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Extra Legal

Contracting for Value: Performance-Based Payments in Contracts Between Health Insurers and Drug Manufacturers

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I. Introduction

Health care in the United States is a complex and expensive industry, and consumers who contribute financially to the industry presumably hope to derive some value or benefit from their participation. However, many consumers may not perceive a proportionate relationship between financial contribution and the value or benefit they receive. For example, "[m]ost Americans do not believe that price and quality of health care are associated" with each other.[1] It is no wonder that Americans today have doubts about whether the amount they spend on health care is associated with the quality of care they receive; despite spending a larger portion per

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[1] Kathryn A. Phillips, et al., *Most Americans Do Not Believe That There Is An Association Between Health Care Prices And Quality Of Care*, 35 HEALTH AFF. 647, 652 (2016).

capita on health care services than many other industrialized nations, the United States lags behind in important measures, such as life expectancy.[2] Although the relationship between health care services and life expectancy is complex,[3] it is clear that the United States is spending more per person on health care than many other countries, but consumers are not benefitting proportionately with regard to certain measured health outcomes.[4]

In response to issues of quality and efficiency of health care in the United States, the government, in recent years, has placed an emphasis on quality improvement and cost management.[5] In turn, there has been an emergence of private sector contractual relationships tying the medical care reimbursement to individuals' health outcomes. In particular, health insurers are entering into contracts with drug manufacturers to tie

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[2] THE ORG. FOR ECON. COOPERATION AND DEV., HEALTH AT A GLANCE 2015: OECD INDICATORS 46-47 (2015), http://apps.who.int/medicinedocs/documents/s22177en/s22177en.pdf .

[3] *See* ELLEN NOLTE & MARTIN MCKEE, DOES HEALTH CARE SAVE LIVES? AVOIDABLE MORTALITY REVISITED 139 (2004).

[4] *See* ORG. FOR ECON. CO-OPERATION AND DEV., HEALTH AT A GLANCE 2015: OECD INDICATORS 46-47 (2015), http://apps.who.int/medicinedocs/documents/s22177en/s22177en.pdf .

[5] *See* Virgil Dickson, *CMS Wants to Overhaul Part B Drug Payments. Oncologists Call the Plan 'Absurd'*, MOD. HEALTHCARE (Mar. 8, 2016), http://www.modernhealthcare.com/article/20160308/NEWS/160309856; *see also* Press Release, U.S. Dept. of Health & Human Services Press Office, Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value (Jan. 26, 2015), http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html; PAUL STARR, REMEDY AND REACTION: THE PECULIAR AMERICAN STRUGGLE OVER HEALTH CARE REFORM (Yale University Press) (2011) (chronicling the politics surrounding different attempts at health care reform); Kristin Madison, *Donabedian's Legacy: The Future of Health Care Quality Law and Policy*, 10 IND. HEALTH L. REV. 325, 325-64 (2013) (discussing the history and development of health care quality law and policy).

payments for drugs to the outcomes they produce in a patient population.[6] While the media reported on this specific type of agreement as recently as February 2016,[7] these contracts are part of a wider trend toward outcomes-based payments, sometimes referred to as "pay-for-performance" in U.S. health care.[8] Furthermore, these types of agreements may be emergent in health care in the U.S., but similar agreements known as performance-based contracts, have existed in the transactional field for some time.[9]

For the purposes of this paper, "outcomes-based payment" refers to any policy, contract, or other arrangement with the purpose of tying payments for health care services to the outcome or outcomes they achieve. "Performance-based" refers to a contract, contractual provision, or resulting payment that is reliant on the quality of performance as determined by one or more outcomes of the performance.

This paper seeks to analyze these performance-based contracts between health insurers and drug manufacturers within the larger trend toward outcomes-based payments in health care. First, uses and criticisms of outcomes-based payments introduce these arrangements in the health care setting. The paper then describes recent performance-based contractual agreements between health insurers and drug

[6] *Id.*

[7] Bob Herman, *Insurers, Drugmakers Wrestle with How to Build Value-Based Contracts*, MOD. HEALTHCARE (Feb. 20, 2016), http://www.modernhealthcare.com/article/20160220/MAGAZINE/302209963?template=print.

[8] Julia James, *Health Policy Brief: Pay for Performance*, HEALTH AFF. 1 (Oct. 11, 2012).

[9] *See, e.g.*, United States v. Nicolo, 597 F. Supp. 2d 342, 349-50 (W.D.N.Y. 2009); Milwaukee Emps. Ret. Sys. v. City of Milwaukee, No. 98-1497, 1999 WL 508657 (Wis. Ct. App. July 20, 1999); Schmucker v. Hanna, 547 A.2d 379 (Pa. Super. Ct. 1988).

manufacturers as portrayed in the media. Finally, the paper examines case law to analyze characteristics and application of performance-based contracts outside of the health care setting. This analysis suggests that performance-based contracts between health insurers and drug manufacturers present an interesting method for tying health outcomes to cost, but that these contracts may also present significant issues in terms of policy and practicality.

II. Goals and Risks of Outcomes-Based Payments

The goal of outcomes-based payments in health care is twofold: to improve patients' health outcomes and, simultaneously, to manage costs.[10] Some iterations of outcomes-based payments include eliminating payments for the treatment of preventable conditions[11] and providing financial rewards for the performance of "activities that have been demonstrated to contribute to positive health outcomes for patients."[12]

While outcomes-based payments may seem like a win-win for the United States health care system and individual consumers, there are legitimate risks and practical issues related to implementing these agreements. For example, outcomes experienced by individual consumers "are often affected by social and clinical factors unrelated to the treatment provided and beyond the provider's control."[13] In addition, there is evidence that outcomes-based payments may decrease payments to providers who care for vulnerable populations with higher incidences of

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[10] *See* James, *supra* note 8, at 1.

[11] *Id.* at 2.

[12] *Id.*

[13] *Id.*

complicated medical conditions, and some fear that decreased reimbursement to these providers may lead to decreased access to care for the populations they serve.[14] One argument is that providers who take on more complicated cases[15] may see decreased financial rewards compared to their peers who treat a higher proportion of healthier patients with less complicated cases or more access to social resources.[16] As a result, physicians may be incentivized to "cherry-pick" less complicated cases, or alternatively, practice in geographical areas where patients have greater access to non-clinical resources.[17]

III. One Iteration of Outcomes-Based Payment: Performance-Based Contracts Between Health Insurers and Drug Manufacturers as Reported in the Media[18]

Media reports illuminate some characteristics of specific outcomes-based payments, such as performance-based contracts between health insurers and drug manufacturers. For example, health insurer Harvard Pilgrim Health Care recently entered into a contract with the drug manufacturer Amgen to tie payments to performance of a cholesterol-

[14] *Id.* at 5.

[15] *Id.* I use "complicated cases" here to refer to, for example, patients with limited access to transportation and those for whom a language barrier exists between patient and doctor.

[16] *Id.*; *see also* Rebecca D. Elon, *The Ethics of Health Care Reform: Unintended Consequences of Payment Schemes and Regulatory Mandates*, 12 J. HEALTH CARE L. & POL'Y 63 (2009). I use "less complicated cases and more access to social resources" here to refer to, for example, patients with transportation or no special language considerations.

[17] Elon, *supra* note 16, at 79.

[18] See Ernst R. Berndt & Joseph P. Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, (Nat'l Bureau of Econ. Research, Working Paper No. 16297, 2010), for a general description of the current standard process for pricing, sale, and distribution of pharmaceuticals.

lowering drug, called Repatha, within Harvard Pilgrim's patient population.[19] Specifically, in the event that cholesterol levels in patients insured by Harvard Pilgrim are not lowered to the levels that were reported in clinical trial reports, Harvard Pilgrim receives a rebate from Amgen.[20] In another recent transaction, "drugmaker Novartis and insurers Aetna and Cigna Corp. agreed to pay-for-performance deals for Novartis' heart drug Entresto."[21] The performance-based piece of this contract bases payments on whether the drug results in fewer hospitalizations to patients within the insured population who take the drug as treatment for congestive heart failure.[22] Media reports assert that performance-based contractual provisions are offered by drug manufacturers as a competitive tool: The health insurers are exposed to less risk of adverse health outcomes, and in exchange, the drug manufacturers gain increased market share and inclusion of their drugs on the insurer's preferred pharmaceutical formulary.[23]

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[19] Bob Herman, *Harvard Pilgrim Cements Risk-Based Contract for Pricey Cholesterol Drug Repatha*, MOD. HEALTHCARE (Nov. 8, 2016), http://www.modernhealthcare.com/article/20151109/NEWS/151109899.

[20] *Id.*

[21] Herman, *supra* note 7.

[22] *Id.*

[23] *Id.*; Susan DeVore, *Six Big Trends to Watch in Health Care for 2016*, HEALTH AFFAIRS: HEALTH AFFAIRS BLOG (Dec. 30, 2015), http://healthaffairs.org/blog/2015/12/30/six-big-trends-to-watch-in-health-care-for-2016/. *See also* Consumer Reports, *Your Health Plan's Formulary: The List of Preferred Prescription Drugs*, http://consumerhealthchoices.org/wp-content/uploads/2012/01/Formulary.pdf (last visited Sept. 7, 2016) (providing a general description of a pharmaceutical formulary).

IV. Performance-Based Contracts in Other Industries as Referenced in Case Law

While an analysis of actual language within a performance-based contract between health insurers and drug manufacturers would certainly be the most direct method of analyzing these agreements, "[a]ll contracts with pharmaceutical companies have confidentiality clauses that prohibit those terms from being disclosed."[24] Therefore, cases regarding performance-based contracts in other fields may serve as a suitable starting point to understanding these agreements.

a. Characteristics of Performance-based Contracts in Other Industries

Performance-based contracts are used within family law, business and tax, government, and finance contexts.[25] These contracts sometimes include benchmark levels of performance that result in different payment amounts.[26] In other instances, they may require a certain level or quality

[24] Bob Herman, *Harvard Pilgrim Cements Risk-Based Contract for Pricey Cholesterol Drug Repatha*, MOD. HEALTHCARE (Nov. 8, 2016), http://www.modernhealthcare.com/article/20151109/NEWS/151109899.

[25] *See generally* Cooper v. United States Postal Serv., 482 F. Supp. 2d 278, 281 (D. Conn 2007); United States v. Nicolo, 597 F. Supp. 2d 342, 349-50 (W.D.N.Y. 2009); Cooper v. United States Postal Service, 482 F.Supp.2d 278, 281 (D. Conn 2007); Schmucker v. Hanna, 547 A.2d 379 (Pa. Super. Ct. 1988); Milwaukee Emps. Ret. Sys. v. City of Milwaukee, No. 98-1497, 1999 WL 508657 (Wis. Ct. App. July 20, 1999).

[26] *See* Philadelphia Workforce Dev. Corp. v. KRA Corp., 156 F. Supp. 3d 616, 616-17 (E.D. Pa. 2016), *appeal docketed*, No. 16-1327 (3rd Cir. Feb. 17, 2016) (referencing an agreement for provision of services for developing work skills in a target population, with performance-based payments based on benchmark levels of performance).

of performance in order to provide payment at all.[27] The level of performance-based payment may depend on a financial result of the performance, such as revenue, cost savings, or return on investment.[28] Additionally, parties may tie payments to a positive outcome or event reached by the beneficiaries of the performance. This may include extra payment for attainment of a benefit by members of the target population.[29] Finally, the parties may tie payments to the measured quality of a good created, with payments increasing as measured quality increases.[30]

b. Application to Health Care

Characteristics of performance-based contracts in other industries may provide clues as to the possibilities that may lie ahead for performance-based contracts in health care. For example, payments could be tied to the absence of an adverse health event, such as a heart attack. Or payments could be directly tied to the decrease in cost a drug or device

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[27] *See Hanna*, 547 A.2d at 380 (citing Leonard v. Leonard, 510 A.2d 827 (Pa. Super. Ct. 1986)) (referencing a contract in which a student had to reach a certain college grade point average in order to be eligible for tuition payments from his father).

[28] *See, e.g.*, *Cooper*, 482 F. Supp. 2d at 281; *Nicolo*, 597 F. Supp. 2d at 349-50; Milwaukee Emps. Ret. Sys. v. City of Milwaukee, No. 98-1497, 1999 WL 508657 at *1 (Wis. Ct. App. July 20, 1999) (illustrating the variation in types of financial performance, in these cases payments were tied to tax deductions on real property resulting from tax assessment services, the revenue from a non-government owned postal unit, and performance of investment portfolios, respectively).

[29] For example, see *Phila. Workforce Dev. Corp.*, 156 F. Supp. 3d at 616. This case regards a situation where a company providing services aimed at improving job skills and qualifications of their clients contracted to receive payments based on their success in providing those services.

[30] *See generally* Atser Research Tech., Inc. v. Raba-Kistner Consultants, Inc., No. SA-07-CA-93-H, 2009 WL 691118 (W.D. Tex. Mar. 2, 2009) (regarding a patent dispute over a device that measured the quality of concrete, and making reference to contracts that tied payments to the measured quality).

passes on to health insurers, measured in decreases in payments by the insurer for services related to adverse health events. Contracts could be created between stakeholders to reward payment for a benefit in the target population, such as overall health of a population. Remote monitoring of certain biological levels in patients could allow for performance-based payments for drug efficacy in real time.

These arrangements may benefit consumers in the long run if they provide incentives for the health care industry to create organizational structures that better promote positive health outcomes for consumers. There may be many more opportunities to experiment with these agreements, especially as government actors such as the CMS continue to promote them through policy.[31] The exact allocation of risk and the identity of the stakeholders involved depends on a complex web of incentives and stakeholder interests in the health care industry.[32]

V. Potential Issues with Performance-Based Contracts in Health Care

Although performance-based contracts in health care present seemingly abundant opportunities to align payments to outcomes, they are not without their difficulties and unintended risks. While there are some policy concerns with outcomes-based payment as discussed above, another major issue with performance-based contracts in the health care context is discernible from the disputes that arise out of performance-based contracts in other industries: Parties could make payments in

[31] *See* Dickson, *supra* note 4; *see also* HHS Press Office, *supra* note 4.

[32] *See, e.g.*, Heather Elms, et al., *Ethics and Incentives: An Evaluation and Development of Stakeholder Theory in the Health Care Industry*, 12 BUS. ETHICS Q. 413 (2002).

situations where the outcome was not actually a result of the performance but was the result of unrelated events or circumstances.[33] This could occur if patients do not take the drug or do not take it as directed, or if an individual responsible for verifying measured outcomes reports perpetrates fraud.

This issue arises partially due to the fact that patient behavior and many aspects of health are beyond the control of providers and insurers. In the previous example, if patients do not follow the course of treatment, parties could exchange or withhold payments, even though the presumed action on the part of the patient (taking the medication as prescribed) is largely out of the control of the provider and other stakeholder parties. One way to address this problem could be to implement remote monitoring of patients' adherence to a prescribed protocol.[34]

Performance-based contracts between health insurers and drug manufacturers also have natural limitations that arise when the possibilities are taken to the extreme. For example, if a drug is absolutely effective, an outcomes-based payment structure will not help contain costs, since a performance-based rebate would never occur, or alternatively, a performance-based extra payment from the insurer to the manufacturer would always occur.

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[33] For example, see *Nicolo*, 597 F. Supp. 2d at 350, where an individual had perpetrated a fraud by backdating contracts in order to make it appear as though an outcome that merited payment was the result of his action.

[34] *See* Jonah Comstock, *Novartis Signs Aetna, Cigna for Pay-for-Performance Drug Deal, But No Remote Monitoring Yet*, MOBIHEALTHNEWS (Feb. 9, 2016), http://www.mobihealthnews.com/content/novartis-signs-aetna-cigna-pay-performance-drug-deal-no-remote-monitoring-yet.

VI. Conclusion

Performance-based contracts between health insurers and drug manufacturers are a relatively new development with the potential to align payment to medical outcomes. These agreements are part of a larger effort to tie payments in health care to the value they produce for consumers and society at large. Performance-based contracts may be a relatively new area of transactional law in health care, but they have been used in multiple other industries for some time. Case law involving performance-based contracts in industries other than health care suggests possible structures of these agreements in the health care context. Additionally, by examining the case law in other industries, some of the potential issues with performance-based contracts in health care can be anticipated. This analysis suggests that these contracts present legal risks and practical issues that must be taken into consideration in order to maximize the potential benefits of their use.