INSURANCE
DEPARTMENT OF BANKING AND INSURANCE
DIVISION OF INSURANCE

Selective Contracting Arrangements of Insurers, Minimum Standards for Network-Based Health Benefit Plans

Proposed Amendments: N.J.A.C. 11:4-37.2, 37.3, 37.4, and 37.6 and 11:22-5

Proposed Repeals: N.J.A.C. 11:4-37.5 and 37.7

Proposed New Rules: N.J.A.C. 11:22-5.8

Authorized By: Donald Bryan, Acting Commissioner, Department of Banking and Insurance

Authority: N.J.S.A. 17:1-8.1, 15e, 17B:27A-54, 26:2J-42 and 26:2J-43.

Calendar Reference: See Summary below for explanation of exception to calendar requirement

Proposal Number: PRN 2005-432

Submit comments by February 3, 2006 to:

Douglas Wheeler, Assistant Commissioner
Department of Banking and Insurance
Legislative and Regulatory Affairs
20 West State Street
PO Box 325
Trenton, NJ 08625-0325
Fax: 609-292-0896
Email: Legsregs@dobi.state.nj.us

The agency proposal follows:

Summary

N.J.A.C. 11:4-37 contains the Department of Banking and Insurance (Department) rules governing New Jersey health carriers' selective contracting arrangements (SCAs). The rules have been in effect since 1994, and apply to all carriers operating pursuant to Title 17B of the New Jersey statutes. The rules do not apply to hospital service corporations operating pursuant to N.J.S.A. 17:48-1 et seq., medical service corporations operating pursuant to N.J.S.A. 17:48A-

1 et seq., dental service corporations operating pursuant to N.J.S.A. 17:48C-1 et seq., dental plan organizations (DPOs) operating pursuant to N.J.S.A. 17:48D-1 et seq., health service corporations operating pursuant to N.J.S.A. 17:48E-1 et seq., and prepaid prescription service organizations operating pursuant to N.J.S.A. 17:48F-1 et seq.

In 2002, the Department adopted Organized Delivery Systems rules at N.J.A.C. 11:22-4 implementing N.J.S.A. 17:48H-1 et seq. The rules establish licensure requirements for organized delivery systems (ODSs) that assume financial risk from carriers. In 2004, the Department of Health and Senior Services adopted Organized Delivery System rules at N.J.A.C. 8:38B-1. These rules apply to both certified and licensed organized delivery systems and address network adequacy, utilization management and quality of care issues. An ODS operates by contracting with a carrier (including insurers authorized to transact the business of health insurance as defined at N.J.S.A. 17B:17-4, hospital service corporations, medical service corporations, health service corporations and health maintenance organizations (HMOs)), directly or indirectly, to provide comprehensive services or benefits under the carrier's benefits plan, or to provide limited health care services that the carrier elects to subcontract as a separate category of benefits or services apart from its benefits under its comprehensive benefits plan. An ODS that accepts financial risk from a carrier must be licensed by the Department, while an ODS that does not accept financial risk from a carrier must be certified by the Department of Health and Senior Services. All ODSs have their network adequacy, utilization management and other functions related to quality of care reviewed and approved by the Department of Health and Senior Services, while ODSs that accept risk also have their financial strength reviewed by the Department. "Limited health care services" as defined in the ODS rules do not include, inter alia, pharmaceutical services. Therefore, a carrier can contract for pharmacy services from an

entity that is neither licensed nor certified in any capacity by the state (that is, a preferred provider organization).

In 2003, the Department adopted rules governing network-based health benefit plans at N.J.A.C. 11:22-5. The rules permit carriers (including insurance companies, health service corporations, hospital service corporations, medical service corporations, and HMOs) issuing network-based health benefit plans that provide hospital and medical coverage to use coinsurance and deductibles, rather than co-payments, as cost-sharing methods for network benefits. The rules establish minimum standards for health benefit plans that provide coverage only when network providers are used, and for health benefit plans that provide different levels of coverage depending on whether a network provider or an out-of-network provider is used. The rules' current definition of "health benefit plan" does not include, inter alia, coverage for prescription drugs when provided as part of a hospital/medical plan, or limited scope dental and drug benefits that are provided by a carrier under a separate policy, certificate or contract of insurance, or are otherwise not an integral part of the plan, because the Department did not intend to set minimum benefit standards for such plans at the time it adopted these rules.

This proposal makes certain amendments to the SCA rules at N.J.A.C. 11:4-37 and the Network-Based Health Benefit Plan rules at N.J.A.C. 11:22-5.

The definitions at N.J.A.C. 11:4-37.2 are being amended to include definitions related to ODSs that are also contained in the ODS rules at N.J.A.C. 11:22-4 and 8:38B-1. The definition of "coinsurance differential" is being deleted as unnecessary because the benefit design minimum standards set forth at N.J.A.C. 11:22-5 apply to SCAs. The definition of "evidence of coverage" is being amended to clarify its meaning as a certificate that may be issued only to the employer, policyholder or other person or association in whose name such policy is issued, and

not issued directly to the covered person, pursuant to N.J.S.A. 17B:27-38. The definition of "formulary" is being deleted because the rules at N.J.A.C. 11:22-5 relating to drug formularies apply to SCAs and that term is defined in those rules. The definition of "health benefits plan" is being revised to include dental, vision, prescription drug and other limited scope or ancillary coverages, and additional definitions relating to prescription drugs are being included. The definition of "preferred provider" is being amended to replace that term with "network provider" for consistency with N.J.A.C. 11:22-5.

Many of the provisions at N.J.A.C. 11:4-37.3(a) and (b) addressing provider network adequacy, cost sharing for emergency care, primary care physician changes, distribution of provider directories, and calculation of out-of-network provider benefits are being amended. Many of the requirements contained in N.J.A.C. 11:4-37.3 are also being deleted because they are unnecessary where a carrier is contracting with an ODS or an HMO since these entities are already licensed or certified. Where a carrier establishes a SCA, other than by contracting with an ODS or HMO, to provide comprehensive or limited health care services (that is, by directly contracting with providers or by contracting with a PPO for prescription drug services), the SCA rules would continue to apply. This proposal is also deleting the 30 percent coinsurance differential provision in the SCA rules at N.J.A.C. 11:4-37.3(b), in light of the benefit design minimum standards set forth at N.J.A.C. 11:22-5. A provision is being added at N.J.A.C. 11:4-37.3(b)7 prohibiting carriers from calculating out-of-network provider benefits by using negotiated fees agreed to by network providers to clarify the Department's long-standing position on this issue. N.J.A.C. 11:4-37.3(c) relating to health benefits plans that utilize SCAs and provide prescription drug benefits through use of a formulary is being deleted because the requirements at N.J.A.C. 11:22-5 apply to those plans.

N.J.A.C. 11:4-37.4 relating to SCA approval and amendment procedures is being updated to include references to ODSs, HMOs and PPOs as entities with which carriers may enter into a selective contracting arrangement, and to delete many provisions that are no longer necessary.

This proposal is repealing as unnecessary N.J.A.C. 11:4-37.5, which establishes the data and information submitted to the Department pursuant to this subchapter that is not considered confidential.

N.J.A.C. 11:4-37.7 relating to monitoring and auditing of carriers' SCAs is being deleted as unnecessary.

N.J.A.C. 11:22-5.1 is being amended to include prescription drug plans and dental plans within the subchapter’s scope.

N.J.A.C. 11:22-5.2 is being amended to include definitions relating to prescription drugs and formularies, and to include dental service corporations, dental plan organizations, and prepaid prescription service organizations within the definition of "carrier."

N.J.A.C. 11:22-5.3 relating to network deductibles, and N.J.A.C. 11:22-5.4 relating to network coinsurance, are being amended to raise the maximum out-of-pocket limit for hospital medical plans with network deductible and/or network coinsurance from $5,000 to $7,500.

A provision at N.J.A.C. 11:22-5.6(c) is being added that prohibits carriers from calculating out-of-network provider benefits by using negotiated fees agreed to by network providers. This provision, as well as the identical provision being proposed at N.J.A.C. 11:4-37.3(b)7, clarifies the Department's long-standing position on this issue.

N.J.A.C. 11:22-5.7 is a new rule that establishes criteria for health benefit plans and stand-alone prescription drug plans providing prescription drug benefits.

N.J.A.C. 11:22-5.8 is a new rule that establishes standards for health benefit plans and stand-alone dental plans providing dental benefits.

N.J.A.C. 11:22-5.9 is being amended to require all previously approved forms not meeting the requirements of this subchapter to be withdrawn as of July 1, 2006 and no longer available for new issue or renewal after that date.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

These proposed amendments, repeals and new rule should have a favorable impact on carriers, providers and consumers. Carriers and providers should be favorably impacted because the amendments provide more consistency among the various types of delivery systems and health benefit plans regarding certain requirements, such as network requirements and benefit design. Carriers' administrative burden should be eased because many of the SCA approval and ongoing requirements have been eliminated. Further, the addition of prescription drug and dental plans to the network-based health benefit plans rules at N.J.A.C. 11:22-5 will enhance the marketability of the carriers' plans, expand providers' practices due to the increased availability of the plans, and increase consumer access to, and affordability of, these types of plans.

Economic Impact

Carriers should be favorably impacted by the inclusion of prescription drug and dental plans in the network-based health benefit plans rules at N.J.A.C. 11:22-5 because, upon adoption

of the proposed amendments, there will be minimum standards for permitted cost-sharing by covered persons under these types of plans. Carriers may incur certain recordkeeping and administrative expenses related to compliance with these rules. N.J.A.C. 11:22-5.7 requires carriers to publish and distribute quarterly to their providers their current formularies or a list of nonformularies; alternatively, carriers may annually distribute new formularies or a list of nonformularies with quarterly updates. N.J.A.C. 11:22-5.7 also requires carriers to include in their contract and evidence of coverage forms information concerning their drug formularies and a description of the approval process to obtain coverage of nonformulary drugs as formulary drugs, as well as the appeal process for denial of such a request. Carriers may also incur administrative expenses in producing marketing materials to explain the new prescription drug and dental plans design. Providers may be favorably impacted if they experience an increase in patients because they will collect additional fees. While the Department's proposed prohibition against carriers calculating out-of-network provider benefits on the basis of in-network negotiated provider fees merely clarifies the Department's long-standing position on this issue, carriers and out-of-network providers may be impacted because carriers would be required to pay additional benefits to out-of-network providers. Persons covered under network-based prescription drug and dental plans will be favorably impacted because greater cost sharing generally results in lower premiums. However, covered persons who receive medical care under these plans may experience greater out-of-pocket costs. Moreover, the maximum out-of-pocket limit for all network-based hospital medical plans with network deductible and/or network coinsurance is being increased by these proposed amendments, repeals and new rule.

Federal Standards Statement

A Federal standards analysis is not required because the Department's proposed amendments, repeals and new rule are not subject to any Federal standards or requirements.

Jobs Impact

The Department does not anticipate that the proposed amendments, repeals and new rule will result in the generation or loss of jobs.

Agriculture Industry Impact

The proposed amendments, repeals and new rule will have no agriculture industry impact.

Regulatory Flexibility Analysis

These proposed amendments, repeals and new rule, as discussed in the Summary above, may apply to some carriers that constitute "small businesses" as that term is defined in the Regulatory Flexibility Act at N.J.S.A. 52:14B-16 et seq. The majority of the proposed amendments to and repeals from the SCA rules at N.J.S.A. 11:4-37 will reduce the administrative burden currently imposed on carriers, in that many of the current SCA approval and monitoring requirements will be eliminated. As described in the Economic Impact statement above, some of the proposed amendments to the network-based health benefit plans rules at N.J.A.C. 11:22-5 may, however, cause carriers offering prescription drug and dental plans to experience additional recordkeeping or other administrative costs related to compliance with these rules. Nevertheless, the standards set forth in these rules must be applied consistently to all carriers choosing to offer the types of health benefit plans described in the rules, and no

exception can be made for small businesses. Compliance with the proposed amendments should not require the employment of professional services.

Smart Growth Impact

The proposed amendments, repeals and new rule will have no impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 11:4-37.5 and 37.7.

Full text of the proposed amendments and new rule follows (additions indicated in boldface **thus**; deletions indicated in brackets **[**thus**]**):

SUBCHAPTER 37. SELECTIVE CONTRACTING ARRANGEMENTS OF INSURERS.

11:4-37.2 Definitions

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

…

"Certified organized delivery system" means an organized delivery system certified pursuant to N.J.S.A. 17:48H-1 et seq., and compensated on a basis that does not entail the assumption of financial risk by the organized delivery system.

…

["Coinsurance differential" means the difference in the coinsurance percentage applicable to in-network and out-of-network benefits.**]**

…

"Evidence of coverage" means **[**any**]** **the** certificate **[**, agreement or contract**]** which includes a statement of the essential benefits, limitations, exclusions and services of the health benefits plan **[**and which**]** **that** is issued to the **employer, policyholder or other person or association in whose name the policy or contract is issued for delivery to the** covered person **[**by the carrier**]**.

["Formulary" means a list of prescription medications that are preferred for use by a health plan.**]**

"Health benefits plan" means a policy, contract or evidence of coverage delivered or issued for delivery in this State that pays benefits and/or arranges for the provision of covered healthcare services and supplies. For purposes of this **[**regulation**]** **subchapter**, health benefits plan shall not include accident only, Medicare supplement coverage, CHAMPUS supplement coverage, coverage for Medicare services provided pursuant to a contract with the United States government, coverage for Medicaid services pursuant to a contract with the State, coverage arising out of a workers' compensation or similar law, automobile medical payment insurance, and personal injury protection issued pursuant to N.J.S.A. 39:6A-1 et seq. **For purposes of this subchapter, health benefits plan shall include dental, vision, prescription drug and other limited scope or ancillary coverages.**

…

"Licensed organized delivery system" means an organized delivery system licensed pursuant to N.J.S.A. 17:48H-1 et seq., and compensated on a basis which entails the assumption of financial risk by the organized delivery system.

"**[**Preferred**]** **Network** provider" means a health care provider or group of health care providers who have entered into selective contracting arrangements with a carrier **[**or**]** **, a**

licensed or certified organized delivery system, a health maintenance organization (HMO) or, with respect to prescription drug coverage only, a preferred provider organization (**PPO**).

"Organized delivery system" or "ODS" means an organization with defined governance that:

1. Is organized for the purpose of and has the capability of contracting with a carrier to provide, or arrange to provide, under its own management substantially all or a substantial portion of the comprehensive health care services or benefits under the carrier's benefits plan on behalf of the carrier, which may or may not include the payment of hospital and ancillary benefits; or

2. Is organized for the purpose of acting on behalf of a carrier to provide, or arrange to provide, limited health care services that the carrier elects to subcontract for as a separate category of benefits and services apart from its delivery of benefits under its comprehensive benefits plan, which limited services are provided on a separate contractual basis and under different terms and conditions than those governing the delivery of benefits and services under the carrier's comprehensive benefits plan.

An organized delivery system shall not include an entity otherwise authorized or licensed in this State to provide comprehensive or limited health care services on a prepayment or other basis in connection with a health benefits plan or a carrier.

"Preferred provider organization" or "PPO" means an entity other than a carrier**, an HMO, a certified ODS, a licensed ODS, and a prepaid prescription drug service organization** that contracts with **[**preferred**]** **network** providers to establish selective contracting arrangements **for prescription drug coverage only.**

"Prepaid prescription drug service organization" means any person, corporation, partnership, or other entity which, in return for a prepayment by a contract holder, undertakes to provide or arrange for the provision of prescription services to enrollees or contract holders pursuant to N.J.S.A. 17:48F-1 et seq.

"Selective contracting arrangement" or "SCA" means an arrangement for the payment of predetermined fees or reimbursement levels for covered services by the carrier to **[**preferred**]** **network** providers**, [**or preferred provider organizations**] HMOs, certified ODSs, licensed ODSs or, with respect to prescription drug coverage only, to PPOs. A SCA includes an arrangement between a carrier and an HMO under which the HMO makes its provider network available to the carrier.**

11:4-37.3 Standards for selective contracting arrangements

[(a) For purposes of paying for covered services under a health benefits plan, a selective contracting arrangement entered into by a carrier shall meet the following criteria:

1. The selective contracting arrangement shall include a mechanism for the review or control of utilization of covered services;
2. The selective contracting arrangement shall provide for an adequate number of preferred providers by specialty to render covered services in the geographic service area(s) where it functions;
3. The selective contracting arrangement shall include a procedure for resolving complaints and grievances of covered persons;
4. The selective contracting arrangement shall provide that information pertaining to the diagnosis, treatment or health of any covered person

receiving health care benefits shall be confidential and shall not be disclosed to any person except as follows:

i. To the extent that it may be necessary to carry out the purposes of this subchapter;

ii. Upon the express consent of the covered person;

iii. Pursuant to statute or regulation;

iv. Pursuant to court order for the production of evidence or the discovery thereof;

v. In the event of a claim or litigation between such covered person and the carrier wherein such data or information is pertinent; or

vi. As otherwise required by law.**]**

(a) A selective contracting arrangement that involves direct contracting between the carrier and network providers or that involves a contract between the carrier and a PPO shall contain an adequate number of network providers by specialty to render the particular covered services in the geographic service area where it operates. A selective contracting arrangement that involves direct contracting between the carrier and a licensed or certified ODS, or under which an HMO makes its network available to a carrier, shall be presumed to have an adequate provider network.

(b) Health benefits plans utilizing selective contracting arrangements shall meet the following criteria:

1. The health benefits plan utilizing a selective contracting arrangement shall provide that covered persons shall not be financially liable for payments to **[**preferred**]** **network**

providers for any sums, other than required co-payments, coinsurance or deductibles, owed for covered services, if the carrier fails to pay for the covered services for any reason**[**.**]** **;**

2. **[**If a covered person is in need of emergency care as defined herein, the health benefits plan utilizing a selective contracting arrangement shall include a mechanism which reimburses emergency care as if the covered person had been treated by a preferred provider.**]** **The health benefits plan shall provide that the cost sharing applied to the covered person for emergency care shall be the same regardless of whether the services were rendered by network or out-of-network providers;**

3. The **health benefits plan shall provide that the** carrier shall provide each covered person with a current evidence of coverage within 30 days of enrollment **[**date**]** and no later than 30 days after any policy or contract changes**;** **[**, including at least:

i. A description of all complaint and grievance procedures, including the address and telephone numbers of the complaint offices of the carrier or PPO, the Department of Health and Senior Services and the Department of Banking and Insurance;

ii. A clear and complete summary of the essential features and services of the PPO coverage, including limitations, exclusions and procedures for accessing out-of-network services; and

iii. A statement of the covered person's rights, which shall include at least the right:

(1) To be provided with information concerning the carrier's and PPO's policies and procedures regarding products, services, providers,

appeals procedures and other information about the organization and the care provided;

(2) To be provided with instructions regarding the selection and procedures for changing a primary care physician. Such selection shall be effected by the carrier within 15 days of receipt;

(3) To seek treatment from the available and accessible specialists included in the network of participating providers following an authorized referral if required; and

(4) To obtain a current directory of preferred providers in the PPO network upon request, including addresses and telephone numbers, and a listing of providers who accept covered persons who speak languages other than English;**]**

4. **[**The carrier issuing health benefit plans utilizing a selective contracting arrangement shall provide that subsequent changes in coverage shall be evidenced in a separate document issued to the covered person**]** **The health benefits plan shall provide that covered persons shall be permitted to change their selection of primary care physician, and such changes shall be effective no later than 15 days after receipt of a request to change a primary care physician**;

5. **[**The carrier utilizing a selective contracting arrangement may provide in its health benefits plan for direct payment to the preferred provider for covered services rendered, and shall establish either the methodology to determine the amount of the actual amount of payment to the preferred provider whichever is applicable**]** **The health benefits plan shall provide that covered persons shall be provided with a current directory of network**

providers in the licensed or certified ODS, HMO, or PPO, or who have directly contracted with the carrier, including addresses and telephone numbers, and a listing of the providers who speak languages other than English. The directory may be made available online provided that covered persons can obtain a hard copy of the directory upon request;

6. **[**The carrier utilizing a selecting contracting arrangement shall include a mechanism which provides that the coinsurance differential, if any, applicable to covered services rendered by a preferred provider, as opposed to covered services rendered by other health care providers, shall be no greater than 30 percent of the allowable expense, provided deductibles and co-payments are equivalent for both in-network and out-of-network benefits. If deductibles and co-payments for in-network and out-of-network benefits are not equivalent, the 30 percent maximum coinsurance differential shall be adjusted to reflect the differences. In no event shall the maximum coinsurance percent for medical services or supplies be greater than 40 percent. Carriers shall submit to the Department as part of their SCA application and any subsequent plan filings a completed Actuarial Justification of Benefit Differentials form attached hereto as an Appendix**]** **The benefit design of health benefits plans utilizing selective contracting arrangements shall be subject to N.J.A.C. 11:22-5; and**

7. Carriers shall not calculate benefits for services provided by out-of-network providers by using negotiated fees agreed to by network providers.

[(c) Health benefits plans that utilize selective contracting arrangements and provide prescription drug benefits through use of a formulary, shall meet the following criteria:

1. The formulary shall be developed by a pharmacy and therapeutics committee composed of health care professionals with recognized knowledge and expertise in clinically appropriate prescribing, dispensing and monitoring of

outpatient drugs or drug use review, evaluation and intervention. The membership of the committee shall consist of at least two-thirds licensed and actively practicing physicians and pharmacists, and shall consist of at least one pharmacist. If the carrier contracts with a third party to develop the formulary, the carrier shall be responsible for guaranteeing that the third party complies with all requirements relating to formularies as set forth in this subsection.

2. All drugs in a formulary shall be approved under the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.).
3. A formulary shall include more than one drug used to treat each covered disease state where more than one drug is available.
4. A drug may be excluded from a formulary only if, based on the compendia listed in (c)6 below, it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of treatment for the specific condition for which the drug is intended over other drugs included in the formulary, and there is a written explanation of the basis for the exclusion that is available to providers and covered persons upon request.
5. Every health benefits plan utilizing selective contracting arrangements that provides benefits for formulary drugs shall also provide benefits for nonformulary drugs. Increased benefits may apply to formulary drugs provided the difference between the total benefit value of formulary drug coverage and the total benefit value of nonformulary drug coverage does not

exceed 30 percent. Compliance with this requirement shall be demonstrated by submitting to the Department as part of the SCA application and any subsequent plan filings a completed Actuarial Justification of Benefit Differentials form (incorporated herein by reference as the Appendix to this subchapter) appropriately modified to reflect prescription benefits rather than medical benefits. There shall no difference in benefit level between formulary and nonformulary drugs obtained from nonparticipating providers.

6. The carrier shall establish an approval process to enable health care providers and covered persons to obtain coverage of nonformulary drugs at the same level as formulary drugs where the prescribing health care provider certifies the medical necessity of the drug.

   i. A nonformulary drug shall be considered medically necessary if:

      (1) It is approved under the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.); or its use is supported by one or more citations included or approved for inclusion in The American Hospital Formulary Service Drug Information or the United States Pharmacopoeia - Drug Information, or it is recommended by a clinical study or review article in a major-peer reviewed professional journal; and

      (2) The prescribing health care provider states that all formulary drugs used to treat each disease state has been ineffective in the treatment of the covered person's disease or condition, or all such drugs have caused or are reasonably expected to cause adverse or harmful reactions in the covered person.

ii. The approval process for nonformulary drugs shall provide that the carrier respond to the prescribing health care provider by telephone or other telecommunication device within one business day of a request for prior authorization. Failure to respond within one business day shall be deemed an approval of the request. Initial denials shall also be provided to the prescribing health care provider and covered person in writing within five business days of receipt of the request for approval of a nonformulary drug, and shall include the clinical reason for the denial. Such denials are appealable to the Independent Health Care Appeals Program in the Department of Health and Senior Services pursuant to P.L. 1997, c. 192, section 11.

7. The carrier shall publish and distribute, at least quarterly, either its current formulary or a list of nonformularies to preferred providers. Such list shall clearly indicate whether the drugs included are formulary or nonformulary. Alternatively, the carrier may annually distribute new formularies or a list of nonformularies, and quarterly updates, to all preferred providers. The current formulary or lost of nonformulary drugs shall be provided by the carrier to covered persons upon request.

8. The contract and evidence of coverage form shall disclose the existence of the drug formulary, describe the approval process to obtain coverage of nonformulary drugs as formulary drugs and describe the process to appeal a denial of a request for approval of a nonformulary drug, including the right to appeal to the Independent Health Care Appeals Program in the Department of Health and Senior Services pursuant to P.L. 1997,

c.192, section 11. The contract and evidence of coverage form shall state that a copy of the formulary will be provided by the carrier to a covered person upon request.

9. The carrier shall file its formulary with the Department of Health and Senior Services at the address set forth at N.J.A.C. 11:4-37.4(b)2 by August 13, 1998. All amendments to the formulary shall be filed with the Department of Health and Senior Services on a quarterly basis.

10. On or before March 31 of each year, the carrier shall file with the Department of Health and Senior Services at the address set forth at N.J.A.C. 11:4-37.4(b)2 a report summarizing all formulary appeals and their resolution for the preceding year on forms prescribed by the Department of Health and Senior Services.**]**

11:4-37.4 Selective contracting arrangement approval and amendment procedures

(a) No carrier shall issue health benefits plans utilizing selective contracting arrangements unless the carrier has entered into such arrangements directly with **[**preferred**]** **network** providers or has contracted with **[**preferred provider organizations**]** **a licensed or certified ODS, an HMO, or a PPO[s] for prescription drug benefits**.

(b) For purposes of obtaining the Commissioner's approval under this subchapter, a carrier issuing health benefit plans utilizing a selective contracting arrangement shall submit four copies of a complete selective contracting arrangement approval application on a form to be provided by the Department. **[**The items set forth at (c)14 and 15 below shall be set forth separately from the remainder of the items to be included in the approval application.**]**

1. Two copies of the entire application shall be submitted to the Department at the following address:

New Jersey Department of Banking and Insurance

[Managed Care**]** **Valuation Bureau**, 11th floor

Office of Life and Health **[**Division**]**

20 West State Street

P.O. Box 325

Trenton, NJ 08625-0325

2. Two copies of the entire application, together with the appropriate filing fee set forth at N.J.A.C. 11:4-37.8, shall be submitted to the Department of Health and Senior Services at the following address;

New Jersey Department of Health and Senior Services

Office of Managed Care

John Fitch Plaza, Room 600

[P. O. Box 360**]**

Warren and Market Streets

P.O. Box 360

Trenton, NJ 08625-0360

(c) A complete selective contracting arrangement approval **[**or amendment**]** application shall include the following:

1. A narrative description of the health benefits plan(s) to be offered, including, but not limited to, the nature of the **[**plan**]** **services and/or supplies**, the market for the plan and a description of the geographic area to be served**[**.**]** **;**
2. A statement that the carrier is **[**either**]** entering into a selective contracting arrangement directly with **[**preferred**]** **network** providers, or is contracting

with a **licensed or certified ODS**, **an HMO, or a** PPO **for prescription drug coverage. [**In the latter case,**]** **Where the carrier is contracting with a licensed or certified ODS, an HMO, or a PPO**, the carrier shall include the following:

i. The identity and a description of the **ODS, HMO or** PPO that will operate and/or administer the selective contracting arrangement;

ii. A description of the relationship between the carrier and the **ODS, HMO or** PPO, and a copy of the contract between the carrier and **the ODS, HMO or** PPO; and

iii. **[**A certification signed by a senior officer of the PPO that the PPO does not engage in the business of insurance in this Stare, and in no way assumes risk in the provision of services for the treatment of injury or illness or preventative care for any person or on behalf of any person other than its own employees**]** **A description of any risk transfer to the ODS, HMO or PPO**;

3. (No change.)

[4. A description of the procedures by which covered services and other benefits may be obtained by covered persons using the selective contracting arrangement;

5. If the carrier is contracting directly with the preferred providers, a narrative description of the financial arrangements between the carrier and the preferred providers. If the carrier is contracting with a PPO, a narrative description of the financial arrangements between the carrier and the PPO, including the manner in which the PPO compensates its providers, a flow diagram of the complete billing and payment cycle that includes all intermediary steps

for each method of reimbursement used (for example, capitation, fee for service) from the time services are rendered until the provider is paid;

6. A copy of every standard agreement, including all versions of variable text, establishing the selective contracting arrangements that will be utilized in the health benefits plan, including the agreement(s) the carrier or PPO has entered into with health care providers, classes of health care providers or any other entity for the provision of administrative or health care services. The agreement(s) shall include a description of the responsibilities of the contracting parties as they relate to the administration, financing and delivery of health care services;

7. Evidence that providers shall maintain licensure, certification and adequate malpractice coverage.

i. With respect to physicians and dentists, malpractice insurance shall be at least $1,000,000 per occurrence and $3,000,000 in the aggregate per year;

ii. With respect to medical groups or health care facility providers, malpractice insurance shall be maintained at least in an amount determined sufficient for their anticipated risk but no less than $1,000,000 per occurrence and $3,000,000 in the aggregate per year.

iii. With respect to all other providers not otherwise under the auspices of a health care facility, malpractice insurance shall be maintained in an amount determined sufficient for their anticipated risk, but no less than $1,000,000 per occurrence and $3,000,000 in the aggregate per year.**]**

[8. A**]** **4. If the carrier is contracting directly with network providers, a** description of the criteria and method used to select **[**preferred**]** **network** providers, including any credentialing plan;

[9. The**]** **If the carrier is contracting directly with network providers or a PPO**, **the** names and addresses of **[**preferred**]** **network** providers by specialty, county, municipality and zip code, accompanied by maps of the geographic service areas identifying the location of these providers, and a copy of the provider directory to be distributed to covered persons;

[10. A description of any provisions which allow covered persons to obtain covered services from a health care provider that is not a preferred provider;**]**

[11 A.**]** **6. If the carrier is contracting directly with network providers or with a PPO, a** description of the utilization review program, including:

i. – ii. (No change.)

[12. A**]** **7. If the carrier is contracting directly with network providers or with a PPO, a** description of the quality assurance program. At a minimum, this shall include:

i. – iii. (No change.)

iv. A description of the staff and their qualifications that will be responsible for the quality assurance program; **and**

[13. A description of the complaint and grievance system available to covered persons, including procedures for the registration and resolution of grievances;

14. A copy of every standard form policy or contract, including all variations of variable test, to be issued by the carrier to the contractholders of health benefit plans, which shall include the requirements set forth at N.J.A.C. 11:4-37.3(b)1, 2 and 3;

15. A copy of every standard form of evidence of coverage to be issued by the carrier to covered persons, setting forth the carrier's contractual obligations to pay for covered services provided to covered persons, which shall include the requirements set forth at N.J.A.C. 11:4-37.3(b)1, 2 and 3;

16. A description of the incentives for covered persons to use the services of preferred providers;**]**

[17. A**] 8 The** provider agreement of the PPO, **licensed or certified ODS,** or carrier stating **shall state** in substance that:

Provider agrees that in no event, including but not limited to nonpayment by the health carrier or intermediary, payment by the health carrier or intermediary that is other than what the provider believed to be in accordance with the reimbursement provision of the provider agreement or is otherwise inadequate, insolvency of the health carrier or intermediary, or breach of this agreement, shall the provider bill, charge or collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a covered person or a person (other than the health carrier or intermediary) acting on behalf of the covered person for services provided pursuant to this agreement. This agreement does not prohibit the provider from collecting coinsurance, deductibles or copayments, as specifically provided in the evidence of coverage. Nor does this agreement prohibit a provider (except for a health care professional who is employed full-time on the staff of a health carrier and has agreed to provide services exclusively to that health carrier's

covered persons and no others) and a covered person from agreeing to continue services solely at the expense of the covered person, as long as the provider has clearly informed the covered person that the health carrier may not cover or continue to cover a specific service or services;

[18. An organizational chart of the carrier or PPO depicting the area responsible for managing selective contracting arrangements;

19. A listing and biographical affidavit of the officers and directors (NAIC Form #280), if any, of the carrier or PPO responsible for managing the selective contracting arrangement;

20. The address of the office of the carrier or PPO responsible for managing the selective contracting arrangement;

21. A copy of the basic organizational documents of the PPO if the carrier is contracting with a PPO, including the articles of incorporation, articles of association, partnership agreement, trust agreement or other applicable documents and all amendments thereto, together with a copy of the bylaws, rules and policies or similar documents regulating the conduct of the internal affairs of the PPO;

22. A copy of the PPO's audited financial statement most recent to the time of application if the carrier is contracting with a PPO; and

23.The following three-year pro-forma information:

i. Enrollment projections indicating the number of covered persons by rating status (that is, single, husband/wife, parent/child and family) and number of covered persons for each county. This data is to be provided quarterly for the first year, and annually for the remaining two years; and

ii. Financial projections for the PPO if the carrier is contracting with a PPO, including balance sheet, revenue and expense statement and a cash-flow statement limited to the selective contracting arrangement business only.

(d) Any changes in the items listed at N.J.A.C. 11:4-37.3 and this section made either during the approval process or at any time after the arrangement has been approved shall be reported in writing to the Department within 30 days, at the following address:

New Jersey Department of Banking and Insurance

Managed Care Bureau. 11th Floor

Life and Health Division

20 West State Street

PO Box 325

Trenton, NJ 08625-0325**]**

[(e)**]** **(d)** The Commissioner, in consultation with the Commissioner of Health and Senior Services as necessary, shall review these documents and grant approval, within 60 days of the carrier's filing its complete application **[**or a complete amendment to its application pursuant to this section**]** to those carriers whose selective contracting arrangements are determined to meet the criteria set forth in this subchapter. **The Commissioner shall notify a carrier of any deficiencies in its application within the 60 day period and the carrier shall have 60 days from such notice to respond to the deficiency notice. Carriers that do not respond within the 60 day period shall have their applications deemed withdrawn. [**The Commissioner may extend the 60-day time frame an additional 30 days for good cause shown and shall provide notice to the carrier of such extension.**]** A **final** decision to deny approval shall be accompanied by a written explanation by the Department of the reasons for denial. A carrier whose selective

contracting arrangement has been denied approval may request an administrative hearing pursuant to the procedures at N.J.A.C. 11:4-**[**37.6] **37.5**.

[(f) The approval of a selective contracting arrangement issued under this subchapter by the Commissioner, in consultation with the Commissioner of Health and Senior Services shall remain in force for a period of three years excepting suspension or revocation pursuant to this subchapter.

(g) A carrier shall apply for triennial renewal of the Department's approval of its selective contracting arrangement on forms provided by the Department at least 60 days prior to the expiration of the previous three-year approved period. Applications for renewal of the Department's approval shall be subject to the filing fee set forth at N.J.A.C. 11:4-37.8. If the Department has not issued a written notice of disapproval within 60 days of receipt of a complete renewal application, which clearly sets forth the reasons for disapproval of the renewal application, the renewal application shall be deemed approved.**]**

(h)**]** **(e)** (No change in text.)

11:4-**[**37.6**]** **37.5** Denial, suspension and revocation

(a) - (b) (No change.)

(c) A carrier requesting a hearing pursuant to (b)3 above shall submit the hearing request to the Department at the following address:

New Jersey Department of Banking and Insurance

[Managed Care Bureau**]** **Valuation Bureau**, 11th Floor

Office of Life and Health **[**Division**]**

20 West State Street

PO Box 325

Trenton, NJ 08625-0325

The hearing request shall include:

1. – 2. (No change.)

3. A statement requesting a hearing;**[**and**]**

4. – 5. (No change.)

(d) – (f) (No change.)

SUBCHAPTER 5. MINIMUM STANDARDS FOR NETWORK-BASED HEALTH BENEFIT PLANS

11:22-5.1 Purpose and scope

(a) This subchapter establishes minimum standards for health benefit plans**, prescription drug plans and dental plans** that provide coverage only when network providers are used, and for health benefit plans**, prescription drug plans and dental plans** that provide different levels of coverage depending on whether a network provider or an out-of-network provider is used.

(b) This subchapter applies to all insurance companies, health service corporations, medical service corporations, hospital service corporations, **dental service corporations, dental plan organizations, prepaid prescription service organizations** and health maintenance organizations that deliver or issue for delivery health benefit plans**, prescription drug plans or dental plans** in this State.

11:22-5.2 Definitions

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

"Brand name drug" means a prescription drug whose manufacture and sale is controlled by a single company as a result of a patent or similar right.

"Carrier" means an insurance company, health service corporation, hospital service corporation, medical service corporation, **dental service corporation, dental plan organization, prepaid prescription service organization** or health maintenance organization authorized to issue health benefit plans**, dental plans or prescription drug plans** in this State.

"Formulary" means a list of prescription drugs that are preferred for use in a health benefit plan or prescription drug plan through lower cost sharing (for example, co-payment, coinsurance, deductible or out of pocket limits) or other financial incentives (for example, quantity limits or inclusion or exclusion from accumulation toward the out-of-pocket limit). A formulary may have multiple tiers. A plan that provides benefits for all brand name drugs at one level of cost sharing and for all generic drugs at another level of cost sharing is not considered a formulary for purposes of this subchapter.

"Generic drug" means any prescription drug which is not a brand name drug.

"Health benefit plan" means a hospital and medical expense insurance policy, health service corporation contract, hospital service corporation contract, medical service corporation contract, health maintenance organization subscriber contract, or other plan for medical care delivered or issued for delivery in this State.

1. "Health benefit plan" shall not include one or more, or any combination of, the following:

[i. Coverage for prescription drugs;**]**

Recodify existing ii. – viii. As **i. – vii.** (No change in text.)

2. "Health benefit plan" shall not include the following benefits if they are provided under a separate policy, certificate or contract of insurance, or are otherwise not an integral part of the plan:

i. Limited scope **[**dental, drug or**]** vision benefits;

ii. - iii. (No change.)

3. - 4. (No change.)

"Network coinsurance" means the percentage of the contractual fee of the network provider for covered services and supplies specified in the contract between the provider and the carrier that must be paid by the covered person, **under the health benefit plan**, subject to deductible and out-of-pocket limit. Network coinsurance cannot be applied to services or supplies provided by capitated providers.

"Network co-payment" means the specified dollar amount a covered person must pay for covered services and supplies rendered by network providers **under the health benefit plan**.

…

"Network out-of-pocket limit" means the annual maximum dollar amount that a covered person must pay as copayment, deductible and coinsurance for services and supplies provided by network providers in a calendar year. All amounts paid as copayment, coinsurance and deductible shall count toward the out-of-pocket maximum, and shall not be excluded because of the nature of the service rendered, the illness or condition being treated, or for any other reason. **A carrier may, however, elect to exclude from the network out-of-pocket limit the cost sharing associated with prescription drug coverage, whether provided as part of the health benefits plan or as a rider.** Once the network out-of-pocket limit has been reached, the

covered person has no further obligation to pay any amounts as copayment, coinsurance or deductible for services and supplies provided by network providers **(other than for prescription drugs, if prescription drugs do not accumulate toward the out-of-pocket limit)** for the remainder of the calendar year.

…

11:22-5.3 Network deductible

(a) An individual network deductible is permitted in a contract issued by a health maintenance organization that provides out-of-network benefits only for emergency and urgent care, in a POS contract issued by a health maintenance organization or health service corporation, and in a SCA policy **providing hospital and medical coverage** issued by an insurance company, provided that:

1. The contract or policy contains an individual network out-of-pocket limit that is no greater than **[**$5,000**]** **$7,500**, and a family network out-of-pocket limit that is no greater than two times the individual network out-of-pocket limit;

2.-4. (No change.)

11:22-5.4 Network coinsurance

(a) Network coinsurance is permitted in a contract issued by a health maintenance organization that provides out-of-network benefits only for emergency and urgent care, in a POS contract issued by a health maintenance organization or health service corporation, and in a SCA policy **providing hospital and medical coverage** issued by an insurance company, provided that:

1. The contract contains an individual network out-of-pocket limit that is no greater than **[**$5,000**]** **$7,500**, and a family network out-of-pocket limit that is no greater than two times the individual network out-of-pocket limit;

i. (No change.)

2. - 4. (No change.)

11:22-5.6 Network and out-of-network coverage

(a) - (b) (No change.)

` **(c) Carriers shall not calculate benefits for services provided by out-of-network providers by using negotiated fees agreed to by network providers.**

11:22-5.7 Prescription drug benefits

(a) Health benefit plans and stand-alone prescription drug plans that provide benefits for prescription drugs listed on a formulary may provide higher benefits for formulary drugs than for nonformulary drugs, provided:

1. The benefit for all tiers of formulary and nonformulary drug coverage shall result in a cost to the covered person of no more than 50 percent of the plan's contracted cost of the drug, after application of any deductibles, for prescription drugs provided by network providers. For prescription drugs provided by out-of-network providers, coinsurance shall not exceed 50 percent;

2. If a health benefit plan has a separate deductible for prescription drugs, or a stand-alone prescription drug plan has a deductible, such deductible shall not exceed

$250.00 per calendar year for all tiers of formulary drugs and $250.00 per year for all tiers of nonformulary drugs; and

3. If a health benefit plan or a stand-alone prescription drug plan has a benefit maximum for prescription drugs, the maximum shall be the same for formulary and nonformulary drugs.

(b) Health benefit plans and stand-alone prescription drug plans that provide prescription drug benefits through use of a formulary, shall meet the following criteria:

1. The formulary shall be developed by a pharmacy and therapeutics committee composed of health care professionals with recognized knowledge and expertise in clinically appropriate prescribing, dispensing and monitoring of outpatient drugs or drug use review, evaluation and intervention. The membership of the committee shall consist of at least two-thirds licensed and actively practicing physicians and pharmacists, and shall consist of at least one pharmacist. If the carrier contracts with a third party to develop the formulary, the carrier shall be responsible for guaranteeing that the third party complies with all requirements relating to formularies as set forth in this subsection.

2. All drugs in a formulary shall be approved under the Federal Food, Drug and Cosmetic Act , 21 U.S.C. §§ 301 et seq.

3. The most preferred tier of a formulary, that is, the tier with the lowest cost sharing, shall include more than one drug used to treat each covered disease state where more than one drug is available.

4. A drug may be excluded from the most preferred tier of a formulary only if, based on the compendia listed in (c)6 below, it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of

treatment for the specific condition for which the drug is intended over other drugs included in the formulary, and there is a written explanation of the basis for the exclusion that is available to providers and covered persons upon request.

5. Each health benefit plan utilizing selective contracting arrangements that provides benefits for formulary drugs shall also provide benefits for nonformulary drugs. There shall be no difference in benefit level between formulary and nonformulary drugs obtained from out-of-network providers.

6. The carrier shall establish an approval process to enable health care providers and covered persons to obtain coverage of nonformulary drugs at the same level as formulary drugs where the prescribing health care provider certifies the medical necessity of the drug.

i. A nonformulary drug shall be considered medically necessary if:

(1) It is approved under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq.; or its use is recognized as being medically appropriate for the specific treatment for which the drug has been prescribed in one of the following established reference compendia: The American Hospital Formulary Service Drug Information or the United States Pharmacopoeia - Drug Information, or it is recommended by a clinical study or review article in a major peer-reviewed professional journal; and

(2) The prescribing health care provider states that all formulary drugs used to treat each disease state have been ineffective in the treatment of the covered person's disease or condition, or all such

drugs have caused or are reasonably expected to cause adverse or harmful reactions in the covered person.

ii. The approval process for nonformulary drugs shall provide that the carrier respond to the prescribing health care provider by telephone or other telecommunication device within one business day of a request for prior authorization. Failure to respond within one business day shall be deemed an approval of the request. Initial denials shall also be provided to the prescribing health care provider and covered person in writing within five business days of receipt of the request for approval of a nonformulary drug, and shall include the clinical reason for the denial. Such denials are appealable to the Independent Health Care Appeals Program in the Department of Health and Senior Services pursuant to P.L. 1997, c. 192, § 11.

7. The carrier shall publish and distribute, at least quarterly, either its current formulary or a list of nonformularies to network providers. Such list shall clearly indicate whether the drugs included are formulary or nonformulary. Alternatively, the carrier may annually distribute new formularies or a list of nonformularies, and quarterly updates, to network providers. The current formulary or list of nonformulary drugs shall be provided by the carrier to covered persons upon request.

8. The contract and evidence of coverage form shall disclose the existence of the drug formulary, describe the approval process to obtain coverage of nonformulary drugs as formulary drugs and describe the process to appeal a denial of a request for approval of a nonformulary drug, including the right to appeal to the Independent Health Care Appeals Program in the Department of Health and Senior Services pursuant to P.L. 1997,

c.192, § 11. The contract and evidence of coverage form shall state that a copy of the formulary will be provided by the carrier to a covered person upon request.

(b) Health benefit plans and stand-alone prescription drug plans may provide higher benefits for generic drugs than for brand name drugs provided:

1. The benefit for both generic and brand name drugs must result in a cost to the covered person of no more than 50 percent of the plan's contracted cost of the medication for prescription drugs obtained from network providers. A deductible, as described in 2 below, does not need to be considered in calculating the covered person's cost. For prescription drugs provided by out-of-network providers, coinsurance shall not exceed 50 percent.

2. If a health benefit plan has a separate deductible for prescription drugs or a stand-alone prescription drug plan has a deductible, such deductible shall not exceed $250.00 per calendar year for generic drugs and $250.00 per calendar year for non-generic drugs.

3. If a health benefit plan or a stand-alone prescription drug plan has a benefit maximum for prescription drugs, the maximum shall be the same for generic and brand name drugs.

11:22-5.8 Dental benefits

(a) The following standards apply to health benefit plans and stand-alone dental plans that provide benefits for dental services only when rendered by network providers, and plans that provide benefits for dental services rendered by both network and out-of-network providers:

1. For services rendered by network providers, the plan shall provide benefits that result in a cost to the covered person of no more than 75 percent of the plan's contracted cost of the covered services, after application of any deductibles; and

2. For services rendered by out-of-network providers, coinsurance shall not exceed 75 percent.

11:22-**[**5.7**]5.9** Effect on previously-approved forms

Any form that was **previously** filed with and approved by the Commissioner **[**prior to November 3, 2003**]**, but does not meet the requirements of this subchapter, shall be deemed withdrawn **[**immediately**]** **as of July 1, 2006** and may not be made available for **[**sale or use**]** **new issue or for renewal on or after that date**.

inoregs/bbsca