

STATE REGULATION OF DOWNSTREAM RISK UNDER MANAGED CARE PLANS: CAN NEGOTIATED RULEMAKING WORK?

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Under Managed Care Health plans, a variety of health care provider organizations have entered into contractual arrangements with the plan to provide services to plan members. These provider organizations include physician hospital organizations, consolidated physician practice groups, and a wide variety of affiliated health care providers. Under some of these arrangements, the health care providers assume, directly or indirectly, substantial financial risk. The nature of the financial risk also varies greatly, including the acceptance of a predetermined monthly payment - a capitation - in exchange for agreeing to provide all reasonably necessary medical services required by plan members who are patients of the health care provider. The risk can also be a “back-end” risk-sharing arrangement, wherein the provided group receives interim payments from the plan or from self-insured employer groups, subject to a year-end reconciliation against a medical expense target. In these arrangements, the provider group can be placed “at-risk” for a “corridor,” expressed as a maximum percentage amount in excess of the medical expense target that actual medical expenditures amount to for a given plan year. There are also per diem, global capitation, and a variety of other risk arrangements currently in place around the country.

The NAIC and some of the insurance departments of the 50 states have been closely examining the nature of these risk arrangements to develop appropriate regulations and safeguards to protect the public interest of those employers, employees and their dependents who purchase health care coverage through health plans or self-insured employer groups.¹

The State of Maine has this year considered legislation, L.D. 2029, which would amend the Preferred Provider Arrangement Act and the Maine HMO Act² to provide a statutory definition of “downstream entities,” and would impose significant new requirements on health plans that contract with such entities to provide health care services.³ A “downstream entity” is defined by the legislation as an entity other than a duly licensed insurance carrier that has assumed all or part of the insurance risk of one or more health benefit plans under a contractual relationship with a carrier or another downstream entity.⁴ A broad coalition, including the Maine HMO council, the major health maintenance organizations doing business in Maine, the Maine Hospital Association, and the Maine Medical Association have presented numerous concerns about the nature, scope, and breadth of these new requirements.⁵ The Maine Legislature has recently voted to hold over this legislation until next year’s session in order for the extensive group of interested parties to have an opportunity to explore the impact with the Maine Bureau of Insurance and address the concerns expressed to date about the structure and content of this legislation.

In essence, L.D. 2029 would impose significant legal and financial obligations upon insurance carriers, health maintenance organizations, and health benefit plans to guarantee continuity of health care services for enrollees of the plan and to insure that numerous contractual provisions, discussed below in greater detail, would be included in any agreement between the plan and the downstream risk entity. In addition, the legislation imposes filing requirements with regard to specimen contracts, risk arrangement details, and financial and other books and records disclosures by any health care provider group that constitutes a “downstream entity.” Taken together, these provisions could be considered a first step toward developing solvency standards and related regulatory requirements that could be developed in the future to protect the public interest of employers, employees and their dependents enrolled in plans contracting with such downstream risk entities to obtain their medical care and related services. A number of other states have considered or will be considering similar legislation. The issues are complex and highly charged politically, and developing any appropriately balanced set of regulatory requirements in this area will be difficult.

L.D. 2029 would not impose solvency standards upon downstream risk entities. The legislation would, however, create a presumption that a downstream entity must be licensed as an insurer or as a health maintenance organization, but that an appropriately licensed health benefit plan (referred to as a “carrier” in the legislation) could obtain a waiver from such licensure requirements when the downstream entity has entered into a contract with the carrier to provide health care services under arrangements where the downstream entity would be accepting a limited degree of insurance risk.⁶ The legislation expressly states that parties to preferred provider arrangements may only receive capitated payments from

a carrier for providing health care services to the extent authorized by these new provisions, and that any other transfer of insurance risk to such an entity would constitute the unauthorized transaction of insurance.⁷ The legislation would impose the ongoing obligation upon the carrier to its subscribers for the delivery of health care benefits and the quality of services provided. The carrier would also remain responsible for compliance with all applicable laws.⁸ The downstream entity may only assume risk within the terms of the waiver granted by the Superintendent of Insurance. The downstream entity may assume risk from more than one carrier only if a separate waiver has been granted to each carrier.⁹

A financial arrangement may not contain incentives for the downstream risk entity or participating provider to limit or deny medically necessary care to individual subscribers.¹⁰ Each carrier receiving one or more waivers pursuant to this subchapter must file with the Superintendent a plan for managing its financial exposure under those contracts and remain in substantial conformance with the terms of that plan. At least sixty days before any material change in a filed and approved exposure management plan, the carrier shall file for the Superintendent's review and approval a modified plan, along with any changes in its standard contracts.¹¹ A waiver from certificate of authority requirements granted pursuant to the legislation would not exempt the downstream entity from any other licensure or prior approval requirements applicable to the kinds of activities conducted by the entity, including but not limited to, utilization review licensure, insurance administrator licensure or preferred provider arrangement registration.¹²

The legislation proposes that the Superintendent adopt rules to establish application procedures and specific standards for waivers granted and exposure management plans filed pursuant to the legislation. The Superintendent may develop financial and other criteria to establish model contractual language that a carrier may use in a generic filing.¹³

The Superintendent may not issue a waiver until the carrier has demonstrated that its contractual arrangement with the downstream entity is sufficient to insure adequate consumer protection, the financial solvency of the downstream entity and its ability to provide health care services on a continuing basis, and the ability of the Superintendent to regulate the downstream entity indirectly through the carrier.¹⁴ In determining whether to grant a request for a waiver, the Superintendent shall consider a variety of contractual provisions specified in the legislation.¹⁵ These include:

- A. Hold harmless provisions providing that the enrollee will not be liable to the provider for any sums owed by the carrier in the event that the carrier fails to pay for the health care services as set forth in the contract;
- B. A provision for the maintenance of books, accounts and records by the downstream entity and the carrier to insure that transactions, including the risk transfer, are clearly, accurately, and completely disclosed;
- C. Appropriate terms permitting the carrier to insure the financial viability and condition of the downstream entity through the term of the contract, including one or more of the following:
 1. A provision authorizing the carrier to access the downstream entity's books, accounts, and records according to terms and conditions on which the carrier and the downstream entity agree;
 2. A provision requiring the downstream entity to provide the carrier with interim unaudited financial statements on a regular and ongoing basis as well as an annual audited financial statement;
 3. A provision authorizing the carrier to receive information regarding the downstream entity's reserves;
 4. A provision for the downstream entity to post a letter of credit or other acceptable financial security;
 5. A provision under which the carrier withholds fees payable to the downstream entity;
 6. A provision for the downstream entity to carry general liability insurance and for participating providers to carry professional liability insurance that is mutually acceptable to the carrier in an amount and from a carrier that is mutually acceptable to the carrier and the downstream entity;

7. A provision for the downstream entity to secure a surety bond to cover the downstream entity's performance under the contract; or
 8. A provision for the downstream entity to secure "excess of loss" insurance in an amount and from another carrier that is mutually acceptable to the carrier and the downstream entity.
- C. A provision prohibiting the assignment of any rights or obligations under the contract in the absence of the consent of the carrier;
- D. A provision granting the carrier the right to be advised of and the right to object to any subcontractor with whom the downstream entity proposes to contract with respect to services required to be performed by the downstream entity under its contract with the carrier;
- E. A provision for the termination of the contract, including consideration of whether the carrier has the right to immediately terminate the contract upon a valid order issued by the Superintendent or another lawful authority;
- F. A provision setting forth circumstances under which the carrier may institute a financial monitoring plan of the downstream entity;
- G. A provision requiring the downstream entity to comply with utilization review, third party administrator or other licensing requirements triggered by the functions it has contracted to undertake on behalf of the carrier;
- H. A provision requiring the downstream entity to timely advise the carrier of relevant matters that may have a material effect on the downstream entity's ability to perform under the contract, including, but not limited to:
1. Whether the downstream entity or participating provider is subject to an administrative order, a cease and assist order, a fine or license suspension; and
 2. Whether legal action has been taken that may have a material effect on the downstream entity's financial condition or the downstream entity's ability to perform under the contract.
- I. The legislation would also impose significant limitations on the extent to which risk could be transferred from the carrier to these downstream entities.¹⁶ Specifically, the Superintendent may deny a request for waiver based on any of the following characteristics:
1. A contract by which 30% or more of the carrier's annual aggregate premium is transferred to a single downstream entity;
 2. Multiple contracts by which 75% or more of the carrier's annual premium is transferred to one or more downstream entities;
 3. A contract with the downstream entity that has "control" of the carrier, as defined in 24-A M.R.S.A. § 222(2)(B) (the Maine Insurance Holding Company Act);
 4. A contract by which the claims processing, claims payment or claims adjudication functions are transferred to the downstream entity from the carrier. Nothing in this provision may be construed to authorize the Superintendent to deny a request based on the transfer of utilization and review functions from the carrier to the downstream entity;
 5. A contract by which managerial control of the carrier's information system is transferred to the downstream entity;
 6. A contract in which there is an overlap between the officers or directors of the downstream entity and the carrier; or

7. A contract that transfers more than 1/12th of the annual capitated payments at one time to the downstream entity.

Finally, this legislation contains a transition provision that would require all carriers with existing downstream risk transfer arrangements, within 90 days after the effective date of the enactment of the legislation, to file applications for waivers from licensure with the Superintendent of Insurance consistent with the requirements of this proposed legislation. The Superintendent may grant waivers on a provisional basis, retroactive to the effective date of the Act, while a full review of the application is pending. Any arrangement in which the Superintendent expressly approves the risk transfer before the effective date of this Act would be deemed approved if the carrier files an exposure management plan within 90 days after the effective date of the Act. The Superintendent may rescind or modify any waiver granted pursuant to this section if the downstream risk arrangement is not in compliance with the requirements of this Act or if the carrier does not provide the Superintendent with the information necessary to determine whether the arrangement is in compliance with the requirements of the Act.

A similar set of issues has been addressed recently at the federal level by the Health Care Financing Administration (HCFA) with respect to developing provider-sponsored organization solvency standards in relation to the Medicare+Choice Program.¹⁷ Under this program, Medicare beneficiaries may elect to receive Medicare health care benefits through Medicare+Choice managed care plans, including plans offered by provider-sponsored organizations (PSO's). The Act defines a PSO as "a public or private entity that (1) is established or organized, and operated, by a health care provider or group of affiliated health care providers; (2) that provides a substantial proportion . . . of the health care items and services . . . directly through the provider or affiliated group of providers; and (3) with respect to which the affiliated providers share, directly or indirectly, substantial financial risk with respect to the provision of such items and services, and have at least a majority financial interest in the entity."¹⁸ The Medicare+Choice Program requires that the PSO, to participate in the program, must be organized and licensed under state law as a risk-bearing entity eligible to offer health insurance or health coverage, unless the PSO qualifies for a waiver.¹⁹

The Balanced Budget Act of 1997 mandated that HCFA establish solvency standards for PSO's under the Medicare+Choice Program through a negotiated rulemaking process.²⁰ A wide variety of interested groups participated in this process, including the American Hospital Association, the American Medical Association, the Association of American Health Plans (AAHP), the American Association of Retired Persons, the National Association of Insurance Commissioners, the Blue Cross/Blue Shield Association, and the Federation of American Health Systems. HCFA was aware of the need to balance the providers' desire for minimal solvency requirements and to avoid using these regulatory requirements to thwart competition from provider-based managed care entities, with the health plans' desire that PSOs be regulated on an equal playing field with HMOs.²¹ In its Notice of Intent to Form a Negotiated Rulemaking Committee published on September 23, 1997, HCFA set forth a list of "fundamental questions about solvency standards and definitions, threshold questions, overarching policy issues, and specific issues identified by Congress for consideration."²²

In short, the negotiated rulemaking process resulted, on March 5, 1998, in a consensus among the participating interested parties. All committee members signed an agreement indicating unanimous concurrence with the committee's written recommendations for PSO solvency standards. As part of the agreement, HCFA agreed that, to the maximum extent possible and consistent with legal obligations, it would release an interim final rule on PSO solvency standards consistent with the committee's statement.²³

It is beyond the scope of this article to explore in detail the components of these solvency standards. In essence, the interim final rule imposes minimum net worth requirements, cash flow requirements, and protections from insolvency for beneficiaries under PSO-sponsored health plans. For the initial application phase of a PSO, the minimum net worth requirement has been set at \$1,500,000, with HCFA having the discretion to reduce this amount by up to \$500,000 if the PSO has an infrastructure appropriate to reduce, control or eliminate start-up administrative costs.²⁴ HCFA will consider such factors as the availability of office space and equipment, computer systems, software, management services contracts, and personnel recruitment fees.²⁵

For the ongoing/operational phase, the minimum net worth requirement is \$1,000,000.²⁶ An additional "trigger point," that is, a point where a state regulator is authorized to take control of the PSO, is also being considered by the

committee. The committee has reviewed the NAIC's Risk-Based Capital Model. Under this Model, a state's Insurance Commissioner may take control of an organization if its actual net worth falls below a trigger point, called the "authorized control level."²⁷

Minimum cash flow requirements have been imposed on PSOs to ensure that these organizations have the resources to meet projected losses on their balance sheets in cash or a form readily convertible to cash in a timely manner.²⁸ The committee agreed to allow PSOs to use guarantees, letters of credit, and other specified means to pre-fund projected losses provided detailed requirements are met. Guarantees are an acceptable resource to fund projected losses, provided HCFA approves the PSO's request to use a guarantor, the guarantor and guarantee documents meet HCFA's requirements, and the PSO timely obtains from the guarantor cash or cash equivalents to fund projected losses. The final interim rule also imposes certain cash flow requirements at both the application and ongoing stages and that the same factors be considered for determining liquidity at both stages. These factors include the timeliness of PSO payments of obligations, the extent to which the current ratio is maintained at 1:1 or whether there is a change in the current ratio over time, and the availability to a PSO of outside financial resources to meet its obligations. In short, the interim final rule requires a PSO to have sufficient cash flow to meet its financial obligations as they become due.²⁹

With regard to beneficiary protections against insolvency, the committee decided that a PSO should make an insolvency deposit of \$100,000, provided that the cash portion of the minimum net worth standard be set at an amount no lower than \$750,000.³⁰ There are other insolvency protection requirements contained in the interim final rule that are beyond the scope of this article.

Overall, according to at least one set of commentators, it appears that the Medicare+Choice solvency standards adopted for PSOs will protect consumers against insolvency and will prevent inflation of public expenditures under this program.³¹ Some have cautioned that this program does little to encourage the creation of PSOs, which is borne out by the fact that as of September 1998, HCFA had received only three applications from PSOs to participate in the Medicare + Choice program.³² Nonetheless, the negotiated rulemaking process in this case suggests that a similar approach could be effective in bringing consensus among the interested parties in the various states and still achieve the public interest in defining downstream risk entities and in imposing reasonable and appropriate regulatory requirements. This is particularly true given the complexity of the issues and the multiplicity of interested parties, groups, and associations involved.

Turning back to the downstream risk legislation currently pending in Maine, it is clear that when compared with the negotiated rulemaking process under the Medicare+Choice Program and the corresponding development of PSO solvency standards, the process of understanding and appropriately regulating the nature of downstream risk in Maine is still in its infancy. The Maine Bureau of Insurance has concerns that health maintenance organizations, health plans, and certain provider groups have "gotten out ahead" of the regulatory process, and that the public interest – covered persons under insured and self-insured plans – is not sufficiently protected from the possibility that a downstream entity might become insolvent, rendering it unwilling or unable to provide services as a result of financial losses under downstream risk arrangements.

L.D. 2029 is a first attempt in Maine to obtain financial information and impose contractual language requirements upon HMOs, insurance carriers, and health plans with respect to their arrangements with downstream risk entities. There is no clear result yet in Maine as to how such entities will be defined, the extent to which they will be required to obtain licensure from the Maine Bureau of Insurance, or the extent to which they might seek waivers to any such licensure requirement in connection with contractual arrangements with insurance carriers, managed care health plans, and HMOs. The experience on the national level of the Medicare+Choice negotiated rulemaking process to develop provider sponsored organization solvency standards suggests that, while not perfect, a negotiated rulemaking process where all directly affected parties work with the regulators can be effective in reaching consensus on these difficult and complex issues.

It is interesting to note that the Maine Legislature is also considering a bill to ensure that state agencies use collaborative decision-making and a stakeholder process that is fair and consistent with the goals of the Maine Administrative Procedure Act.³³ Absent effective collaboration between state regulators and state hospital and medical associations, state councils of health maintenance organizations, and the health insurers doing business in the states, it is uncertain

that appropriate regulatory legislation of downstream risk entities can be enacted. The experience to date in Maine reflects that, since this is such a complex area with so many affected interested groups with substantial political influence, there will not be sufficient legislative support to enact such requirements absent some reasonable degree of collaboration and consensus building through some form of negotiated legislation and rulemaking process.

Endnotes

1. One example of this regulatory analysis is the work of the NAIC Risk-Based Capital Task Force, Health Organizations Risk-Based Capital Working Group.
2. *See* 24-A M.R.S.A. § 2670 et seq. (Maine Preferred Provider Arrangement Act); 24-A M.R.S.A. § 4201 et seq. (Maine Health Maintenance Organization Act).
3. 119th Maine Legislature, First Regular Session - 1999, Legislative Document 2909, An Act to Update and Amend the Preferred Provider Arrangement Act. In addition to incorporating downstream risk arrangements under the regulatory jurisdiction of the Maine Bureau of Insurance, the legislation would add geographic accessibility standards for preferred provider arrangements (“PPA’s”) consistent with those of health maintenance organizations, require these arrangements to generate annual reports, and require PPA’s that handle money to be licensed as a third party administrator pursuant to Chapter 18 of the Maine Insurance Code.
4. L.D. 2029 Subchapter III, § 4331(1).
5. The Maine HMO Council has expressed numerous concerns with L.D. 2029 as drafted, ranging from requests to clarify the definition of a “downstream entity,” to “grandfather” existing downstream risk arrangements, and to clarify the overall standards to appropriately protect consumer interests. Moreover, healthcare providers have raised concerns about the proposed requirement that they turn over financial books, accounts, and records to the carrier. Similar concerns have been voiced with regard to the requirement that audited financial statements be provided to the carriers by the downstream entities. Finally, questions have been raised regarding the reasonableness of the “transfer of risk” standards proposed in the legislation.
6. L.D. 2029 § 4332(1).
7. L.D. 2029 § 2676.
8. *Id.* § 4332(2).
9. *Id.* § 4332(3).
10. *Id.* § 4332(4).
11. *Id.* § 4332(5).
12. *Id.* § 4332(6).
13. *Id.* § 4332(7).
14. *Id.* § 4333.
15. The contractual provisions designated by the legislation appear at L.D. 2029, §§ 4333(1)-(10), which have been set forth in their entirety in the text of this article.
16. The so-called “limitations on risk transfer” appear in the legislation at §§ 4334(1)-(7).

17. The Medicare+Choice program provisions can be found at 42 U.S.C. §§ 1395w-(21)-(28)(Supp. II 1996). This program was created under the Balanced Budget Act of 1997 (“BBA”) as part of Part C of Title 18 of the Social Security Act. 1997 Pub. L. No. 105-33 § 4001-06, 111 Stat. 271.
18. 42 U.S.C. § 1395w-25(d).
19. *Id.* § 1395w-25(a)(1) & (2).
20. *Id.* § 1395w-26(a)(1)(A) (Supp. II 1996).
21. *See generally*, Michael O. Spivey and Jeffrey G. Micklos, “Developing Provider-sponsored Organization Solvency Standards Through Negotiated Rulemaking,” 51 Administrative Law Review, No.1 (Winter 1999), at pages 261-282. This article provides an outstanding overview of the negotiated rulemaking process and a detailed analysis of the substantive issues involved in the development of PSO solvency standards for the Medicare+Choice program.
22. Medicare Program; Solvency Standards for Provider-Sponsored Organizations; Intent to Form Negotiated Rulemaking Committee, 62 Fed. Reg. 49, 649, 49, 651-53 (1997).
23. *See* M. Spivey and J. Micklos, *supra* at page 268n.40, quoting “Negotiated Rule Making Committee on PSO Solvency Standards, Minutes of March 5, 1998 Meeting.”
24. 42 C.F.R. § 422.382(a)(2). The \$1,500,000 requirement is the same as the solvency requirements contained in the Health Maintenance Organization Model Act which was developed by the National Association of Insurance Commissioners (NAIC).
25. Waiver Requirements and Solvency Standards, 63 Fed. Reg. at 25,365.
26. This is the same minimum amount specified in the NAIC HMO Model Act for the ongoing stage.
27. *See* Medicare Program; Waiver Requirements and Solvency Standards for Provider-Sponsored Organizations; Final Rule, 63 Fed. Reg. 25, 360, 25, 366 (1998). The authorized control level is a function of the riskiness of the company’s assets, investments, and products. However, this RBC formula has not yet been adopted and implemented by the states. As a result, the committee recommended that HCFA consider adding the RBC authorized control level to the PSO solvency standards after evaluating whether the RBC is a valid indicator of PSO solvency.
28. 42 C.F.R. § 422.384(d)(1997).
29. 42 C.F.R. § 422.386(a)(1997).
30. Medicare Program; Waiver Requirements and Solvency Standards for Provider-Sponsored Organizations; Final Rule, 63 Fed. Reg. 25, 360, 25, 368 (1998).
31. *See generally* M. Spivey and J. Micklos, *supra* at 278-82.
32. *Id.* at p.281.
33. 119th Maine Legislature, First Regular Session, 1999, Legislative Document 2131. This legislation recognizes that a number of state agencies have been engaging in a so-called “stakeholder rulemaking process” under the Maine Administrative Procedures Act, 5 M.R.S.A. § 8001 et seq. and that each such agency should adopt procedural rules for those processes. These procedural rules must address the appropriateness of a particular policy which is suitable for a negotiated rulemaking process, the ability of all stakeholders to participate, provision for a mutually acceptable neutral facilitator, and creation of a written record of all such negotiated proceedings. L.D. 2131 § 8005 (1)-(3).

The Division of Administrative Hearings within the Department of Labor is to develop model procedural rules to govern the stakeholder rulemaking process in the State of Maine.