A DRUG'S WORTH: WHY FEDERAL LAW MAKES IT HARD TO PAY FOR PHARMACEUTICAL PERFORMANCE

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    High drug costs leave policymakers wondering whether the United States gets what it pays for from drug manufacturers. Pay for performance is a trending concept in health policy literature, but it has been avoided in the prescription drug market. The legal rationale for such avoidance has not yet been the subject of formal study. This Note first defines the nature of performance-based risk-sharing arrangements in the pharmaceutical context. These are contractual arrangements whereby payers and manufacturers allow a drug's price to be determined by its health benefits to individual patients under real-world conditions.

    After outlining the essential features of performance-based arrangements, I describe the impediments to federal attempts to require their use by commercial payers and analyze their legality under the False Claims Act and Anti-Kickback Statute. I conclude that the lack of a fixed price under a performance-based arrangement poses a problem for rebating Medicaid for the discounts offered to commercial payers. I point to the specific federal laws that give rise to

compliance difficulty and end by recommending avenues by which federal regulators can resolve the uncertainty surrounding performance-based drug reimbursement and thereby use it to control drug costs without sacrificing innovation.

INTRODUCTION

The high cost of health care in the United States continues to be an issue of great importance. The Patient Protection and Affordable Care Act ("ACA") included a host of provisions that opened opportunities for providers to coordinate the health care they deliver to patients, most notably through entities such as Accountable Care Organizations ("ACOs").[1] But linking reimbursement to *quality* of care, rather than the *quantity* of procedures, is not a new concept.[2] Many countries have witnessed great innovation in the area of value-based reimbursement.[3] The United States has seen the idea wax and wane for decades, largely in response to recurrent crises over rising health care costs.[4] But progress on value-based reimbursement has not permeated throughout all sectors of the U.S. health care system. The prescription drug market in the United States has largely eluded efforts to tie payments directly to health outcomes among patients.[5]

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[1] *See generally* Jenny Gold, *Accountable Care Organizations, Explained*, KAISER HEALTH NEWS (Sept. 14, 2015), http://khn.org/news/aco-accountable-care-organization-faq/ [https://perma.cc/AR7D-RGH5].

[2] *See* DAVID NEWMAN, CONG. RESEARCH SERV., R41474, ACCOUNTABLE CARE ORGANIZATIONS AND THE MEDICARE SHARED SAVINGS PROGRAM 5-6 (2011) (summarizing older models of care delivery that are similar to ACOs); NICOLE HUBERFELD ET AL., THE LAW OF AMERICAN HEALTH CARE 60-61 (2017) (describing Medicare's prospective payment system, which was adopted by Congress in 1983 to promote efficiency).

[3] Bonny Parkinson et al., *Disinvestment and Value-Based Purchasing Strategies for Pharmaceuticals: An International Review*, 33 PHARMACOECONOMICS 905, 907-14 (2015) (surveying various strategies OECD countries have taken to disinvest from low-value drugs).

[4] *See* NAT'L COUNCIL ON DISABILITY, MEDICAID MANAGED CARE FOR PEOPLE WITH DISABILITIES: POLICY AND IMPLEMENTATION CONSIDERATIONS FOR STATE AND FEDERAL POLICYMAKERS 161-64 (2013), https://ncd.gov/rawmedia_repository/20ca8222_42d6_45a5_9e85_6bd57788d726.pdf [https://perma.cc/4HJR-S3K9].

[5] Louis P. Garrison Jr. et al., *Performance-Based Risk-Sharing Arrangements—Good Practices for Design, Implementation, and Evaluation: Report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force*, 16 VALUE IN HEALTH 703, 707 (2013) (finding only four instances of performance-based processes); *see also* Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 860-62 (2016) (characterizing market exclusivity arising from patent protection and FDA regulatory exclusivity as "most important" factor contributing to high drug prices).

The recent public outcry over substantial price increases by biopharmaceutical manufacturers for certain drugs[6] has led many to question whether the market can allocate resources in a manner that promotes quality.[7] Despite this recent attention, the Trump Administration's statements on drug-pricing policy make the prospect of tighter, more direct regulation of drug prices uncertain, to say the least.[8] Moreover, one can only speculate at this point over the fate of the ACA and proposed changes to Medicaid.[9] Thus, it is important for researchers and policymakers to focus on ways in which payers and manufacturers can improve resource allocation through private bargaining. This Note examines the barriers to one such tool—the performance-based risk-sharing arrangement ("PBRSA"). Though variable in form, a PBRSA is a mechanism by which the payment for a drug varies in direct relation to the actual health benefit that the drug delivers to its treatment population.[10] Despite a fairly robust body of literature espousing the theoretical merits of performance-based drug reimbursement, there is a narrow consensus that uncertainty over the

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[6] *See* OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., OBSERVATIONS ON TRENDS IN PRESCRIPTION DRUG SPENDING 1-3 (2016), https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf [https://perma.cc/A3ZK-H5YR] (finding 12.6 percent increase in overall drug spending in 2014 and noting polling information suggesting public concern). Factoring in rebates illustrates a more "modest" increase—but a sizable increase nonetheless. *See* Katie Thomas, *Under Fire over Prices, Drug Makers Keep Raising Them*, N.Y. TIMES, Apr. 26, 2016, at B1. Most notable has been the rising cost of specialty drugs. One major insurer reported a twenty-six percent increase in list prices (excluding rebates) of specialty drugs from 2013 to 2014. *See* BLUE CROSS BLUE SHIELD, THE GROWTH IN SPECIALTY DRUG SPENDING FROM 2013 TO 2014, at 2 (2016), http://www.bcbs.com/healthofamerica/Specialty-Rx-HoA-Report.pdf [https://perma.cc/SD7H-XN3A].

[7] Here, I am referring to quality in terms of beneficial health outcomes. Although some may draw a distinction between a drug's quality and its ability to deliver beneficial health outcomes, it is my position that the tendency to distinguish between the two concepts impedes progress toward value-based pricing.

[8] Carolyn Y. Johnson, *Trump Just Dropped a Big Hint to the Pharmaceutical Industry*, WASH. POST (Nov. 14, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/11/14/trump-just-dropped-a-big-hint-to-the-pharmaceutical-industry/ [https://perma.cc/VK89-FV4V].

[9] Any change is likely to have some effect on drug-pricing policy. *See infra* Part III. The recent repeal of the individual mandate places questions of cost containment front and center. *See* Tax Cuts and Jobs Act of 2017, Pub. L. No. 115-97, § 11081.

[10] *See* Garrison et al., *supra* note 5, at 704; Adrian Towse & Louis P. Garrison Jr., *Can't Get No Satisfaction? Will Pay for Performance Help?*, 28 PHARMACOECONOMICS 93, 94 (2010).

formation and enforcement of such arrangements stymies their adoption.[11] This Note studies the extent to which that uncertainty is warranted.

Part I analyzes the important economic and regulatory considerations at play in the drug market and how these considerations bear on payer-manufacturer risk sharing. Part II provides an overview of the design and function of PBRSAs. Part III explains how PBRSAs might fare under federal laws targeting fraud and abuse in health care markets. Lastly, Part IV presents recommendations for how these laws could be amended to facilitate the formation and performance of PBRSAs. I conclude that the benefits of PBRSAs will not be realized until the legal and transactional uncertainties surrounding their enforcement are reduced.

I.   ECONOMIC FACTORS, DRUG PRICING, AND REGULATION

Governments face immense obstacles to promoting efficiency in prescription drug markets. Some of these challenges cross over from the market failures traditionally associated with health care,[12] while others are more unique to the biopharmaceutical industry.[13] The presence of moral hazard and asymmetric information largely accounts for the resultant shape of health regulatory schemes.[14] Both because of, and in response to, these conditions, the United States maintains a largely privatized system of health care delivery and health insurance coverage.[15] This produces a highly fragmented system, the effects of which are particularly prominent in the prescription drug market.

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[11] *See, e.g.*, Garrison et al., *supra* note 5, at 705; Steven Morgan et al., *International Best Practices for Negotiating 'Reimbursement Contracts' with Price Rebates from Pharmaceutical Companies*, 32 HEALTH AFF. 771, 773-74 (2013); Peter J. Neumann et al., *Risk-Sharing Arrangements That Link Payment for Drugs to Health Outcomes Are Proving Hard to Implement*, 30 HEALTH AFF. 2329, 2333, 2335-36 (2011).

[12] *See generally* Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963).

[13] *See generally* Patricia M. Danzon & Sean Nicholson, *Introduction* to THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 1, 2-5 (Patricia M. Danzon & Sean Nicholson eds., 2012).

[14] *See id.* at 2; *see also* Ernst R. Berndt & Joseph P. Newhouse, *Pricing and Reimbursement in US Pharmaceutical Markets*, *in* THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY, *supra* note 13, at 201, 203-15.

[15] As of 2015, roughly two out of every three Americans received coverage through private plans, with just over half of all Americans receiving coverage through an employer. JESSICA C. BARNETT & MARINA S. VORNOVITSKY, U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2015, at 3 (2016), http://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-257.pdf [https://perma.cc/6JXU-ENDE]. Approximately thirty-seven percent of Americans received insurance coverage through the government. *Id.* Health care purchased on behalf of private insurance beneficiaries tends to be more expensive for the insurer than that which is purchased through public programs, such as Medicare. *See, e.g.*, Thomas M. Selden et al., *The Growing Difference Between Public and Private Payment Rates for Inpatient Hospital Care*,

The prototypical prescription-drug supply chain is one in which a drug manufacturer first sells to a wholesaler, the wholesaler sells to retail pharmacies, and the pharmacies dispense the prescribed drug to patients.[16] At each link in this chain, transactions occur at incrementally higher prices, creating an opportunity for market participants to reap returns from economization.[17] On the demand side, public and private payers typically contract with pharmacy benefit managers ("PBMs")—purchasing agents that negotiate with manufacturers on behalf of payers to obtain favorable pricing.[18] Contracts between payers and PBMs may specify that the PBM will retain a portion of whatever savings it realizes in its negotiations with manufacturers.[19] PBMs do not pay

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34 HEALTH AFF. 2147, 2147 (2015) (finding that private insurers spend seventy-five percent more per inpatient stay than Medicare).

[16] Berndt & Newhouse, *supra* note 14, at 218-21. For specialty drugs, especially those covered under Medicare Part B, the supply chain may include hospitals or physicians who take title to the drugs before administering them to patients. *See* Patricia M. Danzon, *Regulation of Price and Reimbursement for Pharmaceuticals*, *in* THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY, *supra* note 13, at 266 [hereinafter Danzon].

[17] There are numerous prices. They include, most notably: Average Manufacturer Price ("AMP"), Average Sales Price ("ASP"), Average Wholesale Price ("AWP"), Medicaid's "best price," and Wholesale Acquisition Cost ("WAC"). *See* Berndt & Newhouse, *supra* note 14, at 218-33 (defining various prices and their use in supply chains). The Department of Defense, Veterans' Administration, and other federal entities purchase drugs at prices based on the Federal Supply Schedule, which contains a Federal Ceiling Price above which prices cannot rise. *Id.* at 231.

[18] *See* Berndt & Newhouse, *supra* note 14, at 219-20. By purchasing on behalf of many payers, PBMs obtain greater purchasing power without the ethical concerns that otherwise exist where an insurer who receives a discount also has (some) control over prescriber behavior. Congress signaled its support for the PBM model in enacting the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which allows Prescription Drug Plans to negotiate on behalf of Medicare. Mark Duggan & Fiona Scott Morton, *The Effect of Medicare Part D on Pharmaceutical Prices and Utilization*, 100 AM. ECON. REV. 590, 591 (2010) ("Part D is set up so that the government does not directly purchase drugs, but rather subsidizes participating private prescription drug plans, which then negotiate with pharmaceutical companies over drug prices."). PBMs are distinct from Group Purchasing Organizations ("GPOs"). *See* Berndt & Newhouse, *supra* note 14, at 219-20. This taxonomic distinction can matter for regulatory purposes. Although both PBMs and GPOs are integrated with, or work in conjunction with, third-party payers ("TPPs"), wholesalers, and pharmacies, GPOs are typically known for aggregating purchasing power on behalf of hospitals and other provider groups, whereas PBMs aggregate purchasing power on behalf of public or private payers, and plan sponsors (i.e., employers). *See* U.S. FOOD & DRUG ADMIN., PROFILE OF THE PRESCRIPTION DRUG WHOLESALING INDUSTRY §§ 2.1-2.2, https://www.fda.gov/ohrms/dockets/dockets/05n0403/05n-0403-bkg0001-04-08-5.pdf [https://perma.cc/R9X2-9TSW] (last visited Oct. 15, 2017); Berndt & Newhouse, *supra* note 14, at 219-20 (describing arbitrage-like niche that PBMs and GPOs fill).

[19] Berndt & Newhouse, *supra* note 14, at 219-20.

manufacturers for the drugs. Instead, the manufacturers pay the PBMs, often in the form of a rebate equivalent to whatever discount the PBM was able to extract from the manufacturer.[20] The idea is that these savings are eventually passed on to retail consumers in the form of lower insurance premiums.

Four patterns emerge when observing this market. First, pricing is party-specific and opaque, which limits the extent to which bargaining acts as a signal for value.[21] This opacity is exacerbated by the frequent inclusion of other service fees and allowances for chargebacks in purchase and sale agreements.[22] Second, the monopoly power of a manufacturer, resulting from patent protection, gives rise to a reciprocal tendency for payers to use PBMs as a medium for exerting market power, and to thereby make the drug quantity demanded more sensitive to price.[23] Third, remuneration often comes in the form of rebates and lagged payments because of parties' desires to make price concessions contingent upon the volume of sales and other performance metrics. The difficulty of distinguishing between legitimate and illegitimate forms of remuneration raises concerns about abuse.[24] Finally, lawmakers and regulators have not imposed an artificial ceiling on prescription drug pricing. Thus, although regulations have an indirect effect on pricing negotiations between parties throughout the supply chain, U.S. drug-price determinations are controlled by market forces to a much greater extent than is true elsewhere.[25]

A well-functioning prescription drug market must exhibit static and dynamic efficiency.[26] Static efficiency considers "optimal use of existing drugs," whereas dynamic efficiency considers "optimal investment in [research and

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[20] *Id.*

[21] HAL R. VARIAN, INTERMEDIATE MICROECONOMICS: A MODERN APPROACH 726-30 (8th ed. 2010) (discussing effect of asymmetric information in markets and use of warranties as countermeasures to signal quality).

[22] A manufacturer may pay "service fees" to wholesalers or PBMs for services such as patient adherence monitoring, product stocking allowances, and inventory management fees. *See* Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5176 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447). Service fees raise concerns in the context of the Medicaid Drug Rebate Program, discussed *infra* Part III. A chargeback is a transaction in which a wholesaler charges a manufacturer the difference between the parties' original contracted sale price and the lower price that a third-party payer managed to extract out of the manufacturer. Berndt & Newhouse, *supra* note 14, at 219.

[23] The increase in price elasticity achieved by PBMs' use of tiered formularies also mutes the distortion that insurance has on price. Berndt & Newhouse, *supra* note 14, at 201, 210-12; *see also* Danzon, *supra* note 16, at 268-70.

[24] *See infra* Part III; *see also In re* Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 187-90 (1st Cir. 2009).

[25] Kesselheim, *supra* note 5, at 863 ("[P]rescription drugs are priced in the United States primarily on the basis of what the market will bear.").

[26] Danzon, *supra* note 16, at 272.

development]."[27] Optimal pricing and reimbursement strategies will vary depending upon whether the drug has patent protection or is off-patent and therefore exposed to generic competition, and the extent of insurance coverage among the patient population.[28] For on-patent drugs in countries with universal insurance coverage, one approach may be for the government to set a threshold measure of cost-effectiveness that manufacturers must demonstrate before their drugs can be considered eligible for reimbursement.[29] Rather than relying on co-payments to "deter excess demand," as is common in the United States, strict "eligibility rules and protocols" would fulfill this function.[30] Of course, such protocols carry with them the opposite risk—that drugs will be rationed for patients who need them. The United Kingdom employs a system similar to this,[31] but political and ethical controversy has blocked the uptake of such a scheme in the United States.[32]

Despite restrictions on the ability of federal and state agencies to impose generalizable cost-effectiveness thresholds for prescription drugs, substantial incentives exist for payers and manufacturers to pursue agreements that make drug performance a determinant of reimbursement rates. To illustrate, I begin with the observation that a rational insurer wishes to minimize costs. One way of doing so is to reduce spending on ineffective drugs. Aside from concerns that a drug will produce adverse side effects, ineffective drugs represent failed investments for insurers because the health status of patients who use them is less likely to improve, thus precipitating additional medical treatment (and cost)

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[27] *Id.*

[28] *See* Berndt & Newhouse, *supra* note 14, at 203.

[29] *See* Danzon, *supra* note 16, at 273-74 (discussing proposal to use threshold incremental cost-effectiveness ratio to regulate prices).

[30] *Id.* at 274.

[31] Robert W. Dubois, *Cost-Effectiveness Thresholds in the USA: Are They Coming? Are They Already Here?*, 5 J. COMP. EFFECTIVENESS RES. 9, 10 (2016).

[32] A provision within the ACA created the Patient-Centered Outcomes Research Institute ("PCORI"), tasked with studying, among other things, the "relative health outcomes, clinical effectiveness, and appropriateness of . . . medical treatments." 42 U.S.C. §§ 1320e(b)(1), 1320e(c) (2012). However, the statute explicitly prohibits PCORI's or the Department of Health and Human Services's ("HHS's") use of quality-adjusted life years ("QALYs") when developing or instituting recommendations about the relative cost effectiveness of treatments. *Id.* § 1320e-1(e); *see also* Nancy-Ann DeParle, *The Facts About the Independent Payment Advisory Board*, WHITEHOUSE.GOV (Apr. 20, 2011, 5:46 PM), https://www.whitehouse.gov/blog/2011/04/20/facts-about-independent-payment-advisory-board [https://perma.cc/6GHV-7WNJ] (describing composition, functions, and limitations associated with Independent Payment Advisory Board ("IPAB")—a related agency created by ACA). *But see* Dubois, *supra* note 31, at 10 (referencing major U.S. insurer employing incremental cost-effectiveness ratio ("ICER") per QALY for use in formulary listing decisions).

down the line.[33] For manufacturers, on the other hand, tying reimbursement to health outcomes presents new opportunities for competition with rival manufacturers. Although approval by the Food and Drug Administration ("FDA") signals that a drug's benefits exceed its risks,[34] findings of efficacy in the tightly controlled settings of Phase II and III clinical trials may lose meaning once the drug is subjected to real-world use.[35] Insurers are aware of this, and so a manufacturer that can demonstrate sustained health benefits in post-market studies may distinguish itself from competitors. Additionally, manufacturers may be able to demonstrate the drug's effectiveness through indicia other than those sanctioned by the FDA, thus expanding the potential patient base.[36] A more meritocratic reimbursement system would also direct research and development funds toward creating chemical and biologic compounds that are not only innovative but also possess the greatest likelihood of improving health.

In Figure 1, I provide a framework for analyzing these market forces. The general lesson learned by studying each quadrant is that the type and amount of health information produced is a function of intra- and interindustry competition. Here, competition refers to competition for a single *class* of drugs.

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[33] *See* Editorial, *Costly Hepatitis C Drugs for Everyone?*, N.Y. TIMES, Sept. 2, 2015, at A24. *But see* TARA O'NEILL HAYES, AMERICAN ACTION FORUM, CURRENT IMPEDIMENTS TO VALUE-BASED PRICING FOR PRESCRIPTION DRUGS 10 (2017), https://www.americanaction forum.org/wp-content/uploads/2017/06/2017-06-05-Rx-Value-based-pricing-and-policy-im pediments-FINAL.pdf [https://perma.cc/D7KC-BPNT] (pointing to patient churn (i.e., switching insurers) as one reason insurers may be less committed to long-term health benefits of various treatment courses).

[34] *In re* Plavix Mktg., Sales Practices & Prods. Liab. Litig., 123 F. Supp. 3d 584, 604 (D.N.J. 2015) ("In order for the FDA to consider a drug safe, the drug's 'probable therapeutic benefits must outweigh its risk of harm.'" (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 140 (2000))).

[35] *See* Adrian Towse et al., *Measuring Value: Pharmacoeconomics Theory and Practice*, *in* THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY, *supra* note 13, at 394, 411-12 (pointing to "atypical nature of trial settings," "protocol-driven" diagnosis and treatment, "inappropriate clinical alternatives," and use of surrogate endpoints as factors that limit generalizability).

[36] The practice of using prescription drugs for medical indications other than what is approved by the FDA is called "off-label" use. Off-label uses are reimbursable subject to their listing in compendia. *See In re Plavix*, 123 F. Supp. 3d at 605-06. However, off-label marketing is strictly regulated under the Food, Drug, and Cosmetic Act, violations of which can form the predicate false statement for a False Claims Act ("FCA") claim if they cause claims to be submitted to Medicare or Medicaid. *See, e.g.*, *Pharmaceutical Giant AstraZeneca to Pay $520 Million for Off-Label Drug Marketing*, U.S. DEP'T OF JUSTICE (Apr. 27, 2010), https://www.justice.gov/opa/pr/pharmaceutical-giant-astrazeneca-pay-520-million-label-dru g-marketing [https://perma.cc/5846-9E4D].

Figure 1. Health Information[37] Under Varying Levels of Competition

Payers

		High Competition	Low Competition
Manufacturers	High Competition	(Q2) Demand and supply are highly elastic. Health information is very valuable to both payers and manufacturers.	(Q1) Demand is less elastic; supply is highly elastic. Health information is valuable to manufacturers but not payers.
	Low Competition	(Q3) Demand is highly elastic; supply is less elastic. Health information is valuable to payers but not manufacturers.	(Q4) Supply is less elastic; insurer demand is less elastic, but patient demand remains highly elastic. Health information will only be produced under government mandate.

In quadrant one (low payer competition, high manufacturer competition), payers have a wide choice of which drug to cover, because all drugs in the class are believed to produce equal benefits. Thus, drug manufacturers face a less elastic demand curve, but can prevail over rivals by distinguishing themselves on nonprice characteristics—drug effectiveness, for one. While payers would welcome such information, they will leave it to other parties to produce.[38]

In quadrant two (high payer competition, high manufacturer competition), payers compete to provide the best drug-coverage package to their clients[39] at the lowest price, while manufacturers compete vigorously because of saturated supply. Payers will need to cover a drug in the class but have many from which

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[37] By "health information," I am referring to information about a drug's effectiveness in the patient population.

[38] Under oligopolistic conditions, conscious parallelism among payers would lead them to avoid producing health information because distinguishing characteristics among drugs in the class may force payers to compete with each other on coverage terms, thus threatening profits. For a discussion of oligopoly theory, see PHILLIP AREEDA ET AL., ANTITRUST ANALYSIS: PROBLEMS, TEXT, AND CASES ¶¶ 232-37 (7th ed. 2013). Antitrust courts have recently enjoined mergers in the health insurance industry, citing the high probability of anticompetitive effects in the large-employer market and Medicare Advantage market—both of which are already highly concentrated. *See, e.g.*, United States v. Anthem, Inc., 236 F. Supp. 3d 171, 208-09, 259 (D.D.C. 2017); United States v. Aetna, Inc., 240 F. Supp. 3d 1, 8-10 (D.D.C. 2017).

[39] The range of clients is vast and can include: consumers in the individual insurance market, employers and plan sponsors, Medicare fee-for-service and Medicare Advantage beneficiaries, and Medicaid beneficiaries. *E.g.*, Aetna Inc., Annual Report (Form 10-K) 6 (Feb. 17, 2017).

to choose. And while payers may seek information about those drugs, oligopolistic conditions may encourage conscious parallelism in coverage decisions—dashing hopes that payers will independently invest in producing health information.[40] Meanwhile, manufacturers can distinguish themselves from their peers by demonstrating greater effectiveness. The high value of privately produced health information means that PBRSAs will thrive under these market conditions.

In quadrant three (high payer competition, low manufacturer competition), payers win clients by covering a drug at the lowest premium/cost to the insured. Manufacturers face little competition because they offer a drug that payers believe they must cover. Manufacturers do not seek more information about effectiveness, but payers do because it would improve their bargaining position. Individual payers will find it difficult to enter into a PBRSA absent some form of collusion or informational advantage that equalizes their bargaining position vis-à-vis manufacturers. Successful payers may be those who can offer drug coverage at low cost by offsetting claims in other treatment classes. In sum, health information is valuable to payers but not manufacturers.

Quadrant four (low payer competition, low manufacturer competition) may best describe market conditions for cosmetic drugs—for example, those for hair loss or erectile dysfunction. Under these conditions, payers do not need to compete because their clients' market decisions do not depend on the coverage terms for this class of drugs. Meanwhile, manufacturers do not face supply competition. It may be the case that expensive specialty coverage is available but rare, because the actuarial costs of coverage outweigh the benefits. Yet the manufacturers can still leverage their market power directly against consumers. Under these conditions, health information is not valuable unless it demonstrates high risks or side effects. Manufacturers seek to avoid producing or publicizing such information absent government mandate. Payers will value information on risk to the extent that it influences other actuarial considerations—for example, the costs associated with treating any consequential negative effects of drugs within the class.

To summarize, private ordering in the production of health information is most likely to take place where competitive conditions exist in both the payer industry and manufacturer industry. The market exhibits asymmetric incentives for the production of health information where intraindustry competition is high but interindustry competition is low. In this setting, health information will be underproduced unless there exists collusion or government mandates that

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[40] This mimicry of other payers' coverage decisions raises a free-rider problem and an attendant disincentivization of investments in information-gathering activities if the investor lacks the power to exclude competitors from the information. For a well-known discussion of this rationale, see Int'l News Serv. v. Associated Press, 248 U.S. 215, 239-40 (1918) (endorsing doctrine of misappropriation in news industry).

equalize interindustry bargaining positions. This framework may be used to generate predictions about the desirability of PBRSAs in various drug classes.

II.   PBRSAs: DESIGN, FUNCTION, AND POTENTIAL PARTIES

PBRSAs come in an array of forms, each of which presents unique barriers to implementation. Confusingly, there are a variety of names attached to PBRSAs.[41] However, in all cases and like all contracts, the goals of the key parties to the transaction ultimately determine the form that the arrangement takes. Examples of PBRSAs that have been implemented in the United States and abroad can provide a foundation for understanding their potential value. In analyzing the structure of PBRSAs, it will also be necessary to distinguish between *volume*- or *sales*-based risk-sharing arrangements and *performance*-based risk-sharing arrangements. This Note focuses on performance, which is a quality metric, rather than volume, which is a quantity metric.

A.   *PBRSA Mechanics*

The International Society for Pharmacoeconomics and Outcomes Research ("ISPOR") identifies five distinguishing features of a PBRSA: (1) the parties involved in the arrangement commit themselves to a "program of data collection," which (2) occurs after the drug receives regulatory approval, (3) determines the drug's price or reimbursement, and (4) seeks to reduce uncertainty associated with the drug's health effects, or its clinical and commercial viability; lastly, (5) the arrangement cements an allocation of risk between the parties that is different from the parties' conventional relationship.[42]

These features provide for innovative arrangements that test the limits of our current regulatory approval and reimbursement regimes. In many ways, the very existence of such arrangements signals a deficiency in the more formalized procedures for promoting the safety and efficacy of prescription drugs. If the

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[41] *E.g.*, Garrison, *supra* note 5, at 704 (identifying "outcomes-based schemes, risk-sharing agreements, coverage with evidence development . . . , access with evidence development, patient access schemes . . . , conditional licensing, and managed entry schemes"). To this, I would add the terms value-based payment and alternative-payment model. *Cf.* David Muhlestein, Natalie Burton & Lia Winfield, *The Changing Payment Landscape of Current CMS Payment Models Foreshadows Future Plans*, HEALTH AFF. BLOG (Feb. 3, 2017), http://healthaffairs.org/blog/2017/02/03/the-changing-payment-landscape-of-current-cms-pa yment-models-foreshadows-future-plans/ [https://perma.cc/49QW-N2L8] (discussing effort by HHS to move health care toward "value-based care and alternative payment models").

[42] Garrison, *supra* note 5, at 705-06. ISPOR also surveys how terms can vary to achieve similar purposes. *See id.* at 707. For example, rather than a manufacturer agreeing to an explicitly lower reimbursement if the drug performs poorly relative to an established benchmark, the parties may instead agree to renegotiate reimbursement terms once sufficient data have been collected. *Id.* (identifying agreements that "specify an evidence review point where renegotiation would occur").

FDA approval process is based on licensing standards that fail to provide useful information about drug quality, then it is of little surprise that private parties would resort to private bargaining to craft a system better suited to their needs. Theory predicts that this bargaining will ensue so long as the parties can appropriate at least some of the value of any private information they generate through their arrangement.[43] As already established, the quantity and value of the information generated through a PBRSA will vary in relation to the level of competition between and among payers and manufacturers.[44] Furthermore, the parties have various options for designing each of the five elements of a PBRSA.

First, the data collection process will involve costs that can either be shared by the parties or borne by a single party.[45] Cost apportionment could be tied to provisions establishing what restrictions, if any, will be applied to the data generated from the study. The parties could facilitate data collection by sharing health information or by establishing a protocol for referring patients to the study.[46] The contract should identify the data of interest. Parties may desire data on the biological, chemical, and physical effects that the drug produces for individual patients, or they may prefer data on how the drug changes health care utilization patterns across the broader patient population.[47]

Second, the parties will establish a timeline for data collection. The length of the study could be longer or shorter depending on the nature of the condition, the results sought, or the expected rate of innovation displayed by competitor drugs. Third comes the complicated decision of how to tie pricing or reimbursement to the outcome data generated.[48] If the study focuses on a biomarker within the drug's therapeutic pathway, then the parties could peg the observed measurements to pre-arranged discount (or rebate) amounts. If the study focuses on the utilization rate of other health care services, then parties could be either rewarded or penalized based on complications that lead patients

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[43] The question of how much appropriation is necessary to stimulate investment in innovation is a matter of vigorous debate. *See* Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1046-58 (2005) (setting out array of views and arguing against using limits on free-riding as polestar in the delineation of intellectual property rights); *see also* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 401-12 (9th ed. 2014).

[44] *But see supra* text accompanying notes 37-39.

[45] As a third alternative, data collection could be undertaken by an independent third party, as is the case with registries. *See* Bruce E. Hillner et al., *The National Oncologic PET Registry (NOPR): Design and Analysis Plan*, 48 J. NUCLEAR MED. 1901, 1901-03 (2007).

[46] *See infra* Parts III, IV (discussing legal barriers to these collection efforts).

[47] *See* Garrison, *supra* note 5, at 707, 712.

[48] The distinction between price and reimbursement is meaningful and affects how value flows through the supply chain. *See* Berndt & Newhouse, *supra* note 14, at 218 ("Despite their name, payers do not actually purchase drugs, and the prices involved in the transactions in which payers engage are not the purchase prices of drugs from manufacturers or wholesalers.").

to seek follow-up or ancillary treatments. This relationship between results and payments could be linear, curvilinear, or nonlinear. An example of a curvilinear relationship would be one in which a cholesterol drug garners a $10 payment per unit delivering a five-milligram reduction in total cholesterol per deciliter of blood, up to a level of 250 mg/dl; for further reductions below that level, reimbursement rates accelerate, with the drug garnering a $50 payment per unit for every five-milligram decrease.[49] Alternatively, a nonlinear relationship would be one in which payments for a biologic used for oncology treatment might only be adjusted upward if the compound induces complete remission for a period exceeding thirty days.[50]

These examples also illustrate the fourth element of a PBRSA: translating the parties' desires to reduce uncertainty into targets for clinical or statistical significance.[51] The parties may arrange for the monitoring of results by an independent third party and should institute clear procedures for addressing complications with the study, resolving disputes, and determining the point at which success (or failure) will be declared and the relationship dissolved.[52] To demonstrate this element using my above example of a hypothetical cholesterol drug, the agreement would need to specify the precise methods and timing of blood tests and a system for accurately reporting the results of such tests. A third-party interpreter could stand ready to issue binding conclusions that resolve any ambiguities in test results.

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[49] These figures are based on the rough classification of the health risks associated with different total cholesterol levels. *See Cholesterol Levels: What You Need to Know*, NAT'L INSTS. OF HEALTH: MEDLINEPLUS (Summer 2012), https://medlineplus.gov/magazine/issues/summer12/articles/summer12pg6-7.html [https://perma.cc/VJE2-DAUK].

[50] In August 2017, after receiving approval for its innovative CAR-T drug therapy named Kymriah, Novartis announced that it would sell its treatment to Medicare at a cost of $475,000 per treatment but would only charge the government if the therapy induced a response for the patient. Ed Silverman, *At $475,000, New Cancer Drug Raises Thorny Questions About Drug Pricing—and Value*, STAT (Sept. 4, 2017), https://www.statnews.com/2017/09/04/cancer-drug-pricing-novartis/?utm_source=STAT+Newsletters&utm_campaign=9298c0ca36-On_Call&utm_medium=email&utm_term=0_8cab1d7961-9298c0ca36-149662213 [https://perma.cc/ZU66-MM2A]. Neither Novartis nor CMS has explained how they will determine whether a "response" has occurred sufficient to trigger payment. Further, while the all-or-nothing approach taken by Novartis may skirt some of the thorny legal obstacles that Congress and the courts have erected concerning CMS's bargaining directly with manufactures over price, *see infra* Sections II.B.1, II.B.2, the Kymriah pricing arrangement represents a fairly blunt instrument when it comes to tying payment to value because it focuses on patient performance only in the first thirty days of treatment and incorporates only a binary assessment as to whether the drug worked or not. Such binary assessments—imprecise as they are—may prove to be ill-suited to real-world medical conditions.

[51] *See* Garrison, *supra* note 5, at 707.

[52] *Id.* at 713-15.

Consummating such an arrangement could involve significant transaction costs, which entail legal considerations about how the contract will be enforced and any civil or criminal liability that might arise from the PBRSA.[53] Liability considerations differ considerably depending on whether the government is a party to the PBRSA, so an initial step is to gauge the degree to which government agents are free to participate in such arrangements.

B. *Limitations on Medicare's Participation*

Private payers have latitude in deciding how to structure a PBRSA. They can condition insurance coverage for an approved drug on the manufacturer's promise to collect and report data on a specified sample population, or they can agree to only cover the drug for patients who agree to take part in further studies.[54] As for Medicare, the Centers for Medicare and Medicaid Services ("CMS") has statutory authority to condition coverage decisions upon a promise of further evidence development,[55] but this authority is limited to Medicare Parts A and B, leaving out any drug reimbursed under Part D.[56] Part D, which pays

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[53] The expected benefits of the arrangement must exceed the transaction costs associated with forming the arrangement. *See* Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1, 15-16 (1960).

[54] *Compare* Neumann et al., *supra* note 10, at 2331 (describing agreement involving diabetes drug whereby drug maker Merck rebated Cigna, an insurer, if patients failed to experience improved blood glucose levels), *with* Hillner et al., *supra*, note 45, at 1901-03 (building on decision by CMS to reimburse for positron emission tomography ("PET") scans for use in certain cancer diagnoses only when patients consented to have their results submitted to a national registry for further analysis), *and* Scott D. Ramsey & Sean D. Sullivan, *Evidence, Economics, and Emphysema: Medicare's Long Journey with Lung Volume Reduction Surgery*, 24 HEALTH AFF. 55, 57 (2005) (examining CMS's decision to stop reimbursing for lung volume reduction surgery while simultaneously committing to cover costs of randomized control trial of surgery's effectiveness).

[55] CTRS. FOR MEDICARE & MEDICAID SERVS., *National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development* pt. 2 (July 12, 2006) (citing Section 1862(a)(1)(E) of the Social Security Act ("SSA") (codified at 42 U.S.C. § 1395y(a)(1)(E) (2012)); *see also* Penny E. Mohr & Sean R. Tunis, *Access with Evidence Development: The US Experience*, 28 PHARMACOECONOMICS 153, 156 (2010) (collecting examples of CMS invocation of statutory authority to condition reimbursement of medical procedures on evidence development).

[56] 42 U.S.C. § 1395y(a) (listing items and services for which "no payment may be made under part A or part B"). The statutory authorization for such conditional coverage is murky. Reimbursement under Part B may be sought for certain drugs (usually those administered by a physician in an outpatient setting); but for these drugs, the statute specifies a narrow method whereby CMS can exclude a drug otherwise covered under Part B from reimbursement. *See id.* § 1395y(c)(1)(C) (requiring, inter alia, determination "that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling" and lack of "compelling justification for its medical need"). Outside of this, HHS must reimburse drugs

for most prescription drugs used by Medicare beneficiaries, covers drugs obtainable only through prescription and which are approved by the FDA.[57] Congress explicitly excluded from coverage certain classes of drugs.[58] The authority granted to the Department of Health and Human Services ("HHS") in this process is nondiscretionary—it must look to FDA approval as a trigger for drug coverage,[59] and HHS is forbidden from playing a direct role in price negotiations.[60] Instead, Prescription Drug Plans ("PDPs") bargain with manufacturers on behalf of Medicare beneficiaries by offering access to their formularies.[61] As with commercial insurance, PDP formularies are tiered, such that manufacturers compete to have their drugs listed on a preferred tier.[62] There is empirical evidence that Part D lowered drug prices in its early years.[63] However, the increasing prevalence of specialty drugs calls into question this trend.[64] This raises the question whether HHS has the authority to condition its coverage of prescription drugs under Part B or Part D on further evidence development, as is done by many European public payers.

1.   HHS's Authority to Implement PBRSAs Under Medicare Part B

In March 2016, after noting rapid growth in payments, HHS announced a new model for reimbursing Part B drugs.[65] Invoking its authority under § 1315a to

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under Part B based on a rate designated by statute and may not diverge from this rate of its own accord. *See* Hays v. Sebelius, 589 F.3d 1279, 1282 (D.C. Cir. 2009) (citing 42 U.S.C. § 1395w-3a(b)(1)) ("The statutory formula requires the Secretary to reimburse a particular drug at 106% of the average sales price for drugs within its billing and payment code.").

[57] 42 U.S.C. § 1395w-102(e)(1).

[58] *Id.* § 1395w-102(e)(2) (cross-referencing *id.* § 1396r-8(d)(2), which excludes coverage for weight-loss, fertility, and hair-growth treatments, among others).

[59] *Hays*, 589 F.3d at 1282.

[60] 42 U.S.C. § 1395w-111(i)(1)-(2). *But see infra* Section II.B.2.

[61] Berndt & Newhouse, *supra* note 14, at 249. As discussed *infra* Part III, PDP prices do not factor into "best price" calculations under the Medicaid Drug Rebate program and are confidential. 42 C.F.R. § 447.505(c)(6) (2016); Berndt & Newhouse, *supra* note 14, at 250.

[62] Drugs listed on tiers one through three are usually subject to fixed co-payments, with drugs on tiers four and (sometimes) five being subject to co-insurance. *See* Berndt & Newhouse, *supra* note 14, at 207.

[63] *See id.* at 250 (reporting that "total number of prescriptions dispensed to Medicare beneficiaries increased by 40 percent between 2006 and 2010" but that "price per prescription (measured at WAC) . . . fell at an annual growth rate of [negative] 7.7 percent").

[64] PHARM. CARE MGMT. ASSOC., *New Milliman Study: Hepatitis C Drugs Could Increase Medicare Part D Spending by $2.9 to $5.8 Billion in 2015* (July 2014), https://www.pcmanet.org/new-milliman-study-hepatitis-c-drugs-could-increase-medicare-part-d-spending-by-2-9-to-5-8-billion-in-2015/ [https://perma.cc/G2ED-2WUU].

[65] Medicare Program; Part B Drug Payment Model, 81 Fed. Reg. 13,230, 13,240-41 (Mar. 11, 2016) [hereinafter Part B Payment Model] (proposing to reimburse at 102.5% of ASP, plus $16.80 per drug).

"test innovative payment and service delivery models,"[66] HHS proposed to "allow CMS to enter into *voluntary* agreements with manufacturers to link health care outcomes with payment."[67] This program was an effort to move the needle forward on tying payment to performance. Under current caselaw, however, it is not clear whether such efforts would be consistent with other provisions of the Social Security Act ("SSA").

In *Hays v. Sebelius*,[68] for example, the D.C. Circuit confronted a case in which a Medicare Administrative Contractor ("MAC") reduced its reimbursement rate for a branded inhaler used to treat COPD after determining that the drug failed the "reasonable and necessary" test for reimbursement under § 1395y(a)(1)(A).[69] Rather than halting reimbursement altogether, the MAC relied on a CMS policy allowing it to cover the drug at the same rate as the "reasonably feasible and medically appropriate least costly alternatives."[70] The court stated in clear terms the strictures imposed by the SSA on HHS coverage determinations:

> As written, the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all.[71]

This holding is at odds with the sort of PBRSAs that HHS envisioned in its Part B Payment Model, which contemplated that price might vary based on a drug's performance. Importantly, however, all models created under § 1315a not only receive waivers from other reimbursement mandates in the SSA, but they are largely insulated from judicial review.[72] This grants temporary license for HHS to test innovative strategies for reducing cost and promoting quality that might not otherwise be statutorily authorized, and it explains why HHS felt comfortable going as far as it did in the Part B Payment Model. Additionally, HHS imposed a voluntariness requirement upon the PBRSAs proposed in the model; this obviated any concerns about HHS coercing manufacturers into such arrangements, as it left the decision of whether to participate or not in the hands of manufacturers.[73]

Ultimately, the Part B Payment Model never entered into force. The Obama Administration retracted its proposal due to political fires fanned, in part, by

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[66] 42 U.S.C. § 1315a(a)(1) (2012).

[67] Part B Payment Model, *supra* note 65, at 13,244 (emphasis added).

[68] 589 F.3d 1279 (D.C. Cir. 2009).

[69] *Id.* at 1280.

[70] *Id.* (quoting CTRS. FOR MEDICARE & MEDICAID SERVS., Medicare Benefit Policy Manual § 110.1.C.3 (July 25, 2008) (internal quotation marks omitted)).

[71] *Id.* at 1283.

[72] *See* 42 U.S.C. § 1315a(d)(1), (2) (2012).

[73] Part B Payment Model, *supra* note 65, at 13,244.

sentiments associated with the incoming Trump Administration.[74] But the way the endeavor was structured conveys clues about the agency's opinions on the scope of its own authority. For one, the simple fact that HHS included PBRSAs in a § 1315a *model* may itself indicate that the agency doubts whether it has statutory authority to implement these arrangements in the open market. However, it is interesting to note that § 1315a contemplates that successful models may become permanent upon a continued showing that they improve or maintain levels of patient care without adversely affecting spending.[75] Notwithstanding this possibility, offering PBRSAs on a voluntary basis to manufacturers is a far cry from the take-it-or-leave-it conditions on reimbursement that foreign governments can impose.[76]

2.   HHS's Authority to Implement PBRSAs Under Medicare Part D

The SSA includes two prominent limitations on HHS's role in administering Part D:

> In order to promote competition under this part and in carrying out this part, the Secretary (1) may not interfere with the negotiations between drug manufacturers and pharmacies and [Prescription Drug Plan] sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.[77]

This provision has been read to bar HHS from using its potentially vast market power to negotiate lower prices from manufacturers.[78] If HHS adopted a policy mandating that PDPs enter into PBRSAs for a specific drug, the agency would need to argue that such a requirement is not prohibited by either subsection (1) or subsection (2).

Such an argument might begin with the observation that the statute can be viewed as imposing a jurisdictional limitation on HHS's authority over subject matter that would otherwise fall within its ambit. Characterizing the provision as a jurisdictional bar could open the door to greater interpretive deference. Under *City of Arlington v. FCC*,[79] courts must defer to reasonable interpretations of statutory ambiguities concerning the scope of an agency's jurisdiction.[80] This

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[74] Joyce Frieden, *CMS Halts Medicare Part B Drug Payment Demo*, MEDPAGE TODAY (Dec. 16, 2016), https://www.medpagetoday.com/publichealthpolicy/medicare/62130 [https://perma.cc/YFG8-MJ9B].

[75] 42 U.S.C. § 1315a(b)(3)(B).

[76] *See, e.g.*, Richard Horton, *NICE Vindicated in UK's High Court*, 370 LANCET 547, 547-48 (2007).

[77] 42 U.S.C. § 1395w-111(i)(1)-(2).

[78] Kesselheim, *supra* note 5, at 862.

[79] 569 U.S. 290 (2013).

[80] *Id.* at 306-07; *see also* Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 844-45 (1984).

rule holds even for "statutes designed to *curtail* the scope of agency discretion"—of which this statute is an example.[81] Turning to whether Congress spoke directly to the issue in question, one argument is that subsections (1) and (2) do not unambiguously address HHS's ability to designate a broad framework for how PDPs would arrange for a drug's reimbursement. Not only does subsection (1) focus only on "negotiations" (ignoring the form of the final arrangement), but the plain meaning of "interfere with" refers to actions that tend to create a deviation from a broader goal envisioned.[82] The statute makes clear that this broader goal is to "promote competition"—an objective with which PBRSAs are entirely consistent.[83] A similar argument could be raised for subsection (2), because any HHS policy requiring PDPs to utilize PBRSAs would not inevitably affect formularies or impose pricing structures. These specifics would still be left to the private parties to negotiate.[84]

There are strong reasons to think this argument for deference will fail—some based on the text, others based on the purpose of the statute. Congress chose the word "interfere," which is notably broad and applies to "negotiations," and the provision's extension to both "direct and indirect" interference also supports a broad reading of the prohibition. Mandating the use of PBRSAs would alter the range of options available in negotiations and would probably affect the shape of any final agreement. Such an effect would likely be found to contravene subsection (1). In addition, the prohibitions contained in subsection (2) are directed at subject matter that overlaps substantially with what a PBRSA would cover—drug selection and pricing structures. Reading the sort of deference into these statutes that would be required for HHS to mandate use of PBRSAs by PDPs would materially alter the unfettered negotiations between PDPs and manufacturers that Congress envisioned when it designed the Part D program.[85]

Clearly there is limited room for HHS to require the use of PBRSAs by PDPs. But even if the government cannot require PBRSAs under current law, there is

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[81] *City of Arlington*, 569 U.S. at 303 (citing Chem. Mfrs. Ass'n. v. Nat. Res. Def. Council, Inc., 470 U.S. 116, 123 (1985)).

[82] *See Interfere*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1993) (defining interfere to mean "to come in collision[;] to be in opposition[;] to run at cross-purposes.").

[83] 42 U.S.C. § 1395w-111(i)(1) (2012).

[84] This argument is advanced by allusion to another provision, § 1395w-111(d)(2)(A), which gives HHS authority to control the terms and conditions in its own contracts with PDPs. Even though § 1395w-111(d) subjects HHS's authority in this regard to the noninterference provision in § 1395w-111(i), this becomes irrelevant if it is found that § 1395w-111(i) does not speak to a policy of using PBRSAs. *See also id.* § 1395w-111(d)(2)(B) (giving Secretary "authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans"); H.R. REP. NO. 108-391, at 459 (2003) ("The Secretary has the authority to negotiate the terms and conditions of the [Prescription Drug] plans.").

[85] H.R. REP. NO. 108-391, at 748-49 (2003) ("[P]rivate sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.").

nothing here to suggest that PDPs could not voluntarily pursue a strategy of incorporating performance-based features into their reimbursement contracts with manufacturers. Given the spending pressures faced by the Part D program, there may be ample incentive to pursue such a strategy.[86] In light of this possibility, we next turn to the barriers that private payers face when using PBRSAs.

III. FRAUD AND ABUSE IN PBRSAS

In order to shift risk between the payer and the manufacturer, PBRSAs use incentives to change the parties' behavior. Under a PBRSA, a manufacturer that knows its drug lacks the benefits that it claims cannot rely so heavily on direct advertising to entice patients to request the medication because doing so would be of little benefit if payments are tied to observed health improvements. Similarly, payers would have less recourse to pass costs on to their beneficiaries in the form of higher premiums, citing as justification their lack of knowledge of a drug's therapeutic merits. But this search for value raises concerns that PBRSAs will enable nefarious tactics like price underreporting and illegal kickbacks. Equally problematic is the danger that even benign behavior would be punishable under current laws—a prospect that would deter parties from forming PBRSAs in the first place. Two laws governing health care fraud and abuse are implicated by PBRSAs: the False Claims Act ("FCA") and the Anti-Kickback Statute ("AKS"). I address each in turn.

A. *Concerns Under the False Claims Act and Medicaid Program*

There has been a remarkable uptick in FCA enforcement in recent years, much of it targeting health care entities and involving the use of *qui tam* relators.[87] Among other prohibitions, the FCA imposes liability on any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> . . . .
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly

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[86] There may also be latitude under § 1395w-111(d)(2)(B) for the Secretary to create such an incentive—for example, by giving PDPs that incorporate PBRSAs into their plan preferential treatment in the bidding process.

[87] *See* HUBERFELD ET AL., *supra* note 2, at 317-19.

avoids or decreases an obligation to pay or transmit money or property to the Government.[88]

Here, I will focus my discussion on manufacturers' potential obligations under the Medicaid Drug Rebate Program ("MDRP"), which requires that manufacturers who receive reimbursement from Medicaid for their prescription drugs deliver specified rebates to Medicaid.[89] The rebate is a mechanism for ensuring that Medicaid pays for drugs at a price that is as low as that paid by private payers.[90] This is accomplished by assigning each drug a "best price"[91] and requiring manufacturers to submit a rebate to the relevant Medicaid authority based on the difference or "spread" between the best price and the average manufacturer price ("AMP").[92]

Best price determinations are important to our discussion of PBRSAs because a manufacturer must know what price arises out of the PBRSA to ensure that it rebates the proper amount to Medicaid. If the manufacturer does not know how to treat the PBRSA for the purposes of calculating either the drug's AMP or its best price, then it runs the risk of rebating incorrect amounts or filing incorrect price reports—either of which could result in liability under the FCA.[93]

The formula for calculating the rebate amount is set out by statute[94] and elaborated upon by regulation.[95] For a single source drug or innovator multiple source drug, the formula is:

$$R = Q \ (AMP - best \ price)$$

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[88] 31 U.S.C. § 3729(a)(1)(A), (B), (G) (2012). "Knowingly" is defined to include actual knowledge, as well as deliberate ignorance or reckless disregard of the truth or falsity of information. *Id.* § 3729(b)(1). "Material" is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4). An "obligation" is "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." *Id.* § 3729(b)(3).

[89] United States *ex rel.* Banigan v. Organon USA Inc., 883 F. Supp. 2d 277, 285 (D. Mass. 2012) (citing 42 U.S.C. § 1396r-8(a)(1)).

[90] *See id.*

[91] 42 C.F.R. § 447.505(a) (2017) (defining "best price" broadly as "lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed"). The regulation then goes on to list prices that are excluded from best price determinations. *Id.* § 447.505(c).

[92] 42 U.S.C. § 1396r-8(c)(1)(A)(ii)(I) (2012).

[93] *See, e.g.*, United States *ex rel.* Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 598-603 (E.D. Pa. 2012).

[94] 42 U.S.C. § 1396r-8

[95] 42 C.F.R. § 447.504 (AMP); *id.* § 447.505 (best price); *id.* § 447.509 (rebate amount).

where *R* is the rebate amount associated with the drug, and *Q* is the quantity of units reimbursed under the state Medicaid plan in question.[96] The law requires that manufacturers rebate an amount no less than 23.1% of AMP for each unit sold, which is referred to as the "minimum rebate percentage."[97]

AMP is "the average price paid to the manufacturer for the drug in the United States by *wholesalers* for drugs distributed to retail community pharmacies and [by] *retail community pharmacies* that purchase drugs directly from the manufacturer."[98] Disputes can arise when manufacturers improperly include or exclude certain discounts, rebates, or fees available to wholesalers or pharmacies from their calculations.[99] Under a PBRSA structured so as to provide for payments that flow from the manufacturer back to the payer based on health outcomes, AMP calculations should be unaffected and would be calculated the same as under a conventional reimbursement scheme. AMP is concerned with remuneration between manufacturer and wholesaler, not the manufacturer and insurer; this is explicit in the regulations, which exclude from the calculation "[s]ales, associated rebates, discounts, or other price concessions paid directly to insurers."[100] Health maintenance organizations ("HMOs") and PBMs are subject to a similar exclusion.[101] Because of this, any liability under the MDRP would have to be predicated upon improper calculations of best price.[102]

The best price is "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, [HMO], nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed."[103] Importantly, prices negotiated by private payers under the auspices of Medicare Part D, as well as certain health programs operated by the federal government

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[96] 42 U.S.C. § 1396r-8(c)(1)(A).

[97] *Id.* § 1396r-8(c)(1)(B)(i). The minimum rebate percentage was increased from 15.1 percent to 23.1 percent by the ACA. MEDICAID & CHIP PAYMENT & ACCESS COMM'N, MEDICAID PAYMENT FOR OUTPATIENT PRESCRIPTION DRUGS 7 (Sept. 2015), https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf [https://perma.cc/7FZT-ZC53].

[98] 42 C.F.R. § 447.504(a) (2017) (emphasis added).

[99] *See, e.g.*, United States *ex rel.* Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 598-603 (E.D. Pa. 2012) (allowing FCA claim to proceed in part based on theory that manufacturers recklessly misinterpreted regulations so as to include "bona fide service fees" in their AMP calculations, thus artificially lowering AMP figures and associated Medicaid rebate amounts).

[100] 42 C.F.R. § 447.504(c)(13).

[101] *Id.* § 447.504(c)(6) (HMOs); *id.* § 447.504(c)(18) (PBMs).

[102] *Cf. In re* Pharm. Indus. Average Wholesale Price Litig., 672 F. Supp. 2d 211, 217 (2009) (concluding that manufacturers' rebates to third-party payers should be excluded—treated differently than manufacturers' payments to wholesalers—when calculating list price, of which AMP is example).

[103] 42 C.F.R. § 447.505(a). The term "provider" includes health insurers. *Id.*

(e.g., the VA system and the Department of Defense's TRICARE system) are excluded from best price calculations.[104] The best price calculation accounts for a range of mechanisms (including rebates, discounts, "incentives," and "other transactions") that "adjust prices either directly or indirectly," whether or not the adjustment occurs upfront or subsequent to the initial transaction between the parties.[105] The following payments are excluded from the best price calculation: bona fide service fees; PBM rebates; and manufacturers' coupons, discounts, refunds, and rebates—the full value of which must be passed on to the consumer to qualify for the exclusion.[106] If a transaction squarely falls within this list, best price concerns are greatly minimized, which would benefit the transacting parties.

Suppose, for example, that an insurer wants to provide coverage for a cholesterol drug that could benefit its enrollees. The insurer needs to decide which of the various cholesterol drugs it will cover—and more specifically, which of those drugs will be placed on a preferred formulary tier so as to incentivize patients to use the drug. The insurer (or a PBM acting as its agent) negotiates with several drug manufacturers—one of which agrees to rebate the insurer fifty percent of the cost of any units consumed by patients who do not experience a reduction in cholesterol levels equal to that demonstrated in clinical trials. Assume that the parties successfully agree on an effective data collection program that will control for confounding factors such as poor diet and exercise.[107] Must the rebate payments that flow from the manufacturer to the insurer be incorporated into the best price calculation for the cholesterol drug?

Commentators, insurers, and manufacturers seem to think so—or they at least believe the rules to be unclear on this point.[108] CMS acknowledged this

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[104] *Id.* § 447.505(c). This ensures that government programs and PDPs can negotiate prices with manufacturers without the latter having to give Medicaid plans access to price concessions that are made—avoiding a free-rider problem that might result in higher drug prices for Medicare beneficiaries, veterans, and federal employees.

[105] *Id.* § 447.505(d).

[106] *Id.* § 447.505(c).

[107] This hypothetical is loosely based on an agreement recently reached between Cigna and drug makers Amgen and Sanofi/Regeneron. *See* Press Release, Cigna Corp., Cigna's Two New Value-Based Contracts with Pharma for PCSK9 Inhibitor Cholesterol Drugs Tie Financial Terms to Improved Customer Health (May 11, 2016), https://www.cigna.com/newsroom/news-releases/2016/cignas-two-new-value-based-contracts-with-pharma-for-pcsk9-inhibitor-cholesterol-drugs-tie-financial-terms-to-improved-customer-health [https://perma.cc/TG9V-VNER].

[108] *See, e.g.*, Dana Goldman, *Drop Medicaid 'Best Price' Drug Rules in Favor of Value-Based Strategies*, MODERN HEALTHCARE (Nov. 18, 2015), http://www.modernhealthcare.com/article/20151118/NEWS/151119888 [https://perma.cc/4CYD-PVYA]; Humana, Inc., Comment Letter on Part B Drug Payment Model (May 9, 2016), https://www.regulations.gov/document?D=CMS-2016-0036-0921 [https://perma.cc/4QH3-LPHA]; Pfizer, Inc., Comment Letter on Part B Drug Payment Model (May 9, 2016),

uncertainty in mid-2016, but stated that whether the best price calculation is implicated will depend on the "structure of the [value-based purchasing] arrangement," and the agency has not provided further guidance since this statement.[109] Based on concerns voiced by important industry representatives in comments to the agency,[110] the result has been a reluctance on the part of insurers and manufacturers to enter into PBRSAs.

Whereas the text of the statute does not appear to address this question at all, the implementing regulations could be read to require that a manufacturer account for performance-based rebates it pays out by lowering the best price it reports to CMS. The regulation states that "best price . . . includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly . . . ."[111] Although the use of "other transaction" and "indirectly" seems to expand the scope of the definition significantly, the crucial phrase is "adjust prices," which limits the class of transactions to those that cause a certain result—a change in prices. If price is taken to mean "the quantity of one thing that is exchanged or demanded in barter or sale for another,"[112] then, applying this definition here, the performance-based rebate can be characterized as being both required and given in order to secure preferred placement on the formulary, and it therefore forms the core basis of the bargain struck between insurer and manufacturer.

This conclusion is also consistent with lessons taken from the sorts of transactions that are *excluded* from best price. For example, performance-based rebates most likely would not be classifiable as bona fide service fees because, although the insurer may operate some sort of patient care program designed to promote or monitor the effectiveness of the drug, the size of the rebate is tied to the drug's effectiveness in the patient population, not the value of services that are rendered by the insurer.[113] A similar observation can be made of excludable

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https://www.regulations.gov/document?D=CMS-2016-0036-1260 [https://perma.cc/FJF9-3XCD].

[109] CTRS. FOR MEDICARE & MEDICAID SERVS., *Value Based Purchase Arrangements and Impact on Medicaid* (July 14, 2016), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-099.pdf [https://perma.cc/K6HJ-8VBK] (urging parties to consider statute and regulations when forming arrangements).

[110] *See id.*

[111] 42 C.F.R. 447.505(b).

[112] *Price*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (1993).

[113] Moreover, it is hoped that the insurer would pass on a portion of the rebate to employers and beneficiaries in the form of lower premiums. *See* 42 C.F.R. § 447.502 (defining "[b]ona fide service fee" based in part on its correspondence with the fair market value of services rendered and whether the fee is passed on by the entity). Perhaps the manufacturer could claim that the value of the utilization and monitoring services makes up the full value of the rebate, but it would then need to show that it would have valued its services the same were it not for the PBRSA—a dubious claim given the current state of reimbursement practices. *See* United

coupons, manufacturer-sponsored refund or rebate programs, and free goods, all of which require either the full and direct transfer of value to a patient, the absence of any price concession to the insurer, or the absence of a purchase requirement.[114]

As mentioned above, the general understanding among courts and commentators is that Congress intended the MDRP to operate like a most-favored-customer scheme, whereby one party (here, Medicaid) obtains the benefit of lower prices offered to another party.[115] The MDRP relaxed budgetary constraints that had once restricted the ability of Medicaid beneficiaries to access helpful drugs by requiring manufacturers to extend their most favorable prices to those who were enrolled in the Medicaid program. Taking this into account, Congress could have therefore expected—or indeed intended—that manufacturers would react by forcing private payers to cross-subsidize the favorable pricing granted to poorer populations. This would support a rigid view of the best price regime—one that makes no distinction between a conventional pricing scheme and a PBRSA. Indeed, there is a strong policy rationale for requiring manufacturers to let states and the federal government benefit from the knowledge of a drug's effectiveness created through a PBRSA.

But a problem arises from the differential composition of the population that is enrolled in private insurance versus Medicaid—and, even more generally, differences between any two insurance pools. The core purpose of a PBRSA is to approximate the use-value of a drug to a given patient population by reference to the population's health outcomes. It may very well be the case that a drug would perform differently in a privately insured population than it would in the Medicaid population. Even a difference of several percentage points could be significant because the covered population may be quite large. In such cases, and assuming no risk adjustment is undertaken, the best price regime would undermine the overarching intent of value-based reimbursement and would keep intact the current barrier between health information and drug valuation.[116]

States *ex rel.* Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 597-98 (E.D. Pa. 2012) (applying four-part test devised by CMS to determine whether transaction reflects bona fide service fee).

[114] *See* 42 C.F.R. § 447.505(c)(9), (11)-(13).

[115] United States *ex rel.* Banigan v. Organon USA Inc., 883 F. Supp. 2d 277, 285 (D. Mass. 2012) ("The rebate payment is made to ensure that Medicaid is receiving the best price for any covered outpatient drug."). For a description of "most-favored-customer" clauses in contracts and drug manufacturers' strategic responses, see Fiona Scott Morton, *The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules*, 28 RAND J. ECON. 269, 269-70 (1997).

[116] Note, however, that this suggests a potential strategy for minimizing the strictures of the best price regime: instead of calculating a per-unit value of performance-based rebates and deducting this from the initial unit price of the drug, an accurate measure of best price requires that the manufacturer know the quantity of Medicaid patients that would exhibit health outcomes that are similar to the patient population that participated in the PBRSA. To properly do so, state Medicaid administrators hoping to benefit from PBRSAs must

To summarize, even if parties to a PBRSA wanted to pay the proper rebates to Medicaid, they may be precluded from doing so because they do not know what the drug's value (in terms of health benefits) is in the referent Medicaid population.

At this time, CMS has left it to manufacturers participating in PBRSAs to come up with reasonable systems for calculating the total amount of rebates they owe to Medicaid.[117] If CMS and federal enforcement agencies determine that participants are overestimating best price or submitting fewer Medicaid rebates than required, then the participants could face FCA liability.[118] A primary issue in any ensuing litigation would be whether the alleged conduct satisfies the requisite scienter, meaning that the defendant acted with actual knowledge, reckless disregard, or deliberate ignorance.[119] In recent cases, courts have borrowed a test elaborated by the Supreme Court in *Safeco Insurance Co. of America v. Burr*[120] to determine whether a defendant's reading of a statutory or regulatory provision rises to the level of recklessness required under the FCA.[121] According to the *Safeco* standard, even if a defendant commits a violation under a reasonable reading of the regulation or statute, that violation does not rise to the level of recklessness unless the defendant "ran a risk of violating the law substantially greater than the risk associated with a reading that was merely careless."[122] Consideration is given to the amount of "interpretive guidance 'that might have warned the defendant away from the view it took.'"[123]

If a defendant were to *wholly exclude* a performance-based rebate from its calculation of best price, there is a strong likelihood that such conduct would be found reckless. For one, the CMS guidance document from mid-2016 suggests CMS's view that PBRSAs do implicate best price in some way.[124] The agency's

themselves agree to a program of data collection with the manufacturer. At that point, state Medicaid authorities might simply elect to enter into PBRSAs. This shows that the best price regime could be conceived of as a broader mechanism for disseminating innovative contractual structures, rather than a simple price regulation.

[117] CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 109 (advising MDRP participants to document any reasonable assumptions they make when calculating best price).

[118] 31 U.S.C. § 3729(a)(1)(G) (2012).

[119] *Id.* § 3729(b)(1).

[120] 551 U.S. 47 (2007). *Safeco* was a case brought under the Fair Credit Reporting Act alleging that adverse actions taken on consumer accounts went unreported, in violation of the law. *Id.* at 52-55.

[121] *See, e.g.*, United States *ex rel*. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency, 530 F.3d 980, 983 (D.C. Cir. 2008); United States *ex rel.* Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 592-93 (E.D. Pa. 2012) (applying *Safeco* to FCA claim based on AMP miscalculations).

[122] *Safeco*, 551 U.S. at 69. The test imports principles of lenity into FCA litigation, insulating a defendant from the risk of onerous liability stemming from unclear regulations.

[123] United States *ex rel.* Purcell v. MWI Corp., 807 F.3d 281, 288 (D.C. Cir. 2015) (brackets omitted) (quoting *K & R*, 530 F.3d at 983).

[124] *See* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 109.

recommendation that manufacturers arrive at their calculations by reference to regulations is far from pellucid, but it intimates that certain PBRSAs may involve remuneration of which only a portion could be excluded from best price.[125] At a minimum, the CMS guidance document is a warning that manufacturers should tread lightly in this area, such that a manufacturer's ignoring best price completely would probably satisfy the standard of recklessness under *Safeco*. A safer route would be for manufacturers to attempt to approximate best price by tallying up anything of value flowing between the parties that could potentially be viewed as a retroactive price concession. Unfortunately, such cautious behavior would hinder the uptake of PBRSAs and could explain the relative scarcity of such agreements in the current market.

B.   *Concerns Under the Anti-Kickback Statute*

A PBRSA involves the transfer of something of value—whether rebates, discounts, the assumption of related financial obligations, or valuable health data—between payer and manufacturer for purposes of providing patients with coverage for a prescription drug. The AKS broadly criminalizes the payment and receipt of "any remuneration" if one purpose of the remuneration is to induce patient referrals.[126] To be covered by the AKS, the items or services furnished as a result of the referral must be reimbursable under a federal health care program—commonly Medicare or Medicaid.[127]

Where a private insurer provides coverage for a drug, the AKS is not directly implicated because government funds are not at stake. Conversely, in cases where a private insurer or PBM has contracted with CMS to provide coverage under Medicare Part D, any agreement between manufacturer and payer must comply with the AKS. Because it is administratively cost intensive for large insurers, PBMs, and manufacturers to ensure that government-covered patients are treated separately from privately covered patients, most PBRSAs should be structured to comply with the AKS.[128] Failure to comply with the AKS will not only subject defendants to potential criminal liability and exclusion from Medicare, but can also constitute a predicate false certification under the FCA,

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[125] *Id.*

[126] 42 U.S.C. § 1320a-7b(b) (2012); *see also, e.g.*, United States v. Greber, 760 F.2d 68, 69 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985) (announcing "one purpose" test). The statute requires that a defendant's conduct be knowing and willful to be liable. 42 U.S.C. § 1320a-7b(b).

[127] 42 U.S.C. § 1320a-7b(b)(1), (2).

[128] Furthermore, an attempt to "carve out" patients for whom care is reimbursed using government funds will not escape liability because it is impossible to say that the incentives created by kickbacks do not pollute the medical judgment used when caring for patients covered by government payers—that is, Medicare/Medicaid patients. *See* OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OIG Advisory Opinion No. 13-03 (June 7, 2013).

exposing the party to the full complement of remedies that the FCA provides, including treble damages.[129]

When a private payer enters into a PBRSA, it may do so with the promise that it will incentivize patients to try a certain drug. For example, placing the drug on a preferred formulary tier will lower the patient's cost-sharing obligations, thus increasing the likelihood of prescribing the drug. In the case of an HMO, the payer has some degree of control over the physician, which allows it to establish protocols whereby physicians adhere to prescription and treatment patterns that reflect the HMO's reimbursement obligations.[130] Many large insurers and PBMs possess a similarly high degree of control over the retail, specialty, or mail-order pharmacies that will eventually dispense the prescription. Furthermore, many federal and state laws allow pharmacies to substitute one drug for another where both treat the same medical condition.[131] This influence over treatment plans may constitute a referral even where the patient voluntarily requests a certain treatment.[132] In such cases, the parties may be able to situate their agreement within the bounds of a statutory exemption or regulatory safe harbor to avoid liability.[133]

Although many AKS safe harbors stand out as potentially being amenable to PBRSAs, I will note three that I believe are most relevant. First is the safe harbor for discounts,[134] which was interpreted in *United States* ex rel. *Banigan v. Organon USA Inc.*[135] *Banigan* involved claims that a drug manufacturer funneled illegal kickbacks—in the form of rebates, discounts, data-sharing agreements, and other perks—to long-term care pharmacies in exchange for the pharmacies increasing the volume of the manufacturer's drug that the pharmacies dispensed.[136] For drug buyers, the discount "must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service," and the buyer and seller must, upon request, disclose transactional information to one another and to HHS that permits the accurate calculation of any discount.[137] In rejecting the defendants' attempt to avail themselves of the

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[129] *See, e.g.*, United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 379-80 (1st Cir.), *cert. denied sub nom.* Blackstone Med., Inc. v. United States *ex rel.* Hutcheson, 132 S. Ct. 815 (2011).

[130] *See* Robert Pear, *Doctors Say H.M.O.'s Limit What They Can Tell Patients*, N.Y. TIMES, Dec. 21, 1995, at A1.

[131] Katie Thomas & Andrew Pollack, *When Getting a Refill Is a Battle*, N.Y. TIMES, July 16, 2015, at B1.

[132] *Cf.* United States v. Patel, 778 F.3d 607, 612-13 (7th Cir. 2015).

[133] *See* 42 U.S.C. § 1320a-7b(b)(3)(A)-(J) (2012); 42 C.F.R. § 1001.952(a)-(bb) (2016).

[134] 42 C.F.R. § 1001.952(h).

[135] 883 F. Supp. 2d 277 (D. Mass. 2012).

[136] *Id.* at 283-84.

[137] 42 C.F.R. § 1001.952(h)(1)(iii), (2)(ii).

safe harbor, the *Banigan* court stated that the discount exception "does not embrace collateral kickbacks or reductions in price which are not passed on to Medicaid."[138] In essence, the AKS is being used here to require buyers and sellers to give federal and state governments access to any discounts that the parties negotiate—similar to the direct effect of the Medicaid best price regime.[139] The mechanism presents the same difficulties here that it did there; making parties negotiate not just between each other but also with public payers raises the costs of implementing PBRSAs.

Payments flowing from manufacturers to GPOs can qualify for a safe harbor if the GPO limits or fixes the amount of the fee it charges to vendors for performing its services.[140] Ordinarily this would obviate many problems presented by having money flowing directly from the vendor to a payer or manufacturer because it promotes financial independence. But it is questionable whether such a solution is available in the case of a PBRSA between the GPO and the vendor. PBRSAs rely on variable rebates and discounts, whereas the safe harbor relies on a presumption of fixed payment amounts. The provision does state that setting the GPO's fee at "a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO" would satisfy the requirement[141]—language that does not unequivocally foreclose the possibility that the value of purchases will be adjusted based upon the performance of the good. While the language could—and should—be adapted to make this clearer, it portends an opportunity for GPOs to fill a niche in the early uptake of PBRSAs.

Last, and perhaps most important, is the statutory exemption under § 1320a-7b(b)(3)(F). This provision exempts the following:

> any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title *or* if the written agreement, *through a risk-sharing arrangement*, places the individual or entity at *substantial financial risk* for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide . . . .[142]

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[138] *Banigan*, 883 F. Supp. 2d at 296 ("The term *discount* does not include . . . [a] reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs . . . ." (citing 42 C.F.R. § 1001.952(h)(5)(i)-(iii))).

[139] *See supra* text accompanying note 115.

[140] 42 C.F.R. § 1001.952(j).

[141] *Id.* § 1001.952(1)(ii). The GPO also cannot wholly own or be the subsidiary of a parent corporation that wholly owns any of the entities on whose behalf the GPO acts as purchasing agent. *Id.* § 1001.952(2).

[142] 42 U.S.C. § 1320a-7b(b)(3)(F) (2012) (emphasis added).

This statutory exemption appears to have received incomplete attention in the corresponding regulations. The initial part of the provision refers to § 1395mm, which contains the rules governing Medicare HMOs.[143] The implementing regulations, however, treat the statute as if it spoke only about arrangements between private Medicare contractors and these managed care organizations.[144] A continued reading indicates that the statute seems to contemplate a broader range of risk-sharing arrangements involving entities other than simply HMOs. Indeed, a plain reading of the statute would allow for a PBRSA between a private payer and a drug manufacturer, provided the latter bears "substantial financial risk." The regulations provide only limited insight as to what might constitute substantial financial risk, because the provision seems to have been written with a narrower range of provider-types in mind.[145] Nonetheless, this exemption provides room for parties to argue that their PBRSA exhibits substantial financial risk sharing and that their remunerations are therefore exempt from the AKS.

IV. RECOMMENDATIONS FOR REGULATORY CHANGE TO FACILITATE PBRSAS

This Note largely assumes that PBRSAs will create benefits in the pharmaceutical market—tying prices to patient health, retooling the innovation landscape, and allocating resources in a more meritocratic manner. This assumption will have to be borne out by empirical research. Moreover, any changes to the current regulatory framework will need to anticipate the potentially negative aspects of performance-based drug coverage. After all, the FCA, AKS, and other provisions of the SSA broadly aim to protect patients by interrupting incentives toward nefarious behavior, and it would be naïve to think that PBRSAs are immune from abuse.

In a PBRSA, it is imperative that data be collected and reported accurately because the data dictate the flow of money. There are countless ways in which parties could seek to manipulate such data. Most troubling would be a situation in which one party creates bias in the data collection system. Proper study design can minimize these concerns to some extent.[146] But PBRSAs designed to study

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[143] *Id.* § 1395mm (2012 & Supp. III. 2015).

[144] 42 C.F.R. § 1001.952(u).

[145] *Id.* § 1001.952(u)(i)(C). For example, a risk-sharing contract between an MCO and a physician must abide by a separate swath of regulations that generally arrive at a determination of what constitutes "substantial financial risk" by looking to the previous year's utilization figures and any anticipated changes in the operational landscape, then distributing risk such that at least twenty-five percent of the potential value of the arrangement is subject to performance metrics. *Id.* § 417.479(f).

[146] For example, randomized, double-/triple-blind ("masked"), placebo-controlled studies can minimize bias by making researchers unaware of which patients are receiving the treatment and which are receiving the placebo. ANN ASCHENGRAU & GEORGE R. SEAGE III, ESSENTIALS OF EPIDEMIOLOGY IN PUBLIC HEALTH 185-89 (3d ed. 2014) (emphasizing benefits

health benefits in nonclinical conditions could jeopardize patient privacy by turning daily life into a high-stakes proxy battle over health metrics. If payers stand to gain from bad study results, they may attempt to influence any uncontrolled variables that bear on the target health outcome. Likewise, manufacturers could do the same. The opportunity for strategic maneuvering may create a situation in which the parties impose excessive controls upon the patients, not because such controls lead to better outcomes but because they increase the parties' ability to police their contract.

Monetizing health outcomes in this manner would be an affront to patient dignity. It will be a challenge for parties to balance their desire to monitor conditions against an ongoing concern for patient privacy and welfare. Further research should compare concerns about patient privacy in the context of PBRSAs with concerns that exist under current FDA requirements. Data-use agreements will need to comply with the Health Insurance Portability and Accountability Act's privacy and securities rules, and practitioners will likely face unique challenges in forming such agreements between the parties to a PBRSA. Because a central goal of any PBRSA is to measure drug effectiveness under real-world scenarios, any exemptions from fraud-and-abuse laws opened up to facilitate formation of PBRSAs should be contingent upon maintaining some semblance of real-world conditions in study design.

To comply with the best price regime, manufacturers must give as low a price to Medicaid as they do to any commercial insurer. Complying with the scheme raises the cost of giving any discount or rebate to commercial payers, so PBRSAs create an incentive for both parties to conspire to underreport discounts attributable to effectiveness data. Regulators should identify possible schemes and stay vigilant for signs of underreporting. The nature of such conspiracies will ultimately depend on the approach the agencies take to clarify or alter the legal status of PBRSAs under applicable laws. However, the concerns about underreporting should not differ much from those that exist under the current regime, because the best price rules already impose indirect costs on both sides of any discounted transaction. It could very well be the case that PBRSAs make the incentives more extreme or that they enable new ways to disguise discounts by having more integrated co-conspirators on both sides of the transaction.

To address the impediments created by the Medicaid best price regime, CMS should issue further guidance on how manufacturers must calculate best price to fulfill their obligations under the MDRP and avoid FCA liability. Because each individual patient could conceivably respond differently to a drug, the adjusted price could be very small for patients that respond poorly or higher for patients that respond well. To determine a representative best price, CMS could advise that manufacturers calculate best price using a simple measure of central

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of masking where assessment of clinical results involves subjective judgment). Thus, the fact that clinical staff stand in an employment relationship with the drugmaker should not automatically raise doubts about study results.

tendency—weighted or unweighted—of payers' unit costs across their respective coverage population. By statute, the total amount of each manufacturer's Medicaid drug rebate is dependent on the quantity of units reimbursed by state authorities.[147] Under a performance-based scheme, the term "quantity" may itself be ambiguous because it fails to disaggregate the various Medicaid subpopulations whose reaction to the drug will correspond with a different adjusted price level. This presents an opportunity for CMS to receive deference for its interpretation of the term. A final option would be for CMS to formulate a rule that requires states to enter into PBRSAs in order to obtain the benefits of any performance-based rebates transferred to private payers.[148]

It is conceivable that CMS could issue regulations that completely exclude a narrow set of PBRSAs from the best price calculus—those in which manufacturers agree to bear (in kind) the risk of any medical treatments needed by patients who fail to respond to the drug in question. The phrase carrying the most meaning within the statute is "lowest price available," which, when read in context with the requirement that rebates and cash discounts be included in calculations, is probably clear enough to foreclose rulemaking efforts that exempt direct payments from best price entirely.[149]

The most straightforward avenue for clarifying how PBRSAs can comply with the AKS would be for the HHS Office of the Inspector General ("OIG") to formulate specific requirements for satisfying the statutory exemption for risk-sharing arrangements. This could be accomplished through rulemaking or through informal guidance. OIG should resolve whether drug manufacturers fall within the class of "entit[ies] providing items or services" described in the AKS exemption.[150] OIG should also designate a list of sufficient conditions for determining what constitutes "substantial financial risk" under the AKS exemption.[151] The sufficiency of risk sharing is an issue that arises in antitrust cases,[152] so regulators could borrow lessons learned in that context when

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[147] *See supra* text accompanying note 96.

[148] This approach could raise Tenth Amendment concerns if it is viewed as a federal attempt to coerce or commandeer state regulators into accepting or enforcing federal mandates. *See generally* Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012); Printz v. United States, 521 U.S. 898 (1997). These concerns would be alleviated were CMS or Congress to leave room for states to voluntarily assent to PBRSAs, which many would find appealing if incentives existed.

[149] 42 U.S.C. § 1396r-8(c)(1)(C)(i), (ii) (2012).

[150] *Id.* § 1320a-7b(b)(3)(F).

[151] *Id.*

[152] *See* Texaco Inc. v. Dagher, 547 U.S. 1, 6 (2006) ("When persons *who would otherwise be competitors* pool their capital and share the risks of loss as well as the opportunities for profit . . . such joint ventures [are] regarded as a single firm competing with other sellers in the market." (emphasis added) (internal quotation marks omitted) (quoting Arizona v. Maricopa Cty. Med. Soc'y, 457 U.S. 332, 356 (1982))). Note that *Texaco* involved a joint

formulating an exemption for PBRSAs. There is a danger here of over- or under-specifying the test: if rooted in imprecise, qualitative language, the test would probably fail to resolve the ambiguity; if rooted in untried quantitative thresholds, the test could prove too onerous or inflexible to be realistically attainable. Soliciting industry comment will be important in this respect, and the agency could provide a boundary for the discourse by proposing a test that isolates "good" agreements—those warranting AKS exemption—by assessing the extent to which the expected risk that is transferred between the parties equals or exceeds the financial flows that might otherwise jeopardize fiduciary independence.

CONCLUSION

Despite there being ample interest in value-based reimbursement in the prescription drug industry, there is evidence that the current legal regime is creating uncertainty about how such reimbursement contracts would fare under the governing law. This Note has summarized the defining features of a PBRSA—most notably, the post-market incorporation of an ongoing data collection effort that results in price adjustments over time—and has demonstrated why federal agencies may be unable, due to the non-interference provision in the SSA, to require payers and manufacturers to enter into such contracts. On the theory that PBRSAs will only arise through private ordering, this Note then analyzed the obstacles to PBRSAs under the Medicaid best price regime. Current law and regulatory guidance fails to explain how remuneration designated by a PBRSA would be classified for price-reporting purposes. If PBRSAs are to take hold in the market for prescription drugs, lawmakers and regulators will have to clarify statutes and rules to describe how prices tied to health data in a discrete study population should be used to calculate the Medicaid rebate. Without such clarification, parties will be left to guess about their exposure to liability and will likely decline to enter into PBRSAs. This result would undermine recent efforts to tie prices for medical treatment to the actual health benefits obtained by patients.

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venture between competitors, whereas the PBRSAs studied here would involve vertically integrated parties. *Id.* In light of this, the analogy is perhaps better made to the distinction between agency and nonagency contracts, such as those that arise in consignment relationships. *See* AREEDA ET AL., *supra* note 38, at ¶¶ 417-18.