objected to certain aspects of proposed N.J.A.C. 8:38A-4.10(a)3i. Health Net suggested substituting the phrase “refer the covered person” with the phrase “facilitate access,” because carriers do not make referrals. Oxford and NJAHP suggested revising the language essentially to say “carriers shall assist members in obtaining access to medically necessary covered services.” Horizon argued that the covered person’s treating health care professionals should in all cases refer covered persons to providers for their medical treatment, not the carrier; carriers provide access to care, not referrals. Horizon stated that DHSS likely intended the proposed rule to indicate that the carrier would be required to provide coverage for the non-participating referral at the in-network level of benefits in these circumstances, and if so, the language should be stated thus. Horizon continued, saying there will surely be disputes as to what constitutes “a reasonable amount of time consistent with the medical exigencies of the covered person’s condition,” noting that carriers are already required to publish their waiting time standards and members can and do complain if a specific provider does not meet those standards. Horizon argued that the proper remedy for insufficient network access is to require increased capacity rather than invite disputes over what is a “reasonable” amount of time.

Health Net, Horizon, AmeriHealth, Oxford, and NJAHP raised questions regarding proposed amendments to N.J.A.C. 8:38A-4.10(b)1, which would require carriers to meet network adequacy requirements across age groups. Health Net suggested DHSS should define “age group” to be exclusively the two

used in the example, that is, those over 18 and those under 18 years old, because requiring further subdivisions than this is too speculative and difficult to implement and its usefulness is questionable. Horizon concurred regarding the lack of utility of many subdivisions, but suggested the rules should make it clear that subgroups within the general term PCP are not required (for example, two PCPs within 10 miles should not mean two internists, two family practice physicians, two geriatric primary care physicians, etc.). NJAHP stated that if the concern is about age categories older and younger than age 18, then identifying pediatricians in carriers' networks would be a solution. If that was not the case, then NJAHP requested clarification as to whether carriers would have to submit geoaccess maps by age, and noted that carriers are not able to estimate numbers of new enrollees. AmeriHealth concurred that it is difficult, if not impossible, for carriers to project the number of covered persons in various age groups that the carrier expects to cover. Oxford took the stance that the expanded standards are overly broad, add significant administrative expense for carriers and do not necessarily result in expanded access to care. Oxford stated that carriers are already required to contract an adequate network with certain specialists for certain geographic areas, and if providers are not available in the network, carriers have an additional obligation to make network exceptions on an expedited basis.

AmeriHealth objected to the proposed language of N.J.A.C. 8:38A-4.10(b)1i, which allows carriers to meet the adequacy standards by demonstrating where age groups are located within the geographic service area,

if the carrier expects differences in age group distributions. AmeriHealth stated that this demonstration may be difficult, if not impossible, for a carrier to make.

AmeriHealth, Health Net, Horizon, NJAHP and Carrier Clinic commented on proposed N.J.A.C. 8:38A-4.10(b)1iii(1) through (3), which would require carriers to verify that a PCP's offices in each location listing office hours are actually offices where patients may be seen, not administrative offices. NJAHP stated it is too burdensome to report a specific number of hours for certain specialties, and suggested carriers be permitted to continue reporting consistent with existing network access requirements. Further, NJAHP stated that it is administratively cumbersome and highly unlikely that PCPs would be able to report the data that would allow carriers to demonstrate the number of hours that each office location has committed to a carrier's covered persons. Health Net stated that to require a carrier to reach out to its entire network on a regular basis to verify access is unreasonably onerous. AmeriHealth stated that carriers typically conduct site visits as part of the credentialing process, but otherwise require providers to notify the carrier about any change in office location or hours. AmeriHealth noted that should a complaint arise regarding access or quality of care issues, the carrier would visit the provider's office to investigate the matter, but site visits outside of the credentialing and/or recredentialing process and complaint investigation process are onerous. Similarly, Horizon argued that the current wording of the proposed rules does not address at what point and how often verification would have to occur, but any such regular, periodic requirement represents an additional burden on the carrier's part that really is the provider's

responsibility. Horizon stated it is in agreement that these requirements should take place at the time of initial credentialing but thereafter, the responsibility lies with the physicians to advise the carrier of any changes in their practice locations or office hours. Horizon stated that carriers already monitor member complaints regarding providers and had not seen any noticeable trend in complaints regarding listings of incorrect office locations or lack of availability of office hours, although there have been occasional or anecdotal instances of incorrect information being present in provider directories. However, Horizon added that these instances are most typically attributable to clerical error, systems glitches, or a provider's failure to properly notify us of changes as much as any failure on the part of the company that would be addressed by the new proposed rules. The commenters requested that N.J.A.C. 8:38A-4.10(b)1iii(1) through (3) be deleted.

Carrier Clinic supported N.J.A.C. 8:38A-4.10(b)1iii(1), observing that one of the biggest factors in over-utilization of emergency departments is the lack of PCPs available to see patients. The commenter stated the proposed rules and the other provisions requiring verification of capacity are a good first step to reducing this problem.

Valley Hospital expressed support for proposed N.J.A.C. 8:38A-4.10(b)1iii(1), but requested that DHSS consider more specific language regarding the number of institutional providers as it pertains to skilled nursing and subacute care to reduce inappropriate utilization of acute care facilities.

Health Net, Horizon, Oxford and NJAHP raised questions or gave

suggestions regarding the proposed amendments to N.J.A.C. 8:38A-4.10(b)2, which requires carriers to have an adequate number of specialists within a geographic area. Health Net, Oxford and NJAHP stated they did not know what type of provider is a subspecialist, and suggested the term probably should be deleted. NJAHP stated that the term is not consistent with other States and would be tremendously burdensome to carriers' systems. Health Net also requested clarification of the phrase "other health care professionals" in N.J.A.C. 8:38A-4.10(b)2ii. Horizon suggested the phrase "except in those instances in which no such licensed services are available" should be added.

Oxford suggested a revision to the proposed amendment to N.J.A.C. 8:38A-4.10(b)3, requiring carriers to have an adequate number of health care facilities in their networks. Specifically, Oxford suggested the phrase "12-month projected enrollment" should be deleted.

Horizon suggested that the proposed language at N.J.A.C. 8:38A-4.10(b)3iv and v, regarding network adequacy for certain types of specialized institutional providers, be revised to add the phrase "except in those instances in which no such licensed services are available." In addition, Horizon suggested that the term "institutional providers" as used in N.J.A.C. 8:38A-4.10(b)3 be clarified to refer only to the institutional provider requirements indicated in the subsections that follow it in that particular section of the regulation.

Health Net argued against adoption of the proposed language at N.J.A.C. 8:38A-4.10(b)3v(1) to increase the number of long-term care facilities from one within a geographic area to three, stating that the increase is neither necessary

for adequate access or possible in light of the number of long term care facilities with Medicare-certified skilled nursing beds in the State.

AmeriHealth, Health Net and NJAHP raised issues with respect to the proposed language of new N.J.A.C. 8:38A-4.10(b)3viii, which would require a carrier to have an arrangement with at least one hospital for long-term acute care services in the southern, central and northern regions of New Jersey regardless of the carrier's approved geographic service area. AmeriHealth asked what recourse a carrier would have if it could not contract with a hospital for long-term acute care services outside of the carrier's geographic service area. Health Net requested clarification of what the boundaries of the southern, central and northern regions of New Jersey are, and what exactly is meant by "long term acute care services." NJAHP stated that contracts in geographic areas should not be part of regulations and therefore the language should be removed.

Horizon requested clarification of N.J.A.C. 8:38A-4.10(d), which, as proposed, would require a carrier to demonstrate that travel distances and times were taken into consideration in determining network adequacy. Horizon stated that language was necessary clarifying how accessibility is measured for covered persons who will typically utilize public transportation to access services as opposed to private automobiles. Horizon said this methodology continues to be a concern as the requirement proposed to be amended is difficult to measure and demonstrate based on its reliance on U.S. Census Data and presumably public transportation schedules and travel time estimates, etc. Horizon suggested the language be modified to at least include that the standard for

demonstrating compliance be a “reasonable” showing having been demonstrated by the carrier.

Horizon and NJAHP expressed concerns regarding proposed N.J.A.C. 8:38A-4.10(e), requiring carriers to demonstrate accessibility of the network using projected hourly or service needs of a projected enrollment over a 12-month period by county or service area. Horizon suggested that demonstrating capacity for a “projected 12-month period by county or service area” may be difficult to both verify and demonstrate satisfactorily, and thus, urged that the language be further clarified to include that the standard for demonstrating compliance be a “reasonable” showing having been demonstrated by the carrier. NJAHP stated that a demonstration should not be required from all carriers, but rather, only if there are too many complaints or the member/provider ratio is out of line. NJAHP suggested that alternative language could state that carriers need to verify they have enough providers for the amount of members. NJAHP opined that to require a carrier to reach out to its entire network on a regular basis to verify access is unreasonable and onerous.

MSNJ expressed support for the proposed deletion of N.J.A.C. 8:38A-4.10(f) 3 and 4, which currently allows carriers to consider Advance Practice Nurses and Physician Assistants as PCPs. MSNJ stated that carriers should only consider qualified physicians as satisfying the PCP requirement, not ancillary health care providers and extenders.

Health Net and NJAHP requested a clarification regarding whether the provisions of proposed N.J.A.C. 8:38A-4.10A, regarding access by covered

persons to physician services after hours, generally refer to access for urgent and emergent circumstances.

Horizon and Magellan both commented with respect to N.J.A.C. 8:38A-4.10A(b). Horizon requested that N.J.A.C. 8:38A-4.10A(b), regarding after-hour access of physicians, be limited to accessibility of primary care physicians. Magellan stated that N.J.A.C. 8:38A-4.10A(b), regarding after-hour access of physicians, is onerous as written. Magellan explained that many of its New Jersey outpatient psychiatrists are in singular practices, not a group, and compliance would be very difficult. Magellan recommended that DHSS permit them to use other covering physicians to take calls or some other substitute that would permit the 24/7 compliance.

Oxford objected to the wording of proposed N.J.A.C. 8:38A-4.10A(b)1, regarding carriers arranging with physicians a “triage” call service to address the after-hour physician services requirement, stating that the carrier obligations do not include the provision of medical care or consultation.

AmeriHealth and NJAHP expressed reservations regarding proposed N.J.A.C. 8:38A:4.10A(b)2, which allows carriers to permit participating providers to have arrangements with back-up physicians, as long as the back-up physician is subject to the same medical practice and contractual standards of the participating provider. The commenters stated that, generally, this is a provision that reinforces the expectations of the carrier; however, a carrier may be required to contract with locum tenens (that is, a medical practitioner who temporarily takes the place of another), even in those circumstances when the carrier is not

informed that a locum tenens is used by a participating provider.

Horizon and NJAHP objected to some of the requirements of proposed new N.J.A.C. 8:38A-4.11(b)4ii and iii, which would require carriers to make UM staff available to respond to inquiries from covered persons in urgent situations when a covered person's PCP might not be available. Horizon objected to the requirement that carriers notify covered persons about the availability of the UM staff as proposed at N.J.A.C. 8:38A-4.11(b)4ii, as well as the suggestion at N.J.A.C. 8:38A-4.11(b)4iii that carriers could satisfy the notice requirement by listing the carrier's UM telephone number on the membership ID cards. NJAHP's primary argument was with N.J.A.C. 8:38A-4.11(b)4iii, saying that telephone numbers for medical necessity inquiries are already included on member ID cards. Horizon argued that, while these requirements may appear to be in the interest of covered persons, they could have a significant operational impact on UM program accessibility if covered persons have direct access to the telephone number. Horizon stated that carriers should maintain UM staff availability sufficient to be generally accessible to providers to allow the UM process to function in a manner that does not delay or hinder patient care. Horizon suggested, however, that most member questions can be handled by customer service staff, and having a single point of contact for covered persons is more efficient and member-friendly. Horizon noted that member service staff can transfer calls to UM staff if appropriate, whereas, any increased volume to a carrier's UM program lines due to members calling the number inappropriately could result in delayed access for the providers who have traditionally been the

main users of UM telephone lines, or cause UM units to need increased staffing. Horizon argued that adding undue pressure to carriers' UM telephone units is unnecessary.

Horizon noted that the proposed new language of N.J.A.C. 8:38A-4.13(b)3 lists a number of external quality review organizations, including NCQA, URAC, JCAHO and PRO-NJ, as clarification. Horizon stated that many carriers may seek the review and accreditation from more than one of these organizations, and suggested that the language in the rules clarify that a carrier will only be required to submit a report of one such audit every 36 months. Horizon also stated that dental business should be excluded from this requirement.

In response to the proposed amendments to N.J.A.C. 8:38A-4.14 , regarding health care provider input to a carrier's written clinical criteria and protocols, MSNJ reiterated its comment to N.J.A.C. 8:38A-3.4(b)2, essentially saying that the protocols should be available on the carrier's web page without the necessity of having to request them.

Health Net and NJAHP objected to the proposed deletion of N.J.A.C. 8:38A-4.14(d), allowing carriers to exclude certain information from disclosure. Health Net stated that the permissive exclusion is an important one, and should be retained. NJAHP stated that, even though the Department believes that elimination of this language would make carriers more accountable to their covered persons and health care providers alike, carriers are not exactly sure what the Department means by "quantitative thresholds" and are generally concerned when a regulatory agency says to disclose something even if it is

proprietary.

Horizon expressed support for the proposal to deem provider agreements approved if not disapproved within 60 days of receipt.

In response to proposed N.J.A.C. 8:38A-4.15A, Health Net and NJAHP objected to the inclusion of “service agreement” as defined at N.J.A.C. 8:38A-1.2, reiterating the comments they expressed in response to the proposal of the definition of the term “service agreement.” NJAHP added that service agreements are business support contracts that should not be regulated by DHSS, noting that a multi-state carrier might have a vendor contract in each state and might have to have different service agreements for a vendor in New Jersey

Health Net expressed general concern with the stance DHSS was taking in the provisions regulating provider agreements. Health Net stated that DHSS proposed to prescribe certain provisions in a carrier’s contract with a participating provider that are not authorized by statute and which go far beyond the “minimum standards” of the existing rules for both carriers under Chapter 38A and HMOs under Chapter 38. Health Net opined that a carrier’s contract with a hospital is clearly a contract between arms-lengths negotiators and, except for the areas authorized by legislation, it really is not in furtherance of efficient and affordable health care delivery in the State for the DHSS to require that the carrier include many of the provisions in proposed N.J.A.C. 8:38A-4.15C. Health Net continued by saying that, likewise with the hospital agreements, many of a carrier’s physician contracts are with large groups, which have a great deal of leverage in negotiation with carriers. Health Net noted that the Legislature also

has seen fit to address what it conceived to be a need to provide individual physicians with greater leverage in negotiation with carriers by permitting physicians to collectively negotiate both fees and terms of network participation agreements. Accordingly, Health Net stated it does not believe it is necessary, in furtherance of providing efficient and affordable health care, or that it is within DHSS' authority, to mandate certain provisions in a network contract that have not been authorized by legislation.

Horizon expressed general concern regarding the revamping of the requirements for provider agreements. Horizon stated that the proposed new rules add new requirements and details that are impractical and which would severely hamstring carriers in their efforts to maintain and manage networks of providers to deliver affordable and effective health care. Horizon said that the requirements are extremely detailed and would make the provider contract unwieldy. Horizon noted that, while proposed N.J.A.C. 8:38A-14.5C(d) recognizes that such information could be contained in a manual or other communication, the proposed rules would only allow the information to be in a manual if the contract states that the information is set forth in a provider manual and the manual is **approved prior to use**. Horizon opined that the requirement that a manual be approved prior to use is a sweeping and impractical requirement, and puts the Department in the day-to-day running of the carriers and their provider networks. Horizon argued that delaying changes to and issuance of a provider manual for prior approval (a several month process, even changes to the manual are submitted instantaneously, and approval is not

delayed) takes away from the beneficial nature of this tool. Furthermore, Horizon argued, requiring prior approval of provider manuals is inconsistent with and destroys the very beneficial change DHSS instituted with the Provider Agreement Certification and Checklist procedure.

MSNJ stated that it generally agrees with the proposed new rules regarding provider agreements, because it believes that clearly defining the rights and obligations of all parties to a contract will avoid future disputes and will help providers better determine if they want to enter into a contract or terminate one they are in. MSNJ also expressed support for any provisions that seek to level the playing field between providers and carriers. The commenter said that, while these contracts are freely entered into, the relative bargaining power of the parties is greatly disparate, and that it is only through governmental regulation that physicians can hope to avoid many of the current pitfalls in these contracts and make them more balanced and fair. However, MSNJ requested that DHSS prohibit any clause in a provider agreement that obligates a physician to forego any of his/her legal rights to bring suit against the carrier for violation of state or federal law as an individual or in a class action. MSNJ noted that organized medicine has brought a number of suits against carriers for violations of the law and has settled several, and now many carriers are placing provisions in their provider agreements preventing physicians from entering into any further class action lawsuits. The commenter stated that physicians should not have to forego their legal rights to enter into a contract with a carrier in New Jersey.

Health Net, Horizon, Oxford, NJAHP, and MSNJ commented upon

N.J.A.C. 8:38A-4.15C(a)4, which required the provider agreement to contain provisions regarding the compensation methodology, including the fee schedule between the carrier and provider. Health Net and NJAHP said that the proposed language appears to suggest that all provider agreements include the “fee schedule.” These commenters noted legislation currently is being negotiated by carriers and the legislative sponsors (which the commenters believed was further indication that legislation is needed for this requirement before it can be required in administrative rules) concerning disclosure of fees to be paid to providers. The commenters stated that (at the time the comments were submitted) the parties had agreed that the disclosure of only the most commonly used codes by that provider is advisable because a carrier’s fee schedule is voluminous and only portions pertain to any particular provider. The commenters suggested it may be advisable to leave this to the legislative arena. Oxford supported the argument regarding the volume of the fee schedules stating that providing the entire fee schedule is not administratively possible, especially considering the multiple combinations of possible codes (AMA CPT and CMS HCPCS) that can be billed. Oxford suggested that carriers should only be required to provide a small sample of the relevant fee schedule upon request. Horizon suggested revising the requirements of the provision with the following wording to better reflect the mode of operation in the computer age: “A provision specifying the compensation methodology, including the availability of a fee schedule on paper or online, between the carrier and the provider.”

MSNJ expressed strong support for the concept of disclosure regarding

the fee schedules and compensation methodologies included in the proposed language of N.J.A.C. 8:38A-4.15C(a)4; but stated that, if the intent is for providers to have the information they need to decide whether to enter into a contract in the first place, and know what they should be getting reimbursed once they have a contract, this intent needs to be further clarified and additional language added. The commenter argued that providers should be told, on a carrier's web page at the least, the methodology for determining how a claim is paid, when it will be bundled, downcoded, or changed in other fashion. MSNJ stated further that providers should be given all the fee schedule codes for which they routinely bill, and should be notified of any intent to change any of those fee schedules. The commenter said that, while the Department's intent may be well-placed, the organization's experience is that carriers will seek to provide as little information as possible to providers unless mandated by law.

Health Net objected to the requirement of proposed N.J.A.C. 8:38A-4.15C(a)6 that carriers include provisions in the provider agreement explaining the quality assurance (QA) program. Health Net stated that carriers retain the right to delegate functions, and that business needs and market forces often compel carriers to do so. Health Net said that when a carrier does delegate functions that affect the activities of the contracted providers, it is incumbent upon a carrier by virtue of its contract to provide notice to its participating providers in a number of commercially reasonable fashions, e.g., letter notices, newsletters, websites, etc., and suggested that explaining a quality assurance program in detail in a contract that most providers do not refer to on any type of

routine basis seems to be imposing an administrative cost to effectuate amendments without a counterbalancing benefit.

AmeriHealth, Health Net and Horizon expressed reservations regarding N.J.A.C. 8:38A-4.15C(a)6iii, which requires the provider agreement to identify the entity responsible for day-to-day administration of the quality assurance program. AmeriHealth merely noted this is a departure from existing requirements, as carriers may delegate these services. Health Net stated that it had found that identifying a specific person who is responsible for the day-to-day administration of the quality assurance program as proposed is unnecessary, inappropriate and not helpful, particularly since the company itself is responsible for its quality assurance program, not a specific person. Horizon argued that requiring explanations of the QA programs and the entity responsible for the day-to-day administration of the program is impractical and would severely hamstring carriers in their efforts to maintain and manage networks of providers to deliver affordable and effective health care. Horizon stated that it is in the carriers' interest to inform their network of the QA program so that providers will follow the carriers' procedures, and thus, the rule serves little, if any, useful purpose. Horizon suggested that, if the Department decides to retain the rule, the rule should be revised to require carriers to inform their network providers of the QA program upon joining the network and on a periodic basis thereafter (such as at least every two years), and to inform network providers of significant changes in the administration of the QA program.

Health Net and Horizon expressed reservations regarding N.J.A.C. 8:38A-

4.15C(a)7, which requires the provider agreement to include provisions explaining the UM program. Health Net stated that carriers retain the right to delegate functions, and that business needs and market forces often compel carriers to do so. Health Net said that when a carrier does delegate functions that affect the activities of the contracted providers, it is incumbent upon a carrier by virtue of its contract to provide notice to its participating providers in a number of commercially reasonable fashions, for example, letter notices, newsletters, websites, etc., and suggested that explaining a quality assurance program in detail in a contract that most providers do not refer to on any type of routine basis seems to be imposing an administrative cost to effectuate amendments without a counterbalancing benefit. Horizon repeated the same arguments it made concerning the requirement that the provider agreement identify the entity responsible for the administration of the QA program with respect to requiring that provider agreements also contain provisions explaining the UM program.

AmeriHealth, Health Net and NJAHP noted that proposed N.J.A.C. 8:38A-4.15C(a)7v requires that the provider agreement explain that the provider has the right to rely upon the written or oral authorization of a service if made by the carrier and that services may not be retroactively denied as not medically necessary except in cases of material misrepresentation of facts to the carrier. The commenters stated that the provision does not take into account retroactive denials based on the ineligibility of a member. However, MSNJ expressed support for the provision and being able to rely on UM decisions.

Horizon objected to the proposed requirement of N.J.A.C. 8:38A-

4.15C(a)8, which requires carriers to provide an explanation in the provider agreement regarding the rights and obligations of health care providers in making UM appeals on behalf of covered persons. Horizon argued that requiring explanations of the UM appeals programs and the entity responsible for the day-to-day administration of the program is impractical and would severely hamstring carriers in their efforts to maintain and manage networks of providers to deliver affordable and effective health care. Horizon stated that it is in the carriers' interest to inform their network of the UM appeals program so that providers will follow the carriers' procedures, and thus, the rule serve little, if any, useful purpose. Horizon suggested that, if the Department decides to retain the rule, the rule should be revised to require carriers to inform their network providers of the UM appeals program upon joining the network and on a periodic basis thereafter (such as at least every two years), and to inform network providers of significant changes in the administration of the UM appeals program.

MSNJ requested revisions to proposed N.J.A.C. 8:38A-4.15C(a)12, requiring provider agreements to contain a provision specifying that participating health care providers will hold covered persons harmless for costs of covered services and supplies rendered in-network. MSNJ stated that, while recognizing the need for this rule, the organization believes there needs to be clarification that providers may charge extra for services and procedures not covered by a covered person's policy with a carrier. The commenter said this may seem obvious, but that a clarification in the rules probably would avoid any future disputes on this point.

Horizon objected to proposed N.J.A.C. 8:38A-4.15C(a)13, which requires the provider agreement to include explanations about any obligations regarding credentialing and participation in the carrier's network. Horizon argued that requiring explanations of the credentialing programs and the entity responsible for the day-to-day administration of the program is impractical and would severely hamstring carriers in their efforts to maintain and manage networks of providers to deliver affordable and effective health care. Horizon stated that it is in the carriers' interest to inform their network of the credentialing program so that providers will follow the carriers' procedures, and thus, the rule serves little, if any, useful purpose. Horizon noted that existing N.J.A.C. 8:38A-4.7(e) already gives the Department authority to review credentialing applications, notices and guidelines.

Oxford stated that proposed N.J.A.C. 8:38A-4.15C(a)18i, allowing the contract to have a provision permitting providers to limit the total number of a carrier's covered persons that the provider will treat, is inappropriate. Oxford argued that a provider participating with multiple carriers should not be permitted to limit his or her practice such that the limitations would discriminate between members, or the carriers.

Oxford and NJAHP stated that proposed N.J.A.C. 8:38A-4.15C(a)18ii, which allows the provider agreement to contain a provision permitting health care providers to limit the carrier's products in which the health care provider chooses to participate, is inappropriate and should be struck. The commenters stated that, in order to maintain competition in this market, a carrier should have the

ability to require participation in all products in a geographic area. The commenters further stated that accurately tracking this will be extremely difficult for carriers and result in consumer confusion and frustration, noting the potential problems for a consumer moving from an HMO to a POS product with the same carrier and suddenly being told their PCP is now non-participating. Oxford also stated that allowing providers to cherry pick among the company's products, product by product, will drive up administrative costs, and therefore, premiums.

Horizon objected to proposed N.J.A.C. 8:38A-4.15C(a)19, which requires provider agreements to contain some explanations regarding the procedures for submitting and handling of claims. Horizon argued that requiring explanations of the claims payment program and the entity responsible for the day-to-day administration of the program is impractical and would severely hamstring carriers in their efforts to maintain and manage networks of providers to deliver affordable and effective health care. Horizon stated that it is in the carriers' interest to inform their network of the claims payment program so that providers will follow the carriers' procedures, and, thus, the rule serves little, if any, useful purpose. Horizon went on to say that, as for a provision regarding how interest will be remitted for late payment of claims, and the standards for determining whether submission of claims has been timely, the company respectfully suggested that such level of detail is operational and does not belong in a provider agreement, and that existing rules at N.J.A.C. 11:22-2 regarding prompt payment of claims provide ample regulations of the payment of interest on late payment of claims.

Horizon stated that the proposed language of N.J.A.C. 8:38A-4.15C(b)1i and 2i prohibiting the provider agreement from denying an agency relationship between the provider and the carrier, appears to be based on the ODS rules, and is more apt in that context. Horizon said that outside of the ODS context, it is neither in the interest of the carrier or the provider for the provider to be the carrier's agent, on a wholesale or global basis. Horizon suggested that DHSS' intentions could be better served by prohibiting denial of agency relationship for certain activities, namely, those activities the carrier has specifically authorized the provider to perform, such as making referrals. Alternatively, Horizon suggested that each provision should end after "or other explicit business relationship."

Horizon and Oxford argued against adoption of proposed N.J.A.C. 8:38A-4.15C(c)1, which prohibits provider agreements from establishing "any limitation on the time period during which a provider may bring suit that is less than that set forth under the statutes of limitation established by law." Horizon stated that parties to a contract have the right to contract to narrow the statute of limitation, and submitted that this right should not be taken away. Oxford argued that carriers should be able to require resolutions with providers in a specified timeframe agreed to between the parties and require binding arbitration in lieu of litigation, because the process makes economic sense and makes efficient use of resources for a carrier who is maintaining a robust network which meets or exceeds the network adequacy requirements for covered persons in New Jersey. Horizon argued that the provision is extremely one-sided as it would only apply to

claims of the provider and would not apply to claims asserted by the carrier, and also stated that the provision is inconsistent with reasonable and common time limitations on appeal of UM determinations or claim payment denials.

Oxford, NJAHP, MSNJ, Carrier Clinic and Valley Hospital registered opinions regarding proposed N.J.A.C. 8:38A-4.15C(c)2, which would prohibit provider agreements from containing a provision giving carriers a unilateral right to amend the contract terms. MSNJ, Carrier Clinic and Valley Hospital expressed strong support for the proposed new rule. Carrier Clinic and Valley stated that hospitals often have little negotiating power when presented with a carrier contract, so prohibiting this type of egregious provision and practice will establish protections for all hospitals rather than relying on the bargaining power of a few to secure it in their contracts. MSNJ stated that the organization's reading of the language is that a carrier will no longer be able to change the terms of a contract (such as fee schedules, payment methodologies, or other material aspects) during the term of the contract without offering the physician the option to accept those new terms, but requested a clarification of that intent and perhaps additional language that spells this out. MSNJ also stated that, if that is not the Department's intent, that should be clarified as well, in which event, the organization would ask for such a provision to be added. MSNJ said the organization believes it is blatantly unfair to allow a carrier to change a material aspect of a contract and not allow a provider a reasonable period of time to withdraw from the contract if he/she will not accept those changes.

Oxford argued that proposed N.J.A.C. 8:38A-4.15C(c)2 should be deleted.

because it is not reasonable to require a carrier to negotiate with thousands of individual providers on routine matters. Oxford said this would prohibit a carrier from maintaining an adequate network and would require routine network exceptions, would drive up costs and could jeopardize the effectiveness of any managed care product. Oxford stated that a certain level of standardization allows for timely payment of claims, accurate forecasting of expenses and setting premiums as well as providing coverage of quality health care, while negotiating clinical policies, for example, with each and every participating physician makes no sense, given that what was routine yesterday is outdated today. Oxford questioned whether anyone really wants to go back to promoting varied practice patterns, and questioned why carriers should be expected to negotiate clinical policies when most are developed by the specialty societies anyway (that is, American College of Surgeons). Oxford further noted that there may be other reasons for unilateral amendments, including reacting to safety concerns, such as when Vioxx was withdrawn from the market by the FDA or when providers are sanctioned by their peers (that is, the Board of Medical Examiners). NJAHP's concurred with Oxford's arguments, but NJAHP also stated that standardization of provider agreements is extremely important because it: (1) allows carriers to predict costs and set premiums accurately and affordably, and avoids product over-pricing because of over-adjusting for unknowns and (2) allows for ease of administration of claims payment, with many provider fees tied to the federal or state rates (Medicare and Medicaid). NJAHP pointed out that all hospital contracts and large physician group practices (for example, Summit Medical

Group) are negotiated contracts, while it is contracts with solo physicians and small group practices in which carriers seek standardization because of the practical issues noted above.

Oxford, Carrier Clinic, and Valley Hospital expressed differences of opinion regarding proposed N.J.A.C. 8:38A-4.15C(c)4, which would prohibit provider agreements from containing provisions preventing health care providers from disputing a reassignment of bundling of codes. Carrier Clinic and Valley Hospital stated that hospitals often have little negotiating power when presented with a carrier contract, so prohibiting these egregious provisions and practices will establish protections for all hospitals rather than relying on the bargaining power of a few to secure it in their contracts.

Oxford stated proposed N.J.A.C. 8:38A-4.15C(c)4 should be deleted, because unbundling of codes is generally inconsistent with Medicare and AMA guidelines, drives up medical costs and can be a form of fraud. Oxford stated that it is appropriate for participating providers to agree to reimbursement policies as a condition of becoming network providers.

AmeriHealth, Oxford, Carrier Clinic and Valley commented on proposed N.J.A.C. 8:38A-4.14C(c)5, which would prohibit provider agreements from having provisions that state payment to a provider with respect to medically necessary services will be denied for lack of pre-certification or pre-authorization. AmeriHealth said the standard is contrary to the company's Quality Management policy and would limit the ability of a carrier to indicate breach of contract if the provider fails to obtain precertification or preauthorization. AmeriHealth also

suggested the provision could be construed to require a carrier to pay for any service or supply the provider believes is medically necessary even in the absence of obtaining precertification or preauthorization. Oxford argued that providers agree to the carrier's policies and procedures for network status, and a significant part of the participating provider's responsibilities include the administrative process. Oxford suggested that failure of providers to follow that process, and providing services which may not be covered under the covered person's certificate, will result in higher medical costs.

Carrier Clinic and Valley Hospital supported the proposed language of N.J.A.C. 8:38A-4.15C(c)5, saying that hospitals and carriers often dispute whether a service was authorized, and that the provision will ensure that if the service was medically necessary, it would not be denied because of a dispute about protocol.

Health Net objected to the proposed language of N.J.A.C. 8:38A-4.15C(c)6, which prohibits provider agreements from containing a provision that suggests a covered person cannot dispute his or her eligibility for a covered service, arguing that the paragraph is not germane to a contract between a carrier and a provider.

Carrier Clinic, Valley Hospital, MSNJ, Oxford and NJAHP registered opinions regarding N.J.A.C. 8:38A-4.15C(c)7, which would prohibit provider agreements from containing provisions that require health care providers to always assure that the carrier receives the lowest possible comparative rate from the health care provider (often referred to as a "most favored nation" clause).

Carrier Clinic and Valley supported the proposed language, stating that hospitals often have little negotiating power when presented with a carrier contract, so prohibiting this type of egregious provision will establish protections for all hospitals rather than relying on the bargaining power of a few to secure it in their contracts. MSNJ also expressed strong support of the prohibition against “most favored nation clauses.”

Oxford said the courts have traditionally determined when “most favored nations” (MFN) clauses violate antitrust laws, and thus, the prohibition on any MFN-type of clause is overly broad and vague and unnecessary. Oxford stated that the proposed prohibition at N.J.A.C. 8:38A-4.15C(c)7 arguably precludes carriers from obtaining any assurance from providers that the rates agreed to at the time the contract is executed are, in fact, what the provider represented to the carrier during the negotiation process, and suggested that this type of broad prohibition on the ability of parties to freely contract could, in itself, be anticompetitive in nature. NJAHP concurred with Oxford’s arguments, but also stated that the provision is clearly an anticompetitive rule because it prohibits free contracting and prohibits rate competition in the New Jersey market.

Horizon, Oxford and NJAHP had some concerns about proposed N.J.A.C. 8:38A-4.15C(c)8, which would specify that no provider agreement may require “a provider to be responsible for the actions of a nonparticipating provider.” Oxford suggested that the phrase “with the exception of a non-participating covering physician” be added to the section for clarity. However, Horizon stated there are situations where it is in the member’s interest to make a provider responsible for

certain actions of a nonparticipating provider, and offered as an example, a network provider developing a practice of referring members to a nonparticipating provider, even one located in the network provider's office or down the hall, or a network provider having a nonparticipating physician cover for the network provider, leaving the member with significantly reduced coverage. Horizon opined that this does not benefit the member as the member may assume from the circumstances that the provider to whom he is referred is a participating provider, and suggested that the prohibition is overbroad. NJAHP argued the provision is contrary to carriers' quality management policies and would limit the ability of a carrier to indicate breach of contract if the provider fails to receive pre-certification or preauthorization for a services or supply. NJAHP also suggested the provision could be construed to require a carrier to pay for any services or supplies that the provider believes are medically necessary even in the absence of obtaining precertification or preauthorization for such services.

AmeriHealth objected to the proposed language at N.J.A.C. 8:38A-4.15C(d), which would require that, if a carrier includes reference to a provider manual in its provider agreements, the carrier must submit the manual to the Department for approval prior to use. AmeriHealth stated that submission of a provider manual would be extremely burdensome and is not required by any existing regulation.

Health Net requested a general clarification to the proposed language of N.J.A.C. 8:38A-4.15D, which requires provider agreements to address the issue of termination and when a health care provider is entitled to a hearing prior to

termination being effected. Health Net noted that the statutory requirements for a hearing is only applicable when the provider is terminated without cause. For that reason, Health Net asked DHSS to make it clear that it is not necessary for carriers to cite the language of the rule verbatim so long as the contract complies with the legal requirement set forth in statute.

Horizon expressed concern about proposed N.J.A.C. 8:38A-4.15D(b), which would allow the provider agreement to be terminated without cause, so long as non-cause termination is permitted by either party subject to reasonable prior notice. Horizon suggested that the requirement that noncause termination be permitted by either party is unwise and arbitrary. Horizon opined the covered person is better served by stable provider networks, and if a carrier can persuade a provider to accept provider agreements which permit the health care provider to terminate the contract for cause only, that benefits the covered person and should not be prevented.

Horizon objected to proposed N.J.A.C. 8:38A-4.15F(b) which would specify that provider agreements with PCPs and specialists shall set forth the obligations, if any, of the provider to acquire and maintain hospital admitting privileges. Horizon stated this information is part of the carrier's credentialing standards and it should not be required to be stated in the provider agreement, because doing so not only makes the provider agreement longer, it also discourages carriers from strengthening their credentialing standards and thereby tends to discourage efforts to improve quality of care provided to covered persons.

Health Net and Horizon expressed concern about certain provisions of the proposed language of N.J.A.C. 8:38A-4.15G, which generally addresses provisions specific to provider agreements with hospitals. Health Net stated that many of DHSS' proposed new regulations are vague and confusing, but specifically that the company did not understand the intent of:

(a)1, which would require the provider agreement to specify procedures for hospitals to notify carriers and any other entities designated in the provider agreement when a hospital may alter its standards for admitting and attending privileges; subsection (b), which would require the provider agreement to specify admission authorization procedures; and subsection (c), which would require the provider agreement to specify the procedures for hospitals to notify carriers of the presentation of a covered person at a hospital's emergency department. Horizon stated that the details required in paragraph (a)1 and subsections (b) through (d) (subsection (d) would require the provider agreement to specify procedures for billing and payment), are the types of details that are better covered in a provider manual than in the provider agreement if DHSS expects any detailed specification. Horizon indicated that the sections appeared to be changed from existing N.J.A.C. 8:38A-4.15(d) without any comment or explanation for the change being given by the Department, and requested DHSS to maintain the current language or explain the rationale for any change intended.

RESPONSE: While DOBI appreciates that some commenters are very

supportive of many of the proposed amendments and new rules, DOBI has elected not to adopt any of the amendments, new rules and repeals proposed on June 20, 2005 by DHSS. This decision should not be construed as an indication that any conclusions have been reached by DOBI on the merits of the arguments raised by any commenters.

As stated earlier, DOBI's main goal at this point in time is to ensure that N.J.A.C. 8:38A does not expire. Because expiration of the current rules at N.J.A.C. 8:38A is imminent, it is not possible for DOBI to give the previously proposed revisions and the comments submitted on them adequate consideration at this time. Thus, DOBI is electing to readopt the existing rules without adopting the proposed new rules, repeals and amendments. Again, the decision not to adopt the proposed changes to the current rules should not be viewed as expressing any position with respect to any comments received. Rather, readopting the existing rules with only minor technical changes will allow DOBI time to transition into its new regulatory role and to consider the revisions previously proposed by DHSS and the comments received on that proposal in a thorough and deliberate manner from its new perspective as the agency directly responsible for the implementation and enforcement of the rules.

DOBI notes that it is aware that some of the proposed amendments and new rules were based on guidance issued by DHSS via bulletins that DHSS intended to codify through the proposed amendments, in particular: OMC Bulletins 2000-03 (Hospital Length of Stay Procedures; Denials and Appeals), 2000-04 (Complaints and Appeals), 2001-01 (Supplement to OMC Bulletins

2000-03 and 04), 2001-02 (Binding IHCAP Decisions), 2002-01 (UM Appeal Process -- Stage 1), 2002-02 (Revised IHCAP Form), 2003-01 (Hospital Termination: Notice Requirements and Calculation of the Start of the Four-Month Statutory Extension Period), 2003-04 (Emergency Department Medical Screening Examination Fees), 2004-01 (Review of Provider Agreements), 2004-02 (Side Agreements), and 2004-03 (Use of Carrier-generated Consent Forms). DOBI's decision not to adopt the proposed amendments and new rules related to the DHSS bulletins should not be construed as a rejection of the guidance put forward by those bulletins. Rather, affected parties should continue to abide by the interpretations set forth therein until further notice.

Summary of Agency-Initiated Changes:

1. At N.J.A.C. 8:38A-1.2, DOBI revised the term "Department" upon adoption, by replacing "Health and Senior Services" with "Banking and Insurance." This is a technical change reflecting the transfer of regulatory authority from DHSS to DOBI pursuant to Reorganization Plan 005-2005. The change does not require an additional notice or opportunity for comment.

2. At N.J.A.C. 8:38A-2.2(a)3, DOBI has revised its address (for submission of registration forms), and deleted the address of DHSS. This is a technical change reflecting the transfer of regulatory authority from DHSS to DOBI pursuant to Reorganization Plan 005-2005. The change does not require an additional notice or opportunity for comment.

3. At N.J.A.C. 8:38A-3.2(b)4, DOBI is revising the notice carriers are

required to provide covered persons regarding the binding nature of decisions issued through the IHCAP. Specifically, DOBI is removing the following words or phrase: not, either, or the covered person, so that the structure of the remaining sentence reads as "A statement that the decision of the Independent Health Care Appeals Program is binding upon the carrier." This revision reflects the actual state of the current statutes codified at N.J.S.A. 26:2S-12, which was amended by P.L. 2001, c. 1, making the decisions of the independent utilization review organizations binding upon the carrier. This is a technical change reflecting the amendments to the statute, and does not require an additional notice or opportunity for comment.

4. At N.J.A.C. 8:38A-3.6(i), (k) and (k)1, DOBI has replaced references to recommendations being made by independent utilization review organizations reviewing appeals through the IHCAP with references to decisions. This revision reflects the amendment of N.J.S.A. 26:2S-12 by P.L. 2001, c. 1, which authorized the independent utilization review organizations to issue binding decisions. This is a technical change reflecting statutory standards, and does not require an additional notice or opportunity for comment.

5. At N.J.A.C. 8:38A-3.7 DOBI has revised language throughout to reflect the amendment to N.J.S.A. 26:2S-12 by P.L. 2001, c. 1, making the decisions of the independent utilization review organizations issued through the IHCAP binding upon the carrier, and eliminating the option of the carrier to elect to accept or reject the recommendation. Specifically, DOBI has: revised the heading of the rule by replacing "recommendation" with "decision"; revised

paragraph (a) by substituting the phrase "of its intent to accept and implement or reject" with the phrase "describing how the carrier will implement", replacing the term "recommendation(s)" with the term "decisions" and replacing the term "recommendation" with the term "decision"; deleted paragraph (a)2, which reads as "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 its has rejected a recommendation"; and revised subsection (b) by deleting the phrase "elects to accept and implement" and inserting the term "implements" and removing the phrase ", notwithstanding that the carrier may elect to implement only a portion of the IURO's recommendations." These revisions are technical changes reflecting statutory standards, and do not require additional notice or opportunity for comment.

6. At N.J.A.C. 8:38A-4.10(b)3iii, DOBI is removing the phrase "pursuant to N.J.A.C. 8:33P" because there currently are no rules at N.J.A.C. 8:33P. This is a technical change, and does not require additional notice or opportunity for comment.

7. At N.J.A.C. 8:38A-4.10(f)2, DOBI is replacing the reference to "(e)1 above" with a reference to "(f)1 above" to correct an error in the citation. This is a technical change, and does not require additional notice or an opportunity for comment.

8. At N.J.A.C. 8:38A-5.1(a)1, DOBI is replacing the reference to "N.J.A.C. 8:38-8-7" with a reference to "N.J.A.C. 8:38-8.7" to correct an error in the citation. This is a technical change, and does not require additional notice or an

opportunity for comment.

9. At N.J.A.C. 8:38A-5.1(b), DOBI is substituting the phrase "final recommendation" with the phrase "determination on the appeal" to reflect the amendment to N.J.S.A. 26:2S-12 by P.L. 2001, c. 1, making the decisions of the independent utilization review organizations issued through the IHCAP binding decisions upon the carrier, rather than recommendations that carriers could elect to accept or reject. This is a technical change, and does not require additional notice and an opportunity for comment.

Federal Standards Statement

Currently, covered persons have a right to appeal certain determinations pursuant to both Federal and State law. The United States Department of Labor (USDOL) adopted rules at 29 CFR 2560.503-1, pursuant to sections 503 and 505 of ERISA, 29 U.S.C. §§ 1133 and 1135, requiring that employee benefit plans have in place reasonable claims procedures. The regulation became effective July 1, 2002 (and all coverage subject to the regulations was to be in compliance no later than January 2003). In accordance with the Federal regulation, a principle tenet for demonstrating a reasonable claim procedure is the ability of the claimant to appeal an adverse claim determination. Because of the manner in which the Federal regulations define "claim" and "group health plan," the Federal regulations and New Jersey's rules requiring carriers subject to the HCQA (including HMOs) to establish an internal UM appeal system, overlap in terms of their applicability, although there are areas in which each law applies

distinctly. For instance, the Federal regulations do not apply to any coverage not otherwise subject to ERISA, while New Jersey rules do, and conversely, the State rules apply only to those products defined as health benefits plans, while the Federal regulations apply to other types of health coverage (for instance, disability policies).

The Federal regulations do not preempt State rules, except when compliance with the State rules would make it impossible for the regulated entity to comply with the Federal regulations as well. (See 29 CFR 2560.503-1(k)). In June of 2002, DHSS, the then-regulatory agency with jurisdiction regarding N.J.S.A. 26:2S-1 et seq., and N.J.A.C. 8:38A, issued Bulletin 2002-01 notifying carriers that DHSS would not be enforcing one provision of the rules regarding the Stage 1 internal appeal process (N.J.A.C. 8:38-8.5 and 8:38A-3.5), which required that the same physician who issued the initial UM denial review the appeal at Stage 1. This requirement was inconsistent with the Federal regulations which prohibit the initial decision-maker from rendering any decision on the appeal. DHSS suspended the requirement across all health benefits plans, but all other State requirements remained in effect, and for the most part, carriers appear to have found ways to comply with both the State rules and the Federal regulations.

Arguably, the State rules are more stringent than the Federal regulations. DOBI has elected not to relax the current State rules regarding UM appeals at this time. Because the more stringent standards are the ones that have been in place in New Jersey since at least May of 2000 (since 1997 with respect to

HMOs), DOBI does not believe the more stringent features represent any particular hardship for carriers doing business in the State. DOBI does not believe that any carriers would have to incur any additional staffing, systems changes or costs in order to comply with the more stringent timeframes of the current rules. Further, DOBI believes that the more stringent standards, particularly shorter timeframes for decisions, are more beneficial to members who have postponed obtaining health care services they believe are medically necessary pending the outcome of an appeal.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 8:38A.

Full text of the adopted amendments follows (additions to proposal indicated with asterisks and boldface ***thus***; deletions from proposal indicated with asterisks and brackets *[thus]*):

SUBCHAPTER 1. GENERAL PROVISIONS

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.

...

"Department" means the New Jersey Department of *[Health and Senior Services]* *Banking and Insurance*.

...

SUBCHAPTER 2. PROVISIONS APPLICABLE TO ALL CARRIERS

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.-2. (No change.)

3. Carriers shall file a copy of the HCQA Registration Form with the Department *[and the Department of Banking and Insurance]* at the following address*[es]*:

*[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] *Valuations* Bureau

*[Division of]*Life and Health Division

PO Box 325

Trenton, NJ 08625-0325

(b)-(c) (No change.)

SUBCHAPTER 3. UTILIZATION MANAGEMENT

8:38A-3.2 Disclosure requirements

(a) (No change.)

(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.-3. (No change.)

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-3.6 Independent health care appeals process

(a) -- (h) (No change.)

(i) The IURO shall complete its review and issue its *[recommendation]* *decision* 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.-2. (No change.)

(j) (No change.)

(k) The IURO shall set forth in its written **[recommendation]** **decision** 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 **if so,** shall specify the services the covered person should receive or receive benefits therefor.

1. The IURO shall submit its **[recommendation]** **decision** 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]** **decisions**

(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]** **describing how the carrier will implement** the IURO's **[recommendation(s)]** **decisions** within 10 business days of the date that the carrier first receives the **[recommendation]** **decision** of the IURO.

1. (No change.)

[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 its has rejected a recommendation.]

(b) A carrier that **[elects to accept and implement]** **implements** 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]*.

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

8:38A-4.10 Network adequacy

(a) (No change.)

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

1. -- 2. (No change.)

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. - ii. (No change.)

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. -- vii. (No change)

(c) -- (e) (No change)

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

1. (No change.)

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. -- 6. (No change.)

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] 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.-3. (No change.)

(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. (No change.)

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]* *determination on the appeal* in writing to the Department.

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