

INSURANCE
DEPARTMENT OF BANKING AND INSURANCE
DIVISION OF INSURANCE

Organized Delivery Systems

Adopted New Rules: N.J.A.C. 11:22-4

Proposed: January 7, 2002 at 34 N.J.R. 20(a)

Adopted: September 18, 2002 by Holly C. Bakke, Commissioner, Department of Banking and Insurance

Filed: September 18, 2002 as R. 2002 d. 336 with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 17:1-8.1, 17:1-15e and 17:48H-1 et seq.

Effective Date: October 21, 2002

Expiration Date: November 6, 2005

Summary of Public Comments and Agency Responses:

The Department of Banking and Insurance (“Department”) timely received comments from the following:

1. St. John and Wayne (on behalf of Horizon Behavioral Services);
2. The New Jersey Hospital Association;
3. The New Jersey Association of Mental Health Agencies, Inc.;
4. IPA Coalition of New Jersey;
5. Health Net of New Jersey, Inc.;
6. The Medical Society of New Jersey;
7. The New Jersey Association of Health Plans;
8. The New Jersey Podiatric Medical Society;
9. Mid Coastal IPA, Inc.; and

10. Magellan Behavioral Health, Inc.

COMMENT: Several commenters expressed concern with the net worth, deposit, and bond requirements for licensed organized delivery systems (ODS) at N.J.A.C. 11:22-4.8. The commenters generally believed that these requirements are burdensome and could prevent an entity from acting as an ODS.

Several commenters requested that the Department gradually “phase-in” the net worth and deposit requirements to afford ODSs a period of time following licensure to meet the required standards. One commenter specifically requested a three-year period to meet net worth and deposit requirements. Another commenter requested that the requirements be phased-in over a 48-month period similar to that provided for HMOs under N.J.A.C. 8:38-11.1.

One commenter specifically suggested that the net worth requirement be the lesser of: 1) three percent of annual compensation received by the ODS for all of its contracts in which risk is assumed; or 2) four percent of annual health care expenditures.

Other commenters stated that the rules do not provide flexible net worth, deposit, or insolvency insurance requirements, which, as proposed, are prohibitive for independent physician association (IPA) physician organizations. One commenter believed that the rules should permit a waiver or adjustment by the Commissioner of Banking and Insurance (“Commissioner”) based on the ODS’ characteristics and carrier arrangements, which may address sufficient deposits. Another commenter believed that the requirements in these rules were excessive compared to that required of similar entities in other states (Iowa, Maryland, Ohio, Pennsylvania and Texas). The commenter recommended that the amount required to be maintained in the separate reserve account be limited to the required amount as net worth as reflected in N.J.A.C. 11:22-4.8(a). The commenter believed that the requirement that the ODS maintain net worth as well as deposits

equal to its assets and liabilities is an unnecessary duplication of capital requirements. The commenter stated that the rules will require a licensed ODS to deposit 50 percent of the highest calendar quarterly compensation of the most recent four quarters. The commenter recommended that a limit of \$300,000 be placed on this deposit amount at least for an ODS that provides a specialty service, such as behavioral health. The commenter stated that the deposit amount would be approximately one half of the minimum deposit required for a health maintenance organization (HMO) under N.J.A.C. 8:38-11.4. The commenter stated that, typically, health plan premium associated with behavioral health services is no more than 15 percent of the total health care premium in a given year and therefore the limited service ODS has significantly less financial risk.

Conversely, one commenter believed that the minimum net worth requirements were insufficient to cover costs that may be incurred by the ODS.

RESPONSE: Initially, the Department notes that the net worth and deposit requirements implement the intent of the statute with respect to licensure of an ODS, that is, helping to ensure that an ODS that assumes financial risk from a carrier has the financial ability to meet its contractual obligations. Similarly, the reporting requirements are recognized by the statute and are intended to enable the Department to continue to monitor an ODS' financial position and other aspects of its operations to determine its financial position and otherwise to ensure compliance with applicable law. As set forth below, these requirements are comparable to the rules governing HMOs, but, upon review, modifications will be made upon adoption to ensure greater consistency with requirements that apply to HMOs.

The Department agrees that it is reasonable to provide for a “phase-in” of the net worth requirements over 48 months, and deposit requirements above the minimum \$25,000, over two years, similar to that provided for HMOs under N.J.A.C. 8:38-11.1 and 11.4, respectively. However, such a change cannot be made upon adoption. The Department proposes amendments to the rules to provide for such a “phase-in” in a notice of proposal published elsewhere in this issue of the New Jersey Register. The Department does not, however, agree that the net worth requirements should be based on the “lesser of” three percent of annual compensation or four percent of annual health care expenditures. As noted previously, these standards are comparable to those that apply to HMOs, which the Department believes are reasonable and appropriate in fulfilling the Legislature’s intent of helping to ensure that entities that assume financial risk in providing health care services from carriers should maintain comparable financial strength to that of the carrier from which risk is assumed, to ensure that they will be in a position to pay their contractual obligations when due.

In addition, the Department believes that the rules do provide flexible net worth and deposit requirements insofar as the amount of net worth is based on the compensation received or health care expenditures. These amounts are indicative of the size of the entity. With respect to variations in “insolvency requirements,” it is unclear to what concern this relates. If the concern is the requirement that ODSs maintain insurance, the purpose of this is to ensure that benefits are continued for a period determined in the insolvency plan. The amount of insurance and the cost related thereto would vary depending upon the size of the ODS, that is, the amount of business assumed by the ODS.

With respect to the request that the rules permit a waiver or adjustment by the Commissioner based on the ODS’s characteristics and carrier arrangement, the Department notes

that the commenter provided no basis for such a “waiver.” In addition, the Department reiterates that the amount of net worth and deposit will be based on the amount of risk assumed by the ODS. In addition, the rules do permit a waiver of net worth and deposit requirements insofar as the licensure requirement is waived if the ODS assumes risk that is *de minimis*, pursuant to N.J.A.C. 11:22-4.3(b).

With respect to the comment that the requirements are excessive compared to that required of similar entities in other states, the Department notes that the commenter did not indicate the specific abilities or activities of these entities under the applicable state’s law. The Department believes that it is most instructive to look to requirements in this State of similar entities to determine appropriate requirements. As noted above, the Department based the requirements on those existing for HMOs.

With respect to the comment that the amount required to be maintained in the separate reserve account be limited to the required amount as net worth as set forth in N.J.A.C. 11:22-4.8(a), the Department notes that the amounts required to be maintained as a deposit are considered assets of the ODS and thus would be counted toward determining its net worth.

Finally, with respect to the comment that the net worth and deposit requirements are excessive with respect to limited health care services insofar as health plan premiums associated with behavioral health services are no more than 15 percent of the total health care premium in a given year, and thus a limited service ODS has significantly less financial risk, the Department notes that while a limited service ODS would have less financial risk than a HMO providing comprehensive health care services, the net worth and deposit requirements are based on the risk assumed by the ODS, and, therefore, are appropriate.

COMMENT: Several commenters requested clarification of N.J.A.C. 11:22-4.3(a)1, which provides that nothing in the subchapter shall impair any contract in force as of the effective date of the subchapter for a period not to exceed 24 months. One commenter questioned whether a carrier is still responsible for the actions of its “subcontractors” pending their licensure as an ODS. Another commenter believed that this provision is inconsistent with the statute. The commenter questioned the reason for the 24-month timeframe and when the 24 months begins.

RESPONSE: With respect to whether a carrier will still be responsible for the actions of its “subcontractor” pending licensure as an ODS, it is unclear to what actions the commenter refers. Essentially, if an entity is not licensed as an ODS, it cannot assume financial risk. The Department of Health and Senior Services (DHSS), however, which regulates ODSs not required to be licensed, may express opinions or requirements as to other duties that may be assumed under a contract between a carrier and the ODS.

With respect to the concerns that the rules shall not impair any contract in force as of the effective date of the subchapter for a period not to exceed 24 months, the purpose of this provision is to reflect the requirements in the statute. N.J.S.A. 17:48H-2a provides that beginning one year after enactment of the Act, no person or entity shall operate as an ODS without obtaining certification or licensure. Accordingly, under the law, no entity may act as an ODS on or after January 18, 2001. The purpose of the rule is to provide a transition period for an entity to be licensed or, in the event of the failure of the entity to do so, for the carrier to make other arrangements for the provision of health care services. The 24-month time frame would begin from the effective date of the subchapter.

COMMENT: One commenter expressly supported the rules in their entirety and believed that the new licensing procedures for ODS will go a long way to prevent the financial collapse of such systems, thereby protecting the interest of health care consumers and providers.

RESPONSE: The Department appreciates support of its proposal.

COMMENT: One commenter supported the requirement at N.J.A.C. 11:22-4.5(b)3, which requires the ODS to demonstrate its ability to assure that health care services are available and accessible. The commenter further believed that an ODS should provide assurance that the names of providers it indicates are in the ODS network are in fact under contract with the ODS, have been fully credentialed, and are accepting patients. The commenter believed that absent such verification, the actual network of an ODS could be misrepresented.

RESPONSE: The primary purpose of these rules is to address the assumption of financial risk by an ODS which requires licensure. The issues raised in the comment generally go to quality of care, and review of agreements by DHSS under N.J.S.A. 17:48H-13b. Accordingly, the Department believes that these issues would more appropriately be addressed by DHSS.

COMMENT: One commenter supported N.J.A.C. 11:22-4.5(e), which provides that the Commissioner shall refer all standard forms of provider agreements, quality assurance programs and utilization management programs to be used by the ODS to the Commissioner of DHSS for review. The commenter believed that this consultation should include the review of both

consumer and provider complaints against the applicant, as well as the number of appeals filed and overturned throughout the “three stage appeal process.”

RESPONSE: This issue similarly goes to quality of care and the scope of review by DHSS in review of standard provider agreements.

COMMENT: One commenter requested whether the Department is considering having a licensed ODS contribute to the “HMO Guaranty Fund.”

RESPONSE: ODSs are not subject to the New Jersey Insolvent Health Maintenance Organization Assistance Fund Act of 2000, N.J.S.A. 17B:32B-1 et seq. The purpose of this Act is to provide coverage for individuals and providers against the failure or inability of two HMOs, HIP Health Plan of New Jersey, Inc. and American Preferred Provider Plan, Inc. to perform certain contractual obligations due to their insolvency. See N.J.S.A. 17B:32B-2. Only HMOs are subject to assessments under this statute.

COMMENT: One commenter stated that carriers should not be held harmless in the event an ODS with which it holds a contract becomes insolvent. A contract between a carrier and an ODS should include language that ultimately holds the carrier financially responsible for claims that may be left unpaid in the event the ODS becomes insolvent.

RESPONSE: Upon review, the Department has determined that no change is required. Initially, the Department notes that a change such as that suggested by the commenter could not be made

upon adoption. The Department nevertheless believes that such a change is not necessary and would be inconsistent with the intent of the statute. The statute requires entities that assume financial risk to be licensed by the Department, and requires that provider agreements and related items be reviewed by DHSS to ensure quality of care. To require that the carrier which transfers risk to the ODS essentially be a guarantor of the ODS would obviate the need for the statute and licensure. However, the Department notes that the issue raised may involve disputes under the terms of the agreement between a carrier and the ODS, which ultimately would be decided by the courts.

COMMENT: One commenter stated that the rules do not reference subcontractors of an ODS and questioned whether an ODS is responsible for the performance of its subcontractors.

RESPONSE: A subcontractor could be considered an ODS if it assumes financial risk directly or indirectly (see definition of “organized delivery system”). The Department will regulate all entities required to obtain licensure under these rules. With respect to whether an ODS is responsible for the performance of its subcontractors, please see the Response to the previous Comment. In addition, the Department notes that it is unclear to what “responsibility” the commenter refers. These issues may be addressed by the specific contract involved.

COMMENT: Similar to other commenters, it was stated that the rules should provide general variation in deposit, net worth, and reporting requirements based on the size of the entity and the risks assumed. The commenter stated that smaller entities would not be able to meet these requirements, thus preventing them from contracting with managed care organizations and

limiting competition. The commenters noted that N.J.S.A. 17:48H-19 states that the minimum net worth may vary in accordance with the size of the system, the services provided by the system, and the financial liabilities of the system. The commenter requested that the rules reflect these requirements.

RESPONSE: As set forth in a Response to a previous Comment, the Department believes that the net worth and deposit requirements are appropriate, but has determined to make some modifications to ensure further consistency with the requirements governing HMOs at N.J.A.C. 8:38-11.1 and 11.4, while maintaining adequate protection. The amount of net worth and deposits required are based on business size in that they are based on the amount of business or risk assumed by the entity. In addition, an entity may be exempted from licensure if it assumes *de minimis* risk under N.J.A.C. 11:22-4.3(b). Variation in reporting requirements, however, based on business size would not be feasible. The reporting requirements are similar to those required of any other entity that assumes financial risk and required to be licensed by this Department. These reports enable the Department to monitor an ODS's financial position and operations. These reports must be uniform so that the Department may appropriately monitor these entities. Indeed, the Department notes that N.J.S.A. 17:48H-22, which requires financial reports, does not vary these requirements based on business size nor require variation based on business size.

COMMENT: Several commenters suggested that the following terms be defined in the rules as follows:

“Annual compensation” and “quarterly compensation” should include funds received from carriers for the provision of services, but specifically exclude other revenue that an ODS may receive, such as reimbursement for expenses, fees, bonus payments, administrative costs, non-risk contract revenue, interest income, etc.;

“Annual healthcare expenditures” should include funds expended for the delivery of health care services, less expenditures made on a capitated basis, managed hospital payments, payments made to ODS physicians and stop-loss premiums. Payments to ODS physicians should be excluded as these payments entail business risks assumed by the IPA rather than financial risk as defined in the regulations;

“Contract” should be defined as an agreement with a carrier that entails the assumption of financial risk. Only these contracts should be subject to the provisions of the licensure rules.

Some commenters further stated that to assure that the standards for licensure are applied consistently to all organizations, an otherwise licensed entity, such as a hospital, should be subject to the ODS licensure requirements appropriate to the risk assumed, and should not be automatically exempt from ODS licensure.

RESPONSE: With respect to the comment regarding the definition of “annual compensation” and “quarterly compensation” the Department agrees that a definition of “compensation” should be included in the rule. However, such a change cannot be made upon adoption. Accordingly, the Department is proposing elsewhere in this issue of the New Jersey Register amendments to N.J.A.C. 11:22-4.8 to provide that compensation, for purposes of determining net worth and deposits required, means “amounts paid to the ODS by a carrier or other ODS for specified health care benefits (for example, hospital/medical, dental, radiology, etc.) provided to the

policyholder or members of the carrier pursuant to agreements whereby the ODS assumes financial risk.” Under the rules, administrative only expenses, non-risk contract revenue and investment income are not included. However, the Department believes that administrative expenses related to the provision of service under which financial risk is assumed should be included as compensation for purposes of determining net worth because it is reflective of and related to the financial risk assumed.

With respect to the comment regarding the definition of “annual health care expenditures,” the Department similarly agrees that a definition should be included in the rule. However, such a change cannot be made upon adoption. The Department proposes amendments elsewhere in this issue of the New Jersey Register to N.J.A.C. 11:22-4.8 to provide that health care expenditures, for purposes of determining net worth and deposits required, means “amounts paid for provider services provided under a contractual arrangement and includes salaries, including fringe benefits, paid to providers for delivery of health care services; capitation payments paid by the ODS to providers for delivery of health care services; and fees paid to providers on a fee-for-service basis for delivery of health care services, including capitated referrals; and net of reinsurance recoveries. Annual health care expenditures will not include expenses for the time of providers devoted to administrative tasks.” While capitated payments are included in the definition, these payments are excluded for determining net worth under the rules. The Department believes that it is appropriate to include these expenditures in that they reflect the financial risk assumed by the ODS and are consistent with the manner by which HMOs report these expenditures under annual and quarterly reporting requirements, to which ODSs are also subject.

With respect to the comment regarding the definition of “contract,” while the Department recognizes that only contracts that entail the assumption of financial risk are specifically subject to regulation under the rules, the Department believes that review of all related contracts is necessary to ascertain the nature of the entities’ operations to determine the scope of risk that may be assumed.

With respect to the comment that otherwise licensed entities, such as a hospital, should be subject to ODS licensure requirements, the Department notes that if the entity assumes risk related to the scope of its licensure as a provider, the entity is already licensed by the State to provide those services, and, thus, the Department does not believe that the entity must obtain an additional license to provide services for which it is already licensed. However, if the risk assumed is outside the scope of its licensure, then the ODS rules apply and the entity would be required to be licensed.

COMMENT: One commenter stated that N.J.A.C. 11:22-4.3(b) requires that an application for licensure or exemption from licensure requires review of certain information by DHSS. The commenter questioned how this will be performed in the absence of rules by DHSS governing certification. The commenter further questioned whether the Department will be reviewing applications submitted in 2001 or will require new submissions.

RESPONSE: In the absence of additional specifically defined standards, the Department assumes that DHSS may utilize existing applicable standards with respect to determining quality of care and other relevant issues. The Department reiterates that these rules relate to the transfer

or assumption of financial risk by an ODS from a carrier. The other issues raised may be more appropriately addressed to DHSS with respect to the particular standards that will be utilized.

With respect to applications submitted in 2001, completely new submissions will not be required, but updated information should be provided.

COMMENT: One commenter suggested that the requirement that applicants pay for a risk assessment report at N.J.A.C. 11:22-4.4(b) be waived depending on the nature of the risk being assumed. Another commenter stated that this requirement is not contained in the statute and should be eliminated.

RESPONSE: Upon review of the commenter's concerns, the Department has determined not to change this provision. The rules do not mandate that a risk assessment report be provided in all instances. Rather, it provides that if the Department determines that the report is necessary as part of its evaluation and examination of an entity applying for licensure, the entity shall pay the cost for the report. This is similar to the requirements for entities self-insuring workers' compensation and motor vehicle liability coverages under N.J.A.C. 11:2-33.3(f) and 11:3-30.6(b), respectively. The Department believes that this requirement is reasonable in that it will assist the Department in its review of the financial position of an entity applying for licensure.

COMMENT: Several commenters expressed concern with N.J.A.C. 11:22-4.5(c), which provides that applications accepted after November 1 of each year shall not be reviewed until the next annual statement becomes available and is received for review. The review of such applications shall begin as of April 1 of each year, after receipt of annual statements which shall

be submitted no later than March 1 of each year. The commenters believed that the delay in the review of applications received after November 1 for five months is unreasonable and will substantially delay the review of a new ODS. Another commenter stated that an ODS applying for initial licensure may not have segregated funds and therefore could not submit an annual statement by March 1.

RESPONSE: This rule is consistent with the review of applications for certificates of authority to transact business as an insurer. The purpose of this provision is to ensure that the Department possesses the most recent financial information regarding an entity. However, the Department recognizes that in the case of an ODS, heretofore not required to be licensed and otherwise not licensed as such an entity in another state, the circumstances warrant a change in this procedure. Although such a change cannot be made upon adoption, the Department is proposing amendments elsewhere in this issue of the New Jersey Register to eliminate the requirement that applications received after November 1 shall not be reviewed until the next annual statement becomes available. However, the proposed amendment will provide that based on a review of the information that is provided, the Department may defer review if it determines that it requires more recent financial information in order to evaluate properly the applicant's financial position.

With respect to the comment that an applicant applying for initial licensure may not have segregated funds and therefore cannot submit an annual statement by March 1, the Department notes that the rules require that the applicant submit a financial statement. The rules do not require that the entity maintain segregated funds prior to licensure.

COMMENT: One commenter stated that the requirement for Commissioner approval of new contracts under N.J.A.C. 11:22-4.6(b) should be limited to contracts that involve the assumption of financial risk by the ODS.

RESPONSE: As noted in a Response to a previous Comment, the Department believes that a review of all contracts related to the entity is appropriate in order to determine the nature of the entity's operations and the scope of the risk involved.

COMMENT: One commenter suggested that N.J.A.C. 11:22-4.6(c) be revised to add, as a requirement for contracts between a carrier and a licensed ODS, the information to be reported and the frequency of such reporting by the carrier to the ODS. The commenter also believed the rules should provide for penalties against the carrier for failure to provide this information to the ODS.

RESPONSE: Upon review, the Department has determined that no change is required. Penalties are established by statute and the statute and rules apply to licensed ODSs, not carriers. Accordingly, the statute does not provide any penalties against carriers. An ODS could, however, through its negotiations with the carrier, request that the contract include "penalties" for failure of the carrier to report certain information to the ODS.

COMMENT: One commenter stated that the requirement at N.J.A.C. 11:22-4.8(d) that the ODS provide 45 days notice and obtain Commissioner approval to withdraw more than 10 percent of

the amount in the segregated fund could hinder ODS operations and the timely payment of claims. The commenter requested that the requirement be deleted.

RESPONSE: The rule was not intended to address payments of claims, as the commenter apparently believes. The purpose is to limit the ability of an ODS to make withdrawals, such as a dividend or other payments to owners or managers of the ODS, beyond a certain amount, without prior approval of the Department. The Department did not consider a withdrawal of funds to include disbursements required for payment of benefits and related administrative expenses under a contract. Indeed, the rules at N.J.A.C. 11:22-4.8(b) provide that the segregated account includes the income, and disbursements, associated with the financial risk assuming operations of the ODS. If a withdrawal of funds under this section included disbursements related to its contractual obligations, an ODS would not be able to operate or fulfill its contractual obligations when due. The application of the rule in such a way would preclude operations of any ODS pursuant to the statute and scheme otherwise established in these rules. Accordingly, the rule has been clarified upon adoption to exclude payment of benefits under the contract, including attendant administrative expenses, from the determination whether prior notification to the Department and approval of such withdrawal is required.

COMMENT: One commenter noted that the deposit requirement in N.J.A.C. 11:22-4.8(e) of 50 percent of the quarterly compensation is absolute and not subject to adjustment by the Commissioner, as is the net worth requirement. This commenter proposed that the deposit be changed to 25 percent and be subject to adjustment by the Commissioner based upon the nature of the risk, stop-loss insurance, operational indicators and carrier reserves. The commenter

further stated that the deposit and insolvency insurance requirements should be waived if the carrier's reserves provide the necessary coverage, so as to preclude double reserves, or the ODS has sufficient deposits with the carrier, such as a letter of credit.

RESPONSE: Upon review, the Department has determined not to change this provision. The Department does not believe that the deposit requirement is absolute and unadjustable. Indeed, the deposit requirement does vary based on the amount of risk or payments received by the entity, which is indicative of the size of the ODS. The Department believes that 50 percent is appropriate, and consistent with deposit requirements for HMOs. The purpose of the deposit is to provide for payments in the case of insolvency of the entity and to provide for payments to providers for services. Accordingly, variation based upon the nature of the risk, stop-loss insurance, operational indicators and carrier reserves, would not fulfill the intent of the deposit requirement. The same holds true for the insolvency requirements. However, many of the indicators cited by the commenter would be used in determining whether the entity assumes a *de minimis* risk, and therefore would not be subject to licensure. However, if the entity assumes financial risk, then the entity must make provision through deposits and insurance in the case of its insolvency.

COMMENT: Several commenters stated that the reporting and recordkeeping requirements in N.J.A.C. 11:22-4.9 should be based upon the size of the ODS and the nature of the risk assumed. In addition, one commenter stated that quarterly reporting should be waived for smaller organizations.

RESPONSE: As noted in Response to a previous Comment, it would not be feasible to provide for different reporting requirements based on business size. The Department requires consistent reporting among all entities to determine the financial position and operations of entities subject to licensure. Variations in financial reporting requirements based on business size is not provided in any other context to any entity subject to licensure by the Department.

COMMENT: Several commenters stated that the requirement at N.J.A.C. 11:22-4.11 that the ODS provide for its potential insolvency either through purchase of insurance or through other arrangements to ensure that benefits are continued for the period determined in the insolvency plan, should be waived where insolvency of the ODS does not affect the continuation of member benefits or continuity of care.

RESPONSE: Upon review, the Department has determined not to change this provision. The issue addressed by the purchase of insurance, as noted in response to previous Comments, is not necessarily to provide for the continuation of member benefits or continuity care. It may be to cover the cost of runoff of existing claims in the event of the insolvency of an ODS.

COMMENT: One commenter stated that the reference to certified ODSs in N.J.A.C. 11:22-4.12, regarding confidentiality, should be deleted. The commenter stated these rules deal exclusively with licensed ODSs.

RESPONSE: The Department agrees for the reasons expressed by the commenter. This change has been made upon adoption.

COMMENT: Several commenters expressed concern with the definition of “financial risk” at N.J.A.C. 11:22-4.2. The commenters stated that in the statute, capitation to a provider on a prepaid basis is exempted without qualification from the definition of financial risk. The commenters stated that in the rules, the Department qualifies the exemption with the phrase “per se” that is, that a payment method in the form of a capitation payment shall not “per se” be considered financial risk. One commenter further stated that the sentence “A financial risk shall exist if, under an agreement between the organized delivery system and the carrier, the financial obligations of the organized delivery system for payment of benefits or for providing treatment or services does or potentially may exceed any payments that may be received from the carrier,” is unclear. The commenter stated that it is unclear when capitation will be considered financial risk, and requested clarification of the definition.

RESPONSE: The Department believes that the definition of “financial risk” as stated in the rules is consistent with the statute. The Department has interpreted the definition to mean that capitation payments to providers do not constitute financial risk. However, capitation payments to entities other than a “provider” may constitute the assumption of financial risk. Moreover, the Department believes that the definition is sufficiently clear. In addition, the Department has provided various examples set forth in Exhibit B in the Appendix of the subchapter as to when financial risk will be deemed to have been assumed.

COMMENT: One commenter stated that the definition of “organized delivery system” in N.J.A.C. 11:22-4.2, last sentence of paragraph 2, should be revised to read “This shall include

any agreement to subcontract any separate **health care** service or benefit....” (language in boldface is to be added.) The commenter stated that this would comport with the statutory and regulatory definition of “limited health care service” and make it clear that subcontractors used by carriers for administrative services would not fall under the statute.

RESPONSE: The Department agrees. Accordingly, the rules have been revised upon adoption to reflect this change for the reasons expressed by the commenter.

COMMENT: Several commenters expressed concern with N.J.A.C. 11:22-4.6(b)1 and 2, which provides that contracts between a carrier and an ODS are subject to the following standards: 1) the terms should be fair and reasonable; and 2) charges or fees for services performed shall be reasonable. The commenter believes that the “reasonable” standard is too vague and subjective and thus should be deleted.

RESPONSE: Upon review of the commenters’ concerns, the Department has determined not to change these provisions. The standards track the standards set forth in the New Jersey Insurance Holding Company Systems Act at N.J.S.A. 17:27A-4, with respect to the review of contracts between a domestic insurer and its affiliates. A “reasonable” standard is a commonly recognized statutory standard that the Department believes is appropriate in this context.

COMMENT: Several commenters believed that the requirement at N.J.A.C. 11:22-4.6(c)3, which provides that payments under the contract be made no less frequently than monthly and shall be made prospectively, is too restrictive. The commenter believed that there may be other

payment arrangements that meet the business needs of both the carrier and the ODS without thwarting the legislative intent.

RESPONSE: Upon review of the commenter's concerns, the Department has determined not to change this provision. This rule addresses the cash flow of the ODS. HMOs typically receive payments on a monthly basis, and the Department believes that it is appropriate that payments by carriers to ODSs should be made no less frequently than monthly.

COMMENT: One commenter believed that the fee of \$2,500 for requests for exemption from licensure is excessive. The commenter stated that one test of *de minimis* status is whether the applicant's total compensation is less than \$250,000. The commenter believed that it is unreasonable to impose the same \$2,500 fee on a small, exempted organization that is imposed on a large licensed ODS. If the compensation is less than \$250,000, the fee amounts to at least one percent of this value. The commenter believed that the filing fee should be no more than \$1,000.

RESPONSE: Upon further review, the Department agrees that the \$2,500 fee does not reflect the costs of these applications. Accordingly, the rules have been revised upon adoption to provide for a \$1,000 filing fee for request for exemption.

COMMENT: One commenter stated that the criteria for contracts between an ODS and a carrier at N.J.A.C. 11:22-4.5(b) are vague and fail to provide sufficient protection. The commenter cited as an example those in N.J.A.C. 11:22-4.5(b)3 ("the ability to assure that health care

services will be provided in a manner which will assure the availability and accessibility of the services”) and 4.5(b)4 (“the standard forms of provider agreements to be used by the ODS are acceptable”). The commenter stated that the rules should incorporate the same protections that exist under the Health Care Quality Act, prompt pay legislation, HMO rules, HMO liability law, and other protective measures, so that an HMO or other carrier may not circumvent these obligations by utilizing an ODS.

RESPONSE: Upon review, the Department has determined that no change is required. The language cited by the commenters tracks verbatim the applicable statutory language at N.J.S.A. 17:48H-1 et seq. The Department believes that the statute does provide sufficient protection to claimants. Indeed, an ODS is subject to the Health Care Quality Act, and “prompt pay” requirements. The Department cannot require that an ODS be expressly subject to all requirements and provisions of law as are HMOs. This Department cannot apply statutes that do not apply to ODSs except as specifically required by statute. However, the Department wishes to stress that as part of the review, it will help ensure that an ODS is subject to at least the same level of accountability with respect to its actions.

COMMENT: One commenter stated that N.J.A.C. 11:22-4.7(a), which provides for examinations of the ODS by the Commissioner at the ODS’s expense, should provide for the ability of the Commissioner to retain an independent audit firm to conduct an audit, at the ODS’s expense, when the Commissioner believes that it is warranted.

RESPONSE: Upon review, the Department has determined that no change is required. The scope of any examination will be determined by the Department based on the complexity and issues that may be involved in the particular ODS's business. The Department would not be precluded from utilizing outside consultants to assist it in such examination to the degree it deems necessary.

COMMENT: One commenter stated that N.J.A.C. 11:22-4.10, which provides grounds for suspension or revocation of licensure, should include the failure to honor the patient and provider protections that would be afforded under the Health Care Quality Act, prompt pay legislation, HMO rules, HMO liability law, and other protective measures, as noted in a previous Comment.

RESPONSE: Upon review, the Department has determined not to change this provision. The Department notes that the grounds under N.J.A.C. 11:22-4.10(a) track verbatim the grounds for suspension or revocation under N.J.S.A. 17:48H-23. One of these grounds is failure to comply with N.J.S.A. 26:2S-1 et seq., the Health Care Quality Act. In addition, the determination whether to suspend or revoke could be based "on other reasonable grounds," as noted in N.J.A.C. 11:22-4.10(a)10, reflecting N.J.S.A. 17:48H-23j.

COMMENT: One commenter stated that since the State is taking responsibility for overseeing ODSs, there should be no liability for claims of an ODS on the part of a health plan if the ODS becomes insolvent. The commenter stated that it should be made clear that health plans will have no obligation to pay claims to providers contracting with an ODS licensed under the rules.

RESPONSE: As noted previously, numerous issues may be raised as part of the contract between the ODS and the carrier. For the Department to make a preliminary finding that in no event may a carrier be held responsible for the actions of an ODS, or be required to pay claims to providers contracting with a licensed ODS in any circumstance, would require that the Department make a finding on a complex contractual issue currently not before it that may be subject to court review. The Department believes it would be inappropriate to make such a finding at this time.

COMMENT: One commenter stated that since there will be reserve requirements, there should be a commensurate offset in the reserve requirement of health plans that contract with a licensed ODS.

RESPONSE: There is no requirement that carriers maintain double reserves. Indeed, the concept of a carrier taking credit or offset for risk assumed by a licensed ODS is recognized in the rules at N.J.A.C. 11:22-4.3(b)1ii. However, any credit ultimately allowed will be subject to the Department's analysis of the agreement and the nature of the risk transferred. This is part of the Department's ongoing analysis of a carrier's financial position and statements pursuant to law.

COMMENT: One commenter expressed concern with the timeframes to become licensed. The commenter stated that where an ODS previously received an exemption from licensure, whose exemption was revoked, pursuant to N.J.A.C. 11:22-4.3(b)2, the ODS must obtain licensure within 90 days. The commenter noted that this timeframe is required by statute, but suggested

that it would be more appropriate to provide that the ODS should file for licensure within 90 days. The commenter stated that the Department has at least 60 days, or longer, to approve the application, so it might not be possible for an ODS to complete the process within the time prescribed.

RESPONSE: Upon review, the Department has determined not to change this provision. The timeframe within which an entity whose exemption from licensure has been revoked must obtain licensure is expressly set forth at N.J.S.A. 17:48H-11b. The requirement, therefore, cannot be deleted through administrative rule.

COMMENT: One commenter stated that N.J.A.C. 11:22-4.5(d) should be revised to provide that if no denial is issued within the 90 day time period, the application is deemed approved.

RESPONSE: Upon review, the Department has determined not to change this provision. The intent of the Legislature is to require that entities assuming financial risk from a carrier be licensed and affirmatively approved to engage in such business by the Department in consultation with DHSS. The statute does not provide for a deemer, and the Department believes that the deemer would thwart the intent of the legislation, and would prevent the Department from effective utilization of its resources in the review of these complex applications. The Department notes that N.J.A.C. 11:22-4.5(d) specifically provides that an applicant shall be notified of the decision on an application within 90 days of receipt of a completed application. The Department believes that this addresses the commenter's concern.

COMMENT: One commenter stated that the provisions at N.J.A.C. 11:22-4.5(b)4 and 4.5(e), although identical to the statute, are vague. With respect to N.J.A.C. 11:22-4.5(b)4, the commenter questioned whether the provider agreements are the agreements between the provider and the ODS or agreements between the ODS and the health plan. The commenter also believed that the standard of terms being “acceptable” is vague and that additional criteria should be provided.

Similarly, the provision at N.J.A.C. 11:22-4.5(e) requires that provider agreements shall be referred to DHSS for review in accordance with standards developed by DHSS. The commenter stated that DHSS has not yet published its proposal, and, therefore, there is no way for health plans to know how the rules will fit together. The commenter thus requested that this Department delay adoption of these rules until DHSS publishes its rules for comment.

RESPONSE: With respect to N.J.A.C. 11:22-4.5(b)4, the rule refers to contracts between the ODS and the provider. In reference to concerns regarding the standards of the terms being “acceptable,” the Department reiterates that this reflects verbatim the statutory standard and believes that this is appropriate.

With respect to comments regarding the delay of adoption of the rules until DHSS publishes its rules for comment, the Department reiterates that the standards to be utilized by DHSS in its review, pending adoption of rules by DHSS, may be based on existing standards. The Department believes that delay of adoption of these rules would thwart the legislative intent of having ODSs that assume financial risk subject to licensure and review by the Department.

COMMENT: One commenter expressed concern with certain aspects of the definitions of “organized delivery system” and “financial risk.” The commenter noted that its concerns with respect to the definitions stemmed from the statute. The commenter stated that the definition for ODS uses the phrase “health care services,” while the definition for “financial risk” only uses the terms “services.” As a result, the commenter stated that it is not clear what would be required of an ODS performing only administrative functions for a health plan, rather than working under a contract to provide health care services. The commenter stated that an ODS providing only administrative functions would not be exposed to financial loss. The commenter believed that adding the language “health care” in front of “services” in the definition of “financial risk” would provide additional clarity.

RESPONSE: The Department agrees. The rules have been revised upon adoption to clarify the intent for the reasons expressed by the commenter.

COMMENT: One commenter stated that the requirement that all changes in contracts be submitted to the Department for review under N.J.A.C. 11:22-4.6(c)7 should be revised to require only that material changes be submitted for review. This would reduce burdens both to filers and the Department.

RESPONSE: Upon review, the Department has determined not to change this provision. Requiring only “material changes” to be filed would be problematic in that there is no definition of what would constitute a material change. Review of changes in documents could be expedited if the filer would indicate in the document those areas changed through brackets for deletions,

underlining or boldface for additions, or in some other fashion. The Department believes that this would help reduce the burden to the Department of which the filer is concerned, expedite the review of minimal changes to existing contracts, while ensuring that the Department continues to be fully apprised of all changes to existing agreements and operations with an ODS.

COMMENT: One commenter requested that podiatrists be added to the list of licensed health care providers that provide comprehensive health care services and should be removed from the definition of “limited health care services.” The commenter stated that in the past when podiatrists were listed as ancillary providers, carriers have used this as a justification for discriminating against podiatrists not only in providing the service but in providing reimbursement as well.

RESPONSE: Upon review, the Department has determined not to change this provision. The definitions of “comprehensive health care services” and “limited health care services” track verbatim the statute at N.J.S.A. 17:48H-1. Moreover, the purpose of this distinction does not relate to reimbursement to providers, but reflects the different services that an ODS may provide.

COMMENT: One commenter suggested that N.J.A.C. 11:22-4.5(b)3 be revised to add a requirement that the ODS notify the Commissioner within 30 days if the levels of health care providers, specialists, or hospitals fall beneath the minimum required amount at any time.

RESPONSE: The Department believes that the issue raised by the commenter generally relates to quality of care and would more appropriately be addressed to DHSS, which has the responsibility to determine these areas under the ODS statute.

COMMENT: One commenter suggested that the Commissioner conduct an annual examination of an ODS, with the initial exam being conducted one year after initial licensure.

RESPONSE: Upon review, the Department has determined not to change this provision. The timeframes for conducting an examination are consistent with those mandated by law for insurers. The Department also notes that the rule provides that examinations shall be conducted not less frequently than once every five years, but may be made more frequently if the Department deems necessary. In addition, the Department will be receiving quarterly and annual financial statements from ODSs, which will enable it to monitor an ODS's financial condition. Mandating annual examinations would result in unnecessary additional expense both to the Department and to regulated entities, and would impede the Department's effective use of its resources.

COMMENT: One commenter stated that all entities providing services in this State should be licensed in this State. The commenter apparently alluded to N.J.A.C. 11:22-4.7(b), which provides that where the system is domiciled in another state, and is subject to regulation in a manner substantially similar to that provided under N.J.S.A. 17:48H-1 et seq. and this subchapter, the Commissioner may accept the report of an examination made by that state in lieu of conducting examination under the rules.

RESPONSE: The provisions in the rule track the statute. The rule eliminates the need for duplicate examinations if the entity is already subject to formal examination by its state of domicile and otherwise is subject to comparable requirements.

COMMENT: One commenter suggested that N.J.A.C. 11:22-4.8(i) be revised to require that the involved insurance carrier shall ensure, either with a letter of guarantee, bond, etc., filed with the Department, that it will be responsible for its subcontracted third party administrator's inability to pay for services rendered to consumers. The commenter stated that in the past, there have been instances where an insurer claimed to have paid the third party administrator for services that were provided to consumers, the third party administrator then claimed bankruptcy, and did not pay the provider. Consumers and providers were then left without coverage or payment.

RESPONSE: The Department disagrees with the suggested changes for the reasons substantially set forth in a Response to a previous Comment. The Department believes that the requirements set forth in the statute and these rules are intended to address the concerns raised by the commenter.

COMMENT: One commenter stated that the process is not clear for identifying licensure exemption status following ODS certification by DHSS. Also, when risk is involved, it is not clear if separate application to the Department is required or if additional submissions are needed to follow up the ODS application submitted last year.

RESPONSE: The Department is not clear as to what exemption status would exist following certification by DHSS. These processes are independent. If an entity is not assuming financial risk, it is nevertheless required to be certified by DHSS. Similarly, an ODS that does assume financial risk, but only assumes a *de minimis* risk, would be exempted from licensure, but would be required to obtain certification by DHSS. With respect to the application process, as noted in a response to a previous comment, a separate application is not required. However, updated information reflecting current position should be provided.

Federal Standards Statement

A Federal standards analysis is not required because the adopted rules are not subject to any Federal requirements or standards.

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

11:22-4.2 Definitions

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

...

"Financial risk" means exposure to financial loss that is attributable to the liability of an organized delivery system for the payment of claims or other losses arising from covered benefits for treatment or ***health care*** services other than those performed directly by the person or organized delivery system liable for payment, including a loss sharing arrangement. A payment method wherein a provider accepts reimbursement in the form of a capitation payment for which it undertakes to provide health care services on a prepayment basis shall not per se be considered financial risk. A financial risk shall exist if, under an agreement between the organized delivery system and the carrier, the financial obligations of the organized delivery system for payment of benefits or for providing treatment or ***health care*** services does or potentially may exceed any payments that may be received from the carrier. Financial obligation shall include the attendant administrative costs related to providing the treatment or services.

...

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

1. (No change from proposal.)
2. Is organized for the purpose of acting on behalf of a carrier, directly or indirectly, 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. This shall include any agreement to subcontract any separate ***health care*** service or benefit, unless expressly excluded herein.

An organized delivery system shall not include:

1. – 3. (No change from proposal.)

11:22-4.3 License requirement

(a) An organized delivery system that receives compensation on a basis that entails the assumption of financial risk shall submit an application for licensure to the Commissioner.

1. This subchapter shall apply to any contract renewed on or after ***[the effective date of this subchapter]* *October 21, 2002***. Notwithstanding the obligations imposed by N.J.S.A. 17:48-1 et seq. and this subchapter regarding licensure requirements, nothing in this subsection shall operate to impair any contract in force as of ***[the effective date of this subchapter]* *October 21, 2002*** for a period not to exceed 24 months.

(b) An organized delivery system that receives compensation on a basis that entails the assumption of financial risk, but meets the criteria set forth in this subsection, may apply to the Commissioner for an exemption from the licensure requirements based on the system's current contractual arrangements. Any organized delivery system seeking an application for exemption shall file the information set forth in Exhibit A in the Appendix to this subchapter, incorporated herein by reference, with a non-refundable filing fee in the amount of ***[\$2,500]* *\$1,000***, payable to the Treasurer, State of New Jersey.

1. - 2. (No change from proposal.)

- (c) - (d) (No change from proposal.)

11:22-4.8 Net worth, deposits and bonds

(a) - (c) (No change from proposal.)

(d) *[Funds]* ***Except for payment of benefits under the contract, including attendant administrative expenses, funds*** in the segregated account, which fair market value, together with that of other amounts withdrawn from the segregated account within the immediately preceding 12 months, that exceeds 10 percent of the total net worth of the segregated account as of December 31 immediately preceding, shall not be withdrawn except upon 45 days prior written notice to the Commissioner, and the withdrawal has not been disapproved prior to the expiration of the 45 day period. Notice of intent to withdraw monies shall contain the information and be in the format of Exhibit C in the Appendix to this subchapter, incorporated herein by reference. In no event may the net worth of the segregated account fall below the minimum net worth requirement set forth in (a) above.

(e) - (i) (No change from proposal.)

11:22-4.12 Confidentiality

(a) Any data or information relating to the diagnosis, treatment or health of an enrollee, prospective enrollee or contract holder obtained by a *[certified or]* licensed organized delivery system from the carrier, contract holder, enrollee, prospective enrollee or any provider shall be confidential and shall not be disclosed to any person except as provided by N.J.S.A. 17:48H-30.

(b) (No change from proposal.)