INSURANCE
DEPARTMENT OF BANKING AND INSURANCE
DIVISION OF INSURANCE

Adopted New Rules: N.J.A.C. 11:3-4

PERSONAL INJURY PROTECTION BENEFITS: MEDICAL PROTOCOLS; DIAGNOSTIC TESTS

Proposed: September 8, 1998 at 30 N.J.R. 3211(a) (see also 30 N.J.R. 3748(a)).

Adopted: November 30, 1998 by Jaynee LaVecchia, Commissioner, Department of Banking and Insurance.

Filed: November 30, 1998 as R.1998 d.597, with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30-4.3).

Authority: N.J.S.A. 17:1-8.1, 17:1-15e, 39:6A-3.1a and 39:6A-4a.

Effective Date: December 21, 1998.

Operative Date: March 22, 1999.

Expiration Date: January 4, 2001.

On September 8, 1998, the proposed new rules were published in the New Jersey Register at 30 N.J.R. 3211(a). On October 19, 1998 at 30 N.J.R. 3748(a), the Department published notice of a public hearing to be conducted on November 4, 1998 on certain aspects of the proposal. During the public hearing, testimony was presented by 42 individuals. Many of these individuals supplemented their testimony with written reports, which have also been considered by the Hearing Officer. The following individuals testified at the public hearing:

1. Brian Atkisson, D.C., Atlantic County Chiropractic Society
2. Lu Ann Guerriero, D.C., New Jersey State Board of Chiropractic Examiners
3. Richard Jaffe, Esq., Chiropractic America
4. Irving Ratner, M.D., Medical Society of New Jersey
5. Charles A. Calabrese, D.C., Northern New Jersey Chiropractic Society
6. Richard Klingert, D.C., Council of New Jersey Chiropractors
7. Gerald W. Clum, D.C., International Chiropractors Association
8. Ira Klemons, DDS, Ph.D., American Alliance of TMD Organizations
9. Christopher Kent, D.C., Council on Chiropractic Practice
10. Kenneth Andres, Esq., the Association of Trial Lawyers of America
11. James Healey, D.C., Garden State Chiropractic Society
12. Patrick Gentempo, D.C., Chiropractic Leadership Alliance
13. Larry A. Sabel, D.C.
14. Stephen Jackson, D.C.

15. Elmer Matthews, Esq., American Insurance Association

16. Steven Lomazow, M.D., Neurological Association of New Jersey

17. Ronald Cohen, D.O., New Jersey Association of Osteopathic Physicians and Surgeons

18. Stanley L. Malkin, M.D.

19. Richard Fellows, D.C., Cape May County Chiropractic Society

20. Howard Freedman, D.C., Southern New Jersey Chiropractic Society

21. Garrett Cuneo, D.C., American Chiropractic Association

22. Nancy Pitkin, Bartlott Associates

23. Martin S. Levine, D.O.

24. Michael Goione, D.C., Monmouth/Ocean County Chiropractic Society

25. Joseph Louro, D.C.

26. William Campagnolo, D.C.

27. Barbara Geiger-Parker, Brain Injury Association of New Jersey

28. Kirtley E. Thornton, Ph.D., Center for Health Psychology

29. Cheryl F. Kleefeld, Ph.D., Biodfeedback Society of New Jersey

30. Eli Alson, Ph.D., New Jersey Psychological Association

31. Richard Jermyn, D.O.

32. Martin Spindel

33. Albert Talone, D.O.

34. Barry Gleimer, D.O.

35. Steven E. Ross, M.D., New Jersey Trauma Center Council

36. Alma Saravia, Esq., New Jersey Bar Association and the New Jersey Association of Osteopathic Physicians and Surgeons

37. Linda Tennant, President, New Jersey Occupational Therapy Association

38. Mitch Grier

39. Gary Goldstein, M.D.

40. Theresa Fitzpatrick

41. Mark Kahn, M.D.

42. Arnold Taub, D.C.

In addition to the foregoing, the Hearing Officer also received written comments from the following:

1. Louis Rogers, D.C., New Jersey Chiropractic Society

2. Philip E. Lutz, M.D., New Jersey State PBA Physicians' Association

3. Jeffrey F. Daniels, D.C.

4. Dan Vionito

5. Mary Jane Brubaker

6. Douglas Ashendorf, M.D., New Jersey Society of Physical Medicine and Rehabilitation

7. John K. Tiene, New Jersey Insurance News Service

8. Ilydio Polachini, Jr., American Society of Neuroimaging

9. David Fried, Esq., New Jersey Consumers for Civil Justice

10. Alan Groveman, Ph.D., New Jersey Psychological Association

11. William R. Abrams, New Jersey Association of Health Care Facilities

12. Kevin J. Frederick, State Farm Insurance Companies

13. Donald S. Cleasby, National Association of Independent Insurers

14. Edward H. Olsen, D.C.

15. Michael A. Morrone

In accordance with N.J.S.A. 52:14B-4(g), the Hearing Officer issued a report on November 30, 1998 making recommendations to the Commissioner. The report includes a summary of the public testimony and comments received at the hearing as well as the Hearing Officer's evaluation of the comments and testimony. The Hearing Officer's report is incorporated herein by reference and made a part of the rulemaking file.

Summary of Hearing Officer's Recommendations and Agency Responses:

The Hearing Officer's report includes a brief review of the reasons for the public hearing. The Hearing Officer noted that the Automobile Insurance Cost Reduction Act, P.L. 1998, c.21 (the Act), included provisions for the determination of the medical treatments, diagnostic tests, and services to be provided to injured persons in accordance with the PIP medical expense benefit coverage contained in private passenger automobile insurance. The Act requires the Department to identify commonly accepted protocols and professional standards and practices that are recognized as beneficial in the treatment of persons injured in auto accidents. As noted by the Hearing Officer, the public notice provided that testimony should specifically address published standards for treatment of injuries sustained in auto accidents that have been adopted by National standards setting organizations and national and state professional organizations.

As required by N.J.S.A. 52:14B-4(g), at the beginning of the hearing, a presentation was made by the Department regarding the purpose of the proposed rules and a summary of their components. The Department also outlined certain modifications to the medical treatment protocols as proposed that were being considered by the Department. Specifically, the Department stated that it intended to make several amendments to the rules upon adoption as follows: the "conservative therapy blocks" in care paths 1, 3 and 5 will be revised to describe more clearly what constitutes a basic block of conservative therapy. This will recognize osteopathic spinal manipulation as part of the treatment and will clarify that spinal manipulation and physical therapy treatments, which the proposal shows separately, may total up to 12 visits. The decision point review rules will be revised to encourage insurers to accept comprehensive treatment plans in lieu of decision point review at specific intervals and encourage approval of individual treatment plans in advance; the rules will be revised to clarify that the need for emergency treatment in a hospital may arise a reasonable time after the accident; and the rules will be revised to confirm that the care paths are not fixed standards and must consider factors such as a patient's general health or preexisting conditions. Moreover, the rules will state specifically that treatment must be based on patient need and professional judgment.

The Hearing Officer noted from her review of the record, including the testimony at the hearing, that the following specific changes should be made to the rules upon adoption:

1. The following should be amended upon adoption:

a. The conservative therapy blocks in care paths 1, 3 and 5 should be revised to describe more clearly what constitutes a basic block of conservative therapy and to include specific reference to special manipulation by osteopathic physicians and chiropractors.

b. The decision point review and pre-certification rules should be revised to encourage insurers to accept a comprehensive treatment plan in lieu of decision point review at specific intervals and encourage approval of individual treatment plans in advance.

c. The rules should be revised upon adoption to clarify that the emergency treatment in a hospital may arise a reasonable time after the accident.

d. The rules should be revised upon adoption to confirm that the care paths are not fixed standards and must consider factors such as a patient's general health or pre-existing conditions. The rules will state specifically that treatments must be based on patient need and professional judgment.

e. The Department should make clear that in reviewing decision point review and pre-certification plans, part of its analysis will involve the requirement that timely notifications be made to providers and that there should be procedures to help avoid delays in treatment or gaps in treatment.

f. The Department should revise the rules upon adoption to include licensed occupational therapists in the definition of "health care provider."

g. The Department should clarify in the adoption notice that the 10 day "grace period" before pre-certification requirements may apply is specifically required by the Act.

h. The Department should clarify whether spinal manipulation can be reimbursed under care paths 2, 4 and 6 in instances of radiculopathy.

i. The Department should address patients being moved from one care path to another, if warranted.

The Hearing Officer recommends that N.J.A.C. 11:3-4 be adopted with the changes noted above. As further discussed below, the Department has accepted the recommendations of the hearing officer and incorporated them into the changes made in the rule upon adoption.

The hearing record and public comments may be reviewed by contacting:
Donald Bryan, Assistant Commissioner
Legislative and Regulatory Affairs
Department of Banking and Insurance
20 West State Street
PO Box 325
Trenton, NJ 08625-0325

Summary of Public Comments and Agency Responses:

The Department of Banking and Insurance ("Department") timely received 21,097 written comments on its proposal. The Department also received petitions, which contained approximately 3,594 signatures. Comments were received from 1,720 commenters whose names were illegible. In accordance with N.J.S.A. 52:14B-7(c), the Office of Administrative Law has determined not to publish the list of commenters' names in this notice of adoption. The list may be reviewed at the Office of Administrative Law, 9 Quakerbridge Plaza, Trenton, New Jersey, by contacting (609) 588-6613.

The Department notes that many of the comments also related to N.J.A.C. 11:3-3, Basic Automobile Insurance Policy as well as the Department's proposal PRN 1998-423 (Private Passenger Automobile Insurance Reforms pursuant to P.L. 1998, c.21 found at 30 N.J.R. 3202(a)). To the extent that the comments raised issues which pertain to those other proposals, they may not be addressed here but may have been considered with another proposal. Accordingly, the readers should also review the Department's other adoption notices published in this issue of the New Jersey Register.

COMMENT: Several comments were received that either supported the proposed rules generally or stated support for particular provisions of the rules. Other commenters stated general support for the rules' goals to reduce fraud and abuse in auto accident related medical expenses by eliminating unnecessary medical treatment and tests.

RESPONSE: The Department acknowledges these expressions of support.

COMMENT: The vast majority of the comments were form postcards or form letters sent from chiropractic physicians offices. These cards and letters appeared in about eight different formats. They generally stated that the signer was opposed to the proposed rules; that the rules violate the right to choose a doctor and course of treatment; that they deny adequate care; that they are not in the best interests of consumers; and that they establish a "managed care" system.

RESPONSE: These rules implement the Automobile Insurance Cost Reduction Act, P.L. 1998, c.21 and 22 ("Act") by establishing standards for personal injury protection (PIP) benefits, which are provided in private passenger automobile insurance policies.

The rules provide at N.J.A.C. 11:3-4.3(a) that PIP shall provide reimbursement for "all medically necessary expenses for the diagnosis and treatment of injuries sustained from a covered auto accident. . . ." The rules define "medically necessary" as set forth in the Act, and include standards for certain diagnostic tests and protocols for the treatment of certain common injuries.

It is correct that these rules provide some restrictions on the medical expense benefits that will be provided by automobile insurance policies. That is their purpose. In Section One of Act, the Legislature stated its purpose to provide for "standard treatment and diagnostic procedures against which the medical necessity of treatments reimbursable (by PIP) would be judged. . . ." The Act directed the Commissioner to promulgate rules that establish PIP benefits.

The rules do not restrict the ability of persons injured in auto accidents to select their doctor. Injured persons are afforded the opportunity to seek treatment from a wide variety of health care providers, as evidence by the rules' definition of that term at N.J.A.C. 11:3-4.2. Unlike health insurance plans commonly referred to as "managed care," the care paths do not require pre-selected "gatekeeper" providers. The Act directs the Commissioner to list diagnostic tests and to identify commonly accepted medical protocols which are recognized as beneficial to the treatment of persons injured in automobile accidents. The Department has done so at N.J.A.C. 11:3-4.5, 4.6 and in the medical treatment "care paths" set forth as Exhibits 2 through 8 in the Appendix. The care paths establish the general courses of treatment for common automobile-related accident injuries to the cervical thoracic and lumbar-sacral spine. N.J.A.C. 11:3-4.6(c) provides for variance from the care paths when warranted by reasons of medical necessity. The rules recognize that medical conditions and other circumstances may justify, in the judgment of the treating provider, a deviation from the expected course of treatment. Clarifying language has been added upon adoption in the form of a note on each care path to emphasize the Department's intent that the care paths serve as a measure of comparison to identify unnecessary or inappropriate treatment but not as a fixed standard in every case.

The treatment care paths encourage result oriented medical treatment practices. It has been observed that many patients continue to receive the same treatment and therapy, week after week, over many months and years without any observable improvement. Such practice is not only wasteful but may cause a patient to suffer unnecessarily because more effective and beneficial care might be available from a different type of treatment. Thus, the care paths do not deprive a patient of the opportunity to seek the treatment of choice but rather they encourage alternative choices if a treatment plan becomes unproductive. As a result, the Department believes that the new PIP treatment protocols are in the best interests of consumers.

Regarding the suggestion that these rules violate a patient's constitutional right of free choice, the Department notes that no constitutionally protected right has been identified by the commenters nor does the Department believe that these rules have any constitutional infirmity.

The care paths describe a course of treatment that contains the average pattern of utilization and expected outcomes from the identified injuries. This can be used as a standard against which the medical necessity of a particular course of treatment can be judged as required by the Act.

COMMENT: Many commenters claimed that the Act does not direct the Department to establish fixed care paths but rather requires the Department to create a "loose framework of guidelines" or suggested courses of treatment for injured persons.

RESPONSE: The Department notes that the Act's legislative findings state that these rules should define the benefits available under the PIP medical expense benefits coverage and establish standard treatment and diagnostic procedures against which the medical necessity of treatments reimbursable under medical expense benefits coverage can be judged. This Legislative finding, together with the direction to formulate controls for the use of diagnostic tests and treatment, indicates an intent to create a structure to help identify unnecessary medical treatment, not merely a compendium of suggested or useful tests and treatments. Also, the Act's reference to a "medical necessity" exception to the strict application of the protocols corroborates the Department's implementation of the statutes.

COMMENT: Another large group of commenters claimed that protocol and diagnostic test rules were not formulated in accordance with the process required by the Act. These commenters generally stated that the Department should have consulted more with the Professional Boards in the Division of Consumer Affairs, Department of Law and Public Safety ("Professional Boards") and professional medical associations prior to proposing the rules.

RESPONSE: The Act directs the Commissioner to promulgate rules that state the basic PIP benefits in an auto insurance policy. These benefits should be rendered in accordance with commonly accepted protocols and professional standards for medical treatment and diagnostic test for the care of injuries sustained in auto accidents. These identified

standards are to constitute the PIP medical expense benefits for which reimbursement will be provided under a private passenger automobile insurance policy.

Although the PIP benefits, medical protocols and diagnostic tests are to be established by the Commissioner by rule, the Act directs the Commissioner to consult with the Commissioner of the Department of Health and Human Service (DOHSS) and the Professional Boards. In May 1998, the Department communicated with the Professional Boards to initiate the consultation process. The Professional Boards formed a Task Force and developed recommendations for N.J.A.C. 11:3-4.5, the diagnostic test rule. These recommendations are included in the Department's proposal and individual professional boards have since proposed their own diagnostic testing rules.

In addition, the Department also sought a health benefits consultant ("consultant") to assist the Department in developing the rules as also provided in the Act. Because of the strict time frame allowed (the Act directed that the rules be promulgated by September 17; they were proposed September 8), the Department moved ahead with the proposal while continuing its consultation with DOHSS and the Professional Boards. A copy of the draft proposal was delivered to the Professional Boards on August 3, 1998 before being submitted for publication, and a copy of the proposal as published was sent to the Professional Boards on August 21, 1998. Consultation has continued throughout the required period of publication, public comment and final review. Additionally, the Department met with interested parties, received substantial written public comment, and conducted a public hearing, all of which provided additional information that was used to develop the rules' adopted form set forth in this adoption notice. The Department followed processes fully consistent with the Administrative Procedures Act, as well as with the specific provisions of the Act.

COMMENT: The Department received many comments from chiropractic physicians and from chiropractic professional associations, committees and organizations. Many of these commenters objected to the failure of the rules to mention "chiropractic subluxation." The commenters stated that the chiropractic licensing statute, N.J.S.A. 45:9-41.27, specifically refers to chiropractic subluxation as "the only basis of chiropractic care." The commenters stated that "subluxation" should be specifically mentioned as a clinical condition subject to treatment in the care paths.

RESPONSE: The Department notes that the term "subluxation" is not applicable to other medical disciplines and is subject to different definitions by various chiropractic organizations. The term is defined neither in the chiropractic licensing statute nor the rules promulgated by the Board of Chiropractic Examiners. It is defined by the Association of Chiropractic Colleges as a "complex of function and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health." Two different definitions of this term were provided in documents furnished by the New Jersey Board of Chiropractic Examiners, one of which appeared in the 1993 New Jersey Forum Guidelines for Chiropractic Care ("Forum Guidelines") suggested as an alternate for the proposed protocols. From this literature, it appears that chiropractic care deals mainly with manipulative adjustment of subluxation, which can occur as a clinical condition with or without the trauma associated with auto injury.

Since there is no single definition of subluxation in New Jersey established by the Board of Chiropractic Examiners, and since the condition apparently occurs for many reasons not associated with auto accident related trauma, the Department is unwilling to insert the term into its rules at this time. The Department will continue to consult with the Board of Chiropractic Examiners about this issue.

COMMENT: Many commenters pointed to care paths 2, 4 and 6 and complained that chiropractic care is not referenced. They state that patients will not be able to be treated by their chiropractor when experiencing radicular pain/radiculopathy or when diagnosed with a herniated disc.

RESPONSE: Care paths Number 2, 4 and 6 apply to cervical, thoracic and lumbar-sacral spine injuries with herniated discs and/or radiculopathy. Notwithstanding the opinions expressed by these commenters, it appears that the weight of credible authority indicates that spinal manipulation is not initially indicated in the presence of radicular symptoms. Radiculopathy or radicular symptoms represent an impingement of the nerve, which could be permanently severed or destroyed by spinal manipulation. These authorities appear to agree that spinal manipulation is not indicated until the source of the radicular symptom is identified. Based upon consultation with the Board of Chiropractic Examiners, which urged that spinal manipulation be as a permitted treatment on care paths 2, 4 and 6, the Department has amended these Exhibits upon adoption to permit spinal manipulation after test results to identify the source of the radicular symptoms are negative and the treating provider determines that such a course of treatment would benefit the patient.

COMMENT: Referring to N.J.S.A. 39:6A-4.7, several commenters argued that the Act directs the professional licensing boards to promulgate a list of valid diagnostic tests to be used in conjunction with the appropriate health care

protocols in the treatment of persons sustaining bodily injury in auto accidents. The commenters claimed that it is exclusively within the authority of the Board of Chiropractor Examiners to develop appropriate health care protocols and lists of diagnostic tests to be used in chiropractic care. They further asserted that the rules promulgated by the Department are an illegal usurpation of the authority granted by the Act to the Board of Chiropractor Examiners and to the other Professional Boards. Thus, only protocols and lists of diagnostic tests promulgated by the Professional Boards should be incorporated into the PIP medical expense benefits.

RESPONSE: The Department disagrees with this interpretation of the Act. N.J.S.A. 39:6A-3.1 and 39:6A-4 require the Department to develop policy forms that set forth the benefits provided under a private passenger automobile insurance policy and which include the eligible medical treatments, diagnostic tests and services as well as other benefits that are provided under a policy of auto insurance. Only the Commissioner is responsible to identify those tests and treatments which are included in PIP medical expense benefits.

The commenters appear to rely upon N.J.S.A. 39:6A-4.7, which permits the Professional Boards to develop lists of diagnostic tests that can be used in conjunction with the appropriate health care protocols developed by the Department. The lists of diagnostic tests promulgated by the professional boards are to be part of their consultation with the Commissioner. N.J.S.A. 39:6A-4.7 provides that: "The list of valid diagnostic tests, once approved by the Commissioner shall apply only to benefits under N.J.S.A. 39:6A-4 and 6A-3.1" (emphasis supplied). Thus, it is clear that the professional boards have a responsibility to compile lists of diagnostic tests, but the Commissioner must approve their inclusion as PIP medical expense benefits.

COMMENT: Several commenters referenced N.J.S.A. 39:6A-3.1 and 4, which provide that the Commissioner develop a statement of medical expense benefits including medical treatments, diagnostic tests, and medical services provided by an automobile insurance policy that are rendered in accordance with commonly accepted protocols, professional standards and practices that are commonly accepted as being beneficial for the treatment of covered injuries. These commenters argued that since the Department's rules do not precisely follow chiropractic protocols and standards and practices, as determined and approved solely by the chiropractic societies, the rules should not be adopted. The commenters claimed that only the Professional Boards and societies have the authority to establish appropriate treatment and test protocols.

RESPONSE: While the Department certainly recognizes the role of the Professional Boards and other authorities in the development of treatment and testing protocols, it notes that the Act requires that the Commissioner establish standard benefits provided in automobile insurance policies in consultation with the professional licensing boards. The Department received many different comments from individuals and organizations on behalf of chiropractic care and the comments were not always consistent. Different organizations cite different authorities with different opinions, treatment plans and protocols.

The commenters' assertion that the Act provides the Professional Boards and societies with the authority to establish appropriate treatment and test protocols is incorrect. The responsibility and the authority is placed on the Commissioner to promulgate these rules. The adopted rules represent the Department's findings and conclusions regarding that which is required by the Act.

COMMENT: Several commenters noted that N.J.A.C. 11:3-4.6(c) states that deviation from the care paths is permitted when warranted by reason of medical necessity. The commenters claimed that the term "medical necessity" is not sufficiently defined, and since the definition refers to the "care paths," the definition is circular.

RESPONSE: The Department notes that "medical necessity" is not defined in the rules at all and assumes that the commenters are referring to the definition of "medically necessary." The Department will amend N.J.A.C. 11:3-4.2 upon adoption to include "medical necessity" in the definitions of "medically necessary." The Department further disagrees with the commenters that the definition of "medically necessary" at N.J.A.C. 11:3-3.2 is circular. "Medically necessary" treatment is based on clinically supported symptoms and includes, but is not limited to, the care paths.

COMMENT: Several commenters claimed that N.J.A.C. 11:3-4.5(b) is unreasonable in that it requires that diagnostic tests (and treatment) should be justified by a diagnosis and be a part of a treatment plan which is medically necessary and clinically supported.

RESPONSE: The Department strongly disagrees and construes the Act to provide PIP reimbursement only for tests and treatment that are medically necessary.

As stated in one section of the Act, the Legislature's goal of eliminating payment for treatments and diagnostic tests that are not medically necessary is of primary concern. Specifically, the Department was directed to "establish a basis for determining whether treatments or diagnostic tests are medically necessary." The rules requiring that providers justify tests and treatment with a proper diagnosis and treatment plan are consistent with the Act and good practice. Clinical support requires that the provider has examined the patient to ensure that the proper medical conditions exist to justify the test or treatment; has considered the history and subjective complaints and objective findings; has determined if any prior tests have been conducted that might relate to the issue under consideration; and has recorded and signed the findings and conclusions in the patient's medical record. Clinical support for tests or treatment provides for that measure of accountability that is required by the Act.

COMMENT: Several commenters requested that the definitions in the Appendix, Exhibit 9 be amended as follows (additions in boldface thus; deletions in brackets [thus]):

Acute disease--a disease with rapid onset and short course to recovery[.] or death or development of [Not] chronic phase.

Conservative therapy--treatment which is not considered aggressive; avoiding the administration of *[complex medical modalities]* medicine or utilization of invasive procedures until such procedures are clearly indicated.

RESPONSE: The Department does not believe that suggested changes are significant or would improve the glossary.

COMMENT: Many commenters asserted that the care paths will limit patients to an inadequate trial of chiropractic care and then force these patients into less effective and more costly surgical treatment by referencing that only four chiropractic manipulations in a block of conservative therapy were included on care paths 1, 3 and 5. These commenters claimed that this will result in increased cost to patients and to their insurers as more severe and acute injuries arise resulting from the unavailability of chiropractic care. These commenters complained that the care paths remove the "recognized expert and authority in spinal adjustment" from caring for these patients. They claimed that the chiropractic technique of bringing a spinal joint into its paraphysiological range of motion is the only recognized method of spinal manipulation for traumatic spinal injuries.

RESPONSE: The Department notes that additional medically necessary chiropractic manipulation was always available through the application of N.J.A.C. 11:3-4.6(c). However, in order to confirm that the care paths provide the flexibility to permit the additional chiropractic treatments, the Department has amended the course of conservative therapy upon adoption to specifically reference one to three spinal manipulation treatments per week, which may include other physical modalities. This change provides a course of treatment comparable to the course of physical therapy provided when the treating provider is of a different discipline. This amendment clarifies that up to 12 spinal manipulations may be administered during the four weeks of conservative therapy in care paths 1, 3 and 5. The change is consistent with the literature on spinal manipulation and with the Department's consultation with the Professional Boards and others.

The suggestion of the commenters that the care paths force patients into less effective and more costly surgical treatment is not correct. In fact, the care paths provide that if symptoms are only minimally resolved after the first four weeks, the patient may continue with conservative therapy, which might include additional spinal manipulation if necessary. If symptoms worsen, it is appropriate to explore other treatment alternatives. In no case is the patient forced into other treatment; rather, alternatives are presented if conservative therapy proves to be ineffective.

Regarding the commenters' complaint that the care paths remove chiropractors from the treatment of trauma induced injuries to the spine, the Department disagrees. Chiropractors are included as defined "healthcare providers." Care paths 1, 3 and 5 provide for conservative treatment, which includes chiropractic care. The Department recognizes that chiropractic spinal manipulation has a role in resolving traumatic spinal injuries as is indicated in the care paths. As noted above in a response to a previous comment, spinal manipulation in care paths 2, 4 and 6 is available as a treatment alternative after tests indicated for radicular symptoms are negative and there is no danger from spinal manipulation in the opinion of the treating provider.

COMMENT: Many chiropractic commenters argued that the Department should adopt the Forum Guidelines as the definitive statement of chiropractic care for traumatic spinal injuries and subluxation.

RESPONSE: The Department has reviewed the Forum Guidelines and determined that they are not suitable to be adopted for the purposes of the Act. As noted in response to a previous comment, the purpose of designating protocols

in these rules is to establish the PIP benefits to be provided in an auto insurance policy. A more precise definition of PIP benefits should provide a standard "against which the medical necessity of treatments reimbursable . . . would be judged." In other words, protocols should help identify what may be unnecessary medical treatments. Significant deviation from an expected course of treatment would not be reimbursable by the PIP coverage in the absence of demonstrated, clinically-supported, medical necessity. Protocols approved by the Commissioner must provide a standard for determining medical necessity in particular cases. The Forum Guidelines do not do that.

In essence, the Forum Guidelines set forth the full scope of services that may be provided by licensed chiropractic physicians in New Jersey, together with some standards of proper practice. The Forum Guidelines note that chiropractic care may be provided for the purposes of "Relief Care, Therapeutic Care, Rehabilitative Care or Supportive Care," in visits as frequently as "daily" and extending for a particular length of time "or longer." Finally, the Forum Guidelines specifically state that they are "not meant to provide cut-off points for care, but rather to assist the chiropractor in determining appropriate case management." Notwithstanding that the Forum Guidelines are not appropriate to be adopted by the Commissioner for the purposes of these rules, however, the Department finds many common elements with the care paths. For cervical, thoracic or lumbosacral strains and strains (care paths 1, 3, and 5), the care path protocol provide a period of conservative therapy up to 13 weeks, which therapy may include chiropractic manipulations as appropriate for particular cases. The rules provide for a decision point review at the end of four, eight and 13 weeks to determine whether further treatment is medically necessary. The Forum Guidelines provide a course of conservative therapy of spinal manipulation, which may be accompanied by other physical modalities, one to three times per week. This course of treatment may be expected to continue for up to 30 days for mild injuries, 30 to 60 days for moderate injuries, and 60 to 90 days for severe injuries (although as noted the Forum Guidelines provide that the treatment may continue longer). Additionally, the Forum Guidelines include practice standards for an initial examination, development of a treatment plan, and documentation of clinical support, all of which are consistent with the Department's rules. Furthermore, the Forum Guidelines reference certain diagnostic tests, many of which may be administered consistent with these rules. Finally, the Department notes that a resolution adopted by the Board of Chiropractic Examiners on June 18, 1998 and recently delivered to the Department stated that the Forum Guidelines should serve as "the basis for establishing guidelines for treatment protocols," not as the treatment protocols themselves.

COMMENT: Many comments were received referring to The Mercy Guidelines for Chiropractic Quality Assurance, Practices Parameters, Aspen publication, 1993 ("Mercy Guidelines"). The commenters claimed that any reliance upon the Mercy Guidelines is not appropriate as these guidelines apply only to "uncomplicated cases." As noted above, the commenters believe that only the Forum Guidelines should be considered. Still other commenters endorse the guidelines found in the Clinical Practice Guideline, #1, Vertebral Subluxation in Chiropractic Practice. Council on Chiropractic Practice, 1998. Another group of commenters refer to an article in the Journal of Manipulative and Physiological Therapeutics, November/December, 1996 (Volume 19, No. 9) by D.J. BenEliyahu which refers to a case study that chiropractic management of disc herniation, including spinal manipulation may be safe and helpful for the treatment of cervical and lumbar disc herniations. Other commenters endorsed a work entitled Whiplash Injuries the Cervical Acceleration/Deceleration Syndrome, Steven M. Forman, D.C. and Arthur C. Croft, D.C., Williams and Wilkins, 1995. Each of these commenters claim that their reference is the only reliable source of information for the development of chiropractic protocols.

RESPONSE: The Department notes that it has received many documents that included or referenced chiropractic protocols, rules, guidelines, standards and criteria from local, state and national authorities and associations. The variety among this literature confirmed that there is no universal consensus of opinion by chiropractors regarding the diagnosis, treatment and duration of treatment. For example, one chiropractor-commenter stated that a moderate cervical strain may require one month of spinal manipulation, while another stated that at least three months of spinal manipulation is necessary. Still another stated that any specific treatment duration is impossible to project. The Department has not given full and complete weight to any one authority in the development of the care paths. Therefore, the commenter's concern that the Department relied exclusively on the Mercy Guidelines is not correct. The Department has endeavored to consider all reliable sources. The adopted rules represent the determination of issues regarding technical differences.

COMMENT: Several chiropractic commenters referred to the high incident of adverse reaction to medication as well as the risk of infection and other risks associated with surgery. The commenters argued that chiropractic care involves none of the adverse consequences associated with drugs and surgery and should be encouraged rather than discouraged.

RESPONSE: The commenter's remarks are noted and have been considered. All medical care involves some risks. Because of the risks associated with surgery or more aggressive treatment, the care paths generally provide for conservative therapy in the period immediately after the accident for the specific injuries. The Department notes that the care path protocols permit treatment by physicians of all disciplines.

COMMENT: One commenter referenced N.J.A.C. 11:20, the Individual Health Coverage Program, specifically page 20-81 of the New Jersey Administrative Code, which sets forth part of the policy forms used in the Individual Health Care (IHC) program. The IHC policy provides coverage for "30 visits/covered person, of therapeutic manipulations." The commenter argued that the IHC form permits 30 therapeutic manipulations and, therefore, the PIP medical expense rules should also permit 30 visits.

RESPONSE: The commenters' reliance upon the provision in the IHC Program policy forms which refers to 30 therapeutic manipulations is misplaced. These policy forms simply establish the maximum number of visits covered in the individual health coverage policy in any one year. Even if additional therapeutic manipulations beyond 30 are medically necessary, the IHC policy does not provide coverage.

The Department construes the Act to provide PIP coverage for medically necessary treatment, tests and services, and to avoid both over-utilization and under-utilization. Therefore, it has tried to avoid arbitrary and unyielding limits.

The Department also notes that the IHC policy form referred to does not establish a recognized standard or protocol as a measure of proper utilization for the treatment of particular injuries, which is the purpose of the protocols, but rather simply a statement of the coverage provided.

COMMENT: Several commenters referred to the Chiropractic Practice Guidelines and Parameters (Florida Chiropractic Guidelines) prepared by the joint committees for the Florida Chiropractic Association, Inc. and the Florida Chiropractic Society, Inc., 1997 and asserted that the Department should adopt these guidelines. The document sets forth management of acute conditions and describes treatment of mild, moderate and severe acute conditions. It provides for a set number of visits per week and per month through various levels of care and recovery. The Florida Guidelines provide for chiropractic treatment for up to 12 months beginning with three visits per week and ultimately provides supportive care of two visits per month.

RESPONSE: The Department notes that the Florida Chiropractic Guidelines apparently do not enjoy full recognition and acceptance in the State of Florida. A separate and significantly different group of practice guidelines has been adopted by the Florida Department of Labor and Employment Security, Division of Workers' Compensation and the State of Florida Agency for Health Care Administration (Florida State Guidelines). The Florida State Guidelines provide for the treatment of neck pain or injury and low back pain or injury. One particular difference is the omission of chiropractic spinal manipulation in the presence of radiculopathy and a limitation to four weeks of chiropractic treatment. The Florida State Guidelines state: "there is insufficient evidence to recommend manipulation for patients with radiculopathy," and "a trial of manipulation in patients without radiculopathy with symptoms longer than a month is probably safe, but the efficacy is unproven." Based on its review of the relevant literature, the Department is unwilling to recognize the Florida Chiropractic Guidelines as the sole basis of the protocols.

COMMENT: One commenter objected to the care paths, noting that they failed to contain language recognizing the procedure known as "manipulation under anesthesia." The commenter submitted a list of diagnostic findings which may indicate the need for manipulation under anesthesia as well as standard treatment protocols for this procedure. The commenter requested that this specific method of manipulative treatment be recognized in these rules.

RESPONSE: The Department does not believe any change is necessary. As noted in the proposal of these rules, there are many medical tests, treatments and procedures that are not addressed in the protocols. The Department does not believe that manipulation under anesthesia is part of the standard treatments of injuries to the neck and back sustained in automobile accidents. In those circumstances where the use of manipulation under anesthesia is indicated, the application of the care paths clearly provides for clinically supported, medically necessary treatment.

COMMENT: Several organizations, institutions and individuals endorsed the use of a book entitled Vertibral Subluxation and Chiropractic Practice, Council on Chiropractic Practice, Clinical Practice Guidelines, Council on Chiropractic Practice, 1998. Each commenter sent a copy of the book and claimed that it is a national standard for chiropractic treatment and tests which should be adopted by the Department as the protocol for PIP benefits.

RESPONSE: The Department does not agree with the commenters. As noted above in response to a previous comment, the Department does not believe that there is any one publication that provides the protocols necessary for the

rule. A careful review of the book raises the following concerns which diminish the value of the publication in the Department's opinion. First, the book appears to discourage the use of treatment protocols and guidelines respecting the duration of medical care which, according to the authors, are inappropriate in chiropractic care. This conclusion is contrary to the purpose of these rules.

Secondly, the Department observes that the referred book considers many diagnostic tests, some of which the Professional Boards have recommended as not suitable for reimbursement because they are of little value in the diagnosis and treatment of traumatic injuries. Thus, the Department does not accept this book as a national standard for chiropractic care and treatment.

COMMENT: Several commenters claimed that these rules violate the Americans with Disability Act ("ADA") in that a person suffering from a temporary or permanent disability may be denied the opportunity to obtain chiropractic care.

RESPONSE: The ADA prohibits discrimination against persons with disabilities in access to facilities that are open to the public, employment opportunities, participation in public services and access to telecommunications. A denial of reimbursement under an automobile insurance policy for chiropractic treatment would be made on the basis that it is not medically necessary. The Department does not believe that such a denial constitutes discrimination or would violate the provisions of the ADA.

COMMENT: Many comments were submitted by osteopathic physicians, professional associations affiliated with the osteopathic practice of medicine, osteopathic health care facilities and osteopathic learning institutions expressing concern about the omission of the care paths to refer to osteopathic manipulation and certain ICD-9 codes that deal exclusively with osteopathic care.

RESPONSE: Upon adoption, the Department is amending care paths 1, 3 and 5 to refer to "spinal manipulation" in order to accommodate all disciplines that utilize manipulation in treatment. A note in new Exhibit 10 references all licensed health professionals whose scope of licensure includes spinal manipulation. Also, upon adoption, the Department is adding the following ICD-9 codes: 728.0--disorders of the muscle, ligament and fascia; and 739.0--non-allopathic lesions, not elsewhere classified, which will include those osteopathic care codes that reference the injuries included in the care paths.

COMMENT: Several commenters urged the Department to adopt suggested standards for diagnostic tests developed by the Neurological Association of New Jersey, rather than those recommended by the Professional Boards. These standards would permit only certified neurologists to prescribe and conduct diagnostic tests.

RESPONSE: The Department is unwilling to make the suggested changes to N.J.A.C. 11:3-4.5. It notes that other commenters specifically disagreed with these commenters and urged their suggestion not be adopted.

With regard to who may perform certain tests, the Department's rules are not intended to restrict or lessen the scope of licensure.

COMMENT: Some commenters referred to SEP testing as set forth in care paths 2, 4 and 6 and stated that there should be no qualifier as the age of the patient. These care paths state that SEP testing should only be conducted over 50 years old.

RESPONSE: After a review of the medical literature referred, the Department agrees that the qualifier "after age 50" should be deleted from the SEP test at Care Paths 2, 4 and 6 and has made the change upon adoption.

COMMENT: A commenter suggested that the definition of "clinically supported" at N.J.A.C. 11:3-4.2 be amended to clarify that consideration of previous tests be limited to those "relevant to the proposed treatment or test." The commenter stated that this standard would be more appropriate for specialist consultants' review. The commenter also suggested deleting the requirement that medical records be signed, noting that the Professional Boards have rules that apply to medical recordkeeping.

RESPONSE: The Department agrees and has made these changes upon adoption.

COMMENT: Many commenters suggested specific changes to N.J.A.C. 11:3-4.5, which addresses diagnostic testing and includes lists of tests that are not reimbursable by PIP, and tests that are reimbursable under certain circumstances. Many of these commenters made specific suggestions for altering or amending the list and rules.

RESPONSE: As proposed, the rule for diagnostic tests at N.J.A.C. 11:3-4.5 was recommended to the Department by a task force of representatives from the Professional Boards, as provided in the Act. Some individual Professional Boards have since proposed their own rules addressing diagnostic tests (see 30 N.J.R. 3748(b) for a proposal by the Board of Dentistry; 30 N.J.R. 3751(a) for a proposal by the Board of Medical Examiners; 30 N.J.R. 3755(a) for a proposal by the Board of Physical Therapy; and 30 N.J.R. 3925(a) for a proposal by the Board of Chiropractors Examiners). Since the Act specifically authorizes the Professional Boards to make recommendations about diagnostic tests for these rules, the Department is reluctant to make substantive changes to the rules as suggested by the commenters until the Professional Boards have acted upon the suggestions by adoption of their own rules on the subject. Therefore, the Department will not accept the suggestions of the commenters for substantive changes to the rules. The Department expects the Professional Boards to act on their rules in December and the Department will consider changes to N.J.A.C. 11:3-4.5 immediately thereafter.

The Department notes however, that the rules proposed by the Professional Boards vary slightly from the recommendations of the Professional Boards' task force and are not entirely consistent among all Boards. To the extent that the Professional Boards' proposals vary from the task force recommendations, and demonstrate agreement among all Boards, the Department has determined not to adopt inconsistent provisions in its own rules. Therefore, it is not adopting N.J.A.C. 11:3-4.5(a)1 and 8. It further notes inconsistencies among the various Boards' proposals regarding N.J.A.C. 11:3-4.5(a)7 and (b)4, as well as a number of more detailed changes regarding the proper use of certain tests. The Department will propose amendments to N.J.A.C. 11:3-4.5 promptly after the Professional Boards act to adopt their rules referenced above. The Department is deleting the provision in N.J.A.C. 11:3-4.5(c)2 concerning the time frames for repeat testing since the consensus of the Professional Boards no longer recommends that restriction.

COMMENT: Many comments were received from dentists, professional association of dentists and dental educational institutions asking the Department to recognize temporomandibular disorders (TMD/TMJ) as a disorder for which specific care paths should be developed. In addition, these commenters asserted that sonograms, surface EMGs, CAT Scans, MRI's and temporomandibular tracking should be permitted as diagnostic tests for TMD/TMJ.

RESPONSE: The Department has identified cervical, thoracic and lumbar/ sacral regions for development of the initial care paths. These care paths represent the first effort by the Department to identify traumatic injuries that are suitable to the development of medical protocols for treatment. At this point the Department has not identified TMD/TMJ for development of protocols.

Regarding diagnostic testing, the initial report of the Task Force of the Professional Boards reported that sonograms, surface EMG's, CAT Scans, MRI's and temporomandibular tracking lacked sufficient value in the diagnosis and treatment of TMD/TMJ to warrant inclusion on the list of diagnostic tests. The Department appreciates the commenters' submissions, however, and suggests that they are more appropriately addressed to the Professional Boards for their evaluation and response. As noted in response to a previous comment, the Department will consider changes to the diagnostic test rules after the Professional Boards have adopted their own rules.

COMMENT: The Department has received many comments which endorse thermographic diagnostic testing and object to the Department's denial of reimbursement for this test.

RESPONSE: As noted above, both the Boards of Medical Examiners and Chiropractic Examiners have proposed rules that would permit this test to evaluate pain associated with reflex sympathetic dystrophy (RSD) in certain circumstances. The Department has not adopted the absolute prohibition as proposed and will propose amendments to its own rules after the Boards have acted.

COMMENT: One malpractice insurer claimed that it is concerned that these rules may limit the test and treatment choices of medical providers and expose them to the risk of litigation.

RESPONSE: The Department does not agree. The care paths do not prescribe a course of treatment for a particular patient, but establish typical courses of treatment as a standard for measuring medical necessity.

COMMENT: Several comments were received from pain management specialists, including physiatrists, biofeedback specialists/technicians, psychologists, psychiatrists, neurologists, and others. These providers are concerned that the care paths and these rules will deny patients the opportunity to receive pain management therapy if needed.

RESPONSE: The care paths specifically provide for referral to pain management specialists, including acupuncture, selective nerve route block, psychosocial evaluation, evaluation of pain medications, physical therapy and other

specialists. The Department also notes that biofeedback as a therapy is not affected by the rules which prohibit the diagnostic use of surface EMGs and other devices.

COMMENT: One commenter offered several specific suggestions for the care paths and rules. First, in those care paths where "conservative therapy" is referenced, the words "outpatient services" should be included. In care path 1, the commenter believes that words "including muscle relaxants" should be added to the list of medications in order to avoid overprescribing narcotics. The care paths should specifically reference 12 chiropractic sessions in the first four weeks. With regard to care paths 2, 4 and 6, the commenter suggested the introduction of case management by a certified case manager as soon as there is any indication of progressive neurological deficit as determined by appropriate specialists. The commenter stated that the use of case management specialists would facilitate the coordination of treatment and testing and assist in all phases of medical care. With regard to care paths 1, 3 and 5, the commenter recommends the implementation of case management as soon as there is positive indication of radiculopathy or where the patient fails to become compliant with the treatment plan developed by the treating medical provider. Lastly, the commenter suggested that the Department adopt a definition of "pain management" specialists to include a multidisciplinary team including psychological counseling, physical therapy, orthopedic, neurologic and physiatry.

RESPONSE: As noted below, the Department has addressed the commenter's suggestions that the medication provisions include muscle relaxants, and in clarifying that up to 12 spinal manipulation treatments may be appropriate in the first four weeks. The Department has declined to act on the commenters' other suggestions. "Outpatient servicers" references the provider (a hospital) rather than the service provided. Similarly, the commenter's suggestion to define "pain management specialists" references particular providers rather than the services themselves. The Department's rules are not intended to affect the scope of practice of any licensed healthcare provider; including or defining these terms would appear to have that effect.

The Department cannot conclude at this time that the weight of authority requires case management to be instituted as suggested.

COMMENT: The Department received many comments claiming that the pre-certification rules and the care paths violate the Health Care Quality Act, N.J.S.A. 26:2S-1 et seq., in that they create financial disincentives to not provide necessary medical treatments.

RESPONSE: The Department disagrees with the commenters. N.J.S.A. 39:6A-3.1 and 39:6A-4 and N.J.A.C. 11:3-4 do not provide any financial incentive for a physician to not provide medical care to persons in need of treatment. In fact, the rules encourage the provision of necessary medical care by discouraging under and over-utilization. The Department also notes that many provisions of these rules are consistent with the Health Care Quality Act.

COMMENT: A comment was submitted by the Radiological Society of New Jersey, a member of the American College of Radiology. The commenter noted that "in general, the Radiological Society of New Jersey endorses the goals of the New Jersey Legislature to develop cost containment guidelines to reduce the overall utilization of certain diagnostic tests and studies to appropriately reduce the medical expense benefits of personal injury protection."

The commenter also offered a number of specific remarks and suggestions. Regarding N.J.A.C. 11:3-4.2, the commenter stated that the "physicians assistant" should be added to the list of health care providers covered under the rules. As to N.J.A.C. 11:3-4.5(a), the commenter observed that the excluded tests have little or no value and agrees that these tests should be excluded from reimbursement. Regarding N.J.A.C. 11:3-4.5(b)4, the commenter stated that videoflouroscopy should be available sooner than three months if clinically supported and appropriately documented. Referring to N.J.A.C. 11:3-4.5(b)5, the commenter suggested that the use of an MRI during the acute phase immediately post-injury should be allowed when there are suspected fractures, which may not show up in an x-ray. It may be necessary for MRIs to be performed immediately post-injury when there is an altered state of consciousness. In regard to N.J.A.C. 11:3-4.5(b)6, the commenter suggested that there should be a reference to the guidelines in the American College of Radiology, Appropriateness Criteria for the use of CT and CAT Scans. In regard to the five day limitation on the administration of CAT scans, the commenter stated that such limitations are arbitrary and may be improper in the acute phase immediately post injury to evaluate chest, abdominal and pelvic injuries. Regarding N.J.A.C. 11:3-4.5(b)8, the commenter recommends that "trauma and" be added after the words "pelvis for" and before the words "intra-abdominal bleeding." Thus, it will be clear that sonogram/ultrasound can be used during the acute phase to evaluate abdominal and pelvis for intra-abdominal trauma and bleeding. Additionally, the commenter recommends that the following boldface words be added to this provision were noted: "MRI and CT is performed, sonogram/ultrasound may not be necessary."

Regarding N.J.A.C. 11:3-4.7, the commenter questions if a radiologist is obligated to contact an insurance company at a decision point review or is this the sole responsibility of the referring physician. Additionally, the commenter questions whether a radiologist is obligated to determine if authorization for diagnostic studies have been authorized by the insurer.

RESPONSE: Regarding these specific suggestions, the Department responds as set forth below:

"Physicians assistant" has been added to the list of health care providers upon adoption. In addition, the Department has identified several other categories of licensees who provide health care services that it is adding to the definition of health care provider.

Regarding the commenter's suggestion pertaining to videoflouroscopy, the Department notes that N.J.A.C. 11:3-4.5(c) states that when clinically supported and appropriately documented, the tests can be administered in spite of the restrictions in N.J.A.C. 11:3-4.5(b)1 through 8. Thus, videoflouroscopy can be administered if medically necessary in the first three months if clinically supported and properly documented. No change in the rules is necessary. The Department notes, however, that the Board of Medical Examiners has proposed to move this test to the list of tests that are not reimbursable and the Department may consider such a change if the Board adopts the rule as proposed.

Regarding the commenter's suggestion that reference to the guidelines contained in the American College of Radiology, Appropriateness Criteria be added to N.J.A.C. 11:3-4.5(b)6, as noted above in response to a previous comment, the Department will await the adoption of final rules by the Professional Boards, and then consider changes.

Regarding the suggested changes to N.J.A.C. 11:3-4.5(b)8, the Department likewise will await the adoption of diagnostic testing rules by the Board of Medical Examiners.

In regard to N.J.A.C. 11:3-4.7, the Department would urge any treating medical provider (including radiologists) that expects to be paid by a PIP insurer to assure themselves that any decision point review requirement has been satisfied. In most cases, this review will be in the same format as is used for indemnity health insurance pre-authorizations.

COMMENT: Many commenters expressed the opinion that the Department acted in excess of the authority granted in the Act by making these rules too restrictive and by denying physicians the discretion to practice medicine within acceptable medical standards. The commenters claimed that these rules wrongfully interfere with the patient-physician relationship.

RESPONSE: The Department believes that the rules are clearly authorized by the Act, which recognizes the necessity for the imposition of further controls on the use of medical expense benefits, including the establishment of a basis for determining whether treatments or diagnostic tests are medically necessary; precisely defining benefits available medical expense benefits coverage; establishing standards of treatment and diagnostic testing against which the medical necessity of actual expenditures can be judged; and eliminating wherever possible inappropriate medical treatments and unnecessary expenses which contribute to high auto premiums.

The Act's use of the word "protocol" indicates the intent to set forth commonly accepted standards and practices as the basis against which the treatments and tests administered to individuals could be measured. The "medical necessity" exception for variance from the protocols in sections 4 and 6 of the Act supports the Department's interpretation of the Act as set forth in these rules specifically at N.J.A.C. 11:3-4.6(c). Regarding pre-certification, the Act clearly directs the Department to promulgate rules that permit insurers to establish pre-certification plans. These plans may include procedures for the reasonable provision of diagnostic testing, treatment, goods, care and services as is already common in indemnity health insurance.

The commenters' assertion that these rules unduly interfere with the physician-patient relationship is without merit. The rules promote proper utilization and efficacy of PIP medical benefits.

COMMENT: Several commenters claimed that the care paths should recognize that three to six months of treatment is necessary for cervical and lumbar "soft tissue" injury with non-radiculopathic pain. In the case of lumbar myofascial pain syndromes and pelvic arthropathies, a period of no less than six months treatment is necessary.

RESPONSE: The Department disagrees that the lengths of treatment asserted by the commenters are necessary in most cases, and believes its conclusion is supported by the great weight of medical literature. One commenter, who asserted that a substantial number of cervical sprains/strains do not heal for years, nevertheless acknowledged that at least 20 percent of patients may be discharged after four weeks. Other literature indicates a much higher percentage.

Many other studies indicate that most patients diagnosed with spinal strains and sprains may be discharged within 60 to 90 days.

The care paths are intended to promote proper utilization of benefits. This requires that patients who will not benefit from further treatment be discharged. If patients have not recovered at a decision point and further treatment is necessary, these rules provide that treatment may continue.

COMMENT: Many commenters objected generally to the decision point review provisions at N.J.A.C. 11:3-4.7. Some commenters asserted that the Act did not authorize this process. Many commenters asserted that decision point review would interrupt and delay necessary treatment or diagnostic tests, to the detriment of the health of the injured person. Several commenters complained about the additional burden on the treating provider to comply with the decision point review process.

RESPONSE: Decision point review is appropriate in order to promote proper utilization of PIP medical expense benefits, which the Act provides should cover medically necessary treatment and tests. Rather than establish arbitrary limits on treatment (such as the 30 chiropractic treatments covered in the IHC Program policy, as referenced in a previous comment), these rules provide that PIP covers medically necessary benefits. Since injured persons and injuries vary significantly--as many commenters have noted--decision point review is essential to provide a measure of accountability for treating providers to payors, and ultimately to the premium-paying public. The decision point review permits the insurer to monitor the progress of the patient and ensure that unnecessary or ineffective treatment/therapies are not continued. If symptoms are resolved after a period of treatment, then the patients should be discharged. If a course of treatment is not producing results, other more effective therapies may be considered. Thus, the Department believes that the decision point review processes are fully authorized by the Act in order to promote the most appropriate level of treatment.

With regard to the comments that decision point review will delay and disrupt the course of necessary treatment and tests, the Department notes that the process authorized by the rules is similar to the pre-authorization or precertification processes generally used in indemnity health insurance and permitted by the Act and N.J.A.C. 11:3-4.8. Nevertheless, the decision point review process does not necessarily require an affirmative response by the insurer for treatment to continue. Rather, it provides notice to the insurer about a proposed course of treatment or proposed administration of a particular diagnostic test and an opportunity for the insurer to have the treating provider's findings reviewed by a physician to confirm that the proposed treatment or test is medically necessary. N.J.A.C. 11:3-4.7(b)1iii requires affirmative action by the insurer to deny, based on the determination of a physician. A failure to deny in accordance with that rule means that the treatment may proceed until such time as a denial based on the determination of a physician is communicated by the insurer, in accordance with its decision point review plan that has been filed and approved by the Department. Therefore, the Department does not expect that decision point review in accordance with these rules and the insurer's approved plan should serve to interrupt a course of necessary treatment. Similarly, with regard to the administration of the various tests that are subject to decision point review, failure of the insurer to deny administration of the test based on the determination of a physician means that the test may proceed. The Department notes, however, that the decision point review process will require prompt and clear communications between the insurer and the treating provider, and that N.J.A.C. 11:3-4.7(d) requires that the insurer notify the injured party and the treating provider promptly about how to comply with the insurer's decision point review plan requirements. It is likely to be necessary that providers identify the responsible PIP insurer promptly upon undertaking treatment of a particular patient, in order to assure that the patient's needs are properly addressed. While there is, of course, some administrative action required by the treating provider, it is not much different than is required for other health care coverage, and in most cases would simply require that notice to the PIP insurer occurs at the outset of treatment. Therefore, the Department does not believe that decision point review establishes an unwarranted new burden on treating providers.

Nevertheless, the Department is of course interested in promoting prompt and efficient provision of necessary medical treatment to injured motorists without undue interruption in a course of treatment. It is therefore appropriate to emphasize that the insurer's decision point review plan should not unduly interrupt treatment and encourage insurer's decision point review plans to operate as simply as possible for both treating providers and insurers. Therefore, the Department has upon adoption added provisions to the rules at N.J.A.C. 11:3-4.7(b)4 and 5 (and parallel provisions at N.J.A.C. 11:3-4.8(h) and (i) in the precertification plan rules) to establish a further standard that treatments not be unduly interrupted and to encourage insurers' decision point review plans to accept a comprehensive treatment plan for review, so as to avoid piecemeal review, with the potential for unnecessary delay, expense and uncertainty. The standard to avoid undue interruption is consistent with the Department's proposal as is the provision for review of a comprehensive treatment plan. A decision point review plan under the rules proposed could have so provided, but adding

these standards may promote the submission of better plans for the Department's review and approval. Insurers and providers are encouraged to cooperate to avoid disruptions and to use comprehensive treatment plans for common injuries with predictable treatment that would include pre-authorization for certain tests and treatment over a period of one or more decision points. For example, the insurer and provider could agree on a course of conservative treatment beyond the four-week decision points, which would continue under normal circumstances without interruption. Of course, medical necessity when present may require deviation from the treatment plan with further notice to the insurer. In addition, the Department has deleted the last phrase in N.J.A.C. 11:3-4.7(b)2i. The deletion is intended to emphasize that treatment should not be unduly interrupted in the event a physical examination is required. The Department notes that many circumstances referred to by the commenters may be appropriate cases for the use of extended treatment plans.

COMMENT: Several commenters asserted that the decision point review rules will require that every injured person be examined by an independent physician after every four weeks of treatment, and the substantial additional expense of these examinations will offset any potential cost savings.

RESPONSE: The Department expects that relatively few physical or mental examinations will be required after blocks of conservative treatment. If further treatment is necessary, the treating provider will transmit his or her findings that support further treatment to the insurer for review. If the need for further treatment is clinically supported by the treating physician's records, it should proceed. If not, the review physician may determine to deny it.

COMMENT: Many commenters stated that the decision point review process set forth at N.J.A.C. 11:3-4.7 exceeds the authority granted by the Act regarding the 50 percent penalty permitted by N.J.A.C. 11:3-4.7(b)3 for failure to cooperate with an insurer in giving notice of tests and treatment in a timely fashion or failing to appear with records or at a scheduled physical examination and improperly imposes arbitrary limits and financial penalties on persons seeking medical treatment for accidents.

RESPONSE: N.J.A.C. 11:3-4.7(b)3 establishes a standard for decision point review plans that limits an additional co-payment to a maximum of 50 percent of the eligible charge. This additional co-payment may be applied when an insured or his or her designed (usually the treating provider) fails to notify the insurer about continuing treatment or specific diagnostic tests, or the injured person fails to appear for a properly scheduled physical examination. In the absence of any standard limiting the amount of the copayment, insurers might file policy forms providing no coverage for failure to comply with the decision point notification and cooperation requirements. Additional co-payment penalties have long been utilized in indemnity health insurance to encourage responsible compliance with precertification administrative processes. (See N.J.A.C. 11:4-42.8.) The Act itself at N.J.S.A. 39:6A-3.1a and 39:6A-4a specifically recognizes that reasonable additional co-payments may be established in order to avoid over-utilization or under-utilization of benefits. Since decision point review is intended to encourage proper utilization and, as noted above, the maximum copayment is the same as permitted for indemnity health insurance in similar circumstances, the Department believes that the Act clearly authorizes these provisions.

COMMENT: Some commenters suggested that N.J.A.C. 11:3-4.7(b)2iv, which provides that a physical or mental examination be conducted at a location "reasonably convenient" to the injured person, provide a tighter standard. The commenters suggested that the standard be that the examination be performed in the injured person's municipality of residence or be within some fixed distance, or time of travel.

RESPONSE: The Department at this time is unwilling to define more specifically the term "reasonably convenient." It notes that N.J.S.A. 39:6A-5, as amended, uses this term for the independent medical examinations referenced there (although the reference to the municipality of residence of the injured party is also retained). For some injured persons, an examination close to a worksite may be more convenient, and for others without personal transportation, a particular mileage or commute time standard may prove unreasonably inconvenient. The Department does not wish to establish some maximum standard, since it may not apply in every case. The Department will, however, continue to monitor the application of these rules and may consider amendments in the future to establish a more objective standard, if necessary.

COMMENT: With regard to N.J.A.C. 11:3-4.7(b)2v, one commenter expressed concern about the transmission of medical records from the treating physician to the examining physician. The commenter stated that the rule appears to require that the injured person carry the records, and notes that this may be impractical in many cases. The commenter further notes that often such records are transmitted electronically.

RESPONSE: The intent of this rule is to provide the examining physician with information about the case, not to prescribe the method of transmission. The Department recognizes that in most cases it will be the treating provider that

arranges for transmission of the records, on behalf of the injured person, and therefore has added this reference to the rule at N.J.A.C. 11:3-4.7(b)2v upon adoption. Additionally, the second sentence of this provision has been modified to avoid the implication that the injured person is reponsible to transport the records.

COMMENT: One commenter asked that N.J.A.C. 11:3-4.3(b), which provides that certain non-medical expenses be covered by PIP for catastrophic injuries, be expanded so as to require insurers to reimburse for any temporary or permanent non-medical expenses prescribed by a physician when deemed necessary for the enhancement of the quality of life of any person injured in an auto accident.

RESPONSE: The purpose of this provision is to confirm that PIP will not cover non-medical expenses, except in connection with certain catastrophic injuries. PIP has historically paid for some non-medical costs, such as home or vehicle modifications to accommodate persons permanently and severely disabled by auto accident injuries. Most other forms of health coverage do not provide these benefits. The Department intends that these benefits continue to be provided only for the severely disabling injuries mentioned.

COMMENT: Regarding N.J.A.C. 11:3-4.7(b)1iii, the Department received many comments requesting that any denial for reimbursement of treatment or tests should be based upon the determination of a physician, independent of the insurance company, who is currently practicing in a like medical field as the treating medical provider.

RESPONSE: The Department believes that the PIP dispute resolution rules, adopted elsewhere in this issue of the New Jersey Register, address these commenters' concerns. It notes that the provisions for denial of reimbursement of tests and treatment by a physician for the insurer are similar to the Health Care Quality Act, which at N.J.S.A. 26:2S-6b(1) provides that any decision to deny reimbursement must be based on the determination of a physician.

COMMENT: Numerous commenters objected to N.J.A.C. 11:3-4.7(b)2, which requires that insurers notify the patient or his or her designee that a physical examination will be required when the patient reaches a decision point review. They also complained that N.J.A.C. 11:3-4.7(b)2ii requires that the physical exam be conducted within seven days of the notice (unless extended by the patient) and that N.J.A.C. 11:3-4.7(b)2vi requires that the results of the exam be conveyed to the patient and his or her designee within three days. The commenters claimed that these rules impose an unnecessary burden on the insurer and are not practical.

RESPONSE: The Department does not agree that these provisions create an improper burden. The rules set forth standards for decision point review plans. If an insurer intends to conduct a physical examination of the injured party as part of the decision point review, the insurer must notify the injured person (or their designee) that an examination is required and the time, date and place of the examination. In establishing these standards, it is the Department's intent that medically necessary treatment and tests not be inordinately delayed for a physical or mental examination. The insurer's decision point review plan should provide that the treating provider convey to the insurer the clinically supported findings that are the basis for the treating provider's determination that the test or further treatment is necessary. In most cases, the review of these documents will avoid the need for a physical or mental examination, and the decision point review determination can be promptly transmitted to the treating provider. (As noted in response to a previous comment, failure to deny reimbursement based on the determination of a physician in accordance with the insurer's decision point review plan means the treating provider may proceed.) When the insurer or reviewing physician determines that a physical or mental examination is necessary, it should be promptly scheduled. If a decision point review physical or mental examination cannot be scheduled by the insurer within the time permitted by the rules, then treatment may proceed in the interim.

COMMENT: Some commenters suggested that the Department ought to require a public comment and hearing process for insurers filing pre-certification plans under N.J.A.C. 11:3-4.8. They also expressed objection to N.J.A.C. 11:3-4.8(f), which permits insurers to file pre-certification plans that will require injured persons to obtain durable medical goods directly from the insurer or its designee. The commenters claimed that injured persons should be permitted to obtain durable medical goods anywhere they want, or, at least, from any source at the same or less than the cost paid by the insurer.

In addition, the commenters suggested that an additional subsection (h) should be added to N.J.A.C. 11:3-4.8 to require that all pre-certification plans provide for quick response to pre-certification requests.

RESPONSE: Although the commenters appear to contemplate a "legislative type" hearing, the Department notes that rating system filings (including form filings) would require a "contested case" hearing, pursuant to N.J.S.A. 17:29A-14. The parties to such a proceeding are the filer and the Department and the statute describes the process and

sets relatively prompt deadlines for completion. There is no provision for a legislative type public hearing as contemplated by the commenters.

N.J.A.C. 11:3-4.8(f) permits insurers the opportunity to save costs on items of durable medical equipment that will be available to injured persons. The commenter offers no compelling reasons why this potential cost saving provision should be changed or eliminated.

Regarding the suggestion that the Department add a provision to N.J.A.C. 11:3-4.8 establishing a maximum "turn around time" for pre-certification requests, the Department is unwilling to establish such "ceilings" at this time in order that they not become "floors." The medical director overseeing the precertification plan is responsible for utilization decisions. Any denial of pre-certification must be based on the determination of physician and the utilization management program must be available, at a minimum, during normal working hours to respond to authorization requests. The Department will monitor how these provisions are implemented and will amend the rules in the future if necessary.

COMMENT: One commenter suggested that N.J.A.C. 11:3-4.2 and 4.3 should be amended to recognize that medical expenses can include any non-medical religious treatment rendered in accordance with a recognized method of healing. The commenter claimed that religious healing and the expenses associated therewith should be included in PIP reimbursement for medical expenses.

RESPONSE: The Department does not believe that the requested changes are necessary. N.J.S.A. 39:6A-2e recognizes that medical expenses also include any non-medical remedial treatment rendered in accordance with a recognized religious method of healing. That statutory language was not changed by the Act and thus it appears that the opportunity to obtain reimbursement for services rendered in accordance with recognized religious healing continues.

COMMENT: One commenter requested that the definition of "eligible charge" at N.J.A.C. 11:3-4.2 be amended so as to be the provider's usual charge based upon the geographic area where the treatment is performed.

RESPONSE: The Department disagrees. The definition of "eligible charge" establishes the connection with the medical fee schedule at N.J.A.C. 11:3-29.6. N.J.A.C. 11:3-29.3 refers to the regions within the State of New Jersey which are the basis for differentiation of eligible charges. No change to this rule is necessary.

COMMENT: Several commenters expressed concern that the decision point review process in N.J.A.C. 11:3-4.7 may permit injured persons to intentionally fail to appear for a scheduled physical examination. These commenters stated that the rules should contain provisions requiring that injured persons attend scheduled examinations and that insurers are not obligated to provide reimbursement of medical expense that are incurred after decision point review when the injured fails to appear for a scheduled physical examination. These commenters are concerned that there appears to be no explicit event in the decision point review process that triggers an appeal pursuant to the PIP dispute resolution rules, N.J.A.C. 11:3-5, adopted elsewhere in this issue of the New Jersey Register. Some insurers expressed concern that medical providers will dispute everything while some medical providers are concerned that insurers will deny all treatment and tests.

RESPONSE: The rules are not intended to provide a basis for denying payment of necessary medical expenses. Rather these rules permit insurers the timely opportunity to review the clinically supported medical necessity of tests and treatment. This opportunity should not be misused to deny medically necessary care.

The decision points establish the time frame when insurers can review the course of treatment and should not unnecessarily interrupt needed medical care. As noted in response to a previous comment, the insurer's decision point review plan should not permit or require an undue cessation of treatment pending a physical examination by the insurer.

N.J.A.C. 11:3-4.7(b)3 provides for a 50 percent additional co-pay of an eligible charge for all tests and treatment occurring if the injured party fails to appear for an examination or fails to give notice to the insurer as provided by the insurer's decision point review plan. If, on the other hand the physical examination verifies the need for continued treatment or a specific test, then it will be reimbursed.

Regarding the event or events which would trigger the alternate dispute resolution (ADR) process, the Department notes that either party may request ADR.

COMMENT: In regard to N.J.A.C. 11:3-4.8, several commenters noted that the benefit of pre-certification plans will be undermined if treatments, tests and other medical expenses in the first 10 days after the accident are not subject to pre-certification requirements. The commenters claimed that the 10 day exclusion from pre-certification apparently leaves the insurer at the mercy of the medical provider and injured persons. Furthermore, the commenters expressed

concern that the costs associated with development, implementation and operation of a system capable of exercising the kind of supervision and control over PIP medical expenses as required by the rules will far exceed any possible savings realized.

RESPONSE: The 10-day limitation on pre-certification comes from the Act (N.J.S.A. 39:6A-3.1a) which states that "no pre-certification requirements shall apply within 10 days of the insured event." The Department's rules reflect this statutory limitation. This does not mean, however, that expenses for treatment or tests that are not medically necessary must be reimbursable. Pursuant to N.J.A.C. 11:3-4.3, PIP will reimburse only medically necessary expenses, and N.J.A.C. 11:3-4.5(b) still requires that only those diagnostic tests that are medically necessary and consistent with the clinically supported findings shall be reimbursable.

Regarding the commenters' concerns, the Department is aware that there will be costs. These rules require insurers to be able to respond to requests for certification of tests and treatment and to participate in decision point review. This effort will require systems and trained personnel to properly exercise the control over costs that is permitted by the Act and the rules.

Nevertheless, the Department believes that the rules provide insurers with the opportunity to reduce costs and obtain substantial savings by eliminating unnecessary and wasteful tests and treatment. Insurers are also permitted to develop pre-certification plans which the Department believes can also generate substantial cost savings. Each insurer must, of course, exercise this opportunity in a manner that considers both the expense and the cost savings. The Department notes that indemnity health insurers have developed appropriate systems that balance the expense and the cost savings, and believes that auto insurers can do likewise.

COMMENT: Several commenters questioned if insurers could establish pre-certification plans that have no co-pay or deductible.

RESPONSE: N.J.A.C. 11:3-4.4(d) permits insurers to offer alternative deductible and co-pay options as part of an approved pre-certification plan established in accordance with N.J.A.C. 11:3-4.8. Thus, insurers may file policy forms establishing a low or no co-pay/deductible medical expense benefit as part of a pre-certification plan.

COMMENT: One commenter made suggestions regarding the definitions contained in N.J.A.C. 11:3-4.2 as follows:

"Eligible charge" should be amended to require that medical providers include the CPT code with all billings.

"Emergency care" should indicate that the medically necessary care immediately following an automobile accident should be for a covered loss under the policy.

"Health care provider" or "provider" should indicate that the treatment being billed for is within the area of licensing or certification of the person providing the treatment or service.

"Non-medical expense" should be limited to include only catastrophic injuries and only be reimbursable when rendered in accordance with a prescription by a treating medical provider.

"Medical expense" should not include non-emergency transportation unless pre-certified by the insurer.

"Medically necessary" should be defined so as to exclude reimbursement for palliative care.

RESPONSE: The term "eligible charge" is taken directly from N.J.A.C. 11:3-29.6 which is the medical fee schedule and includes the CPT codes. Thus, any reference to include a CPT code when referencing the eligible charge is unnecessary.

"Emergency care" is as defined; its use in rules providing substantive standards and the terms of the policy already describe its application as suggested by the commenter.

"Health care provider" or "provider" likewise needs no further change in definition. The commenter's suggestion addresses substantive applications of the definition in the rules or policy, not the definition of a provider. Providers should not be billing for services or treatment beyond their scope of licensing or certification. However, some providers may also supply durable medical equipment requiring no special certification or licensing and injured persons should be permitted to obtain this equipment from their health care provider.

The definition of "non-medical expenses" accurately sets forth the Department's intent and no change is required. N.J.A.C. 11:3-4.3(b) limits those circumstances when non-medical expenses are reimbursable by PIP medical expense coverage.

Regarding "medical expense," the commenter interpreted the words "medical expense" to cover non-emergency transportation expenses only when pre-certified. N.J.S.A. 39:6A-2e states that "other transportation, medication and other services as may be deemed necessary for, and subject to, such limitations as provided for, in the policy, . . ." are included. No special licensing or certification is required by persons rendering non-emergency transportation to injured persons. Insurers may however impose pre-certification or other preconditions or may offer non-emergency travel through an insurer contracted service. In such case the transportation must be reasonably available to accommodate the needs of the injured person.

Regarding "medically necessary," the commenter's assumption regarding palliative care is not correct. "Palliative care" may include treatment that is directed at lessening the pain associated with an injury or medical condition but does not cure the cause. These rules specifically permit pain management care.

COMMENT: Several commenters questioned how N.J.A.C. 11:3-4.4(b)1, which addresses medical expense deductibles, should be applied. These commenters assert that the rule is more restrictive than the Act, in that the Act requires that deductibles apply only to the named insured and any resident relative in the named insured's household. These commenters suggest that the rules should permit the deductible to be applied to any individual claiming benefits under the policy.

RESPONSE: The Department does not agree; it does not construe the elimination of the standard deductible and co-payment provisions as evidencing legislative intent to alter the standard deductibles and co-payment provisions that have been approved by court decisions as appropriate for those not resident relatives or named insureds. Persons not covered as a named insured or resident relative will have the "default" deductible and co-pay: $ 250.00 deductible and 20 percent co-pay on all medical expenses between $ 250.00 and $ 5,000.

COMMENT: One insurer objected to N.J.A.C. 11:3-4.4(c), which applies the deductibles and co-pays on a per accident basis. The commenter claimed that this language was deleted from the Act and should be deleted from these regulations.

RESPONSE: The Department disagrees; it does not find any clear evidence of legislative intent to make such a change to the statute. It is reasonable and consistent with the application of PIP for deductibles and co-pays to be applied on a per accident basis.

COMMENT: Regarding N.J.A.C. 11:3-4.6(d), which states that the care paths do not apply to emergency care, one commenter claimed that the diagnostic tests listed in N.J.A.C. 11:3-4.5(b) should still be subject to pre-certification by the insurer.

RESPONSE: The Department disagrees. The rules' exception from decision point review for emergency care at an acute care or trauma hospital also includes the administration of necessary tests in order to provide these institutions with the ability to address injuries properly and completely.

COMMENT: Several commenters noted that N.J.A.C. 11:3-4.7(b)1i employs the term "prompt review" in reference to the notice and supporting material to be submitted by a provider when requesting authorization for tests or treatment. The commenters argued that a specific time frame such as three days should be adopted.

RESPONSE: The Department does not agree. The notice of decision point review for additional tests, treatment, equipment or other services should be handled in the most expedient and efficient fashion. The Department expects that many insurer's decision point review plan will provide for electronic receipt of the decision point review notice, and telephone response by the insurer. If additional consultation, information or documentation is required, providers and the insurer's reviewer should employ the most efficient and effective means such as telephone, telefax or e-mail. The Department at this time is unwilling to establish a maximum number of days by rule, because to do so may serve to create an expected "floor" that could delay prompt review when possible. The Department will monitor implementation by providers and insurers and may propose more specific standards in the future if required.

COMMENT: Several commenters stated that N.J.A.C. 11:3-4.5(a) should be changed to reflect the proper tense of the rules.

RESPONSE: The Department agrees and upon adoption has amended this subsection to substitute the words "which have been determined." This is not only grammatically correct but also correctly reflects the events.

COMMENT: In reference to N.J.A.C. 11:3-4.6(a) concerning the medical protocols, one commenter recommended that the words "medically necessary" be substituted for the word "appropriate."

RESPONSE: The Department agrees. As provided in the Act, the care paths are intended to set forth the protocols established by the Commissioner as a "medically necessary" course of treatment. Thus, upon adoption, the Department is changing the word "appropriate" to "medically necessary."

COMMENT: One commenter observed that the provisions of N.J.A.C. 11:3-4.4(e) indicated that commercial automobile insurance policies do not appear to provide for an opportunity to development alternative deductible and co-payment options as part of an approved pre-certification as is found in N.J.A.C. 11:3-4.4(d) for private passenger automobile policies.

RESPONSE: The commenter is correct. Commercial automobile insurers should provide coverage in accordance with the standard "default" provisions, that is, a $ 250.00 deductible with 20 percent copay on medical expenses between $ 250.00 and $ 5,000 with a maximum medical benefit coverage of not to exceed $ 250,000 per person per accident. The Department believes that it is appropriate that commercial auto insurance policies in which no natural person is named as the insured should not be subject to a payment structure not agreed to by the parties. When the named insured on a commercial auto policy is a natural person, the alternative deductible and co-pay options must be offered.

COMMENT: One commenter observed that the term "non-compliant patient" is used in care paths 1, 3 and 5 but there is no definition for a "non-compliant patient." The commenter suggested that a "non-compliant" patient is one who does not participate in at least 50 percent of the prescribed treatments.

RESPONSE: The Department agrees that it is appropriate to define this term but believes that the commenter's suggestion is too rigid. The following definition of non-compliant has been added to the Glossary in Exhibit 1, of the Appendix upon adoption, "a patient who wilfully chooses not to participate in the treatment plan agreed upon by the patient and his/her healthcare provider and does not have secondary issues such as lack of transportation, pre-existing conditions or comorbidities."

COMMENT: One commenter observed that the term "radiculopathy" is used at various points in the rules and care paths. In fact, the severity of radiculopathy is a critical factor in determining the direction taken under care paths 2, 4 and 6. Thus, the commenter concluded that there should be definitions included for mild radiculopathy, moderate radiculopathy, and severe radiculopathy. The commenter also noted the clinical guidelines of the American Academy of Orthopaedic Surgeons (AAOS) contains the following definitions:

"Mild radiculopathy"--the presence of a neurological deficit.

"Moderate radiculopathy"--the presence of significant or progressive deficit.

"Severe radiculopathy"--the presence of significant or progressive neurological deficit with the quality of the patient's life significantly impaired.

The commenters also suggested that care paths 2, 4 and 6 should be amended to replace the word "radiculopathy" with the proper modifier of "mild, moderate or severe" radiculopathy as appropriate.

RESPONSE: The Department has reviewed this issue with its health benefit consultant and determined to revise these care paths for clarity, as described in the Summary of Agency-Initiated Changes below.

COMMENT: Several commenters suggested that the issue of causation needs to be addressed in the initial diagnosis and at each decision point. Thus, the care paths should require a clinical finding by the treating practitioner that the injuries being treated resulted from the accident.

RESPONSE: The Department agrees that it is medically and legally appropriate for the treating practitioner to make an initial diagnosis which identifies the conditions being treated and makes a finding that the cause is a motor vehicle accident. This is part of the clinical support that must be in the patient's chart and is not necessary to reference in the care paths as requested.

COMMENT: One commenter referenced the July 14, 1994 New England Journal of Medicine in which a study found that 52 percent of all non-symptomatic patients have disc abnormalities. The commenter concluded that a disc

herniation may be present but not discovered until the occurrence of an auto accident. The commenter wanted care paths 2, 4 and 6 amended to require a finding by the treating medical provider that the disc herniation being treated is a result of the auto accident and not a previous condition.

RESPONSE: The Department disagrees. While it is necessary for the treating medical provider to find that the injuries being treated for are a result of the automobile accident in order to be reimbursable by PIP, it is possible that a pre-existing condition becomes symptomatic upon injury. The necessity of a causal relationship between the accident and the medical condition should be referenced in the policy. No change is necessary in the rule and Appendix to state this.

COMMENT: Several insurers asked if policy forms can be filed with elements of the care paths together with aspects of pre-certification plans. One commenter is specifically interested in creating special pre-certification requirements for chiropractic and physical therapy treatment as related to neck and back injuries.

RESPONSE: While the Department has no objection to an insurer including elements of the care paths in pre-certification plans, it cannot approve the form until it is filed.

The Department notes, however, that the pre-certification plan must include decision point review, and certification programs may not result in unnecessary or discriminatory limitations on any form of permitted medical discipline.

COMMENT: Several commenters inquired whether members of insurance groups with affiliated companies must each offer the same PIP benefits options or could each insurer offer different options with individual pre-certification plans.

RESPONSE: The Department's rules do not prohibit each company in a group of affiliated companies from offering different PIP benefit packages. Each must, of course, be approved.

COMMENT: Several insurers noted that the definition of "clinically supported" is critical to the operation and effectiveness of these rules. The commenters suggested that the words "clinically supported" be added to the definition of medical expense as well as to N.J.A.C. 11:3-4.3(b) which provides for the reimbursement of non-medical expenses. The use of the words "clinically supported" will make it clear that medical expenses and reimbursement of non-medical expenses must be justified by the elements of "clinically supported."

RESPONSE: The Department agrees in part. Adding the phrase "clinically supported" will clarify that non-medical expenses are only reimbursable when properly related to a course of rehabilitative therapy, or otherwise necessary for the injured person function. Therefore it is appropriate to amend N.J.A.C. 11:3-4.3(b) to include the words "clinically supported."

The Department does not see the need to add the phrase to the definition of "medical expense" at N.J.A.C. 11:3-4.2, since it is already in the substantive standard at N.J.A.C. 11:3-4.3(a) by use of the term "medically necessary."

COMMENT: One commenter noted that the words "reimbursable" and "not recommended" are not proper in the context of N.J.A.C. 11:3-4.5(b). Specifically, N.J.A.C. 11:3-4.5(c) references the use of the terms "normal," "normally," "appropriate" and "indicated" in referring to the tests found in subsection (b). Thus, the commenter suggested that the term "appropriate" or "indicated" should be substituted in place of "reimbursable" and "not recommended."

RESPONSE: The Department agrees. The suggestion promotes consistency, and the Department will make appropriate amendments to N.J.A.C. 11:3-4.5(b)2 and 7 upon adoption.

COMMENT: Several insurers noted that N.J.A.C. 11:3-4.8(g) permits imposition of an additional co-payment not to exceed 50 percent of the eligibile charge where there is a failure to comply with an approved pre-certification plan. These commenters questioned if the additional co-payment is also required in those instances in which the injured party fails to appear with medical records at a scheduled physical examination as in N.J.A.C. 11:3-4.7(b)3.

RESPONSE: The additional co-payment not to exceed 50 percent of the eligible charge is permitted when an injured party under an approved pre-certification plan fails to comply with the reasonable administrative provisions of the pre-certification plan, including the failure to appear for a properly scheduled physical examination.

As noted above in response to a previous comment, provision for obtaining medical records in connection with an examination should be practical and recognize the role of the treating physician who produces the records.

COMMENT: Several commenters expressed concern regarding the apparent open-ended use of physical therapy treatments and all of the modalities used therein. Specifically, one commenter pointed to the use of hot/ cold pack treatments as a separate billable treatment modality.

RESPONSE: These issues are under consideration and will be addressed in a forthcoming proposal which will revise the New Jersey auto medical fee schedule rules at N.J.A.C. 11:3-29.

COMMENT: Several insurers expressed concern that the Department's reference to physical therapy, psychiatric evaluation and treatment, acupuncture and other pain management techniques may promote unnecessary and inappropriate treatment and expenses.

RESPONSE: The Department notes that all treatment including physical therapy, psychiatric, acupunture and pain management are subject to a determination of medical necessity, either pursuant to a decision point review or an insurer's pre-certification plan. All treatments must be medically necessary and clinically supported. As noted below, the Department has sought to clarify the use of psychosocial evaluations in conjunction with the kinds of injuries in which care paths have been developed.

COMMENT: One commenter claimed that N.J.A.C. 11:3-4.3(b) should be amended so as to totally deny reimbursement for all non-medical expenses such as improvements to vehicles, improvements to real estate, recreational activities, trips and other leisure activities. The commenter claimed that this rule is an invitation to fraud and abuse and will result in huge unnecessary claims.

RESPONSE: The Department does not agree. Necessary non-medical expenses are only permitted in the case of permanent or significant brain, spinal cord or disfiguring injuries where clinically supported (as noted above) and necessary in connection with a course of therapy or rehabilitation or to permit the injured person to function outside of an institution. This rule limits reimbursement of such expenses to the cases of serious and permanent injury.

COMMENT: One commenter noted that N.J.A.C. 11:3-4.7(b)2ii requires that a physical examination be scheduled within seven calendar days of when an insurer receives notice from the provider that additional treatment or tests are needed unless the injured party agrees to extend the time. The commenter believes that seven days, especially during holiday and weekend periods, is inadequate and should be at least 20 business days.

RESPONSE: The Department recognizes that such an examination may, as a practical matter, require more time to schedule. Nevertheless, injured persons should not have test or necessary treatment unnecessarily delayed. In the event the insurer requires more time to schedule the examination, the injured party may continue treatment as directed by the treating provider in the interim. Insurers should develop the necessary network of physicians who are willing to accommodate these time constraints. The application of these rules will continue to be monitored by the Department and changes will be made if necessary.

COMMENT: With regard to non-medical expenses, one commenter questioned if over-the-counter medications such as aspirin, etc., are reimbursable as non-medical expenses if supported by the prescription of a treating medical provider.

RESPONSE: Medically necessary expenses, including prescription and non-prescription medications, are reimbursable.

COMMENT: A group of orthotic providers objected to the care paths which only mention soft neck collars in the care path 1 for soft-tissue injury/cervical spine. The commenter noted that the other care paths do not mention any of the devices and mechanisms that might be available to assist in recovery and treatment. This includes TENS units and other orthosis which can be used pre- and post-surgery.

RESPONSE: Treating medical providers may prescribe medically necessary and clinically supported durable medical equipment and orthosis. If braces and collars are prescribed by the treating medical provider, they are covered if medically necessary.

COMMENT: One commenter stated that the care paths do not and should not define the specific kinds of physical therapy given, since the modality changes with the specific need. The commenter requested that "physical therapy" be redefined to read "the evaluation, assessment, and treatment of dysfunction caused by disease or injury. Treatment shall consist of therapeutic exercises, education and other modalities and procedures that focus on improving posture, locomotion, strength, endurance, balance coordination, joint mobility, flexibility and individual's ability to go through the functional activities of daily living (ADLS) and on alleviating pain." Another commenter suggested modifying "radia-

tion" in the description of modalities that constitute physical therapy as "non-ionizing" to distinguish it from other types of radiation therapy.

RESPONSE: The Department agrees with the commenters and is amending, upon adoption, the definition of physical therapy, as contained in the Glossary of Terms, Appendix Exhibit 1, to incorporate the suggested language into the existing definition and to refer to "non-ionizing" radiation.

COMMENT: One commenter expresses concern that N.J.A.C. 11:3-4 may limit access to emergency care. The commenter is concerned that the definition of emergency care does not specifically include the hospital-based "medical screening examination" (MSE) which it states is required by Federal and state law to be done in any emergency medical situation. The commenter suggested that the rules should specifically define "medical screen examination" as meaning an examination and evaluation within the abilities of the hospital's emergency department, including ancillary services routinely available to the emergency department, performed by qualified medical personnel to determine whether or not an emergency medical condition exists.

The commenter also recommends that the term "emergency care" be replaced and referred to as "care of an emergency medical condition." Further, the commenter recommends that the definition of "emergency medical condition" or "emergency care" be the following: "care of an emergency medical condition or emergency care--means all medically necessary treatment of an emergency condition manifesting itself by acute symptoms of sufficient severity (including severe pain and/or psychiatric disturbance) such that the absence of immediate medical attention could reasonably be expected to result in: placing the health of an individual (or with respect to a pregnant woman, the health of a woman or her unborn child) in serious jeopardy; serious impairment of any bodily functions or serious dysfunction of any bodily organ or part."

The commenter also recommends that emergency medical condition shall be deemed to include all medically necessary care following an automobile accident, when initial access to medical care occurs no later than 120 hours after such accident.

RESPONSE: The Department's definition of "emergency care" is the same as that set forth at N.J.A.C. 11:3-25 and has not caused any difficulty in determining what is and what is not covered under PIP Emergency Medical Care. Clearly, any medical problem arising out of an auto accident for which the injured person needs to be examined by a doctor, including an emergency medical screening, is covered medical care. Thus, the Department does not agree with the comments that this point requires any change in the rules.

The Department does, however, agree that the term "immediately after the accident" is not sufficiently definite to set the appropriate standards for testing and treatment and may be construed to deny reimbursement. Thus, the Department, upon adoption, is amending "emergency care" to establish a presumption of emergency care when treatment is initiated at a hospital within 120 hours after the accident. This clarification should eliminate any misunderstanding.

COMMENT: Several radiologists submitted comments regarding N.J.A.C. 11:3-4.5(b)6 which states that "CAT Scan is not normally administered immediately post-injury." The commenter stated that CAT Scans are absolutely necessary in the abdominal and pelvic evaluation of trauma patients and will substantially help reduce mortality and morbidity of patients. They are also commonly used in blunt chest trauma.

RESPONSE: N.J.A.C. 11:3-4.5(c) states that the use of the terms "normal, normally, appropriate and indicated" only establish the usual, routine, customary, or common experience. Unusual circumstances based on medical necessity and clinical supported findings offer flexibility in the application of these rules. N.J.A.C. 11:3-4.5(e) specifically states that the diagnostic rules found in subsections (b) and (d) do not apply to diagnostic tests administered during emergency care. The kind of emergencies referred to by the commenters would fall within these exception, and the rules would not prevent reimbursement for the tests.

COMMENT: One insurer questioned whether the medical director in a pre-certification plan is required to be on the staff of the insurance company or whether the medical director may be employed by a vendor or an independent contractor used as part of the pre-certification plan.

RESPONSE: N.J.A.C. 11:3-4.8(d) requires that the medical director of a pre-certification plan be a licensed physician in the State of New Jersey. The medical director could be a member of the staff of the insurer or part of an independent organization contracted by the insurer. The duties and responsibilities of the medical director are set forth in this rule, and any arrangement should assure that the medical director is available to perform the required duties.

COMMENT: An insurer has advised the Department that it has been recognized by the American Accreditation Health Care Commission/ Utilization Review and Accreditation Commission Incorporated ("URAC") as meeting certain stringent standards for the governance of utilization management in health care. The insurer notes that those companies recognized and accredited by URAC have attained a level of standards and practices which permits the decisions of its physicians to be considered final without any alternative dispute resolution as set forth in these rules. The commenter also inquired whether the Department will waive the application process for approval of pre-certification plans if the insurer is URAC certified.

RESPONSE: The Act provides in sections 24 and 25 for alternate dispute resolution to resolve PIP disputes. These rights of the parties will be reflected on the policy form approved by the Department, and the Department will not approve policy forms that do not include such provisions. In the absence of these provisions for alternate dispute resolution, all disputes under the policy would have to be resolved in court.

Regarding "waiver of approval of the pre-certification plan," the Department notes that the pre-certification plan is set forth in the insurer's policy forms, which are required to be filed for approval pursuant to N.J.S.A. 17:29A-1 et seq. There is no provision there or in the Act for a "waiver" of these processes.

COMMENT: One insurer inquired whether the rules permit an insurer to enter into an arrangement with a health care provider that would provide for the prepayment of health services pursuant to a pre-approved health care treatment plan providing the arrangement does not abridge the policyholders' choice of health care providers.

RESPONSE: N.J.A.C. 11:3-4.8 provides for pre-certification plans to be filed for approval, consistent with standards in the Act and these rules. The Department would be unwilling to approve any pre-certification plan that unduly restricted an injured party's choice of treating provider, and will propose additional standards for pre-certification plans as they are developed.

COMMENT: One insurer inquired whether these regulations prohibit an insurer from requiring policyholders to remit all copayments and deductibles for medical expenses to the insurer, which would then remit the full payment to the health care provider.

RESPONSE: While these rules do not specifically address this issue, the Department notes that it has not approved such policy form provisions in the past.

COMMENT: The Department received one comment from a health care insurer that asked if these rules will allow health insurers access to the claim information maintained by PIP insurers in order to facilitate adjudication of claims and to determine if duplicate payments of medical treatment exist.

RESPONSE: Nothing in these rules addresses release of information from auto insurers to health insurers. The commenter is directed to the Insurance Information Practices Act, N.J.S.A. 17:23A-1 et seq., which restricts release of information obtained by insurers and others.

COMMENT: One insurer requested that the Department take no action on the adoption of these rules at this time. The commenter stated that the potential costs involved to the insurer in processing medical expense benefit claims pursuant to the rules will far exceed any possible savings. The insurer noted that the Act requires insurers to reduce PIP medical expense benefit premiums by over 25 percent. The commenter stated, however, that there is no assurance that the implementation of these rules will, after the expenses associated with implementation and administration, save an amount equal to the cost of the premium reduction.

RESPONSE: The Department acknowledges the concerns of this insurer. The Act mandates the reduction in premiums, which is not discretionary. In order to reduce costs, the Act directs the Department to promulgate these rules which, together with other provisions, the Legislature found will support the premium reductions.

COMMENT: Many comments also contained a demand by the commenter to examine the Department's adoption file pursuant to the "Right-to-Know" Act, N.J.S.A. 47:1A-1 et seq.

RESPONSE: The Department's rulemaking file is available for public inspection during normal business hours. Interested parties should write for an appointment to facilitate this process.

Summary of Agency-Initiated Changes to Appendix, Exhibits 2 through 9:

Upon review of comments received and after consultation with the Department's benefit consultant and the Professional Boards of the Division of Consumer Affairs, Department of Law and Public Safety, the Department will make changes to the Appendix, Exhibits 2 through 9 upon adoption. The changes upon adoption are not shown by means of boldfacing and bracketing of text in the Exhibits themselves but are described below by bracketing deleted text *[thus]* and boldfacing new text thus. Explanation of the location of the changes is in italics, thus.

The following Note has been added to the Care Path Overview and Care Paths 1 through 6 (Exhibits 2 through 9):

NOTE: These Care Paths identify typical courses of intervention. There may be patients who require more or less treatment. However, cases that deviate from the Care Paths may be subject to more careful scrutiny and may require documentation of the special circumstances. Treatments must be based upon patient need and professional judgment. Deviations may be justified by individual circumstances, such as pre-existing conditions and/or co-morbidities. The Care Paths are only intended for use when the injury was caused by a motor vehicle accident (MVA). If at any point in the decision making process, the health care provider finds evidence that the injury was not caused by a MVA, the provider must contact the patient's PIP carrier and medical insurance carrier.

The text in the box entitled "Clinical and Diagnostic Evaluation" has been changed in the Care Path Overview (Exhibit 2) as follows:

May include:
- X-rays--Cervical Spine5 views or more
- CT if (+) or suspected fracture to cervical spine
- MRI if abnormal neurologic findings below level of injury or if required as follow up to earlier films

The text in the box entitled "Conservative Therapy" has been changed in Care Paths 1, 3 and 5 (Exhibits 3, 5 and 7) as follows:
- Provider office visits (up to 5)
- Medication Specific drug recommendations are no longer listed in the box but a superscript note refers to Addendum to Care Paths, new Exhibit 10
- Increasing exercise
- Consider PT program (2-3 times per week, up to 4 weeks) includes a superscript note referring to Addendum to Care Paths (new Exhibit 10)
- Spinal manipulation (includes superscript note referring to Addendum, new Exhibit 10)

1-3 visits per week, up to 4 weeks
(The total number of visits for physical therapy and spinal manipulation should not exceed 12)

Where there is a positive (+) test result under the Box entitled "Diagnostic Re-evaluation," the boxes concerning a determination that the injury was not related to the motor vehicle accident have been deleted in Care Paths 1, 3 and 5 (Exhibits 3, 5 and 7). A positive test result now leads directly to the box entitled, "Treat Diagnosis."

The text in the box entitled "Continue Conservative Therapy" has been changed in Care Paths 1, 3 and 5 (Exhibits 3, 5 and 7) as follows:
- ConsiderPsychosocial Evaluation with a superscript note referring to the Addendum (new Exhibit 10)

The text in the left hand box under the shaded box in Care Paths 2, 4 and 6 (Exhibits 4, 6 and 8) has been changed as follows:

HERNIATED DISK with or without *[MILD]* RADICULOPATHY

The box entitled "Conservative Therapy" in Care Paths 2, 4 and 6 (Exhibits 4, 6 and 8) has been changed as follows:
- Provider office visits (up to 5)
- Medications Specific drugs are no longer listed in the box but a superscript note refers to the Addenum to Care Paths (new Exhibit 10)

- Bed rest (maximum 1-2 days).
- Increasing exercise
- Consider PT program (2-3 times per week, up to 4 weeks) includes a superscript note referring to Addendum to Care Paths (new Exhibit 10)

The box entitled "Diagnostic Evaluation" has been changed in Care Paths 2, 4 and 6 (Exhibits 4, 6 and 8) as follows:

May include:

- EMG (if the diagnosis of radiculopathy is obvious & specific on clinical examination, EMG testing is not recommended)
- SEP

The right hand box under the shaded box has been changed in Care Paths 2, 4 and 6 (Exhibits 4, 6 and 8) as follows:

HERNIATED DISK with *[MODERATE TO SEVERE]* RADICULOPATHY and SEVERE NEUROLOGICAL COMPRESSION or COMPROMISE

Going down the right side of Care Paths 2, 4 and 6 (Exhibits 4, 6 and 8), the second box has been changed as follows:

Referral to Neurology, Physiatry, Neurosurgery, or Orthopedic Surgery

The third box "Diagnostic Evaluation" has been changed as follows:

- MRI
- CT
- Myelogram
- Discogram

Under the "Diagnostic Evaluation" box in Care Paths 2, 4 and 6 (Exhibits 4, 6 and 8), two new boxes have been added corresponding to the results of the evaluation as follows:

Test Result (-) Go to Conservative Therapy; with a diamond symbol [diams]
and
Test Result (+)

On Care Paths 2, 4 and 6 (Exhibits 4, 6 and 8), a new box has been added above the box entitled "[diams] Continue Conservative Therapy," with the following text:

Test Result (-) After Evaluation for Surgery

that leads to the box with a diamond symbol, [diams] entitled, "Continue Conservative Therapy," which has been changed as follows:

Specialist Referral

- ConsiderPsychosocial Evaluation with a superscript note referring to the Addendum (Exhibit 10)
- Consider PT
- Consider limited course of spinal manipulation and if no improvement within 1 month, discontinue

The other box entitled "Continue Conservative Therapy" (without the diamond symbol) has been changed as follows:

- Re-evaluation pain medications now includes a superscript note referring to the Addendum (Exhibit 10)

Federal Standards Statement

A Federal standards analysis is not required because these adopted new rules set forth requirements with respect to automobile insurance and are not subject to any Federal requirements or standards.

Full text of the adoption follows (additions to proposal indicated in boldface with underlining and asterisks ***thus***: deletions from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 4. PERSONAL INJURY PROTECTION BENEFITS; MEDICAL PROTOCOLS; DIAGNOSTIC TESTS

11:3-4.1 Scope and purpose

(a) This subchapter implements the provisions of N.J.S.A. 39:6A-3.1, 39:6A-4 and 39:6A-4.3 by identifying the personal injury protection medical expense benefits for which reimbursement of eligible charges will be made by automobile insurers under basic and standard policies and by motor bus insurers under medical expense benefits coverage.

(b) This subchapter applies to all insurers that issue policies of automobile insurance containing PIP coverage and policies of motor bus insurance containing medical expense benefits coverage.

(c) This subchapter shall apply to those policies that are issued or renewed *[90 days after the effective date of these rules]* ***on or after March 22, 1999*.**

11:3-4.2 Definitions

The following words, phrases and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Basic automobile insurance policy" or "basic policy" means those private passenger automobile insurance policies issued in accordance with N.J.S.A. 39:6A-3.1 and N.J.A.C. 11:3-3.

"Clinically supported" means that a health care provider prior to selecting, performing or ordering the administration of a treatment or diagnostic test has:

1. Personally examined the patient to ensure that the proper medical indications exist to justify ordering the treatment or test;

2. Physically examined the patient including making an assessment of any current and/or historical subjective complaints, observations, objective findings, neurologic indications, and physical tests;

3. Considered any and all previously performed tests that relate to the injury and the results ***and which are relevant to the proposed treatment or test***; and

4. Recorded*[,]* ***and*** documented *[and signed]* these observations, positive and negative findings and conclusions on the patient's medical records.

"Decision point" means those junctures in the treatment of identified injuries where a decision must be made about the continuation or choice of further treatment. Decision point also refers to a determination to administer one of the tests listed in N.J.A.C. 11:3-4.5(b).

"Eligible charge" means the treating health care provider's usual, customary and reasonable charge or the upper limit of the medical fee schedule as found in N.J.A.C. 11:3-29.6, whichever is lower.

"Emergency care" means all medically necessary treatment of a traumatic injury or a medical condition manifesting itself by acute symptoms of sufficient severity such that absence of immediate attention could reasonably be expected to result in: death; serious impairment to bodily functions; or serious dysfunction of a bodily organ or part. Such emergency care shall include all medically necessary care immediately following an automobile accident, including, but not limited to, immediate pre-hospitalization care, transportation to a hospital or trauma center, emergency room care, surgery, critical and acute care. Emergency care extends during the period of initial hospitalization until the patient is discharged from acute care by the attending physician. *Emergency care shall be presumed when medical care is initiated at a hospital within 120 hours of the accident.*

"Health care provider" or "provider" means those persons licensed or certified to perform health care treatment or services compensable as medical expenses and shall include, but not be limited to:

1. A hospital or health care facility that is maintained by State or any political subdivision;

2. A hospital or health care facility licensed by the Department of Health and Senior Services;

3. Other hospitals or health care facilities designated by the Department of Health and Senior Services to provide health care services, or other facilities, including facilities for radiological and diagnostic testing, free-standing emergency clinics or offices, and private treatment centers;

4. A nonprofit voluntary visiting nurse organization providing health care services other than a hospital;

5. Hospitals or other health care facilities or treatment centers located in other States or nations;

6. Physicians licensed to practice medicine and surgery;

7. Licensed chiropractors;

8. Licensed dentists;

9. Licensed optometrists;

10. Licensed pharmacists;

11. Licensed chiropodists (podiatrists);

12. Registered bioanalytical laboratories;

13. Licensed psychologists;

14. Licensed physical therapists;

15. Certified nurse mid-wives;

16. Certified nurse practitioners/clinical nurse-specialist;

17. Licensed health maintenance organizations;

18. Licensed orthotists and prosthetists;

19. Licensed professional nurses; *[and]*

20. Licensed occupational therapists;

21. Licensed speech-language pathologists;

22. Licensed audiologists;

23. Licensed physicians assistants;

24. Licensed physical therapy assistants;

25. Licensed occupational therapy assistants; and

[20.] ***26.*** Providers of other health care services or supplies, including durable medical goods.

"Identified injury" means those injuries identified by the Department in the subchapter Appendix as being suitable for medical treatment protocols in accordance with N.J.S.A. 39:6A-3.1a and 39:6A-4a.

["Non-medical expense" means charges for those:]

[1. Products and devices, not exclusively used for medical purposes or as durable medical equipment, such as any vehicles, durable goods, equipment, appurtenances, improvements to real or personal property, fixtures; and]

[2. Services and activities such as recreational activities, trips and leisure activities.]

"Medical expense" means the reasonable and necessary expenses for treatment or services rendered by a provider, including medical, surgical, rehabilitative and diagnostic services and hospital expenses and reasonable and necessary expenses for ambulance services or other transportation, medication and other services, subject to limitations as provided for in the policy forms that are filed and approved by the Commissioner.

"Medically necessary" ***or "medical necessity"*** means that the medical treatment or diagnostic test is consistent with the clinically supported symptoms, diagnosis or indications of the injured person, and:

1. The treatment is the most appropriate level of service that is in accordance with the standards of good practice and standard professional treatment protocols including the Care Paths in the Appendix, as applicable;

2. The treatment of the injury is not primarily for the convenience of the injured person or provider; and

3. Does not *[involve]* ***include*** unnecessary testing or treatment.

"Non-medical expense" means charges for those:

1. Products and devices, not exclusively used for medical purposes or as durable medical equipment, such as any vehicles, durable goods, equipment, appurtenances, improvements to real or personal property, fixtures; and

2. Services and activities such as recreational activities, trips and leisure activities.

"Pre-certification" means a program, described in policy forms in compliance with these rules, by which the medical necessity of certain diagnostic tests, medical treatments and procedures are subject to prior authorization, utilization review and/or case management.

"Standard automobile insurance policy" or "standard policy" means a private passenger automobile insurance policy issued in accordance with N.J.S.A. 39:6A-4.

11:3-4.3 Personal injury protection benefits applicable to basic and standard policies

(a) Personal injury protection coverage shall provide reimbursement for all medically necessary expenses for the diagnosis and treatment of injuries sustained from a covered automobile accident up to the limits set forth in the policy and in accordance with this subchapter.

(b) Personal injury protection coverage shall only provide reimbursement for ***clinically supported*** necessary non-medical expenses that are prescribed by a treating medical provider for a permanent or significant brain, spinal cord or disfiguring injuries.

11:3-4.4 Deductibles and co-pays

(a) Each insurer shall offer a standard $ 250.00 deductible and 20 percent copayment on medical expense benefits payable between $ 250.00 and $ 5,000.

(b) Each insurer shall also offer, at appropriately reduced premiums, the option to select medical expense benefit deductibles of $ 500.00, $ 1,000, $ 2,000 and $ 2,500 in accordance with the following provisions:

1. Any medical expense deductible elected by the named insured shall apply only to the named insured and any resident relative in the named insured's household, who is not a named insured under another automobile policy and not to any other person eligible for personal injury protection benefits required to be provided in accordance with N.J.S.A. 39:6A-3.1 and 39:6A-4;

2. Premium credits calculated and represented as a percentage of the applicable premium shall be provided for each deductible. The premium percentage shall be uniform by filer on a statewide basis; and

3. The deductible option elected by the named insured shall continue in force as to subsequent renewal or replacement policies until the insurer or its authorized representative receives a properly executed coverage selection form to eliminate or change the deductible.

(c) All deductibles and co-pays in (a) and (b) above shall apply on a per accident basis.

(d) Notwithstanding (a) and (b) above, an insurer may offer alternative deductible and co-pay options as part of an approved pre-certification program pursuant to N.J.A.C. 11:3-4.8.

(e) For private passenger automobiles insured under a commercial automobile insurance policy where no natural person is a named insured, insurers shall only provide personal injury protection with medical expense benefits coverage in an amount not to exceed $ 250,000 per person, per accident, with the deductible and copayment amount set forth in (a) above.

11:3-4.5 Diagnostic tests

(a) The personal injury protection medical expense benefits coverage shall not provide reimbursement for the following diagnostic tests, which *[are]* ***have been*** determined to yield no data of any significant value in the development, evaluation and implementation of an appropriate plan of treatment for injuries sustained in motor vehicle accidents:

1. *[Thermographs/thermograms;]* ***(Reserved)***

2. Spinal diagnostic ultrasound;

3. Iridology;

4. Reflexology;

5. Surrogate arm mentoring;

6. Brain mapping;

7. Surface electromyography (surface EMG);

8. *[Tomography studies for temporomandibular joint disorder (TMJ/D)]* ***(Reserved)***; and

9. Mandibular tracking and stimulation.

(b) The personal injury protection medical expense benefits coverage shall provide for reimbursement of the following diagnostic tests, which have been determined to have value in the evaluation of injuries, the diagnosis and development of a treatment plan for persons injured in a covered accident, when medically necessary and consistent with clinically supported findings:

1. Needle electromyography (needle EMG) when used in the evaluation and diagnosis of neuropathies and radicular syndrome where clinically supported findings reveal a loss of sensation, numbness or tingling. A needle EMG is not indicated in the evaluation of TMJ/D and is contraindicated in the presence of staph infection on the skin or cellulitis. This test should not normally be performed within 14 days of the traumatic event and should not be repeated where initial results are negative. Only one follow up exam is appropriate.

2. Somasensory evoked potential (SSEP), visual evoked potential (VEP), brain audio evoked potential (BAEP), or brain evoked potential (BEP), nerve conduction velocity (NCV) and H-reflex Study are reimbursable when used to evaluate neuropathies and/or signs of atrophy, but not within 21 days following the *[insured event. Less than a three month testing interval is not normally reimbursable]* ***traumatic injury***.

3. Electroencephalogram (EEG) when used to evaluate head injuries, where there are clinically supported findings of an altered level of sensorium and/or a suspicion of seizure disorder. This test, if indicated by clinically supported findings, can be administered immediately following the insured event. When medically necessary, repeat testing is not normally conducted more than four times per year.

4. Videofluroscopy only when used in the evaluation of hypomobility syndrome and wrist/carpal hypomobility, where there are clinically supported findings of no range or aberrant range of motion or dysmmetry of facets exist. This test should not be performed within three months following the insured event and follow up tests are not normally appropriate.

5. Magnetic resonance imaging (MRI) when used in accordance with the guidelines contained in the American College of Radiology, Appropriateness Criteria to evaluate injuries in numerous parts of the body, particularly the assessment of nerve root compression and/or motor loss. MRI is not normally performed within five days of the insured event. However, clinically supported indication of neurological gross motor deficits, incontinence or acute nerve root compression with neurologic symptoms may justify MRI testing during the acute phase immediately post injury.

6. Computer assisted tomographic studies (CT, CAT Scan) when used to evaluate injuries in numerous aspects of the body. With the exception of suspected brain injuries, CAT Scan is not normally administered immediately post injury, but may become appropriate within five days of the insured event. CAT Scan is not appropriate for TMJ/D. Repeat CAT Scans should not be undertaken unless there is clinically supported indication of an adverse change in the patient's condition.

7. Dynatron/cyber station/cybex when used to evaluate muscle deterioration or atrophy. These tests should not be performed within 21 days of the insured event and should not be repeated if results are negative. Repeat tests are not *[recommended]* ***appropriate*** at less than six months intervals.

8. Sonograms/ultrasound when used in the acute phase to evaluate the abdomen and pelvis for intra-abdominal bleeding. These tests are not normally used to assess joints (knee and elbow) because other tests are more appropriate. Where MRI is performed, sonogram/ultrasound are not necessary. These tests should not be used to evaluate TMJ/D. However, echocardiogram is appropriate in the evaluation of possible cardiac injuries when clinically supported.

(c) The terms "normal," "normally," "appropriate" and "indicated" as used above in (b), are intended to recognize that no single rule can replace the good faith educated judgment of a trained medical professional. Thus, "normal," "normally," "appropriate" and "indicated" pertain to the usual, routine, customary or common experience and conclusion, which may in unusual circumstances differ from the actual judgment or course of treatment. The unusual circumstances shall be based on clinically supported findings of a trained medical professional. The use of these terms is intended to indicate some flexibility and avoid rigidity in the application of these rules in the decision point review required in (d) below.

(d) Except as provided in (e) below, a determination to administer any of the tests in (b) above shall be subject to decision point review pursuant to N.J.A.C. 11:3-4.7.

(e) The requirements of (b) and (d) above shall not apply to diagnostic tests administered during emergency care.

11:3-4.6 Medical protocols

(a) Pursuant to N.J.S.A. 39:6A-3.1 and 39:6A-4, the Commissioner designates the care paths, set forth in the subchapter Appendix incorporated herein by reference, as the standard course of *[appropriate]* ***medically necessary*** treatment, including diagnostic tests, for the identified injuries.

(b) Where the care path indicates a decision point either by a hexagon in the care path itself or by reference in the text to a second opinion, referral for a second independent consultative medical opinion, development of a treatment plan or mandatory case management, the policy shall provide for a decision point review in accordance with N.J.A.C. 11:3-4.7.

(c) Treatments that vary from the care paths shall be reimbursable only when warranted by reason of medical necessity.

(d) The care paths do not apply to treatment administered during emergency care.

11:3-4.7 Decision point review

(a) Insurers shall file for approval policy forms that provide a plan for the timely review of treatment of identified injuries at decision points and for the approval of the administration of the diagnostic tests in N.J.A.C. 11:3-4.5(b).

(b) The decision point review plan shall meet the following requirements:

1. The plan shall include procedures for the injured person or his or her designee to provide prior notice to the insurer or its designee together with the appropriate clinically supported findings that additional treatment or the administration of a test in accordance with N.J.A.C. 11:3-4.5(b) is medically necessary, as follows:

i. The prompt review of the notice and supporting materials submitted by the provider and authorization or denial of reimbursement for further treatment or tests;

ii. The scheduling of a physical examination of the injured person in accordance with (b)2 below where the notice and supporting materials and other medical records if requested, are not sufficient to authorize or deny reimbursement of further treatment or tests; and

iii. Any denial of reimbursement for further treatment or tests shall be based on the determination of a physician.

2. A physical examination of the injured party as part of a decision point review shall be conducted as follows:

i. The insurer shall notify the injured person or his or her designee that a physical examination is required *[before reimbursement of further treatment or tests is authorized]*;

ii. The physical examination shall be scheduled within seven calendar days of receipt of the notice in (b)1 above unless the injured person agrees to extend the time period;

iii. The medical examination shall be conducted by a provider in the same discipline as the treating provider;

iv. The medical examination shall be conducted at a location reasonably convenient to the injured person;

v. The ***treating provider or*** injured person, upon the request of the insurer, shall provide medical records and other pertinent information to the provider conducting the medical examination. The requested records shall be provided *[at]* ***no later than*** the time of the examination *[or before]*; and

vi. The insurer shall notify the injured person or his or her designee whether reimbursement for further treatment or tests is authorized as promptly as possible but in no case later than three days after the examination. If the examining provider prepares a written report concerning the examination, the injured person or his or her designee shall be entitled to a copy upon request.

3. The plan may provide that failure to notify the insurer as required in the plan; failure to provide medical records; or failure to appear for the physical examination scheduled in accordance with b(2) above shall result in an additional co-payment not to exceed 50 percent of the eligible charge for medically necessary diagnostic tests, treatments, surgery, durable medical goods and non-medical expenses that are incurred after notification to the insurer is required but before authorization for continued treatment or the administration of a test is made by the insurer. No insurer may impose the additional co-payment where the insurer received the required notice but failed to act in accordance with its approved decision point plan to authorize or deny reimbursement of further treatment or tests.

4. The plan shall avoid undue interruptions in a course of treatment.

5. Insurers are encouraged to provide decision point review plans that permit the treating provider to submit for review a comprehensive treatment plan so as to minimize the need for piecemeal review.

(c) Notwithstanding the requirements of (b) above, a pre-certification plan filed and approved pursuant to N.J.A.C. 11:3-4.8 shall satisfy the requirement to have a decision point review plan.

(d) All decision point review plans, including a pre-certification program filed and approved pursuant to N.J.A.C. 11:3-4.8 shall contain provisions for the disclosure of the procedures in the decision point review plan to injured persons and providers.

1. The information required to be disclosed pursuant to this subsection shall include a description of:

i. The financial responsibility of the injured person including co-payments and deductibles;

ii. The financial responsibility of the provider for providing treatment or administering tests without authorization from the insurer; and

iii. How authorization for treatment and the administration of tests may be obtained.

2. In addition to the description of the plan set forth in the policy form, the insurer shall provide any information necessary to comply with decision point review in accordance with this rule to the injured person, the provider, or both, promptly upon receiving notice of the claim.

(e) No decision point requirements shall apply within 10 days of the insured event. *This provision should not be construed so as to require reimbursement of tests and treatment that are not medically necessary.*

11:3-4.8 Pre-certification plans

(a) Insurers may file for approval policy forms that provide for a pre-certification of certain medical procedures, treatments, diagnostic tests, or other services, non-medical expenses and durable medical equipment by the insurer or its designated representative.

(b) No pre-certification requirements shall apply within 10 days of the insured event.

(c) Pre-certification shall be based exclusively on medical necessity and shall not encourage over or under utilization of the treatment or test.

(d) An insurer that wishes to use a pre-certification plan shall designate a licensed physician to serve as medical director for services provided to covered persons in New Jersey. The medical director shall ensure that:

1. Any utilization decision to deny reimbursement for further testing or treatment because the treatment or diagnostic tests are not medically necessary, shall be made by a physician. In the case of treatment prescribed or provided by a dentist, the decision shall be by a dentist;

2. A utilization management decision shall not retrospectively deny payment for treatment provided when prior approval has been obtained, unless the approval was based upon fraudulent information submitted by the person receiving treatment or the provider; and

3. The utilization management program shall be available, at a minimum, during normal working hours to respond to authorization requests.

(e) The insurer shall include with its filing, the information about its pre-certification plan that will be given to consumers with new and renewal policies after the pre-certification plan is approved and upon notice of a claim. The consumer information shall include at a minimum the items in N.J.A.C. 11:3-4.7(d).

(f) A pre-certification plan may include provisions that require injured persons to obtain durable medical equipment directly from the insurer or its designee.

(g) Policy forms may include an additional co-payment not to exceed 50 percent of the eligible charge for medically necessary diagnostic tests, treatments, surgery, durable medical equipment and non-medical expenses that are incurred without first complying with an approved pre-certification plan.

(h) Pre-certification plans shall avoid undue interruptions in a course of treatment.

(i) Insurers are encouraged to provide pre-certification plans that permit a treating provider to submit a comprehensive treatment plan for pre-certification so as to minimize the need for piecemeal review.

11:3-4.9 Assignment of benefits

Insurers may file for approval policy forms including reasonable procedures for, or restrictions on, the assignment of personal injury protection benefits, consistent with the efficient administration of the coverage.

APPENDIX

TREATMENT OF ACCIDENTAL INJURY
TO THE SPINE AND BACK
CARE PATHS
Exhibit 1
Glossary of Terms

Acute Disease--a disease with rapid onset and short course to recovery. Not chronic.
Care Path--a recommended extensive course of care based on professionally recognized standards.
Case Management--a method of coordinating the provision of healthcare to persons injured in automobile accidents, with the goal of ensuring continuity and quality of care and cost effective outcomes. The Case Manager may be a nurse, social worker, or physician, preferably with certification in case management.
Cauda Equina--a collection of spinal roots that descend from the lower part of the spinal cord. They exist in the lower part of the vertebral canal.
Chronis Disease--a disease with long duration that changes little and progresses slowly. The apposite of acute.
Clinical Evaluation--the evaluation of the symptoms and signs of an injured person by a treating practitioner.
Conservative Therapy--treatment which is not considered aggressive; avoiding the administration of medicine or utilization of invasive procedures until such procedures are clearly indicated.

TREATMENT OF ACCIDENTAL INJURY
TO THE SPINE AND BACK
CARE PATHS
Exhibit 1
Glossary of Terms

Contusion--an injury to underlying soft tissues where the skin is not broken. A bruise.
Diagnostic Evaluation--the process of differentiating between two or more diseases with similar signs and symptoms through the use of evaluative procedures such as imaging, laboratory, and physical tests.
Herniation--the protrusion or projection of an organ or other body structure through a defect or natural opening in a covering membrane, muscle, or bone.
Independent Consultative Opinion--physical examination by a physician of similar specialty to the injured person's treating practitioner to provide a second medical opinion. The independent physician may support, refute, or provide alternatives to the current diagnosis and treatment plans.
Non-Compliant--a patient who wilfully chooses not to participate in the treatment plan agreed upon by the patient and his/her healthcare provider and does not have secondary issues such as lack of transportation, pre-existing conditions or comorbidities.
PT--Physical Therapy--the therapeutic use of heat, light, water, electricity, massage, exercise, and non-ionizing radiation in treatment of injuries to the soft tissue and muscles/skeleton. PT rendered to persons injured in automobile accidents must be provided by a person whose scope of licensure includes physical therapy.
Radicular--pertaining to a root (such as a nerve root) disorder.
Radiculopathy--a disorder of a nerve root.
Sign--an objective manifestation, usually indicative of a disease or disorder. Signs can be observed by the clinician, as opposed to symptoms, which are perceived only by the affected individual.
Soft Tissue Injury--injuries sustained to the muscle, skin, connective tissue.
Spine--the vertebral column.
Spinal Shock--an acute condition resulting from spinal cord severance. Characterized by a total sensory loss and loss of reflexes below the level of injury and flaccid paralysis.
Sprain--an injury at a joint where a ligament is stretched or torn.
Strain--an injury caused by the over-stretching or tearing of a muscle or tendon. In its most severe form, the muscle ruptures.
Symptom--a subjective manifestation, usually indicative of a disease or disorder. Symptoms are experienced only by the affected individual, as opposed to signs, which can be observed by others.
Treatment Plan--specific medical, surgical, chiropractic, acupuncture, or psychiatric procedures used to improve the signs or symptoms associated with injuries sustained in automobile accidents, e.g., physical therapy, surgery, administration of medications, etc.

OFFICE OF ADMINISTRATIVE LAW NOTE: The Department of Banking and Insurance has made changes upon adoption to proposed Appendix Exhibits 2 through 8, as described in the Summary of Agency-Initiated Changes above. For clarity of presentation, Exhibits 2 through 8 below incorporate the changes upon adoption without addition or deletion symbolism.

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EXHIBIT 9
TREATMENT OF ACCIDENTAL INJURY
TO THE SPINE AND BACK
CARE PATH
DIAGNOSIS CODING

The following International Classification of Diseases, 9th Revision Clinical Modification--fifth edition ICD-9-CM diagnostic codes are associated with Care Path 1 through Care Path 6 for treatment of Accidental Injury to the Spine and Back and are included on each appropriate Care Path. The ICD9 codes referenced do not include codes for multiple diagnoses or co-morbidity.

Care Path	728.0	Disorders of muscle, ligament and fascia
1	728.85	Spasm of muscle
	739.0	Non allopathic lesions--not elsewhere classified
	739.1	Somatic dysfunction of cervical region
	847.0	Sprains and strains of neck
	847.9	Sprains and strains of back, unspecified site

EXHIBIT 9
TREATMENT OF ACCIDENTAL INJURY
TO THE SPINE AND BACK
CARE PATH
DIAGNOSIS CODING

	922.3	Contusion of back
	922.31	Contusion of back, excludes interscapular region
	953.0	Injury to cervical root
Care Path	722.0	Displacement of cervical intervertebral disc without myelopathy
2	722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
	722.70	Intervertebral disc disorder with myelopathy, unspecified region
	722.71	Intervertebral disc disorder with myelopathy, cervical region
	728.0	Disorders of muscle, ligament and fascia
	739.0	Non allopathic lesions--not elsewhere classified
	953.0	Injury to cervical root
Care Path	728.0	Disorders of muscle, ligament and fascia
3	728.85	Spasm of muscle
	739.0	Non allopathic lesions--not elsewhere classified
	739.2	Somatic dysfunction of thoracic region
	739.8	Somatic dysfunction of rib cage
	847.1	Sprains and strains, thoracic
	847.9	Sprains and strains of back, unspecified site
	922.3	Contusion of back
	922.33	Contusion of back, interscapular region
Care Path	722.0	Displacement of cervical intervertebral disc without myelopathy
4	722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
	722.11	Displacement of thoracic intervertebral disc without myelopathy
	722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
	722.70	Intervertebral disc disorder with myelopathy, unspecified region
	722.72	Intervertebral disc disorder with myelopathy, thoracic region
	728.0	Disorders of muscle, ligament and fascia
	739.0	Non allopathic lesions--not elsewhere classified
Care Path	728.0	Disorders of muscle, ligament and fascia
5	728.85	Spasm of muscle
	739.0	Non allopathic lesions--not elsewhere classified
	739.3	Somatic dysfunction of lumbar region
	739.4	Somatic dysfunction of sacral region
	846	Sprains and strains of sacroiliac region
	846.0	Sprains and strains of lumbosacral (joint) (ligament)
	846.1	Sprains and strains of sacroiliac ligament
	846.2	Sprains and strains of sacrospinatus (ligament)
	846.3	Sprains and strains of sacrotuberous (ligament)
	846.8	Sprains and strains of other specified sites of sacroiliac region
	846.9	Sprains and strains, unspecified site of sacroiliac

EXHIBIT 9
TREATMENT OF ACCIDENTAL INJURY
TO THE SPINE AND BACK
CARE PATH
DIAGNOSIS CODING

		region
	847.2	Sprains and strains, lumbar
	847.3	Sprains and strains, sacrum
	847.4	Sprains and strains, coccyx
	847.9	Sprains and strains, unspecified site of back
	922.3	Contusion of back
	922.31	Contusion of back, excludes interscapular region
	953.2	Injury to lumbar root
	953.3	Injury to sacral root
Care Path	722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
6	722.10	Displacement of lumbar intervertebral disc without myelopathy
	722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
	722.70	Intervertebral disc disorder with myelopathy, unspecified region
	722.73	Intervertebral disc disorder with myelopathy, lumbar region
	728.0	Disorders of muscle, ligament and fascia
	739.0	Non allopathic lesions--not elsewhere classified
	953.3	Injury to sacral root

The following ICD-9-CM supplemental classification of external causes of injury may be used in addition to the specific diagnostic codes noted above and on each Care Path:

. E 810 through E 819, selected E 820 series codes.

These codes may be used to indicate cause of injury as motor vehicle accident but should not be used without an associated diagnostic code.

EXHIBIT 10
ADDENDUM TO CARE PATHS

1. Medications

Muscle Relaxants

. Muscle relaxants are an option in the treatment of patients with acute neck, thoracic, and low back problems. While probably more effective than placebo, muscle relaxants have not been shown to be more effective than NSAIDs.
. No additional benefit is gained by using muscle relaxants in combination with NSAIDs over using NSAIDs alone.
. Muscle relaxants have potential side effects in 30 percent of patients. When considering the option of using relaxants, the clinician should balance the potential patient's intolerance of other agents.

Opioid Analgesics

. When used for a time-limited course, opioid analgesics are an option in the management of patients with acute neck, thoracic,

EXHIBIT 10
ADDENDUM TO CARE PATHS

and low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options.

. Opioids appear to be more effective in relieving neck, thoracic, and low back symptoms than safer analgesics, such as acetaminophen or aspirin or other NSAIDs.
. Clinicians should be aware of the side effects of opioids, such as decreased reaction time, clouded judgment, and drowsiness, which lead to early discontinuation by as many as 35 percent of patients.
. Patients should be warned about dependence and the danger of opioids while operating heavy machinery.

Oral Steroids

. Oral steroids are not recommended for the treatment of acute neck, thoracic, or low back problems.
. A potential for severe side effects is associated with the extended use of oral steroids or steroids in high doses.

2. Who May Perform Spinal Manipulation:

Spinal manipulation may be performed by those providers licensed or certified to perform this procedure within their scope of practice.

3. Spinal Manipulation

Manipulation is most helpful for patients with acute neck, thoracic, and low back problems without radiculopathy when used within the first month of symptoms.

A trial of manipulation in patients without radiculopathy with symptoms longer than a month is probably safe, but efficacy is unproven.

If manipulation has not resulted in symptomatic improvement that allows increased function after 1 month of treatment, the patient should be reevaluated.

When findings suggest progressive or severe neurologic deficits, an appropriate diagnostic assessment to rule out serious neurologic conditions is indicated before beginning manipulation therapy. There is insufficient evidence to recommend manipulation for patients with radiculopathy.

4. Mental Health/Rehabilitation Assessment Option If Patient Has Not Responded To Treatment

A mental health/rehabilitation assessment can be obtained if psychological/psychosocial or psychiatric distress is obvious from the history, i.e., presence of "non-organic" physical signs, repetitive back injuries, failed previous treatments, litigation or disability compensation claims, family or financial problems, apparent secondary gain, boredom and dissatisfaction with job, frequent bouts of pain, depression, alcohol and substance abuse, extreme obesity, and apparent psychiatric behavior.