

# Provider Payment Reform in New Hampshire: Legal Considerations for Policymakers

*Prepared for New Hampshire Insurance Department*



JUNE 2014

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## I. Executive Summary

New Hampshire's health care delivery system has limited but growing exposure to innovative provider payment systems, which attempt to replace the traditional fee-for-service payment model with one that prioritizes the Triple Aim, improving population health and patient care, while also reducing costs.<sup>1</sup> This report, commissioned by the New Hampshire Insurance Department (NHID) as part of a multi-stage evaluation of provider payment reform in the state, assesses legal and regulatory obstacles to provider payment reform and discusses options for policymakers—in New Hampshire executive agencies and the General Court. It follows a survey commissioned last year of stakeholder views of provider payment and delivery system reform. NHID will use these two reports to shape policy recommendations on facilitating reform.

This assessment focuses on three areas: state regulation of provider risk-bearing, state and federal fraud and abuse laws, and state and federal antitrust laws. The analysis is conducted in the context of three trends: the movement to innovative provider payment methodologies, including accountable care; the prominence and growth of self-insured employment-based coverage that is largely exempt from state regulation; and the state's intention to expand Medicaid coverage by purchasing commercial individual market health insurance coverage for Medicaid beneficiaries.

Based on an analysis of New Hampshire and federal law, and comparisons with relevant laws from other states, the following appear to be areas that merit further consideration by New Hampshire policymakers:

- *Implementing a regulatory approach to provider risk-bearing that would permit or even encourage self-insured plans to adopt provider payment reforms.* Under existing law, self-insured employers and providers who contract with them may be deterred from entering into risk arrangements because it is unclear how such arrangements would be treated under state insurance law. Reforms in this area could clarify responsibilities and ensure the state's traditional interest in consumer protection is preserved. One approach could be creating intermediate regulatory authority that could permit providers to bear risk from self-insured employers as limited benefit coverage or state-certified risk-bearing providers rather than as major medical insurers. The state may also be able to regulate service providers to self-insured plans, such as third-party administrators and stop loss insurers, to incentivize payment reform.
- *Evaluating circumstances when it would be appropriate to relax state antikickback restrictions on Medicaid contracting that could inhibit provider payment reform.* Federal fraud and abuse laws have been waived for the Medicare Shared Savings Program (MSSP) and providers may be able to leverage those waivers for use with other payers. But the federal waivers do not address state laws, including New Hampshire's Medicaid

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<sup>1</sup> See Inst. for Healthcare Improvement, The IHI Triple Aim, <http://www.ihl.org/Engage/Initiatives/TripleAim/Pages/default.aspx> (last visited 5/29/14).

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antikickback law, and so it may be helpful to evaluate if there are Medicaid payment reforms that would be inhibited by the kickback prohibition.

- *Adopting antitrust enforcement policies similar to those adopted by federal regulators and evaluating whether further action is appropriate to protect providers from antitrust liability.* New Hampshire antitrust law is designed to parallel federal antitrust law. Federal waivers with respect to the MSSP do not automatically waive state antitrust law, and the state might consider adopting similar waivers. The state might also consider whether it seeks to create the sort of pervasive state supervision of payment methods that would immunize the arrangements from state and federal antitrust review.

In each of these domains, close legal analysis is appropriate once state policymakers have clarified their policy goals.

## II. Introduction

New Hampshire healthcare stakeholders are actively working to replace the traditional fee-for-service payment system with a provider payment and healthcare delivery system designed to improve population health and the patient experience (including quality of care) and to reduce costs. Although these efforts are well underway, they remain limited. In 2013, the New Hampshire Insurance Department (NHID) commissioned a survey of existing provider payment reforms that found only 12% of provider payments were made in 2011 using methods other than fee-for-service and only 0.1% of payments used a bundled payment methodology, where a provider receives a single payment for an episode of care rendered by multiple providers. Accountable care organizations (ACOs)—combinations of providers that contract with payers, generally on a risk basis—represent a small but significant portion of the New Hampshire healthcare landscape.<sup>2</sup>

These healthcare delivery system and provider payment reforms represent a challenge to the traditional concerns of healthcare regulators in New Hampshire and elsewhere. Healthcare law and regulation has been designed to protect consumers in the traditional payment paradigm, in which payers bear insurance risk and pay providers on a fee-for-service basis. In the fee-for-service context, this has meant regulating the solvency of payers and ensuring providers do not overbill payers or form anticompetitive combinations. These topics—generically, the regulation of risk bearing, the enforcement of fraud and abuse laws, and the policing of antitrust concerns—remain important in the context of provider payment and delivery system reform. However, their application is often different than it would have been in the past:

- When risk shifts from payers to providers, regulators can examine how the law should encourage—or limit—provider risk bearing.
- Fraud and abuse laws generally police against overuse of services in the fee-for-service environment, but when the payment methodology may itself check overuse, the fraud and abuse laws may need to play a different role.
- Accountable care involves financial or clinical integration of providers to enhance care coordination, but some combinations may create anticompetitive market power.

Even as these traditional healthcare regulatory concerns may need to adjust in some respects to accommodate value- and quality-oriented provider payment reforms, regulators should ensure consumers remain protected.

Building on the 2013 survey, NHID commissioned this report to examine legal and regulatory considerations in provider payment reform. The principal legal regimes discussed are provider risk bearing regulation, fraud and abuse laws, and antitrust concerns. These are analyzed in the context of three major trends in health coverage in New Hampshire. The first is the shift to innovative provider payment methodologies already mentioned. The second is the large and

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<sup>2</sup> Michael G. Grenier et al., Univ. of Mass. Med. School, *New Hampshire's Health Insurance Market and Provider Payment System* 54 (2013).

growing role of self-insured employer-sponsored coverage (including self-insured union-sponsored coverage). About 59% of New Hampshire residents are covered by employer-sponsored coverage and 61% of New Hampshire residents with private sector employer coverage are in self-insured plans, a self-insurance rate somewhat above the national average.<sup>3</sup>

Under federal law, the Employee Retirement Income Security Act of 1974 (ERISA), many private sector self-insured plans are exempt from much state regulation, presenting a challenge for state regulators.<sup>4</sup> Some provider payment reforms are easier to implement if payers use similar payment methodologies; ERISA may make it difficult for the state to achieve a coordinated approach between state-regulated payers and self-insured plans. Furthermore, self-insured plans may be inhibited from voluntarily contracting on a risk basis with healthcare providers for fear of triggering state insurance regulation, as discussed in part three of this report. In light of federal health reform, various trends for self-insured employers could occur. Employer coverage could decline as publicly subsidized individual market coverage becomes more attractive,<sup>5</sup> employers could move from insured to self-insured coverage to avoid the benefit mandates and premium taxes associated with insured coverage,<sup>6</sup> or some combination could occur. In any case, self-insured plans will remain a significant payer type in New Hampshire for at least the immediate future.

The third major trend shaping this analysis is the expansion of the individual market for health insurance due to enrollment under the Affordable Care Act (ACA) and the state's expansion of Medicaid under the New Hampshire Senate Bill (SB) 413. Through 2015, the state intends to use Medicaid managed care entities to cover individuals with household income up to 138% of the federal poverty level. The more significant change occurs beginning in 2016, when this population will be covered in commercial health insurance coverage using Medicaid dollars to pay premiums. This expansion is contingent on the federal Centers for Medicare & Medicaid Services (CMS) approving New Hampshire's waiver application, but, if CMS approves, the federal government will initially cover 100% of the costs of the expansion program. Thus, SB 413 will significantly increase the size of the commercial individual market for health insurance.

This report analyzes how these three trends—shifts towards innovative provider payment methodologies, growth in self-insured plans, and growth in the individual market—impact legal and regulatory considerations in provider payment reform.

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<sup>3</sup> Paul Fronstin, Employee Benefit Research Inst., *Self-Insured Health Plans: State Variation and Recent Trends by Firm Size*, Ebri.org Notes, Nov. 2012, at 6 fig. 5; Kaiser Family Fdn., Health Insurance Coverage of the Total Population, <http://kff.org/other/state-indicator/total-population/> (2013).

<sup>4</sup> Self-insured employer-sponsored coverage for state and local government employees are permitted to be regulated by states, and are therefore not included in this discussion of self-insured employer plans. See ERISA §§ 4(b), 514(a); 29 U.S.C. §§ 1003(b), 1144(a).

<sup>5</sup> See, e.g., Robb Mandelbaum, *Why Employers Will Stop Offering Health Insurance*, N.Y. Times, Mar. 26, 2014, <http://boss.blogs.nytimes.com/2014/03/26/why-employers-will-stop-offering-health-insurance> (citing Ezekiel J. Emanuel, *Reinventing American Health Care* (2014)).

<sup>6</sup> See, e.g., Fronstin, *supra* note 3, at 2.

### III. Regulation of Provider Risk Bearing

State insurance regulators traditionally regulate insurance risk.<sup>7</sup> While *business* risk involves the risk that a particular business's own costs of performing will exceed its contracted prices, insurance risk typically involves assuming the risk of performance by a third party or other contingency, such as the future health of a patient population. Provider risk bearing is a key feature of accountable care and other provider payment and delivery system reforms, and under these reforms it may sometimes be helpful for providers to be at risk for the cost of services beyond traditional business risk. Some states have begun to regulate the assumption of insurance risk by providers. For example, in Massachusetts, a provider that bears "downside risk"—when the provider "is responsible for either the full or partial costs of treating a group of patients that may exceed the contracted budgeted payment arrangements"—is required to obtain a "risk certificate" from the state.<sup>8</sup>

The spectrum of provider payment reforms include pay-for-reporting and pay-for-performance in which providers receive incentive payments for reporting certain quality measures and achieving certain levels on them; patient-centered medical homes, in which providers receive a capitated amount to manage primary care, in addition to their usual fee-for-service payments; bundled or global payments that make a single payment to a group of providers for an episode of care, sometimes including risk-adjustment or quality bonuses; and accountable care organizations (ACOs), where providers take financial risk for the total cost and quality of care of a defined population.

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<sup>7</sup> Although the United States Supreme Court has ruled that the federal government may regulate the business of insurance under the Constitution's Commerce Clause, *United States v. Se. Underwriters*, 322 U.S. 533 (1944), Congress has generally avoided doing so, including explicitly exempting insurance companies from most generally applicable federal law, including antitrust laws, in the McCarran-Ferguson Act, of 1945, 15 U.S.C. §§ 1011-1015. As discussed elsewhere in this paper, in 1974, ERISA reconfigured the types of insurance arrangements that may be subject to federal or state regulation. (And, although beyond the scope of this paper, the Affordable Care Act has significantly increased the scope of federal health insurance regulation.)

<sup>8</sup> Mass. Gen. Laws ch. 176T, §§1, 3.

**Diagram A: Risk-Sharing Models**



Some of these, such as pay for reporting or performance, appear to involve only business risk, which would not ordinarily be a concern for insurance regulators. In other reforms, such as global payments or ACOs, a provider may play a role that has traditionally been played by an insurer. This part analyzes how these types of arrangements might be viewed under New Hampshire law and what legal or regulatory reforms policymakers might consider. The first section addresses considerations when self-insured employers shift risk to providers; the second when the payer is an insurance company or Medicaid; and the third section analyzes issues associated with third-party administrators, stop loss insurers, and other service providers to self-insured plans.

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**Non-Regulatory Approaches: Harnessing the State's Role as a Purchaser and as a Facilitator**

Beyond the legal and regulatory levers identified in this report, New Hampshire has important non-regulatory tools it can use, separately or in tandem, to encourage payment reform. First, New Hampshire is a significant purchaser of health care in its role as an employer and can use that leverage to move providers away from fee-for-service reimbursement. Second, the expansion and transformation of New Hampshire's Medicaid program provides an opportunity to implement payment reform. Third, the state can encourage private employers to move to innovative payment methods, either by modeling payment methods in state programs that private employers could also use or by directly facilitating collaboration among employers.

The state has begun these efforts by forming the New Hampshire Purchasers Group on Health (PGH), a coalition of four major public employee health plans: the State of New Hampshire Employee Health Benefits Program, the University System of New Hampshire, the New Hampshire Local Government Center HealthTrust, and the New Hampshire School Health Care Coalition, representing more than 120,000 covered lives. PGH has developed a New Hampshire Hospital Cost and Quality Scorecard,<sup>1</sup> which is designed to help employers and patients select hospitals based on quality and cost, using a methodology developed by the Maine Health Information Center. PGH has launched limited pilot projects on patient-centered medical homes and accountable care, and could take on additional initiatives modeled on public payer initiatives in other states. In California, for example, the Public Employees' Retirement System (CalPERS) has developed a reference pricing model for hip and knee replacements. Plan participants are liable for any amount above a reasonable reference price, encouraging plan participants to shop for hospitals that can perform the surgery for less than the reference price and driving hospitals to bring their costs under the reference price. Other payers are considering adopting this model, and applying it to a broader range of services, in light of CalPERS's success.<sup>2</sup>

New Hampshire's expansion of Medicaid presents another opportunity for the state to model payment reform for other payers. Under Senate Bill 413, beginning in 2016, the state plans to buy commercial health insurance coverage for Medicaid beneficiaries, pending CMS approval. This approach, known as premium assistance, is based on similar efforts in Arkansas. In Arkansas, premium assistance Medicaid expansion is linked to the Arkansas Health Care Payment Improvement Initiative, which seeks to put providers at risk for each episode of care, on top of traditional fee-for-service payments. Depending on how New Hampshire's premium assistance program is eventually developed, the state could choose to link insurer participation in the expansion with payment reform. This could drive insurers toward quality-based payments and could be a model for self-insured employers.

Finally, employer-led coalitions are often leading voices for payment reform and the state could play a role in convening employers. PGH has seen little interest to date from private employers in payment reform, which may be due to the limited number of New Hampshire-based private employers who are large enough to initiate such an effort. In other states, private employer-led coalitions, such as the National Business Group of Health and its state and regional affiliates, have adopted common standards for quality and used those as a basis for contracting with providers. Catalyst for Payment Reform, a coalition of employers and health plans, has developed a toolkit that employers can use to develop innovative payment methods. New Hampshire could convene employers to help them understand what has worked in other states and what private employers can gain from state government provider payment initiatives. One caution is that when employer collaborations become so tightly integrated that the employers are said to have a single employee benefit plan, the state can regulate the arrangement as a multiple employer welfare arrangement (MEWA), which may be undesirable to employers. General collaboration among employers about payment methods, with each employer still maintaining its own benefit plan, does not constitute a MEWA, and private sector self-insured employers would remain exempt from direct state insurance regulation.

<sup>1</sup> <http://www.nhpghscorecard.org/>

<sup>2</sup> See Amanda E. Lechner et al., Ctr. for Studying Health System Change, Research Brief No. 30, *The Potential of Reference Pricing to Generate Health Savings: Lessons from a California Pioneer* (2013). Federal regulators have raised questions about whether reference pricing is consistent with federal limits on cost sharing. The Department of Labor indicated that, pending further federal guidance, reference pricing does not violate the federal rule on cost sharing, but the agencies are seeking public comment and may take further action. See FAQs About ACA Implementation (Part XIX) 5 (2014), available at <http://www.dol.gov/ebsa/pdf/faq-aca19.pdf>.

A. *Self-Insured Employers Shifting Risk to Providers*

- Absence of clear regulations may inhibit self-insured employers contracting with providers on risk basis
- There are intermediate options for regulating provider risk bearing
- Financial standards and other consumer protections could be tailored to particular risks

Like many other states, New Hampshire’s principal concern in regulating risk-bearing entities is ensuring that whenever insurance risk exists there is a state-licensed entity or government entity with ultimate financial responsibility to the policyholder or beneficiary.

The New Hampshire approach is described in the insurance code: any entity that provides “coverage” in New Hampshire for medical expenses—“whether such coverage is by direct payment, reimbursement, or otherwise”—is presumed to be subject to NHID jurisdiction except when regulated by another state or federal agency while providing such services.<sup>9</sup> Thus, accountable care, global payments, and other insurance risk-shifting arrangements between providers and *Medicare* or *Medicaid* would not fall under NHID jurisdiction because they are under the jurisdiction of other state and federal agencies. Furthermore, to date, managed care in Medicare and Medicaid has operated only through state-licensed insurers or health maintenance organizations (HMOs). This approach will continue under the state’s proposed Medicaid expansion, which will be carried out by state-licensed managed care entities and then commercial insurers, assuming CMS approves the state’s waiver. Finally, commercial insurers themselves are clearly within NHID’s jurisdiction. When commercial insurers shift insurance risk to providers, that payment arrangement could itself be considered “coverage” subject to NHID’s jurisdiction, although the state has not historically regulated it as such. (Section B describes some other approaches to risk-sharing between providers and licensed insurers.) This leaves arrangements between providers and self-insured employers.

Employers see several advantages to self-insuring their group health plans:

- Under ERISA,<sup>10</sup> employee benefit plans are exempt from state regulation, although state regulation of health insurance sold to an employee benefit plan is permitted. Thus, insured plans would be subject to state premium taxes and benefit mandates and self-insured coverage would not be.
- The ACA imposes additional benefit, premium rate setting, and premium tax requirements on health insurance that do not apply to self-insured coverage. The additional regulatory requirements associated with insured coverage makes it less attractive to many employers.<sup>11</sup>

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<sup>9</sup> N.H. Rev. Stat. § 415:23(l).

<sup>10</sup> § 514(a), (b)(2), 29 U.S.C. § 1144(a), (b)(2).

<sup>11</sup> Another type of self-insured coverage is offered through multiple employer welfare arrangements (MEWAs), in which, as the name implies, multiple employers band together to collectively provide health benefits to their employees. Because of historic abuse of the MEWA form to circumvent state insurance regulation, ERISA treats MEWAs differently than other self-insured group health plans: MEWAs that are not fully insured may be subject to

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- ERISA limits the potential liability employers face from wrongfully denied benefits. While insurers may have to pay for consequential or punitive damages under state law, self-insured employers are liable under ERISA to pay for only the benefits owed.<sup>12</sup>

NHID is not currently aware of arrangements where New Hampshire-based self-insured employers have sought to contract on a risk basis with providers. If employers did contract with providers on a risk basis, it could potentially make those providers subject to the NHID's jurisdiction, because they would appear to be providing coverage to the employer which is not otherwise subject to the NHID's jurisdiction. If NHID were to determine that providers that contract on a risk basis with self-insured employers should be treated as major medical insurance companies, that decision would effectively halt these arrangements: it would mean self-insured employers would lose the advantages of self-insurance. Furthermore, providers may be interested in bearing risk, but not if it means having to satisfy the full financial and regulatory requirements that apply to a major medical insurance company.

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state insurance law, to the extent the state laws do not directly conflict with ERISA provisions. ERISA § 514(b)(6), 29 U.S.C. § 1144(b)(6). New Hampshire regulates non-fully-insured MEWAs, see N.H. Rev. Stat. § 415-E:2. Therefore, for the purpose of this analysis, non-fully-insured MEWAs are treated as commercial insurers. Insurance sold to fully insured MEWAs may be regulated comparably to any health insurance sold to a group health plan.

<sup>12</sup> ERISA § 502, 29 U.S.C. § 1132(a)(1)(B).

### Comparative Approaches

- Colorado licenses providers to bear risk for a limited range of services, so far only used for behavioral health
- Massachusetts newly requires providers that bear downside risk from payers – insured or self-insured – to obtain a “risk certificate.”

Insurance regulators typically start with the premise that provider risk sharing that resembles HMO risk sharing should require a health insurance license. This was the position taken by the National Association of Insurance Commissioners (NAIC) in 1998. Recognizing that risk-bearing providers “perform the same or similar functions as state regulated entities such as HMOs and other health plans,” the NAIC recommended that the same solvency and consumer protections apply to these providers as apply to HMOs. The NAIC suggested that state insurance commissioners apply HMO risk-based capital requirements to providers that bear insurance risk, unless the provider is downstream from another licensed entity.<sup>13</sup>

A small number of states have tried to establish a middle path that recognizes a continuum of risk-bearing by providers that are not downstream from licensed insurers. Three examples that predate the current wave of payment reform occurred in Colorado, Minnesota, and with the federal Balanced Budget Act of 1997. The Minnesota and federal efforts have since been abandoned (see sidebar). More recently, regulators in Massachusetts have taken a more comprehensive approach.

#### Two Abandoned Efforts at Special Rules for Provider Risk-Bearing

During the 1990s, at least two efforts were undertaken to create a regulatory structure for providers to bear risk without obtaining a health insurance license. It does not appear any providers were certified under these regimes.

- In 1995, Minnesota adopted a law that allowed previously existing health provider cooperatives, regulated by the Commissioner of Health, to provide health care services to previously existing self-insured employer plans.<sup>1</sup> The Minnesota insurance regulator is not aware of any cooperatives that actually operated under this law, and the law expired in 1999 under a sunset provision. Current Minnesota law prohibits provider cooperatives and other providers from taking insurance risk except under contract with a licensed health insurer.<sup>2</sup>
- An intermediate licensing scheme was envisioned for providers in the federal Balanced Budget Act of 1997, which authorized provider-sponsored organizations to contract directly with Medicare, in the program now known as Medicare Advantage. Generally, only state licensed insurers can contract with Medicare to provide Medicare Advantage plans, but the Balanced Budget Act allowed certain provider-sponsored organizations to do so without a state insurance license if they met certain solvency requirements specially designed for provider organizations.<sup>3</sup> This provision was intended as a safety valve if state licensing of provider-sponsored organizations interfered with program implementation through long delays or burdensome requirements, but state licensing proved satisfactory and federal licensing has not been pursued.

<sup>1</sup> See MinnesotaCare Act of 1994, art. 1 §§ 3, 4, art. 9 § 1, available at <https://www.revisor.mn.gov/laws/?doctype=Chapter&year=1994&type=0&id=625>.

<sup>2</sup> Email from Tim Vande Hey, Deputy Commissioner, Ins. Div., Minn. Dep’t of Commerce, to Joel Ario regarding Providers Taking Risk (June 7, 2014).

<sup>3</sup> See 42 C.F.R. §§ 422.350-390.

<sup>13</sup> Nat’l Ass’n of Ins. Commissioners, *Suggested Bulletin Regarding Provider Sponsored Organizations* (1998), available at <http://www.naic.org/store/free/HCP-OB.pdf>; see also Nat’l Ass’n of Ins. Commissioners, *Suggested Bulletin Regarding Certain Types of Compensation and Reimbursement Arrangements Between Health Care Providers and Individuals, Employers and Other Groups* (1995).

In Colorado, regulations establish licensing rules and risk-based capital requirements for risk-bearing providers that are not downstream from an insurer. The rules apply only if the provider is bearing risk for a limited range of services: either a narrowly defined medical specialty, services rendered at a single type of licensed facility, or services performed in a patient's home. The regulation imposes financial requirements commensurate with the services the provider offers.<sup>14</sup> Colorado regulators report that these risk-bearing limited-service provider networks have been established only for behavioral health services, and that the Colorado regulation has not provided a solution for self-insured plans interested in direct contracting with risk-bearing providers offering broader services.<sup>15</sup>

More recently, Massachusetts regulators sought to incentivize large scale risk-bearing by provider groups, including through direct contracting with self-insured plans. Under its 2012 health care cost control legislation, Massachusetts requires providers to obtain a "risk certificate" in order to bear downside risk under any non-fee-for-service arrangement.<sup>16</sup> The requirement applies both when the provider is downstream from a licensed insurer and from a self-insured employer. The default rule under this law appears to be that a provider that bears downside risk from a self-insured employer would need to be licensed as an insurer, but under proposed regulations that have not yet been finalized, there is a provision for a provider bearing risk from a self-insured employer without being licensed as an insurer: if a provider bears downside risk under its contract with an insurer, the provider can also bear downside risk when the same insurer serves as a third-party administrator for a self-insured plan and the provider payment terms under the insured arrangement are substantially the same as the provider's payment terms under the self-insured arrangement.<sup>17</sup> To receive a risk certificate, providers would have to tell regulators what insurers and employers they intend to contract with (and whether they will contract directly with individuals for coverage). Under the proposed regulation, the provider also would need an actuarial certification that the risk-sharing will not threaten the provider's solvency, an internal and external appeal process, and a utilization review process.<sup>18</sup> Insurance regulators may conduct financial examinations of risk-bearing providers.

### *Implications*

- Absence of clear regulations may inhibit self-insured employers contracting with providers on risk basis
- Underutilization is a concern when providers bear risk and regulatory approach could control underutilization

Treating a risk-bearing provider entity as an insurance company that issues major medical health insurance contracts or policies would change its treatment under federal law, as well as

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<sup>14</sup> See 3 Colo. Code Regs. § 702-2:2-1-9.

<sup>15</sup> Telephone interview with Cindy Hathaway, Dir., Corporate Affairs Div., Colo. Dep't of Regulatory Agencies (June 5, 2014).

<sup>16</sup> Mass. Gen. Laws ch. 176T, § 3.

<sup>17</sup> Proposed to be codified as 211 Mass. Code Regs. 155.03(3).

<sup>18</sup> Proposed to be codified as 211 Mass. Code Regs. 155.06(2).

under state law. For example, if such a provider/insurance company provides coverage to small employers, it would be considered health insurance coverage in the small group market and the provider organization would need to provide coverage for the full essential health benefits package required under the ACA, which may not align with the provider's intended business model.<sup>19</sup> In contrast, an approach like Colorado's treats providers that bear risk for a limited range of services in the same way as dental and vision plans are treated by regulators. They are subject to some state regulation but the state financial requirements are limited and these entities are not considered providers of health insurance coverage for the purpose of federal health insurance regulation.<sup>20</sup> It may be possible that the existing limited benefit exceptions to what constitutes major medical coverage under state and federal law could be expanded to include one or more additional categories that are treated differently than major medical coverage for purposes of serving self-insured employers.

Concerns about underutilization also arise when providers bear risk. While a similar dynamic exists for insurers, insurers are pervasively regulated and monitored, with regulatory standards for claims administration, internal appeals, external reviews, and grievances processes.<sup>21</sup> Furthermore, the separation between the provider and insurer offers some independent limitation on underutilization for financial reasons. These sorts of controls are difficult to implement when the provider is at financial risk for care; clinical decision making is not as amenable to review as insurer coverage determinations. Medicare has attempted to address some of these concerns in its payment reforms. In the inpatient context, where Medicare pays hospitals on the basis of a prospective payment system, not billed fees, hospitals are prohibited from giving physicians incentives to reduce or limit care.<sup>22</sup> In the MSSP, CMS monitors accountable care organizations to ensure financial incentives are not resulting in underuse of appropriate care.<sup>23</sup> Massachusetts addresses this concern by requiring providers to have an internal appeal and external review process and to disclose their utilization review process to the state. State regulators should consider whether there is a role for them to play in ensuring that providers that bear risk, from self-insured plans or other payers, are not driving underutilization.

### **Policy Options: Self-insured Employers Shifting Risk to Employers**

Given the complicated interplay between financial solvency, consumer protection and payment reform, New Hampshire policymakers may be most interested in situations that involve shifting risk from self-insured employers to providers, where the providers are not currently licensed or regulated by the state as risk-bearing entities. The size of

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<sup>19</sup> See Public Health Service Act §§ 2707, 2791(b), 42 U.S.C. §§ 300gg-6, -91(b).

<sup>20</sup> Vision and dental plans are explicitly exempt from ACA requirements. See Public Health Service Act § 2791(c), 42 U.S.C. 300gg-91(c). Risk-bearing providers for other services do not have the same federal statutory exception, but might be considered not insurance companies and therefore entirely exempt from federal insurance regulation under the ACA.

<sup>21</sup> See, e.g., N.H. Stat. § 415-A:4-a.

<sup>22</sup> Social Security Act § 1128A(b)(1), 42 U.S.C. 1320a-7a(b)(1).

<sup>23</sup> Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802, 67871 (Nov. 2, 2011).

the self-insured employer market, including the growing prominence of self-insured plans in the mid-sized employer market, and the growing interest in provider risk-bearing to drive value and quality improvements in healthcare make this an important area. Several types of policy reforms may be considered:

- New Hampshire could consider clarifying when risk shifted to providers makes the provider an HMO under the current regime.<sup>24</sup> The absence of state guidance that speaks directly to when a provider becomes an HMO may prevent providers and employers from entering risk arrangements that could improve care and reduce costs. On the other hand, the state may prefer not to offer guidance on this topic because it preserves flexibility for the state to apply HMO law to provider organizations on a case-by-case basis.
- New Hampshire could consider establishing reporting obligations for providers that bear risk, in anticipation of further regulation. This reporting obligation could be modeled on the reporting obligations that Massachusetts is considering imposing in connection with its proposed regulation on provider risk certificates. These reporting requirements could help the state understand what types of risks providers are bearing and who their counterparties are. If these reports indicate interest in contracting between risk-bearing providers and self-insured employers, the state could examine further regulatory options.
- Another incremental reform, also drawn from Massachusetts, might be to define limited circumstances in which a provider entity that is bearing risk downstream from an insurer can bear similar risk from a self-insured plan that is serviced by the same insurer.
- One broader reform that builds on the Colorado approach might be a regulatory regime that establishes intermediate licensing for risk-bearing providers, but on a wider scale than what Colorado has done to date. The regime would need to distinguish between risk-bearing providers and HMOs, perhaps based on the range of services they offer or to whom the services are offered, and would indicate what elements of state insurance law, if any, would apply to such providers. Such a policy could use a calibrated risk-based capital (RBC) approach to impose limited RBC standards based on the range of services offered, the effectiveness of medical management, the number of covered lives, the speed of growth, the degree of risk assumed, and other factors.<sup>25</sup> Some provider payment reforms might involve no insurance risk and therefore present no need for

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<sup>24</sup> New Hampshire law defines an HMO as an organization that (1) makes available health care services to enrolled participants, (2) is compensated “on a primarily predetermined periodic rate basis,” and (3) provides physician services through employed or partner physicians or arrangements with one or more physicians or groups of physicians. N.H. Rev. Stat. § 420-B:1(VII).

<sup>25</sup> See, e.g., Nat’l Ass’n of Ins. Commissioners, Risk-Based Capital General Overview 3 (2009), available at [http://www.naic.org/documents/committees\\_e\\_capad\\_RBCoverview.pdf](http://www.naic.org/documents/committees_e_capad_RBCoverview.pdf).

insurance regulation. Others might be so broad that they should be undertaken only by licensed HMOs. But many might fit somewhere else on this continuum.<sup>26</sup>

- Another regulatory approach, either in conjunction with solvency regulation or independently, is establishing standards or processes that could be used to protect patients from underutilization in cases where providers have financial incentives to limit care. As Massachusetts appears to be doing, New Hampshire could consider applying appeal, grievance, and utilization management standards to risk-bearing providers.

*B. Licensed Insurers and Medicaid Shifting Risk to Providers*

- Regulators not as concerned with providers taking downstream risk from insurers
- But risk contracting could undermine consumer protection and threaten insurer solvency
- There are options for regulating provider risk contracting with both insurers and Medicaid
- In New Jersey, large risk transfer between a licensed HMO and a large provider organization undermined the solvency of both the HMO and the provider
- In New York, state has regulated provider risk transfers from licensed insurers

A second concern for some regulators is providers bearing risk under contracts with insurers and Medicaid, not just self-insured employers. NHID may be reluctant to regulate risk arrangements between providers and insurers, because doing so may undermine the general approach that the main state-licensed entity (i.e. the insurer) is required to maintain full financial responsibility. While it appears that the state Medicaid agency would have primary jurisdiction over contracting between Medicaid and providers, some insurance regulators have viewed it as within their responsibility to regulate risk arrangements downstream from licensed insurers, and some states have imposed requirements on providers that contract on a risk basis with Medicaid, such as the current New Hampshire requirement that Medicaid managed care organizations be licensed HMOs. In New York, the health department is considering regulations that would require ACOs that seek to contract directly with fee-for-service Medicaid to be certified, which would impose governance and other requirements on the ACO,<sup>27</sup> and insurance regulators already regulate provider risk arrangements downstream from licensed insurers.

There are several reasons regulators might be interested in regulating risk arrangements downstream from licensed insurers:

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<sup>26</sup> It is unclear how such an intermediate licensing would be treated by federal regulators. Federal regulation has a broad definition of health insurance, but with exception for limited benefit coverage such as dental or vision coverage, or fixed indemnity coverage. See Public Health Service Act § 2791(b), (c), 42 U.S.C. § 300gg-91(b), (c). Depending on the particular state regulatory approach, it may be possible to argue that the risk-bearing providers do not offer health insurance or, if they do, it is exempt under one of the existing exceptions. But some state provider-risk bearing licensing regulations could require a federal law amendment to be exempted from the federal definition of health insurance.

<sup>27</sup> New York has not yet published a proposed regulation, but has circulated a draft to stakeholders that we have read.

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- Providers that are being paid on a risk basis might go bankrupt, jeopardizing continuity of care for patients and potentially threatening the solvency of the upstream insurer. States have mechanisms for dealing with transitional coverage, but they often impose unwelcome burdens on consumers and other providers.
- Providers may not have sophisticated financial systems to measure risk and so may be assuming more risk under provider payment reforms than is appropriate for their financial capacity. Regulators may want to ensure that when providers have responsibility for coverage they are not made vulnerable by their payment arrangements, and otherwise have the capacity to absorb the risk they are assuming.
- Even where the provider is financially healthy, provider payment arrangements could have an adverse impact on the solvency of insurers, if the payment methodology provides significant upside potential to providers that is not properly accounted for by the insurer. The interrelationship between insurer and provider risk is well illustrated by a late 1990s case in New Jersey, where an undercapitalized HMO, the HIP Health Plan of New Jersey, contracted with a provider network, PHP Healthcare Corp., so that PHP became responsible for most of HIP's healthcare delivery. PHP was not licensed as an insurer, and given the large-scale transfer of risk to PHP, New Jersey regulators took the position that PHP itself needed an insurance license. PHP refused and the state nonetheless permitted the arrangement to operate. A year after the deal was struck, it collapsed. PHP stopped paying providers and eventually filed for bankruptcy. HIP entered voluntary rehabilitation.<sup>28</sup>

In the face of such risks, New York adopted regulations of risk transfers from licensed insurers to health care providers, apparently on the theory that providers that bear risk are engaging in the business of insurance, even if they are downstream from a licensed insurer. Under these regulations, the insurer retains full financial responsibility to enrollees in case of a provider's insolvency. Nonetheless, providers must demonstrate financial responsibility—which can be demonstrated through a security deposit, stop loss coverage, a letter of credit, or a minimum net worth—to enter into these arrangements. Certain small risk-sharing arrangements are exempt from these requirements.<sup>29</sup> New York's health department has also considered but not yet adopted regulations for ACOs that contract with fee-for-service Medicaid. Finally, in Medicare managed care (Medicare Advantage), plans are permitted to download risk to providers but in some situations the providers must have stop-loss coverage when they are at significant financial risk for medical care provided by others.<sup>30</sup> This reflects a federal interest in limiting provider risk, even in situations where a licensed insurer, such as a Medicare Advantage organization, maintains full financial responsibility.

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<sup>28</sup> See Linda R. Brewster et al., Ctr. for Studying Health Sys. Change, Issue Brief No. 26, *Insolvency and Challenges of Regulating Providers that Bear Risk 2* (2000), available at <http://www.hschange.com/CONTENT/56/56.pdf>.

<sup>29</sup> 11 N.Y. Codes R. & Regs. §§ 101.4-.10

<sup>30</sup> 42 C.F.R. § 422.208.

### **Policy Options: Providers Bearing Risk From Insurers and Medicaid**

- New Hampshire policymakers should evaluate the risks to consumers from significant risk shifting to providers, even when there is an upstream insurer. Any regulatory approach should require that insurers retain full financial accountability, but the regulations could still put some procedural or substantive limits on provider risk bearing. Procedural limits could require filing for certificates of authority so that the state is aware when these arrangements occur. Substantive limits could require stop-loss coverage so there is a maximum amount of risk that providers can retain, or require particular financial requirements for providers to enter into these arrangements, such as a minimum net worth or a security deposit. Like the New York insurance regulator, NHID might be able to regulate providers under its current statutory authority by deeming providers that bear risk to be engaging in the business of insurance. Even if a risk-bearing provider is downstream from a licensed insurer, the provider could still meet the statutory definition of an HMO and NHID might be able to prescribe particular requirements for such a provider under the authority of the HMO law.
- New Hampshire currently operates its Medicaid managed care program through licensed HMOs and intends to expand Medicaid through commercial health insurance coverage, but to the extent fee-for-service Medicaid options exist and pay providers on a risk basis, the state may want to consider regulating provider risk bearing in Medicaid. Although NHID may not have jurisdiction over these arrangements, NHID may want to work with the state Department of Health and Human Services (DHHS) to understand circumstances when the Medicaid program shifts risk directly to providers, without a managed care entity involved. It may be appropriate for DHHS to impose solvency, stop loss, or other requirements on providers in these circumstances in a manner similar to what the federal government has done with Medicare Advantage coverage.

#### *C. Regulation of Group Health Plan Service Providers (TPAs and Stop-Loss)*

- ERISA puts some limits on state regulation of TPAs
- Conflicting case law makes it difficult to predict where these limits lie
- Stop loss coverage with low attachment points may encourage self-insurance and further splinter payers, which could undermine alignment on payment reform

Apart from directly regulating provider arrangements with group health plans, New Hampshire policymakers may wish to consider whether they can incentivize provider payment reform through their authority to regulate the third-party administrators (TPAs) and stop loss insurers that provide services to group health plans.

## *TPAs*

Most self-insured employers use TPAs to contract with providers and process claims. TPAs may also include specialized entities, such as pharmacy benefit managers (PBMs) or behavioral health organizations. Although ERISA preempts state regulation of employee benefit plans, insurance regulation is not preempted, which has generated confusing jurisprudence as to what regulation is actually preempted by ERISA. The NAIC has promulgated a model TPA regulation that many states have adopted in whole or in part.<sup>31</sup> ERISA preempts only state laws that relate to or reference an employee benefit plan. This suggests that a state law that regulates a TPA would not be preempted. However, when the state law is designed to regulate indirectly a group health plan that the TPA administers, federal courts have held that such laws are preempted. The line between regulating a TPA and regulating the plan the TPA administers is indistinct, and indeed different federal appeals courts have differed in their determination of whether particular types of laws are preempted. To illustrate how courts have wrestled with these questions, we discuss six types of regulations of TPAs: any willing provider laws, mental health parity laws, provider prompt payment laws, payment methodologies, PBM regulation, and claims data reporting requirements.

*Any willing provider laws.* A leading case in this area is a 2003 Supreme Court decision, *Kentucky Association of Health Plans, Inc. v. Miller*.<sup>32</sup> A Kentucky law required health plans to contract with any provider willing to meet the plan's standard terms and conditions. The Supreme Court ruled that the requirement related to employee benefit plans, but was not preempted because it also regulated the business of insurance, a type of state law that ERISA explicitly saves from preemption. The Supreme Court here established the current test for determining whether a state law regulates the business of insurance: it must (1) be specifically directed at entities engaged in insurance and (2) substantially affect the risk pooling arrangement between the insurer and insured.<sup>33</sup> In addition to applying to insurers, the Kentucky any willing provider law applied to HMOs that were acting as TPAs for self-insured plans. The Supreme Court held that because the law principally applied to insurers, the law continued to be not preempted when it applied to TPAs: "there is no reason to think Congress would have meant such minimal application to noninsurers to remove a state law entirely from the category of insurance regulation saved from preemption."<sup>34</sup> This language suggests a broad reading of the savings clause to protect TPA regulation. However, as illustrated below, federal appeals courts have not consistently followed the Supreme Court on this point.

*Mental health parity laws.* In 2005, the Eighth Circuit ruled that a Nebraska mental health parity law could not be applied to a self-insured plan via its third-party

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<sup>31</sup> Nat'l Ass'n of Ins. Commissioners, NAIC Model Reg. Serv., Registration and Regulation of Third Party Administrators (2011), available at <http://www.naic.org/store/free/GDL-1090.pdf>.

<sup>32</sup> 538 U.S. 329 (2003).

<sup>33</sup> *Id.* at 341-42.

<sup>34</sup> *Id.* at 336 n.1 (quoting *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 372 (2002) (quotation marks omitted)); see also *Prudential Ins. Co. v. Nat'l Park Med. Ctr., Inc.*, 415 F.3d 897 (2005) (upholding Arkansas any willing provider law's application to third-party administrators in light of *Kentucky Association of Health Plans*).

administrator, even if the mental health parity law also applied to the third party administrator in its capacity as an insurer.<sup>35</sup> This ruling is hard to reconcile with the statement in *Kentucky Association of Health Plans* that permits states to continue to enforce regulations that minimally affect noninsurers, and raises the question of whether the Kentucky case truly established a new test for preemption of state insurance regulations that apply to third party administrators or only a special rule for any willing provider laws.

*Prompt payment laws.* Earlier this year, the Eleventh Circuit ruled that Georgia’s prompt payment law, which required both health insurers and third party administrators of group health plans to pay claims within fifteen days or provide notice explaining why the claim was not being paid, was preempted with respect to self-insured group health plans.<sup>36</sup> The Eleventh Circuit relied on a formal distinction between insured and self-insured plans, and held that a state law could not regulate the timeliness of benefit payments of self-insured plans.<sup>37</sup> The Eleventh Circuit did not acknowledge the language in *Kentucky Association of Health Plans* that apparently permits regulation of TPAs to the extent it is incidental to regulation of insurers. Instead, the Eleventh Circuit concludes: “We are not persuaded by the argument that the challenged . . . provisions are not preempted to the extent that they only apply to TPAs, as this position ignores the fact that TPAs would be acting pursuant to the underlying self-funded ERISA plans. Whether direct or indirect, state insurance regulation of self-insured ERISA [plans] is not allowed.”<sup>38</sup>

*Payment methodologies.* In another leading Supreme Court case decided in 1995, the Supreme Court upheld a New York requirement that hospitals be paid by both insurers and third-party administrators on behalf of self-insured ERISA plans using a diagnosis-related group (DRG) methodology. Instead of holding that this was a regulation of the business of insurance that is saved from ERISA preemption, the Supreme Court held that this was actually regulation of hospitals and therefore did not relate to an employee benefit plan, so as not to come within the ambit of ERISA preemption in the first place.<sup>39</sup> This case has led lawyers to conclude that state regulations that principally regulate the relationships between plans and providers, including setting provider payment methodologies, may not be preempted, whereas laws that regulate the relationship between plan participants, the plan, and the employer (such as laws that set requirements for benefits) are more vulnerable.

*Claims Data Reporting Requirements.* Earlier this year, the Second Circuit struck down a Vermont statute that required TPAs to report claims to an all-payer claims database on behalf of their self-insured employer clients. The Vermont requirement applied to both

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<sup>35</sup> Daley v. Marriott Int’l, Inc., 415 F.3d 889, 895 (10th Cir. 2005).

<sup>36</sup> Am.’s Health Ins. Plans v. Hudgens, 742 F.3d 1319 (11th Cir. 2014).

<sup>37</sup> *Id.* at 1333-34.

<sup>38</sup> *Id.* at 1333 n.18.

<sup>39</sup> N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers, 514 U.S. 645 (1995).

insurers and TPAs of self-insured plans. The Second Circuit concluded that ERISA explicitly preempts state laws governing “reporting, disclosure, fiduciary responsibility, and the like.”<sup>40</sup> Nevertheless, the Second Circuit’s opinion was decided on a 2-1 vote and the dissenting judge argued that Vermont’s reporting requirement, which focused on medical claims information, did not conflict with ERISA’s reporting requirements, which focus on a plan’s financial condition, and that reporting requirement did not affect claims administration or benefits, and therefore should not have been preempted.<sup>41</sup> Given the closeness of the Second Circuit decision, it is quite possible other appeals courts would diverge from its holding.

*PBM regulation.* One type of TPA, pharmacy benefit manager (PBMs), has faced particular scrutiny. The First Circuit, whose jurisdiction includes New Hampshire federal courts, has upheld a Maine law that requires PBMs to act in the fiduciary interest of their clients, including self-insured plans, and to disclose conflicts of interests and certain financial arrangements with third parties. The First Circuit concluded that these requirements did not prevent self-insured plans from governing the structure or administration of their plans.<sup>42</sup> The D.C. Circuit, however, has declined to follow this opinion, concluding that a nearly identical District of Columbia law impermissibly prevents the national uniform administration of employee benefit plans.<sup>43</sup>

These ERISA cases illustrate how difficult it can be to predict how the courts will interpret TPA cases that involve insurance-based regulation but also relate to employee benefit plans. This makes it likely that states will continue to search for permissible ways to regulate in-state TPAs as a means of integrating self-insured employers, who play a significant role in all state marketplaces, into their multi-payer payment reforms. Existing New Hampshire TPA law imposes some minimal regulations on TPAs, including limiting compensation systems that incentivize TPAs to restrict care.<sup>44</sup> The experiences of other states described here demonstrate that additional reforms may survive scrutiny, but further regulations will require careful analysis. Given the conflicting guidance from the courts to date, the potential for additional litigation is high, and it may be difficult to predict outcomes with a high degree of certainty.<sup>45</sup>

### *Stop Loss Insurance*

In addition to using TPAs, many self-insured employers obtain stop loss coverage to protect against catastrophic financial losses (this coverage is often provided by the TPA). Regulators

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<sup>40</sup> Liberty Mut. Ins. Co. v. Donegan, 746 F.3d 497, 508 (2d Cir. 2014).

<sup>41</sup> *Id.* at 511 (Straub, J., dissenting).

<sup>42</sup> Pharm. Care Mgmt. Ass’n v. Rowe, 429 F.3d 294 (1st Cir. 2005).

<sup>43</sup> Pharm. Care Mgmt. Ass’n v. Dist. of Columbia, 613 F.3d 179, 190 & n.\* (D.C. Cir. 2010).

<sup>44</sup> See N.H. Rev. Stat. § 402-H:8.

<sup>45</sup> Payment reform encourages alignment across payers within a state, but as discussed here that is often difficult to achieve with self-insured employers, particularly those out-of-state. One of ERISA’s goals is to permit employers to establish national uniform benefit plans, without regard to fifty different sets of state requirements. As these cases demonstrate some states have attempted to address these cross border issues by regulating in-state service providers to out-of-state employers, to mixed results.

generally view stop-loss as coverage that insures against financial risk to the employer to distinguish it from health insurance, which insures against the medical risk of plan participants. For example, some regulators believe coverage is not considered stop-loss if benefits can flow to the plan participant in the case of the employer's bankruptcy, although there is dispute on this point.<sup>46</sup>

At present, stop loss coverage is not generally subject to state and federal regulations applicable to health insurance. ERISA generally permits states to regulate stop loss coverage sold to self-insured plans.<sup>47</sup> For example, states may impose taxes on stop loss coverage that are calculated based on reference to benefits paid out by self-insured plans that the stop loss coverage applies to.<sup>48</sup> However, the Fourth Circuit has ruled that a Maryland statute that would have applied health insurance benefit mandates to stop-loss coverage below a certain attachment point was preempted by ERISA because the Maryland statute was attempting to "mandate the benefits that certain self-insured plans may offer."<sup>49</sup> The Fourth Circuit distinguished stop-loss insurance and health insurance based on who was insured (the plan v. the plan participant) and acknowledged that states may regulate stop-loss insurance, but could not impose the same type of benefit mandates they could apply to health insurance.<sup>50</sup> Other federal appeals courts have embraced this distinction.<sup>51</sup> Given that the states have some authority in this area, it may be possible to use stop loss regulation as a means to encourage provider payment reform among self-insured plans, but specific policy proposals would require careful legal analysis under the ERISA preemption case law.

New Hampshire currently prohibits stop loss coverage from being written with an individual attachment point below \$20,000.<sup>52</sup> The intent is to prevent stop loss from functioning like a high deductible health insurance policy, where most of the risk is transferred to the stop loss carrier, rather than retained by the employer who is claiming to be self-insured. Nationally, regulators, consumer groups and others have expressed concern that the development of stop loss coverage with lower attachment points is designed to circumvent state and federal regulations of health insurance by allowing small employers to purchase stop loss coverage that functions more like health insurance than a backup policy to self-insurance. Regulators have been considering various approaches to this problem through the NAIC, though no consensus reform has emerged.<sup>53</sup> Nevertheless, policymakers might consider stop loss regulation as one tool in facilitating provider payment reform, especially as it relates to clarifying the line

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<sup>46</sup> See Nat'l Ass'n of Ins. Commissioners, Health Ins. & Managed Care Comm., ERISA (B) Working Grp., Meeting Minutes (Dec. 3, 2013), [http://www.naic.org/meetings1312/committees\\_b\\_erisa\\_2013\\_fall\\_nm\\_materials.pdf](http://www.naic.org/meetings1312/committees_b_erisa_2013_fall_nm_materials.pdf).

<sup>47</sup> See, e.g., *General Motors Corp. v. Cal. St. Bd. of Equalization*, 815 F.2d 1305 (9th Cir. 1987); *Tex. Dep't of Ins. v. Am. Nat. Ins. Co.*, 410 S.W.3d 843, 853 (Tex. 2012).

<sup>48</sup> See *id.*

<sup>49</sup> *Am. Med. Security, Inc. v. Bartlett*, 111 F.3d 358, 365 (4th Cir. 1997).

<sup>50</sup> *Id.* at 361-62, 365.

<sup>51</sup> See *Bill Gray Enterprises, Inc. Employee Health & Welfare Plan v. Gourley*, 248 F.3d 213-15 (3d Cir. 2001) (collecting cases).

<sup>52</sup> N.H. Rev. Stat. § 415-H:3.

<sup>53</sup> See, e.g., *Manatt Health Solutions, Analysis of New Hampshire Stop Loss Options (2012)*, available at [http://www.nh.gov/insurance/reports/documents/manatt\\_nhsl\\_op.pdf](http://www.nh.gov/insurance/reports/documents/manatt_nhsl_op.pdf).

between health insurance and stop loss insurance. If low-attachment-point stop loss were prevalent, it could encourage self-insurance and undermine efforts at alignment on payment reform across payers.

### **Policy Options**

New Hampshire could evaluate what role the regulation of TPAs or stop loss insurers could play in light of the state's goals for provider payment and delivery system reform. In light of the state's particular policy goals, further close legal analysis may be necessary to determine whether such regulations of TPAs or stop loss insurers would be exempt from ERISA preemption. As discussed above, regulation that directly affects providers but only indirectly affects plans may be saved from preemption because courts could conclude the state regulation does not "relate to" or "refer to" an employee benefit plan. In this manner, New Hampshire may be able to indirectly influence TPAs and self-insured plans. On the other hand, because ERISA explicitly exempts state regulation of the business of insurance from preemption, the state has significantly greater authority over payment reform with respect to insurers than self-insured employers. The state may want to evaluate whether stop-loss arrangements with particularly low attachment points permit insured groups to masquerade as self-insured groups. The state could regulate stop-loss coverage, either to prevent it from being used to circumvent health insurance law, or, potentially, to influence the provider payment decisions of self-insured employers.

## IV. State and Federal Fraud and Abuse Laws

- Federal fraud and abuse laws are waived for Medicare ACOs
- State may consider similar approaches

Healthcare fraud and abuse laws have traditionally been designed for the fee-for-service paradigm, where providers could increase their revenue by providing more services and there was a risk of inflated billings or inappropriate care. This paradigm may be in tension with the ACO model. ACOs are often built around a hospital or physician network, which may have financial incentives for affiliated physicians to refer patients within the integrated health system. The health system as a whole may be accountable for the cost and quality of care and by treating patients within an integrated delivery system, population and enrollee health may improve, at lower costs. Even though referrals may be part of the design of the healthcare delivery model, they could be viewed as a kickback or improper financial relationship under fraud and abuse laws. This part examines how state and federal fraud and abuse laws apply to provider payment reforms, what steps have already been taken to accommodate fraud and abuse laws to these new models, and what further steps New Hampshire might consider.

### *State and Federal Legal Background*

The federal antikickback statute prohibits remuneration in connection with Medicare or Medicaid business,<sup>54</sup> criminalizing a broad range of financial transactions that could be viewed as acceptable marketing or other routine business activities in other industries. The New Hampshire antikickback statute has a similar affect but applies only to Medicaid, not Medicare or commercial business.<sup>55</sup> The Medicare physician self-referral law, known as the “Stark” law, prohibits physicians from referring Medicare patients to providers with which the physician has a financial relationship. The New Hampshire self-referral law permits physician self-referrals (outside Medicare) but requires patient disclosures of the self-referral.<sup>56</sup>

An early provider payment reform was Medicare’s prospective payment system for hospitals, which pays a set fee per discharge, based on diagnosis-related groups, regardless of the volume of services provided. This payment model creates incentives to limit services to patients. As a consequence, federal law imposes civil monetary penalties on hospitals that give physicians incentives to reduce or limit services for Medicare or Medicaid patients (so-called “gainsharing” arrangements).<sup>57</sup> Although these federal civil monetary penalties apply only to hospitals and not other provider organizations, the threat of these penalties does present a real hurdle to some payment innovations that hospitals would like to use to incentivize physicians to manage utilization. For example, it appears that hospital-owned physician practices would be at risk if they compensate physicians based on savings from a global budget. This represents the real tension between modern payment reform and traditional concerns about overutilization.

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<sup>54</sup> Social Security Act § 1128B(b)(1), 42 U.S.C. § 1320a-7b(b)(1).

<sup>55</sup> N.H. Rev. Stat. § 167:61-a(I)(i).

<sup>56</sup> N.H. Rev. Stat. §§ 125:25-a, 25-b.

<sup>57</sup> Social Security Act § 1128A(b)(1), 42 U.S.C. § 1320a-7a(b)(1).

*Application to Innovative Provider Payment Arrangements*

Because of the tension between the reform models and the fraud and abuse laws, in connection with the development of Medicare ACOs, the U.S. Department of Health and Human Services Office of Inspector General (OIG) and CMS have waived the federal antikickback, Stark, and gainsharing laws for providers participating in the MSSP ACOs.<sup>58</sup> Providers that participate in commercial ACOs may take advantage of some of these waivers even if they do not participate in the Medicare ACOs.<sup>59</sup> While these federal waivers do not waive state fraud and abuse laws, it does not appear that anything in New Hampshire law would inhibit the development of *Medicare* ACOs that are authorized under federal law. There is a question, however, of what effect state law would have on provider payment reforms in Medicaid and commercial coverage.

The U.S. Department of Health and Human Services has offered its opinion that the federal antikickback statute does not apply to commercial coverage, including coverage sold on the ACA health insurance Marketplaces.<sup>60</sup> As discussed earlier, the state antikickback statute applies only to Medicaid (the physician self-referral laws are not an impediment in Medicaid and commercial markets, because the federal law applies only to Medicare and the state law does not prohibit self-referrals). But the planned expansion of Medicaid using commercial coverage in 2016 raises the question whether the state and federal antikickback statutes could apply to commercial coverage when it is provided to Medicaid beneficiaries, and if so whether revisions or exceptions to the state or federal kickback laws are appropriate. New Jersey's ACO statute authorizes the state commissioner of human services to obtain necessary waivers or exemptions from state fraud and abuse laws for Medicaid ACOs.<sup>61</sup>

Because the coverage is paid for with Medicaid dollars, and there is an argument that it should be subject to Medicaid fraud and abuse laws. However, there also appears to be an argument that these plans would not be covered by the Medicaid kickback statutes: In New Hampshire and other states, it is already possible for employed Medicaid beneficiaries to receive Medicaid dollars to pay the employee's share of employer-sponsored coverage; that is, Medicaid dollars are already being used to pay the premiums for commercial coverage in the employer market. In that case, the employer coverage has not to date been subject to the kickback statutes or other Medicaid laws, and it appears that by analogy individual market policies would not be subject to the kickback statutes when their only connection to Medicaid is that Medicaid is paying the premium.<sup>62</sup> In contrast, Medicaid managed care plans, which are subject to the

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<sup>58</sup> Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011).

<sup>59</sup> *Id.* at 68006.

<sup>60</sup> Letter from Kathleen Sebelius, Secretary of Health and Human Services, to the Hon. Jim McDermott, U.S. House of Representatives (Oct. 30, 2013).

<sup>61</sup> N.J. Stat. Ann. § 30:4D-8.10(a). Furthermore, New York is considering a process by which Medicare ACOs could receive waivers from state laws that would inhibit their activity.

<sup>62</sup> Given the expansion of Medicaid through premium assistance, regulators may want to consider whether it is appropriate to exclude premium assistance from the kickback laws.

kickback laws, are subject to detailed federal regulations and state Medicaid contracts that prescribe the particular benefits and cost sharing they must offer.

### **Policy Options**

As ACOs grow in New Hampshire, there will be greater interest in such providers contracting with Medicaid, along with commercial plans that enroll Medicaid beneficiaries under the state's Medicaid expansion. If the state's Medicaid antikickback statute prevents these types of payment arrangements, it could stymie reform. It does not appear that the New Hampshire self-referral law, which only requires disclosure, would be an obstacle to reform. Policymakers should consider whether the state's antikickback statute could be a hindrance to the provider payment reforms they are considering.

- The state's attorney general and Department of Health and Human Services could determine whether the Medicaid antikickback statute would apply to innovative Medicaid provider contracting, under either traditional Medicaid or the expansion, and if so under what circumstances.
- The attorney general and the Department of Health and Human Services could evaluate whether they have authority to exempt entities from the antikickback statute that meet ACO requirements, as the federal government has done for Medicare ACOs under the federal laws. If not, the legislature could consider appropriate legislative exemptions. For example, section 2999-r of New York's Public Health Law permits ACOs supervised by the state to be exempt from state fraud and abuse laws and New Hampshire could adopt a similar exemption.

## V. State and Federal Antitrust Laws

Anticompetitive pricing and marketing have traditionally been a significant concern of healthcare regulators. Despite the current focus on collaboration and coordinated care, antitrust regulators continue to police anticompetitive behavior. For example, a federal appeals court recently ordered the unwinding of a hospital merger because it would substantially lessen competition in acute care and obstetrics in Ohio.<sup>63</sup>

Successfully managing provider payment reform requires weighing the anticompetitive effects of consolidation with the potential improvements in quality and value from clinical integration.

The New Hampshire legislature attempted to address these concerns in Senate Bill (SB) 308, which was considered during the most recent legislative session. Although the Senate-passed version of SB 308 would have created special authority for provider combinations to potentially be immunized from antitrust review, the version considered in the House would have established a study committee on policy issues surrounding provider consolidation and payment reform. While this study committee was not established, critical to any future examination of these issues will be identifying situations where the benefits to the state's delivery system outweigh the anticompetitive

### State Action Immunity: Two Case Studies

As this report describes, activity that would ordinarily violate antitrust law may be permissible if the state is actively and pervasively supervising the activity, such that the state can be said to have clearly articulated a policy to replace competition with regulation or monopoly power.<sup>1</sup> Two examples demonstrate how these principles might be applied.

- *Ambulance Regulation*—Emergency medical transportation is an area that may be ripe for regulation because patients and purchasers generally have exceedingly limited ability to bargain over benefits or prices. New Hampshire has in the past evaluated how this market functions.<sup>2</sup> Several states regulate competition among private ambulance providers. California's regulation of ambulance competition has been challenged on antitrust grounds—and upheld—several times. Under the California law, local agencies may award exclusive contracts to ambulance providers to provide emergency medical transport within a service area, and the state authorizing statute explicitly says that this contracting is designed to immunize this monopoly from federal antitrust liability.<sup>3</sup> A small number of states set rates for ambulance services, including Connecticut. Under Connecticut's law, the commissioner of public health sets statewide maximum ambulance rates by service type (basic life support, advanced life support, etc.), and allows under certain conditions charges for mileage, waiting time, and other factors. Ambulance providers are required to submit financial and operational information and the state sets rates based on anticipated operating costs and utilization and takes into account cross-subsidies with other payers. A state statute explicitly gives the commissioner authority to establish a process for rate setting.<sup>5</sup>
- *Alternative Payment Models in Massachusetts*—Since the adoption of state health reform in 2006, Massachusetts has enacted three laws designed to control the cost of its healthcare system. The most recent was adopted in 2012; the 2012 legislative debate focused on adopting global budgets that would require providers to bear significant risk. But the final legislation did not require providers to accept global budgets. Instead, the legislation establishes a new Health Policy Commission that monitors spending targets and may impose corrective action plans on providers that the commission believes are contributing to excess medical costs in the state.<sup>4</sup> Although these corrective action plans arguably could restrain trade in the state, they have not been challenged under antitrust law presumably because they would be upheld as permissible state action.

<sup>1</sup> See *City of Columbia v. Omni Outdoor Advertising*, 499 U.S. 365, 372 (1991).

<sup>2</sup> See N.H. Ins. Dep't, *A Study of Ground Ambulance Transport Commercial Claims*, [http://www.nh.gov/insurance/reports/documents/nhid\\_amb\\_trans\\_study022411.pdf](http://www.nh.gov/insurance/reports/documents/nhid_amb_trans_study022411.pdf) (2011).

<sup>3</sup> See, e.g., *A-1 Ambulance Service, Inc. v. County of Monterey*, 90 F.3d 333 (9th Cir. 1996).

<sup>4</sup> See Robert E. Mechanic et al., *The New Era of Payment Reform, Spending Targets, and Cost Containment in Massachusetts: Early Lessons for the Nation*, 31 *Health Affairs* 2334, 2337 (2012).

<sup>5</sup> Conn. Gen. Stat. § 19a-177(9); Conn. Agencies Regs. § 19a-179-21. Similar regulations exist in Utah, Utah Admin. Code r. 426-8, and Arizona, Ariz. Rev. Stat. § 36-2239.

<sup>63</sup> *ProMedica Health System, Inc. v. FTC*, No. 12-3583, -- F.3d --, 2014 WL 1584835 (6th Cir. Apr. 22, 2014).

effects of provider consolidation. These concerns are discussed first in the context of the MSSP and then with respect to other ACOs.

*A. Providers Participating in the Medicare Shared Savings Program*

- Federal antitrust laws have been partially waived for Medicare ACOs
- State might consider similar waivers

Under federal antitrust law, naked price fixing or market allocation agreements are per se illegal. However, when providers are financially or clinically integrated and the agreement is reasonably necessary to accomplish procompetitive benefits of integration, the arrangement will be considered under a “rule of reason,” weighing the pro- and anti-competitive effects of the collaboration. The U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) consider an ACO approved for the MSSP to be automatically eligible for rule of reason analysis.<sup>64</sup> Absent extraordinary circumstances, DOJ and FTC will not challenge MSSP ACOs that have less than 30% market share within a particular medical service/specialty, when at least two ACO participants provide that service within a service area.<sup>65</sup> ACOs can nevertheless satisfy the rule of reason outside of this safety zone, and DOJ and FTC have described behavior that ACOs should avoid that might jeopardize their eligibility for the safety zone.

Although the DOJ/FTC safety zones apply only to ACOs that participate in the MSSP, these providers can use the same infrastructure for commercial payers and still be protected from federal antitrust noncompliance.

New Hampshire antitrust law is designed to parallel federal law and courts generally treat New Hampshire and federal antitrust law as coterminous.<sup>66</sup> Nevertheless, the DOJ/FTC enforcement policy does not automatically apply to state antitrust law. The New Hampshire attorney general’s office, which enforces state antitrust law,<sup>67</sup> may need to decide if it will take the same enforcement posture as the federal government has. In any case, the federal safety zone may provide limited protection in New Hampshire, especially in rural areas where limited competition among providers may make it difficult for provider combinations to overcome rule of reason analysis.

**Policy Options**

It may be appropriate for the New Hampshire attorney general, in consultation with other executive agencies, to consider adopting the FTC/DOJ enforcement policy with respect to state law for ACOs participating in the MSSP. However, given the state’s size

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<sup>64</sup> Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026, 67028 (Oct. 28, 2011).

<sup>65</sup> *Id.*

<sup>66</sup> N.H. Rev. Stat. § 356:14; *U.S. Health Care, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 599 (1st Cir. 1993); *Donovan v. Digital Equipment Corp.*, 883 F. Supp. 775, 785 (D.N.H. 1994).

<sup>67</sup> N.H. Rev. Stat. § 356:9.

and provider availability, there could be reasons unique to New Hampshire why the state would not want to adopt the same enforcement posture.

*B. ACOs Not Participating in the Medicare Shared Savings Program*

- ACOs not in Medicare program are not shielded from antitrust review
- State action can immunize ACOs if the state is actively involved in rate-setting
- Absent state action, ACOs must ensure benefits outweigh anticompetitive effects

Even when the DOJ/FTC enforcement safety zones do not apply to providers because they are not participating in the MSSP, these ACOs may still be able to satisfy the rule of reason under both state and federal law so that they are not viewed as an anticompetitive combination. Furthermore, both state and federal law include a state action doctrine that exempts activities from antitrust liability that are actively supervised by a regulatory agency.<sup>68</sup> Several states, including, Oregon, Texas, New Jersey and New York, have enacted laws that permit the state to actively supervise ACOs, with the intent of exempting them from state and federal antitrust law.<sup>69</sup> However, it is not yet clear whether ACO-type activity would, in fact, violate the rule of reason and, if it would, what sort of state action would be pervasive enough to constitute active supervision that would exempt the combination from federal antitrust liability.

In order for a provider combination to receive state action immunity, there likely must be actual ongoing involvement in setting rates, not merely the possibility of state action.<sup>70</sup> It seems unlikely that SB 308, as it had been approved by the Senate, would have offered sufficient state supervision to truly immunize providers from federal antitrust review—and it remains unclear from a policy perspective whether such immunity would have been desirable for the combinations envisioned in the Senate-approved version of SB 308.

Pursuing an approach that could successfully invoke state action immunity requires an assessment of whether the state is willing to play an active role in the organization and setting of provider payments. If the state is not willing to play that role, ACOs that do not participate in the MSSP will be limited to operating in such a way that they do not violate the rule of reason: they must be able to demonstrate that the procompetitive aspects of their combination outweigh the anticompetitive aspects.

**Policy Options**

- NHID could play a convening role with providers, payers, and community groups in assessing the pro- and anti-competitive effects of ACOs.

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<sup>68</sup> See, e.g., N.H. Rev. Stat. § 356:8-a.

<sup>69</sup> See Ore. H.B. 3650 § 18 (2011), Tex. S.B. No. 7 § 2.01(c) (2011); N.J. Rev. Stat. 30:4D-8.1(1)(g); N.Y. Pub. Health L. § 2999-r(1).

<sup>70</sup> See Fed. Trade Comm'n v. Ticor Title Ins. Co., 504 U.S. 621 (1992).

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- NHID and other state policymakers could evaluate whether there are circumstances in which it would consider actively supervising payment arrangements in order to shield them from antitrust review.
- If the state does create a comprehensive regulatory scheme for non-Medicare ACOs—whether to protect them from antitrust liability or the kickback statute, or to regulate provider risk bearing—the state could consider imposing governance requirements on ACOs that promote transparency and consumer protection. As states have developed accountable care regulations, they often include requirements for public participation and representation on governing boards by providers, patients, and others.<sup>71</sup>

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<sup>71</sup> See Nat'l Acad. of State Health Pol'y, Governance, <http://nashp.org/aco/governance> (last visited 6/8/14).

## **VI. Conclusion**

Legal and regulatory implications will flow from policy decisions the state makes as it moves toward risk- and quality-based healthcare provider payment arrangements. Policymakers' first task is to identify the particular reforms that they seek to encourage and then to develop regulatory and legal structures that best fit those reforms. As described in this report, some provider payment reforms are potentially in tension with the traditional state and federal health insurance law doctrines. Nevertheless, it does seem possible to encourage payment reform while still protecting consumers from fraud, insolvency, and anticompetitive behavior.