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Regulating Risk in a Managed Care Environment: Theory vs. Practice, The Minnesota Experience

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Abstract
The purpose of this Article is to illustrate the challenges state regulators face when attempting to translate theory into practice in the context of health care risk regulation. Section I reviews the evolution of the risk-bearing market in health care, recognizing that while risk is an inherent part of everyday life, it takes on a delicate meaning when used in the context of health care. Cost and demographic data will be discussed to provide a compelling rationale for the ongoing forceful movement toward cost containment strategies embodied in managed care strategies, as well as the need to develop the next generation of risk-bearing entities. Sections II and III provide an overview of state health care regulation and an examination of Minnesota's regulatory experience. Sections IV through VII detail the emergence and ongoing development of direct contracting strategies.

Throughout this Article, strategies will be reviewed from both a theoretical and practical perspective. These experiences can teach valuable lessons and underscore the challenges inherent in translating theory into practice, and the obvious, yet unwilling tradeoffs that are necessary to truly reform the health care regulatory infrastructure. The Article will conclude with a set of guiding principles that should be considered by state regulators in the development and oversight of new and emerging risk-bearing entities.

Keywords
Health insurance--Minnesota, Consumer protection--Minnesota

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Insurance Law | Medical Jurisprudence

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*Barbara C. Colombo and Robert P. Webber**

INTRODUCTION

As the twentieth century draws to a close, it seems fitting to take a collective step back and examine the triumphs and struggles that illustrate the last one hundred years. Health care is certainly no exception. For the better part of this century, the private sector health care delivery system presented a relatively uncomplicated, stable picture. The *patient*, complaining of some sort of *ailment*, sought *curative* medical care from the family *doctor,* who was fully reimbursed for each and every service provided. The last ten years, however, have made up for this relatively uneventful past with health care reform proposals and regulatory changes occurring at a dizzying pace.

Today, the health care delivery system is anything but uncomplicated. Now, the *consumer* receives a *predetermined set of benefits,* oftentimes with a *preventive* focus, which may or may not emanate from regulatory mandates, delivered through a network of health care *providers*, including, but rarely limited to, physicians, who are compensated through a variety of complicated reimbursement schemes. This new and evolving health care system is a work in progress and continues to provoke a wide range of debate at both the state and federal level.

Minnesota has certainly contributed to the evolution of this system and is recognized as one of the most dynamic markets in the country, at times referred to as "the land of ten thousand examples." One clear and inevitable byproduct of Minnesota's evolving market has been a growing level of apprehension, confusion and frustration among some health care consumers.

These concerns do not stop at Minnesota's borders, however. Indeed, the national media would suggest that consumer dissat-

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isfaction with the United States' health care system is at an all-time high.[1] Popular opinion continues to be concerned about consolidation, compromises in quality and lack of provider choice.

Consumer dissatisfaction is predictable if one considers society's long-standing and irreconcilable expectations of health care: unlimited freedom of choice and the highest quality in health care. Although unwilling to pay the necessary price, Americans support and believe they deserve universal coverage because any other position would be politically distasteful. The vast majority of Americans view health care as an entitlement, similar to, and no less deserved, than education. Such comparisons are not only inaccurate, but lead to an ever-expanding gap between expectations and reality.

As a result, national health policy is at a crossroads. The health care system must either undergo a fundamental metamorphosis, abandoning a market-driven system for one in which services are available for all and guaranteed by the government through aggressive taxation, or consumers must adjust their expectations to more closely match the limitations that are necessarily a part of reality. This conclusion does not suggest that aspirations of mediocrity are desirable, but that economic, political and practical constraints of the health care system must factor into any meaningful debate.

Consumers are not alone in their dissatisfaction with the health care system. Providers sense limitations in their freedom to practice medicine, looming financial pressures imposed by managed care, and a general concern about corporate and government intrusion into the patient-provider relationship. Employers are also experiencing unprecedented challenges. With unemployment at some of the lowest rates ever, prospective employees often may choose among multiple attractive offers. Clearly, employee benefit packages that include health care coverage can be highly influential.

1. *See, e.g.*, Sandra G. Boodman, *"The High Price of Health" Traces Managed Care's Rise; PBS Show Looks at Quality and Accountability*, WASH. POST, Apr. 14, 1998 (describing a PBS documentary characterizing HMOs in an extremely negative fashion); Louise Kertesz, *Backlash Continues: Survey Finds Managed Care Is Still the Bad Guy in Many Americans' Eyes*, MOD. HEALTHCARE, Nov. 10, 1997, at 33; Susan Brink & Nancy Shute, *Are HMOs the Right Prescription?*, U.S. NEWS & WORLD REP., Oct. 13, 1997, at 60; Norman Ornstein, *HMO's Rightful Credo: No Pain, No Gain*, USA TODAY, Mar. 24, 1997, at 15A; Edward Dolnick, *Death by HMO—One Woman's Horror Story*, GLAMOUR, Feb. 1996, at 158 (all of these articles describe by anecdote the criticisms of HMOs and managed care).

In view of these wide-ranging concerns, elected officials have come under intense pressure to create new health care strategies and to do so in short order. In the end, the state regulator is left with the unenviable task of implementing the reform strategy of the week, one which can often be characterized as well intended, but ill conceived, and either potentially in conflict with existing law, or simply impractical.

The purpose of this Article is to illustrate the challenges state regulators face when attempting to translate theory into practice in the context of health care risk regulation. Section I reviews the evolution of the risk-bearing market in health care, recognizing that while risk is an inherent part of everyday life, it takes on a delicate meaning when used in the context of health care. Cost and demographic data will be discussed to provide a compelling rationale for the ongoing forceful movement toward cost containment strategies embodied in managed care strategies, as well as the need to develop the next generation of risk-bearing entities. Sections II and III provide an overview of state health care regulation and an examination of Minnesota's regulatory experience. Sections IV through VII detail the emergence and ongoing development of direct contracting strategies.

Throughout this Article, strategies will be reviewed from both a theoretical and practical perspective. These experiences can teach valuable lessons and underscore the challenges inherent in translating theory into practice, and the obvious, yet unwilling tradeoffs that are necessary to truly reform the health care regulatory infrastructure. The Article will conclude with a set of guiding principles that should be considered by state regulators in the development and oversight of new and emerging risk-bearing entities.[2]

I. The Evolution of the Health Risk-Bearing Market

A. The First Generation

For most of this century, health care services were provided through a traditional fee-for-service system.[3] Physicians, acting

2. This article is not meant to be an exhaustive, fifty-state study of risk regulation, but considers one state's regulatory approach to risk-bearing health care entities.

3. A fee-for-service medical system is one where "patients, sometimes directly, but more often through their employers, purchased indemnity insurance plans that reimbursed physicians retrospectively for care on a fee-for-service basis." *See* Stephen R. Latham, *Regulation of Managed Care Incentive Payments to Physicians*, 22 Am. J. L. & Med. 399, 399-400 (1996) (describing the traditional fee-for-service system and the financial incentives for physicians that encouraged excessive treatment).

largely on their own and on behalf of their patients, determined the manner and extent to which health care services were provided.[4] They submitted their bills to the insurance company, and the company paid the bills.[5] This system went on unchecked for years because payers, often employers, demanded little, if any accountability.

The fee-for-service system survived virtually unchallenged until after World War II. Over time, however, the costs of this system began to rise considerably and became subject to greater scrutiny.[6] Unfortunately, few incentives existed for physicians to control costs.[7] The payment structure lacked a cost-control incentive, and new technology and new drugs accelerated the rising cost of health care.[8]

Many observers considered the fee-for-service system to be a recipe for disaster, given escalating costs, capital-intensive technology, and an aging population. Employers in particular began to assume a more aggressive posture as a purchaser of health care, expecting not only accountability but aggressive cost containment strategies.[9] Using classic entrepreneurial creativity, employers sought alternatives to the costly, fee-for-service system, recognizing the desire to maintain high quality care for their employees, but also the need to control costs. It was out of this clear mandate to control costs that the concept of managed care emerged.[10]

For more information on the fee-for-service system and the move to managed care, see PAUL DEMURO, MANAGED CARE AND INTEGRATED DELIVERY SYSTEMS 1-4 (1995); *see also infra* notes 32 to 38 and the accompanying text.

4. *See* Latham, *supra* note 3, at 400.

5. *See id.*

6. *See* Eleanor D. Kinney, *Procedural Protections for Patients in Capitated Health Plans*, 22 AM. J. L. & MED. 301, 302-07 (1996) (describing in more detail the rise of managed care in the face of accelerating health care costs).

7. *See* Latham, *supra* note 3, at 400.

8. *See* Michael E. Chernew, et al., *Managed Care, Medical Technology, and Health Care Cost Growth: A Review of the Evidence*, 55 MED. CARE RES. & REV. 259 (1998).

9. While numerous stakeholders would contribute to health care reform efforts, including physicians, policy makers, regulators and consumers, employers demonstrated unique leadership in promoting change.

10. Managed care is a term to describe a broad set of strategies, including copayments, deductibles, utilization review, prior authorization and gatekeepers, all designed to contain costs. *See* Latham, *supra* note 3, at 400. *See also* MINN. DEP'T OF HEALTH, COMMONLY USED HEALTH CARE TERMS GLOSSARY FOR CONSUMERS (1997) (defining managed care as "a system to integrate the delivery and financing of comprehensive health care services to covered individuals by means of arrangements with selected health care providers; explicit criteria for the selection of health-care providers; significant financial incentives for members to use providers and procedures associated with the plan; and formal programs for quality assurance and utiliza-

The Health Maintenance Organization ("HMO") became the most prevalent and aggressive embodiment of managed care and represented the first true risk-bearing health care delivery system.[11] By combining health care delivery and financing, the HMO promised to maintain high quality care while creating incentives to control costs.[12] Early proponents of this model suggested that in addition to controlling costs, HMOs would greatly *improve* the quality of care by reducing unnecessary, potentially harmful medical procedures, including unnecessary surgery or excessive drug prescription.[13]

Critics of the HMO model, however, now warn that the very same incentives designed to control costs either inadvertently or purposely promote under-utilization, placing patients at risk of receiving too few services.[14] Critics today argue that HMOs have created a system in which health care decisions are not ex-

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tion review. Providers of managed care include health maintenance organizations ("HMOs") and preferred provider organizations ("PPOs"), as well as traditional insurance companies.").

11. An HMO "takes fixed periodic payment from its enrollees; in return it provides for the financing and delivery of their medical services for a fixed period of time." *See* Latham, *supra* note 3, at 400. There are various kinds of HMOs. Among the most common are the staff model, the group model, and the Individual Practice Association ("IPA") model. A staff model HMO directly employs physicians who provide services to members on an outpatient basis. Staff model physicians are typically paid a salary with bonuses for productivity. A group model HMO is an entity that contracts with a multi-specialty group of physicians for services for its members. The physicians are generally paid a fixed amount per patient, and the group divides the monies between the physicians. The IPA model HMO is similar to a group model. It contracts with an IPA, which is a group of independent practitioners who see non-HMO patients in addition to HMO patients. The IPA is typically paid by the HMO on a per patient or capitated basis, and the physicians are reimbursed by the IPA on either a fee-for-service or capitated basis. Numerous other HMO models exist, and the entities are often only limited by the creativity of their founders. NATIONAL ASSOC. OF INSURANCE COMMISSIONERS ("NAIC") WHITE PAPER, THE REGULATION OF HEALTH RISK-BEARING ENTITIES, I-9 (1997) [hereinafter "NAIC White Paper"]. For more information about capitation, *see infra* note 38 and the accompanying text.

12. *See* Robert T. Holley & Rick J. Carlson, *The Legal Context for the Development of Health Maintenance Organizations*, 24 STAN. L. REV. 644, 649-53 (1972); *see also* Philip C. Kissam & Ronald M. Johnson, *Health Maintenance Organizations and Federal Law: Toward a Theory of Limited Reformmongering*, 29 VAND. L. REV. 1163, 1175-78 (describing arguments made by early HMO proponents).

13. *See* Holley *supra* note 12.

14. *See, e.g.*, Henry T. Greely, *Direct Financial Incentives in Managed Care: Unanswered Questions*, 6 HEALTH MATRIX 53, 69-70 (Winter 1996); *see also* David Orentlicher, *Paying Physicians More to Do Less: Financial Incentives to Limit Care*, 30 U. RICH. L. REV. 155, 161 (1996); *see also* Alan L. Hillman, *Financial Incentives for Physicians in HMOs: Is There a Conflict of Interest?*, 317 NEW ENG. J. MED. 1743, 1747-48 (1987) (all of these articles discuss the potential for under-utilization under managed care).

clusively based on what is in the best interest of the patient, but are unduly influenced by a corporate balance sheet, resulting in the rationing of limited resources.[15] Despite the strong reservations held by many about the ethical framework of the HMO model, its popularity among purchasers is now undeniable.[16]

B. The Need for Next Generation Risk-Bearing Models

Despite ongoing reservations about the ethical underpinnings of health care risk-bearing systems, and HMOs in particular, the rate of increase in health care costs has in fact slowed.[17] Nevertheless, the most recent cost and demographic data suggest a tentative future. Almost five years after the demise of the Clinton health care reform proposal, the United States maintains the world's most expensive health care system, outstripping the health expenditures of all other countries by a significant margin.[18] In fact, in 1997, the U.S. spent about $4,000 per person on health care, as compared to the next most expensive country, Switzerland, which spent approximately $2,500.[19] According to the Health Care Financing Administration ("HCFA"), health care spending will again begin to grow faster than the rest of the economy.[20] HCFA predicts that by 2020, health care expenditures will consume 16.6% of the gross domestic product or $2.1 trillion.[21]

Although many factors influence health care spending, advances in medical technology and the aging of the U.S. population are particularly influential. First, some research suggests that the development and diffusion of medical technology ac-

15. *See* GEORGE ANDERS, HEALTH AGAINST WEALTH: HMOs AND THE BREAKDOWN OF MEDICAL TRUST (1996) (providing numerous examples of HMO "horror stories" and criticizing the corporate nature of managed care).

16. *See* Jon Gabel, *Ten Ways HMOs Have Changed During the 1990s*, HEALTH AFF., May/June 1997, at 134 (documenting the dramatic increase in the number of people in managed care plans). For a statistical treatment of the decline of traditional indemnity insurance, see HEALTH INSURANCE ASSOC. OF AMERICA ("HIAA"), HIAA SOURCE BOOK OF HEALTH INSURANCE DATA (1997-1998).

17. *See* Katherine R. Levit et al., *National Health Care Trends in 1996*, HEALTH AFF., Jan./Feb. 1998, at 35 (documenting the dramatic slowdown in health care costs over the last five years); *see also* Kenneth E. Thorpe, *The Health System in Transition: Care, Cost, and Coverage*, 22 J. HEALTH POL. POL'Y & L. 339 (1997) (documenting that the rate of increase in health care costs has declined substantially in recent years).

18. *See OECD Health Data 1998: A Comparative Analysis of 29 Countries, 1998*, Organization for Economic Cooperation and Development, *available in* CD-ROM.

19. *See id.*

20. *See* Sheila Smith, et al., *The Next Ten Years of Health Spending: What Does the Future Hold?*, HEALTH AFF., Sept./Oct. 1998, at 128.

21. *See id.*

counts for as much as seventy percent of health care spending growth since 1960,[22] underscoring that while advances in technology have improved and extended human life, they come with a substantial price.

The second factor is one of demographics, and in particular, the impact of aging baby boomers. The U.S. population age sixty-five and over is projected to increase from 12.5% in 1990 to 15.7% in 2020, an increase of over 25%.[23] Equally alarming, by this same year, the U.S. population age eighty-five and older is projected to increase from 1.2% in 1990 to 2.1%, an increase of over 75%.[24] The aging of our population is not a temporary phenomenon. It is a permanent change in the profile of the country, and one that will have a profound impact on health care spending.

Cost and demographic data suggest that the United States will continue to move away from a fee-for-service system toward new and evolving managed care risk-sharing arrangements.[25] Policy makers recognize that despite mounting consumer skepticism, the system cannot afford to retreat to the fee-for-service environment.

II. State Regulation of Health Care Risk-Bearing Entities

A. *What Triggers State Regulation?*

State regulators have a keen interest in new and emerging managed care strategies because of an inherent desire to contribute to the ongoing evolution of the American health care system. However, it is the transfer or assumption of risk that truly piques the interest of state regulators, because arrangements involving the transfer or assumption of risk involve the essential elements of *insurance risk* or the *business of insurance*, and trigger state regulation.[26]

22. *See* E.A. Peden & M.S. Freeland, *A Historical Analysis of Medical Spending Growth, 1960-1963*, Health Aff., Summer 1995, at 235.

23. *See Percent 65 Years and Over and 85 Years and Over Of the Total State Population: 1980 to 2020*, Health Care Almanac & Y.B. § A at A68 (1997).

24. *See id.*

25. *See* Robert H. Miller & Harold S. Luft, *Managed Care Plan Performance Since 1980: A Literature Review*, 271 JAMA 1512, 1518 (1994) (concluding that HMO enrollment will continue to grow under the current regulatory scheme given the cost and level of quality currently provided by HMOs).

26. Two schools of thought emerged concerning the regulation of traditional risk-bearing entities. Some policy makers argued that HMOs were no different than insur-

The federal McCarran-Ferguson Act[27] specifies that primary jurisdiction for the regulation of the business of insurance lies with the states. In determining whether a particular arrangement is subject to insurance laws, state regulators rely on a variety of sources, including statutes and state and federal court opinions. In 1982, the United States Supreme Court provided significant guidance in determining whether an arrangement involves the business of insurance. The Court identified three relevant criteria: (1) whether the activity included the underwriting or spreading of risk; (2) whether the activity involved an integral part of the insurer-insured relationship; and (3) whether the activity was limited to entities within the insurance industry.[28] An analysis of these criteria assists in determining whether a particular activity is tantamount to insurance, and subject to state regulation.

With the explosion of various managed care strategies over the past decade, the determination of whether an entity is bearing insurance risk has become extremely complex. New and emerging *hybrid* risk-bearing entities often rely on complicated reimbursement schemes, which may or may not include capitation,[29] risk adjustment,[30] fee-for-service, withholds,[31] or a combi-

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ance companies because they charged monthly premiums and assumed insurance risk based on actuarial determinations. Therefore, they argued that HMOs should be regulated like insurance companies. Other policy makers, more sensitive to the unique place health care has in society, argued that public health officials should be involved in regulating HMOs to ensure that the public receives high quality care. *See* Holley, *supra* note 12, at 656-57 (discussing the implications of state regulation as an obstacle to the development of HMOs).

27. 15 U.S.C. § 1011-1015 (1998).

28. *See* Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119, 129 (1982); *see also* Metropolitan Life Ins. Co. v. Mass., 471 U.S. 724 (1985). *But cf.* WILLIAM R. VANCE, THE HANDBOOK ON THE LAW OF INSURANCE (3rd ed. 1951) (listing five elements as required for an insurance agreement: (1) the insured possesses an insurable interest; (2) the insured is subject to a risk of loss; (3) the insurer assumes that risk of loss; (4) the assumption of the risk of loss is part of a general scheme to distribute actual losses among a large group of persons with similar risks; and (5) the insured pays a premium to the insurer).

29. For a definition and more explanation of "capitation," see *infra* note 38 and accompanying text.

30. Risk adjustment is defined as a process of shifting premium dollars from a plan with generally healthy enrollees to another with sicker members. Risk adjustment is intended to minimize any financial incentives health plans may have to select healthier than average enrollees. In a risk adjustment process, those health plans that attract higher risk members and providers would be compensated for any differences in the proportion of their members that require higher levels of care as compared to other plans. AGENCY FOR HEALTH CARE POL'Y & RES., GLOSSARY OF QUALITY OF CARE TERMS (1997).

nation of all of the above. These new hybrid arrangements cannot be readily evaluated by the same criteria as their predictable predecessors.

Determining the payment structure is the single most important element in evaluating whether a particular entity is bearing risk.[32] Payment methods utilized in a managed care context vary tremendously. Some involve insurance risk while others clearly do not. For example, a particular managed care plan may employ a variety of strategies to contain cost, including prior authorization,[33] utilization review,[34] and gatekeeper options,[35] but this plan may use a payment method that is directly linked to the actual delivery of identifiable services to a specific enrollee. This payment method is therefore a form of fee-for-service[36] and does not involve the transfer of insurance risk.

Another plan may utilize a payment method involving the prepayment of a premium in exchange for all covered services, even if those services exceed the amount of the premium. This method is called "capitation." Capitation has been defined as "a set dollar payment per patient per unit of time (usually per month) that an organization pays a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided."[37] A plan using a capitated payment method involves the essential elements of insurance risk and triggers state regulation.[38]

The proliferation of new and emerging hybrid risk-bearing entities, together with an increasing level of consumer skepticism, requires state regulators to consider how to most appropriately

31. "Withhold pools" are arrangements whereby providers assume partial insurance risk. To fund withhold pools, part of a provider's payment is put into a pool, and this money is used if the cost of services delivered exceeds a pre-arranged budget. *See* NAIC White Paper, *supra* note 11, at I-14. The NAIC has said that a "withhold pool" compensation arrangement may or may not constitute insurance. Depending on the arrangement, the providers may be responsible for specialty referrals and therefore may be spreading risk in an area where they have no control. In such a case, the provider would likely be assuming insurance risk because of lack of control of the risk.

32. *See* NAIC White Paper, *supra* note 11, at I-12.

33. *See generally* Barry R. Furrow, *Managed Care Organizations and Patient Injury: Rethinking Liability*, 31 GA. L. REV. 419 (1997) (discussing managed care cost containment techniques).

34. *See id.*

35. *See id.*

36. *See supra* note 3 and accompanying text for more explanation of fee-for-service.

37. 42 C.F.R. § 417.479(c) (1998).

38. *See* NAIC White Paper, *supra* note 11, at I-14.

modify the current regulatory structure to accommodate this changing environment. In re-evaluating the fundamental regulatory framework that state regulators have relied upon for years, protecting consumers and promoting market competition must remain the highest priority.

B. The Cost of Regulation

The primary objectives of state health insurance regulation are protecting consumers against insolvency while, at the same time, promoting market competition. Unfortunately, these two objectives are often in direct conflict. Consumer protection regulation does not come without costs, and these costs are often real barriers to doing business in the health care market. For instance, in Minnesota, risk-bearing health care entities must satisfy numerous consumer protection regulations and comply with reporting, oversight, reserve, capital and surplus requirements.[39] Satisfying these requirements can be costly and promote, at least implicitly, economies of scale. Even if a smaller, less capitalized entity can satisfy the initial capital requirements, administrative and data collection regulations require substantial and ongoing financial resources. Assuming equal efficiency in other areas of business, a larger entity will be more efficient and create a lower per capita regulatory cost as compared to a smaller entity.[40] Thus, regulation, to a certain extent, promotes consolidation. While consolidation may offer lower costs, expanded provider networks, and increased consumer protection from insolvency, these benefits may be offset by consumer concerns about reduced innovation, reduced competition, and homogeneity of plans offered.[41]

The public's suspicions of a highly consolidated health care market should not be underestimated in its impact on public

39. *See* MINN. DEPT. OF COMMERCE ("MDC") & MDH, JOINT FINAL REPORT TO THE LEGISLATURE, DIRECT CONTRACTING FOR HEALTH CARE SERVICES, Feb. 1997, at 12 [hereinafter "Minn. Report"]; *see also* Kent G. Rutter, *Democratizing HMO Regulation to Enforce the "Rule of Rescue,"* 30 U. MICH. J. L. REFORM 147, 163 n.100 (1996) (indicating that Minnesota's HMO regulations, like that of 27 other states, are patterned after the MHO Model Act, adopted by the NAIC in 1973).

40. *See generally* Edward Hirshfeld, *Interpreting the 1996 Federal Antitrust Guidelines for Physician Joint Venture Networks*, 6 ANNALS HEALTH L. 1, 33-49 (1997) (analyzing regulatory costs and administrative efficiencies in the context of legal joint ventures by physicians).

41. *See* James D. Rusin, *Reality Check, Please: Suggestions for Change in Health Care Delivery*, MINN. PHYSICIAN, Feb. 1997, at 32 (describing the negative aspects of a consolidated health care market in Minnesota).

policy. The public's distrust of large HMOs is undeniably playing a role in elected officials' desire to "correct" the system. Candidates for public office and their accomplices in the media have contributed to public fears and bias against large, dominant HMOs by recounting numerous testimonials involving individuals who were purportedly denied access to care or prohibited from seeing the provider of their choice.[42]

Elected officials face intense pressure from a variety of different constituencies. The public demands greater protections from abuse and limitations on health care choices; employers cry out against rising costs; and HMOs complain of an increasingly burdensome regulatory framework, in which the list of mandated benefits seems to increase whenever the legislature is in session. In addition, physicians seek the freedom necessary to simply practice medicine without micro-management from corporate executives or inflexible government officials. These multi-focal pressures contribute to the ongoing evolution of the U.S. health care system.

III. Minnesota Regulation of Health Risk-Bearing Entities

A. Traditional Health Maintenance Organizations

Minnesota law makes it clear that because an HMO assumes insurance risk, it is in the business of insurance. Therefore, it is subject to state regulation. HMO regulations address a myriad of issues, including licensing, net worth and working capital requirements, financial standards, geographic accessibility, governing body requirements, quality assurance requirements, annual reporting requirements, fees, complaint systems, benefits, claims practices, and other reporting requirements.[43] Although the Minnesota Department of Commerce regulates most insurance, the Department of Health has regulatory responsibility over HMOs.[44]

By placing HMO regulation in the Department of Health, the state legislature has sent a strong message that the delivery and

42. Minnesota's new Attorney General, Mike Hatch, for example, campaigned heavily on HMO reform citing numerous examples of treatment denials. Hatch has proposed a litany of reforms. *See* Mike Hatch Press Release (June 24, 1998) on file with author; *see also* Glenn Howatt & Dane Smith, *Hatch Renews Fight for HMO Patients*, Minneapolis Star-Trib., Feb. 6, 1999, at B1; *supra* note 1 (for more articles negatively portraying HMOs and managed care).

43. *See* Minn. Stat. § 62D et seq. (1998).

44. *See id.*

regulation of health care services, including health care risk-bearing entities, require expertise found only in a public health agency. Further, while most states have enacted consumer protection regulations, Minnesota is the only state to require all HMOs to be non-profit entities, and to carefully monitor and regulate HMO surplus revenue.[45] By prohibiting for-profit HMOs, Minnesota has made a strong statement about the financing and delivery of health care and voiced its collective opposition to exposing consumers to a profit motive when it comes to health care.[46]

B. Community Integrated Service Networks

An early outgrowth of Minnesota's health care reform legislation, known as MinnesotaCare, is embodied in Minnesota Statutes Section 62, which allows for the creation of Community-Integrated Service Networks ("CISNs").[47] The purpose behind CISNs was to enable smaller rural communities to develop their own provider networks capable of delivering a broad range of prepaid health care services to their members. CISNs would serve smaller populations and provide services that were more appropriately shaped to meet the specific needs of the local community. To ensure that the needs of the local community were a priority for the CISN, the state legislature mandated that at least fifty-one percent of the governing body's members be residents of the CISN's service area. The theory behind this requirement was that individuals who were familiar with the needs of the local community would also receive services from the CISN and be encouraged to contribute to the total health care of the community. Additionally, by ensuring local control over

45. *See* MINN. STAT. § 62D.02, Subd. 4. (a) (1998).

46. It is unclear what the implications are for only allowing non-profit HMOs in the state. Some have argued that not having for-profit HMOs has somewhat ironically only exacerbated the public's complaints about managed care; that is, by only allowing non-profit HMOs in the state, Minnesota has actually promoted consolidation and decreased choice. *See* Rusin, *supra* note 41 (considering that for-profit HMOs in the state would reintroduce market competition). *But cf.* Amy Phenix, *The Nonprofit Mission: Allina Defends Its Role in Providing Community Benefit*, MINN. PHYSICIAN, Mar. 1997, at 24 (arguing that non-profits are able to take a long-term view on health issues by not facing the scrutiny of short-term oriented shareholders and that non-profits are able to invest in the community through their foundations).

47. Legislation to reform Minnesota's health care system was first passed in 1991, but was vetoed by then Governor Arne H. Carlson. In 1992, a bipartisan group of legislators, referred to as the "Gang of 7," worked with Governor Carlson to develop a comprehensive health care reform bill known as MinnesotaCare, which was subsequently adopted (materials on file with author).

CISNs, fewer health care decisions would be made away from the community by individuals who were unaware of local needs. Theoretically, CISNs represented an attractive option for rural areas that lacked a sufficient number of providers and patients to develop large integrated delivery systems.

Since CISNs were developed as an *alternative* for smaller rural communities, Minnesota lawmakers were interested in developing an alternative regulatory structure to the HMO statute, considered by many to be overly burdensome. Such an alternative regulatory structure never truly materialized. While CISNs were offered some administrative flexibility to meet licensure and quality standards, regulatory requirements were not appreciably different and were actually viewed by many as an insurmountable barrier to the implementation of this particular model.[48]

It became clear over time that the CISN theory would not provide the practical alternative that lawmakers had hoped. Only four entities were ever awarded CISN licenses, and only one of those, as of this writing, remains a CISN.[49] Many providers rejected the CISN concept, citing its complex and overly burdensome regulatory scheme and arguing that the intent of the CISN concept had been lost in the drafting of laws by which it was to be governed.[50]

The laudable theory whereby rural Minnesota would develop smaller integrated networks to serve the needs of a community translated into an unattainable goal. The development of the CISN concept represents a textbook example of policymakers' genuine desire to develop an alternative to what was considered by many to be large dispassionate oligopolies. This desire seemed reasonable, yet it was eventually overpowered by a collective unwillingness to accept any regulatory scheme that did not embody the consumer protection standards set forth in existing law.[51]

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48. *See infra* Appendix A (MDH spreadsheet comparing the regulatory requirement of different health care risk-bearing entities).

49. *See* Interview with Tom Johnson, Health Care Analyst of the Managed Care Section of MDH, (November 24, 1998) (materials on file with author).

50. Materials on file with author.

51. Regulatory requirements for CISNs included the provision of prepaid health services to 50,000 or fewer enrollees; mandatory participation in publicly funded programs; compliance with HMO statutes and rules with some minor exceptions; 51% of governing board residents of CISN service area; compliance with HMO benefits set; compliance with HMO deposit requirements. *See infra* Appendix A.

IV. The Emergence of Direct Contracting Strategies

The health care market, both nationally and in Minnesota, has been in a period of rapid and dramatic change in recent years. To best cope with the changing marketplace, public and private purchasers of health care services have actively pursued new purchasing strategies, including the formation of direct contracting arrangements. "Direct contracting" refers to a contract for health care services offered by a provider-sponsored organization ("PSO")[52] typically to an employer or group of employers. The PSO accepts full or partial risk for utilization of health care services above the anticipated level.[53] This type of arrangement is in contrast to the typical situation where an employer purchases health care coverage from an insurer or from a health plan such as an HMO or Blue Cross/Blue Shield, or where the health care coverage is provided by a self-insured employer on a fee-for-service basis.

The question of whether direct contracting arrangements should be, as a matter of public policy, recognized as an acceptable alternative model for delivering health care services has been the subject of much debate at both the state and federal level.[54] An examination of the advantages and disadvantages of direct contracting arrangements is instructive.

Many providers consider direct contracting arrangements to be an attractive alternative to participation in an HMO or indemnity insurance plan, because the structure is thought to afford greater autonomy in the practice of medicine.[55] Further, providers suggest that an arrangement in which the provider has primary responsibility for *both* cost and quality will produce a

52. For purposes of this Article, the term "PSO" refers to a variety of provider-centered health care entities that seek to assume risk directly. Such entities could include Provider Hospital Organizations ("PHOs"), Preferred Provider Organizations ("PPOs"), and Independent Practice Associations ("IPAs").

53. *See* Minn. Report, *supra* note 39, at 2.

54. The direct contracting/PSO debate spurred the development of the NAIC White Paper and the Minnesota Report. *See* NAIC White Paper, *supra* note 11; *see also* Minn. Report, *supra* note 39.

55. *See, e.g.*, Glenn Howatt, *Physicians Form Own Health Plan.* Minneapolis Star-Trib., Nov. 25, 1998, at B1; *see also* Brian O'Reilly, *Taking on the HMOs*, Fortune Mag., Feb. 16, 1998, at 96, 100; Judith Yates Borger, *Eliminating the Middleman*, St. Paul Pioneer-Press, Aug. 27, 1997, at B1; *see also* Edward B. Hirshfeld, *Provider Sponsored Organizations and Provider Service Networks-Rationale and Regulation*, 22 Am. J. L. & Med. 263, 272-93 (1996) (arguing why providers can be more efficient deliverers of health care and why public policies should promote and facilitate the formation of entities in which providers assume insurance risk).

more efficient and effective health care delivery system.[56] Under such arrangements, the risk is placed in the hands of providers, who are most able to assess and influence cost and quality.

Proponents of direct contracting suggest that when health care is purchased from large integrated health plans, individual providers are not held accountable for the quality of care or the cost of such care. Alternatively, direct contracting arrangements, as opposed to large plans, result in competition among providers and require that providers be accountable for both the cost and quality of the care *they* provide. In other words, if providers have autonomy and a financial incentive, they will provide the appropriate level of care in the most cost-effective manner without diluting quality.[57] Other advantages of direct contracting include the potential to help counter trends toward consolidation in the health care market, presumably because smaller provider groups will be able to enter the market and create more competition at both the plan and provider level.[58] This type of market diversification could theoretically result in increased choice of providers and decreased costs to consumers.

Although the theory of direct contracting certainly has some intellectual (and emotional) appeal, serious questions remain about the practical application of this alternative model, particularly in a health care system that historically has emphasized consumer protection as a primary objective.[59] Critics argue that enrollee access to comprehensive care will be diminished because it is unlikely that smaller provider groups will have all necessary specialties represented within the group, or have adequate geographic availability of all provider types.[60] The issue of access as it relates to direct contracting arrangements may have added significance in rural, less populated areas where consumers are currently under-served. Additionally, enrollees in direct contracting arrangements may be more vulnerable in the areas of quality control, utilization review, marketing and disclosure, and appeal rights, to the extent that these arrangements fall outside the state regulatory structure.

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56. *See* Hirshfeld, *supra* note 55, at 272.
57. *See id.*
58. *See* Minn. Report, *supra* note 39, at 3-4.
59. *See id.* at 1.
60. *See id.* at 4-5.

Perhaps the most significant concern raised about direct contracting arrangements, however, and the one that has continually blocked their acceptance in the market, relates to financial sustainability and the risk of enrollee coverage termination due to provider insolvency.[61] Regulators are concerned that groups of providers that have no experience or expertise in assuming insurance risk may underestimate the assets required to prevent insolvency. Furthermore, because the size and assets of the provider group are likely to be relatively small, the number of high cost cases needed to cause insolvency will be fewer, thereby increasing the risk to consumers.

Despite a number of valid concerns, developments at both the state and federal level reflect an ongoing interest in promoting the development of direct contracting arrangements. Elected officials will likely continue to pursue this alternative risk-bearing strategy in an effort to improve quality, decrease cost, and preserve the physician/patient relationship.

V. Minnesota's Experience with Direct Contracting Arrangements

Advocates for direct contracting in Minnesota refer to themselves as "Mainstreeters" and market an idea that no rational elected official can oppose. They advocate that direct contracting arrangements will bring back "viable, community-focused options for providers and small businesses."[62] Because the rhetoric is so appealing, Minnesota lawmakers have actively promoted direct contracting through legislation in recent years.[63] In doing so, the legislature has moved in two seemingly opposite directions to "reform" the health care system. Specifically, in 1997, the Minnesota legislature passed, by a substantial

61. *See id.*

62. Elisabeth Quam Berne, *Directing the Contract: Independent Providers and Small Businesses Get in on the Action*, Minn. Physician, Feb. 1998, at 32; *see also* Ken Heithoff et al., *Health Care on Main Street: New Solutions for Community-Based Care*, Minn. Physician, May 1997, at 26 (both articles arguing in support of the APN legislation).

63. A 1995 MinnesotaCare amendment specifically authorized a demonstration project of direct contracting between a certain provider cooperative and qualified employers or self-insured employer plans. The law requires that the provider cooperative notify the MDH upon entering into a contract with a self-insured employer. Two additional pilot projects were authorized by the 1996 Legislature, and while all three of these provider co-ops are located in southwestern Minnesota, none is currently contracting with employers. *See* Minn. Dep't Health, Direct Contracting, Health Economics Program Issue Paper (1996).

margin, a consumer protection bill known as the Patient Protection Act ("PPA"), purportedly because existing HMO laws did not adequately protect the rights of health care consumers.[64] The PPA prohibits certain types of provider contracts that limit the free exchange of information between the provider and the patient. It also prohibits exclusive arrangements and retaliation by a health plan against a provider.[65] Additionally, the PPA mandates that a health plan must disclose to a consumer the general nature of the reimbursement methodology used to pay providers.[66] The Patient Protection Act applies to all regulated health plans.[67]

Within days of the passage of the PPA, Minnesota lawmakers introduced legislation that would allow for the assumption of insurance risk by unlicensed providers.[68] The legislation provided for Accountable Provider Networks ("APNs") and created an option for providers, particularly small rural providers, to be directly involved in the delivery and financing of health care.[69] The bill, as originally drafted, allowed APNs to exercise substantial autonomy, provided unprecedented flexibility, and streamlined many of the consumer protections that exist in licensed health plan regulations. Though the bill eventually became law, it was stripped of nearly all the provisions that made it look and feel appreciably different from the existing regulatory structure, especially those provisions relating to capital requirements and ongoing reserve requirements. During key legislative hearings, regulators convinced lawmakers that if risk was to be transferred under an APN model, the consumer protection laws that the legislature had reaffirmed only days earlier should not be compromised.[70]

Considerable pressure by special interests made the APN legislation a reality,[71] but despite this pressure and fanfare, as of the date of this writing, only one group has applied for an APN license, and this group differs from the kind promoted as most likely to benefit from the legislation.[72] Providers do not view

64. *See* MINN. STAT. § 62J (1998).
65. *See id.*
66. *See id.*
67. *See id.*
68. *See* MINN. STAT. §§ 62N, 62T (1998).
69. *See* MINN. STAT. § 62T (1998).
70. Materials on file with author.
71. *See, e.g.*, Berne, *supra* note 62; *see also* Heithoff, *supra* note 62.
72. *See* Johnson Interview, *supra* note 49. A review of the only APN application the state has received indicates that the APN is an urban and suburban provider

the APN legislation as an attractive alternative, since it is not appreciably different than existing law.[73] The APN legislative battle underscores the challenge of introducing new alternatives into a market that is unwilling to accept any compromises in consumer protection regulations for an opportunity to enhance market competition.

VI. Reflections on Minnesota's Record of Mixed Success

There are a number of possible explanations for the failure of CISNs and APNs to become the popular alternative to the highly consolidated market in Minnesota. A comparison of the regulatory schemes under which HMOs, CISNs, and APNs are governed is particularly enlightening.[74] As Appendix A makes clear, there is very little difference between an HMO, CISN, and APN in terms of regulatory requirements. HMOs, CISNs, and APNs must all be licensed by the Commissioner of Health. The deposit, net worth and capital requirements are the same for HMOs, CISNs, and APNs, unless the APN is granted a waiver from the Commissioner of Health.[75] The required financial standards and geographic accessibility is the same for HMOs, CISNs, and APNs; the required annual reporting requirements and quality assurance requirements are also essentially the same.

One reason for this lack of distinction between the three health care risk-bearing models is presumably because the state legislature is unwilling to compromise consumer protections and views the HMO regulatory structure as a baseline that should apply to all health care risk-bearing entities, regardless of form. This philosophy is likely rooted in principles of basic equity.

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group created with the intention of competing directly with HMOs. Thus, the group differs from the model put forth by early supporters of the legislation that suggested that APNs would allow small town doctors to band together to offer capitated services. (The lone APN application is public information and is on file with author.)

73. *See infra* Appendix A.

74. *See infra* Appendix A.

75. The waiver language, which was amended on to the bill in an attempt to maintain even modest distinctions from HMOs, allows for some flexibility in regulatory compliance and was created to satisfy the concerns of some APN proponents. No one has applied for the waiver, and the criteria is quite rigorous. An entity seeking a waiver must satisfy each of the following criteria: (1) more choice in benefits and prices; (2) lower costs; (3) increased access to health coverage by small businesses; (4) increased access to providers who have demonstrated a long-term commitment to the community being serviced; and (5) increased quality of health care than otherwise occur under the existing market conditions. *See* Minn. Stat. § 62T (1998).

Consumers expect certain minimum standards irrespective of the manner in which they access the health care system. Based on the plain and unambiguous language embodied in current regulations, it is clear that the legislature is unwilling to compromise baseline consumer protection standards in order to promote new, fairly untested risk-bearing entities.[76]

VII. New and Emerging Direct Contracting Arrangements

Although direct contracting arrangements, at least in Minnesota, still face significant challenges, there are opportunities in which these arrangements can thrive both outside and within the Minnesota regulatory framework. These new arrangements challenge state regulators to carefully balance the need to protect consumers with the desire to encourage market diversification through alternative risk-bearing models.

A. "Downstream Risk" Arrangements

One of the ways in which provider groups have taken on additional risk and autonomy is by assuming what is known as "downstream risk." Downstream risk arises when a provider-centered organization contracts with a licensed entity and assumes part of the licensed entity's insurance risk.[77] While provider groups engaged in downstream risk have been examined by some states, the assumption of downstream risk should not necessarily trigger the need for serious state regulation of provider groups.[78] The HMO or other licensed entity involved in the contract is already required to comply with state insurance regulations and, therefore, the provider group is "downstream" from the actual insurance risk.[79] Thus, the consumer is protected by having a relationship with at least one regulated entity.[80]

Downstream risk contracting opportunities provide a realistic, tangible way for providers to assume additional risk and financial control, yet not be directly subject to rigorous state regulation.

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76. *See* James S. Matthews, *A Modest Proposal: An Alternative to Insurance Regulation of Direct Contracts*, Minn. Physician, Sept. 1997, at 32 (arguing that Minnesota PSOs be given special regulatory consideration).

77. *See* NAIC White Paper, *supra* note 11, at I-24, I-25.

78. *See id.* at I-29.

79. *See id.*

80. *See id.*

B. Direct Contracting with Employers

Employers assert that contracting directly with providers can be an effective cost containment alternative. Nevertheless, Minnesota regulators have clearly stated that direct contracting between PSOs and employers, where the PSO assumes risk, is the business of insurance and will be regulated by the state to protect the public. A key, but unresolved, question is at what level of risk-sharing should the state impose regulation. "It remains to be clarified whether a PSO that assumes any amount of risk will be considered to be in the business of insurance, or whether there is some threshold level of risk-sharing that will require regulation."[81]

Provider groups can avoid state regulation entirely by falling into the ERISA exemption,[82] which prohibits states from regulating the health care benefits of self-insured employers.[83] In Minnesota, the biggest and best known experiment in direct contracting under the ERISA exemption is the Buyer's Health Care Action Group ("BHCAG").[84] BHCAG is a coalition of some of the largest employers in the state of Minnesota, including such well-known names as Cargill, 3M, Honeywell, Dayton-Hudson, and Pillsbury. BHCAG-member employers offer an employer-sponsored health plan known as ChoicePlus to approximately 250,000 eligible covered lives.[85] Under a direct contracting approach that began in 1997, BHCAG created an internal health care market where consumers choose among competing care systems. A care system is an integrated team of providers including hospitals, specialty groups, and primary care physicians. Primary care providers participate in only one care system within ChoicePlus, and each care system determines its own network of providers.[86] To establish premiums, the care

81. *See* Minn. Report, *supra* note 39, at 27.

82. *See* 29 U.S.C. § 1144 (a) (1998).

83. Analysis of PSOs under ERISA is a complex issue outside the scope of this article. For an analysis on this subject, see for example, Margaret G. Farrell, *ERISA Preemption and Regulation of Managed Care: The Case for Managed Federalism*, 23 AM. J. L. & MED. 251, 252 (1997); *see also* Allison Overbay & Mark Hall, *Insurance Regulation of Providers that Bear Risk*, 22 AM. J. L. & MED. 361, 378-82 (1996).

84. *See* Ann L. Robinow, *The Buyers Health Care Action Group: Creating a Competitive Care System Model*, 5 MANAGED CARE Q. 61 (1997).

85. *See* BHCAG Benefits Plan, Marketing Literature, and ChoicePlus Performance Results (materials on file with author).

86. *See* Robinow, *supra* note 84, at 63.

systems submit targets.[87] Based on their targets, BHCAG rates each care system, and each is placed into a premium category: high, medium, or low cost. Providers prefer this method because it allows the network to retain some autonomy in pricing and creates incentives for self-policing and internal management as opposed to extensive outside cost-containment pressures.

Based on the care systems' stated targets, employees choose their care system and decide how much they want to spend on health care. The health benefit set is the same for all care systems.[88] BHCAG provides employees with an array of comparative information, allowing employees to make informed choices about a care system. BHCAG argues that this system allows for active consumer participation in which individuals consciously choose their plan based on information related to cost and care.[89]

Because the employers in BHCAG are currently deemed self-insured, the care systems are outside state regulation.[90] The care systems, therefore, are not required to comply with reserve requirements or state reporting requirements.[91]

Thus, the BHCAG system relies on a sophisticated quality rating system and competition between care systems. Its provider reimbursement scheme is quite complex.[92] The BHCAG model has been viewed by many as a success, and costs within that system have been lower than comparable costs by local HMOs, satisfying employers.[93]

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87. Setting targets for premiums has become increasingly accurate by the use of technology, including ambulatory care groups (ACGs). For a discussion of ACGs and BHCAG's use of technology, see Brent A. Metfessel, *Advances in Risk Adjustment: Leveling the Playing Field in Provider Profiling*, MINN. PHYSICIAN, Apr. 1997, at 26.

88. *See* Robinow, *supra* note 84.

89. *See id.*

90. Despite BHCAG's apparent immunity to state regulation based on the ERISA exemption, HMOs have put pressure on state government to regulate BHCAG to put it on a level playing field with HMOs. *See* Tom Majeski, *Self-funded Plans Fear State Regulation Consumer-Protection Bills Set Health Groups Squabbling*, ST. PAUL PIONEER PRESS, Mar. 4, 1997, at 3B.

91. *See* Minn. Report, *supra* note 39, at 6.

92. For a detailed look at BHCAG's reimbursement scheme, see Allan Baumgarten, *The Minnesota Experiment; Buyers Health Care Action Group BHCAG Conducts Market Study in Minneapolis/St. Paul Minnesota,* BUS. & HEALTH, July 1996, at 24.

93. For statistics on BHCAG's costs, see Glenn Howatt, *BHCAG Expects Relatively Small 1999 Price Increase*, MINNEAPOLIS STAR-TRIB., July 24, 1998, at B2; *see also* John Manning, *BHCAG Budgets Rise More Slowly*, MINNEAPOLIS-ST. PAUL CITYBUS, July 24, 1998, at 4.

Though reports suggest that this model has had success in containing costs while maintaining quality, the applicability of the BHCAG model is likely limited. Minnesota regulators have made clear that even though the BHCAG provider reimbursement system clearly involves the transfer of some risk, they have not defined this program as insurance for two primary reasons. First, the risk adjustment methodology in the plan provides some assurance that the care systems will not inadvertently assume more risk than they are capable of covering. Second, and more significantly, the Minnesota Departments of Health and Commerce have refrained from regulating and instead monitor BHCAG because they are confident that companies such as Cargill, 3M, and Dayton-Hudson will continue to provide for their employees even if one of the care systems becomes insolvent. State regulators are unlikely to have similar confidence in Mom & Pop's Groceries or the local pizzeria. Thus, although the BHCAG model has been held out as a potential national model for how costs can be controlled by promoting provider competition, its application may be limited. The BHCAG model is likely not appropriate for (1) small employers, who cannot be relied upon to financially support failed care systems; (2) high risk populations, where costs are difficult to estimate; and (3) rural areas, where care system competition is limited by a limited number of providers.

Nevertheless, Minnesota's regulatory response to the BHCAG model should be commended because it looked beyond the strict theoretical application of insurance law and considered, from a practical perspective, the actual exposure to consumers receiving health care services in a system that clearly represents a creative alternative to the existing framework.

C. Direct Contracting in Government Health Programs

The growth and development of direct contracting arrangements is not limited to the private health care market. These arrangements have also gained popularity in serving populations receiving health care through government-sponsored programs.[94]

94. The federal government, as the sponsor of Medicare and Medicaid programs, represents this country's single largest health care customer. As part of the Balanced Budget Act of 1997, major changes were made to Medicare, including the development of the Medicare+Choice plan. Under the Medicare+Choice plan, consumers on Medicare can receive their benefits from an approved managed care entity. Congress believed that this plan would encourage more Medicare recipients to use managed

The state of Minnesota has expanded the direct contracting theory through its application to government sponsored health plans. This strategy, known as County-Based Purchasing ("CBP"), gives Minnesota counties the option of taking control of the purchasing of health care services for Medicaid recipients.[95]

CBP arose out of discussions that began in the early 1980s, when the Minnesota Department of Human Services ("DHS") began working with three Minnesota counties as demonstration projects for the implementation of the Prepaid Medical Assistance Program ("PMAP"). PMAP enables the DHS to enter into contracts with health plan companies to provide services to

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care plans, and therefore the costs of the Medicare, which have been skyrocketing, would be controlled. While some commentators have questioned the wisdom of pursuing managed care for Medicare recipients, Congress appears convinced that what is good for the private sector is good for the public sector. As part of Medicare+Choice, certain PSOs may qualify to compete for Medicare business. To qualify as a Medicare PSO, the PSO must meet state HMO requirements or apply for a waiver. The federal waiver process allows PSOs to contract for Medicare business without satisfying a state's HMO requirements. A waiver is possible if a PSO is unable to receive a state license; however, the recent regulations promulgated on Medicare PSOs appear at least as rigorous and probably more confusing than any state requirements. At least in part due to the confusing regulations, the Health Care Financing Administration ("HCFA") only received three Medicare PSO applications in the first year. *See* Milt Freudenheim, *So Far, 'Medicare Plus Choice' is Minus Most of the Options,* N. Y. TIMES, Oct. 4, 1998, § 3, at 1; *Medicare: HCFA Receives Only Three Applications for New Medicare+Choice Options,* HEALTH CARE POL'Y REP. (BNA) No. 1392, (Aug. 31, 1998); Doreen A. Mohs, *A New Take on Medicare Contracting: Provider-Sponsored Organizations Can Now Compete for Business*, MINN. PHYSICIAN, Oct. 1997, at 34 (all discussing the problems associated with Medicare direct contracting). Thus, the development of Medicare PSOs faces the same problems as APNs in the state of Minnesota. Congress, like the Minnesota legislature, wants to promote new health care entities and empower providers; however, Congress, like the Minnesota legislature, is unwilling to compromise consumer protection for a new, untested entity. Not only are the regulations confusing and cumbersome, would-be Medicare PSOs are well aware that HMOs are fleeing the Medicare market in droves because of an inability to make money under increasingly scrutinizing reimbursement schedules. *See* Glenn Howatt, *Cuts to Medicare HMOs Put Strain on Senior Citizens*, MINNEAPOLIS STAR-TRIB., Nov. 1, 1998, at B1. As many as 200,000 elderly will be dropped from HMOs this year because of changes in the law. *See id.* Nevertheless, despite all the problems, the Medicare market remains a substantial market, and in the years to come, direct contracting with the federal government will be a trend to watch.

95. Medicaid is a federally aided, state-administered program providing medical benefits for some indigent or low-income persons. The program is authorized by Title XII of the Social Security Act and covers only those individuals who meet certain eligibility criteria. Subject to federal guidelines, states determine covered benefits, program eligibility, payment rates for providers, and the methods of administering the program. In Minnesota, Medicaid is also called Medical Assistance. *See* MINN. DEP'T OF HEALTH, COMMONLY USED HEALTH CARE TERMS GLOSSARY FOR CONSUMERS, (1996).

eligible Medicaid recipients. The services are provided on a capitated basis, with the contractual relationship existing between the DHS and the licensed health plan. By 1993, PMAP was expanded to Ramsey County, the second largest Minnesota county. It was during this transition that counties began identifying substantial cost shifting of health care services from licensed health plans to county government.[96] Specifically, county government was concerned that while it had an ever-increasing level of responsibility to provide health services to the Medicaid populations, it had no authority to influence the delivery and financing of health care services, because the PMAP contract was exclusively between the licensed health plan and the state.[97]

In response to this growing concern, the Minnesota legislature enacted CBP. The legislature noted that counties should have the opportunity to directly operate a purchasing system for the health care of families, children and the elderly in the Medical Assistance program.[98] CBP represents a complex relationship between county, state, and federal government, whereby a county or group of counties purchase and/or provide health care services on behalf of persons eligible for Medicaid. Similar to health plans under PMAP, counties are paid by the DHS on a capitated basis. Counties involved in CBP must ensure that enrollees have access to covered services and a reasonable choice of providers. Counties are free to manage their programs and negotiate with providers. If the costs of providing care to Medicaid recipients surpass prepaid funding by the state, the county, and not the state or federal government, is responsible for any shortfall, similar to a licensed health plan providing services on a capitated basis. Counties are, therefore, encouraged to take steps to limit insurance risk through various means, including stop-loss coverage or reinsurance.[99]

Counties that participate in CBP are not required to obtain a certificate of authority from the Minnesota Department of

96. In Ramsey County alone, the financial impact was approximately $600,000 in the first year of implementation. *See* Ramsey County Human Services Department documents (materials on file with author).

97. Materials on file with author.

98. Thomas Moss, AMC-DHS-MDH AGREEMENT, AN INTERNAL AGREEMENT BETWEEN THE ASSOCIATION OF MINNESOTA COUNTIES ("AMC"), DHS, and MDH, (1996) [hereinafter "AMC-DHS-MDH Agreement"].

99. *See id.*; *see also* MINN. DEP'T OF HEALTH, MINNESOTA HEALTH CARE MARKET REPORT, (1995) (defining re-insurance as "the resale of insurance products to a secondary market thereby spreading the costs associated with underwriting").

Health, as a private health plan is, but are still required to meet all consumer protection regulations through a contract with the DHS.[100] State regulators support this arrangement even though counties are clearly assuming the same risk as a licensed health plan. If a county fails to comply with any of the consumer protection regulations required of licensed health plans, DHS has the authority to terminate the contract and reinstate PMAP.[101]

Ramsey County chose to pursue CBP, citing a number of advantages, including: (1) the county has the authority to negotiate and manage contracts with providers; (2) in the event that a care system denies services, the county will be more effective in negotiating resolutions because it has a legally recognized relationship with the providers; (3) county management is more sensitive to specific county issues than a licensed health plan; and (4) the county will more effectively manage any excess revenue or interest for the benefit of county taxpayers.[102]

While this new heightened level of autonomy has its advantages, CBP faces some criticism. Critics argue that it is highly unlikely that this system will result in cost savings, noting that county government lacks the requisite level of sophistication to effectively manage a capitated health plan.[103] Furthermore, critics are concerned that the management of such a plan will be especially difficult in light of unique utilization challenges associated with the Medicaid population.[104]

The implementation of CBP is a work in progress and requires a certain level of regulatory discretion. For example, state regulators recognized that had they demanded compliance with the rules governing licensed health plans, particularly those governing capital requirements, few, if any counties could realistically participate. Regulators also recognized that a legally binding contract between the DHS and the county would be as effective in protecting consumers as the license that is required of a health plan. Finally, regulators acknowledged that CBP could provide invaluable information about the delivery of

100. *See* AMC-DHS-MDH Agreement.

101. Under county-based purchasing, a county may elect to contract directly with providers, licensed health plans, or a variety of both. The county also has the authority to utilize any reasonable reimbursement method. It is the county, however, that maintains responsibility for the implementation of the delivery system and for any excess costs associated with county-based purchasing. *See* AMC-DHS-MDH Agreement.

102. *See* Ramsey County Documents, *supra* note 96.

103. Materials on file with author.

104. *See id.*

health care using a non-traditional strategy (namely, CBP), with non-traditional partners (namely, counties), that would undoubtedly help shape future health policy.

Conclusions from the Minnesota Experience

The Minnesota experience in regulating risk in a managed care environment can be reduced into several guiding principles. First, risk regulation must be commensurate with real and appreciable exposure. The BHCAG experience is instructive. Despite the fact that BHCAG's plan clearly involves the transfer of some risk, the state chose not to exert regulatory authority. Instead, regulators are monitoring and evaluating this direct contracting model, recognizing primarily that consumers are not at risk because of the size and financial resources of the BHCAG employer group.

Second, ongoing tension will continue to exist between protecting consumers and promoting a competitive marketplace. Until expectations of the health care system change, the primary objective of state regulators must be to protect consumers against insolvency.

Third, the regulatory framework among risk-bearing entities should foster a level playing field. In other words, form should follow function.

Fourth, state regulators must use discretion in evaluating new risk-bearing strategies, thoughtfully using the law as opposed to robotically applying it.

Finally, and perhaps most importantly, for innovation to occur in the health care marketplace, everyone, including health plans, consumers, policy makers and regulators, must allow for compromise and flexibility. If compromise and flexibility are not attainable, it is likely that we will find a cure for the common cold before we find any real elixir for current consumer dissatisfaction with the American health care system.

APPENDIX A

HMO, CISN, AND APN REGULATORY REQUIREMENTS

Regulatory Category	Health Maintenance Organizations (HMOs) *Minn. Stat. § 62D*	Community Integrated Service Networks (CISNs) *Minn. Stat. § 62N*	Accountable Provider Networks (APNs) *Minn. Stat. § 62T*
Regulating Entity	Licensed and regulated by the Commissioner of Health.	Licensed and regulated by the Commissioner of Health.	Licensed and regulated by the Commissioner of Health.
Required Deposit	■ $500,000 before receiving certificate of authority ■ By the 1st qtr. of the 1st year of operation, deposit = (33% of uncovered expenses from the first year of operation — initial deposit) ■ By the 1st qtr. of each following year, deposit = (33% of uncovered expenses from the first year of operation — amount deposited to date). *(Minn. Stat. § 62D.041)*	Same as HMOs. *(Minn. Stat. § 62N.32)*	Same as HMOs and CISNs, unless the Commissioner grants a waiver. In that case, the APN must meet the following deposit requirements: ■ $500,000 ■ Assets supporting the deposit must meeet the standards for deposits in Minn. Stat. § 62N.32 and the investment guidelines in Minn. Stat. § 62N.27.
Net Worth & Working Capital Requirements	■ Start-up: 8⅓% of the sum of all expenses expected to be incurred in the 12 months following the date of the Cert. of Authority, or $1.5 million, whichever is greater. ■ After 1st full year of operation: at least 8⅓% and at most 16⅔% of the sum of all expenses incurred during the most recent calendar year. ■ In all cases, must be at least $1 million. *(Minn. Stat. § 62D.042)*	CISN must maintain a net worth equal to the greater of: ■ $1 million; ■ 2% of first $150 of annual premium revenue plus 1% of annual premium revenue in excess of $150 million ■ 8% of annual health services costs except those paid on a capitated or managed hospital payment basis + 4% of annual capitated hospital payment costs. ■ 4 months uncovered health services costs. *(Minn. Stat. § 62N.28)*	Same as HMOs and CISNs, unless the Commissioner grants a waiver. In that case, APNs must maintain the following requirements for net worth: ■ $500,000 plus the greater of an estimated 15% of gross premium revenues or twice the net retained annual risk up to $750,000 on a single enrollee

Source: Minnesota Department of Health, 1997.

Regulatory Category	Health Maintenance Organizations (HMOs) *Minn. Stat. § 62D*	Community Integrated Service Networks (CISNs) *Minn. Stat. § 62N*	Accountable Provider Networks (APNs) *Minn. Stat. § 62T*
Phase-In for Net Worth	None.	A 3 year phase-in is allowed with the following requirements: ■ First Enrollee = 50% of net worth; ■ End of Year 1 = 75%; ■ End of Year 2 = 87.5%; ■ End of Year 3 = 100% *(Minn. Stat. § 62N.29, subd. 4)*	■ Same as CISN if CISN standard is used. See above for requirements if Commissioner waives the CISN requirements.
Guaranteeing Organizations	Guaranteeing organization may assume responsibility for HMO's net worth requirements. *(Minn. Stat. § 62D.043)*	Guaranteeing organization may assume responsibility for CISN's net worth requirements. *(Minn. Stat. § 62N.29)*	Same as HMOs and CISNs.
Financial standards	■ Incurred but not reported liabilities *(Minn. Rules 4685.0815)* ■ Reinsurance and catastrophic loss protection *(Minn. Stat. § 62D.042, Subd. 4.)* ■ Internal financial records using GAAP/SAP principles *(Minn. Rules 4685.1960)*	Same as HMOs.	Same as HMOs and CISNs, unless the Commissioner grants a waiver. An APN may propose an alternative method of reporting income, expenses, claims payments, and other financial information.
Geographic Accessibility	■ Primary care or general hospital provider: 30 miles or 30 minutes. ■ Specialty physician, ancillary services and specialized hospital services: 60 miles or 60 minutes ■ Exceptions granted in the case of the absence of providers from a service area or a part of a service area. *(Minn. Rules 4685.1010, Subd. 3)*	Same as HMOs.	Same as HMOs and CISNs.

Source: Minnesota Department of Health, 1997.

Regulatory Category	Health Maintenance Organizations (HMOs) *Minn. Stat. § 62D*	Community Integrated Service Networks (CISNs) *Minn. Stat. § 62N*	Accountable Provider Networks (APNs) *Minn. Stat. § 62T*
	■ MDH approves initial service area and any subsequent expansions, including evidence of acceptable contracts with providers to provide comprehensive services to enrollees. *(Minn. Rules 4685.3300)*		
Governing Body	■ 40% must be consumers elected by enrollees from among the enrollees. ■ HMOs that are also local units of government are exempt from the governing board requirement. Instead, after one year of licensure, these entities must establish an enrollee advisory board consisting of enrollees elected by the enrollees from among the enrollees. *(Minn. Stat. § 62D.06)*	Same as HMOs, except for one additional requirement: ■ 51% must be residents of the CISN's service area. *(Minn. Stat. § 62N.25, subd. 4)*	Must be a nonprofit corporation or a health care cooperative.
Quality Assurance (QA) Requirements	■ Quality evaluation activities must address clinical, organizational and consumer components. ■ File a written QA plan annually. ■ Implement a system for ongoing evaluation of QA program. ■ Must conduct 3 focus group studies each year. ■ MDH performs QA audits at least once every 3 years. *(Minn. Rules 4685.1100 through 4685.1300)*	Same as HMOs with the following exemptions: ■ Focus studies; and ■ Filing written QA plan. *(Minn. Stat. § 62N.25, subd. 7)* MDH performs QA audits at least once every 3 years.	Same as HMOs or CISNs, unless the Commissioner grants a waiver from those requirements. An APN may propose an alternative quality assurance program that incorporates effective methods for reviewing and evaluating data related to quality of care and ways to identify and correct quality problems.

Source: Minnesota Department of Health, 1997.

Regulatory Category	Health Maintenance Organizations (HMOs) *Minn. Stat. § 62D*	Community Integrated Service Networks (CISNs) *Minn. Stat. § 62N*	Accountable Provider Networks (APNs) *Minn. Stat. § 62T*
Annual Reporting Requirements	■ Financial statement; ■ Number of enrollees; ■ Summary of Certificate of Authority documents; ■ Report of financial arrangements between board, principal officers and shareholders; ■ Utilization data; ■ Performance management data; ■ Contracts sold under Medicare, Title XVIII of Social Security Act; and ■ Any information regarding the performance of the HMO. *(Minn. Stat. § 62D.08 & Minn. Rules 4685.1910 through 4685.2600)*	Same as HMOs.	Same as HMOs and CISNs, except for possible differences in financial reporting requirements, as mentioned above.
Other MDH Reporting Requirements	The following items must also be filed with MDH: ■ Provider contracts *(Minn. Stat. § 62D.123)*; ■ Collaboration Plans *(Minn. Stat. § 62Q.075)*; ■ Action Plans *(Minn. Stat. § 62Q.07)*; ■ Expanded provider networks *(Minn. Stat. § 62Q.095)*; ■ Quality assurance plan and related work plan *(Minn. Rules 4685.1100 through 4685.1300)*; ■ Must report changes in provider network within 10 days *(Minn. Stat. § 62D.08, subd. 5)*; ■ Changes in service area *(Minn. Rules 4685.330)*;	Same as HMOs with the following exemptions: ■ Filing quality assurance plan and work plan, although CISNs must have such a plan available, which may be reviewed at any time by MDH; ■ Maintaining statistics under *Minn. Rules 4685.1200*; ■ Filing contracts with network providers though MDH retains the right to review contracts at any time to confirm compliance with Minn. Stat. § 62D.123; and ■ Must report changes in provider network on a quarterly basis. *(Minn. Stat. § 62N.25, subd. 7)*	Same as for HMOs and CISNs, except for possible alternative reporting of financial information, as listed above. Also, an APN, in conjunction with a health care purchasing alliance, may propose alternative methods to present marketing and disclosure information.

Source: Minnesota Department of Health, 1997.

Regulatory Category	Health Maintenance Organizations (HMOs) *Minn. Stat. § 62D*	Community Integrated Service Networks (CISNs) *Minn. Stat. § 62N*	Accountable Provider Networks (APNs) *Minn. Stat. § 62T*
	■ Quarterly financial statements *(Minn. Rules 4685.1980)*; ■ Enrollee's Certificates of Coverage *(Minn. Stat. § 62D.07)*; ■ Changes to Certificate of Authority of license application *(Minn. Rules 4685.3300)*;		
Complaint System	■ Internal complaint system that must include: A) Impartial arbitration provision, B) Reasonable provision for resolution of written enrollee complaints re. scope of coverage, quality of care and administrative operations, and C) An alternative dispute resolution process which must be made available at no cost to enrollees upon their request. ■ Dispute resolution by Commissioner of Health — Enrollees may file a complaint directly with MDH at any time. *(Minn. Stat. § 62D.11, Minn. Stat. § 62Q.105, & Minn. Rules 4685.1700 through 4685.1900)*	Same as HMOs.	Same as HMOs and CISNs.

Source: Minnesota Department of Health, 1997.

Regulatory Category	Health Maintenance Organizations (HMOs) *Minn. Stat. § 62D*	Community Integrated Service Networks (CISNs) *Minn. Stat. § 62N*	Accountable Provider Networks (APNs) *Minn. Stat. § 62T*
Fees/Renewal Fees	■ Certificate of Authority: $1500; ■ Annual Report: $200; ■ Quarterly Report: $100; ■ Amendments to Certificate of Authority: $90; ■ Request of Waiver of Open Enrollment: $100; ■ Demonstration Project Applications: $100; ■ Expense and Revenue Reports: $100; and ■ Annual Renewal Fee for Certificate of Authority: $16,000 + $.46/enrollee. *(Minn. Stat. § 62D.21, 62D.211 & Minn. Rules 4685.2800)*	Same as HMOs.	■ application: $500 ■ amendment to a license: $90 ■ annual report: $200 ■ licensure renewal: $1,000 per 1,000 enrollees, with renewal every three years ■ other filing fees as specified by rule
Benefit Set	Mandated comprehensive health maintenance services include: ■ Emergency care; ■ In-patient hospital care; ■ In-patient physician care; ■ Outpatient health services; and ■ Preventive health services. *(Minn. Stat. § 62D.102 and Minn. Rules 4685.01000, Subp. 5)* In addition, *Minn. Stat. § 62A* mandates that health plans provide certain specific benefits.	Same as HMOs.	APNs may offer and sell any benefits permitted to be offered and sold by health plan companies under Minnesota law.
Claims practices	Must comply with Minn. Stat § 72A.201, Regulation of Claims Practices, including record keeping, claims review procedures, and timeliness of payments to nonparticipating providers.	Same as HMOs.	Same as HMOs and CISNs.

Source: Minnesota Department of Health, 1997.

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