



*State Medicaid Alternative
Reimbursement and Purchasing Test for
High-cost Drugs(SMART-D)*

Legal Brief

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I. Introduction

In 1990, Congress responded to reports that Medicaid was overpaying for prescription drugs by enacting the Medicaid Drug Rebate Program (MDRP). Enactment of the MDRP, codified as Section 1927 of the Social Security Act,¹ ensured that states receive a discount on a drug's average manufacturer price (AMP) and never pay more than a brand name drug's best price (Best Price) in the U.S. pharmaceutical market. Although administration of the MDRP over the past 26 years has evolved considerably and Congress has amended Section 1927 on multiple occasions, the program's design is still rooted in an era that is dramatically different from our current health care system. Blockbuster drugs like Solvaldi and Harvoni that cost more than \$80,000 for a course of treatment were not on the market in 1990. Pharmaceuticals were less integral to patient treatment protocols and the overall cost of that treatment. In addition, migration of the Medicaid program from fee-for-service to managed care and the advent of Medicaid drug purchasing pools were still in their infancy.

As drug costs have climbed and medication-based therapies have increased in importance, new strategies and tools have emerged to help ensure that payment for pharmaceuticals and drug-related services are reasonable and properly tied to evidence-based standards of clinical care. These strategies and tools sometimes referred to as value-based purchasing (VBP) arrangements are premised on the idea that the value of a given drug should be based on its clinical performance and that coverage and payment policies should be driven by data demonstrating the drug's success in improving patient outcomes. They are part of a broader shift to value-based purchasing in other areas of the health care market, a shift that was propelled by several new initiatives established under the Affordable Care Act (ACA).²

The Centers for Medicare and Medicaid Services (CMS), which is charged with administering the Medicare program, is an active proponent of value-based purchasing.³ Some prescription drug-related VBP initiatives are focused on manufacturers and others are directed at providers.

¹ 42 U.S.C. § 1396r-8.

² Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

³ Under Medicaid, CMS is implementing the Value-Based Purchasing: Managed Care Innovations MAC Collaborative to design contracting arrangements around VBP for managed care organizations. CMS. *Value-Based Purchasing, Managed Care Innovations*, <https://www.medicaid.gov/State-Resource-Center/MAC-Learning-Collaboratives/VBP-Phase-Two.html> (accessed June 16, 2016). Medicare also has VBP programs. Under Medicare's Comprehensive Primary Care Initiative, CMS collaborates with commercial and state health insurance plans to offer population-based care management fees and shared savings opportunities to participating primary care practices. CMS. *Comprehensive Primary Care Initiative*, <https://innovation.cms.gov/initiatives/comprehensive-primary-care-initiative/> (last updated June 16, 2016). Accountable care organizations and the Medicare Shared Savings Program serve as another example. CMS. *Shared Savings Program*, <https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/sharedsavingsprogram/index.html> (accessed Dec. 2, 2015). Other VBP initiatives include the Hospital Readmission Reduction Program, Hospital Value-Based Purchasing Program, Hospital Acquired Conditions Program, and Value Modifier Program. CMS. *What Are the Value-Based Programs?* <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html> (accessed June 16, 2016).

Parallel to the rise of value-based purchasing is another movement by private and public sector payers to manage drug utilization and cost by instituting alternative payment models (APMs). An APM is a contract between a payer and drug manufacturer that ties payment to an agreed-upon measure. The measure can be applied to an entire product line or, in the case of high-cost specialty drugs, at the individual drug level. The most common APM is one in which the price of a drug, or class of drugs, declines as purchase volume increases. APM measures can therefore be strictly financial. But they can also be based on health outcomes, which is where the APM and VBP movements intersect. APMs are more common in other countries because, in contrast to the United States, purchasing power is centralized rather than spread across a wide array of payers and providers.

As one of the largest payers of prescriptions drugs in the U.S., the Medicaid program has grown increasingly interested in using VBP strategies and/or APMs to improve health outcomes and manage drug costs. Movement toward value-based purchasing is being integrated into state Medicaid demonstration waivers.⁴ Most of the Medicaid managed care organizations (MCOs) under contract with state Medicaid agencies subcontract with pharmacy benefit managers (PBMs) that are already implementing VBP programs and APMs for their commercial market customers. The ability of state Medicaid agencies to take advantage of these opportunities for prescription drug coverage and purchasing is limited because states are legally obligated to comply with an MDRP designed for the challenges of another time and because of other barriers inherent in working within the Medicaid program and the U.S. pharmaceutical and health care markets. The ACA made changes to the MDRP, but left intact many of the barriers established under the original legislation.

The purpose of this report is to provide a detailed legal analysis of the MDRP and other federal and state laws relevant to Medicaid drug coverage and payment in order to identify legal pathways for establishing prescription drug APMs within the Medicaid program. Although state Medicaid agencies can seek to address the problem of rising drug costs and utilization through VBP arrangements with providers and pharmacies, the focus of this report is on state opportunities to enter into innovative arrangements with manufacturers. Many of the manufacturer-focused opportunities seek to align drug payment with performance, and virtually all of them can be supported and augmented by combining them with VBP arrangements with providers. But not all APM arrangements are tied to patient outcomes, which is why this report will guide states in

⁴ Examples include New Hampshire's section 1115 Medicaid demonstration waiver, "Building Capacity for Transformation," which CMS approved on January 5, 2016, and California's section 1115 Medicaid demonstration waiver, "California Medi-Cal 2020 Demonstration," which CMS approved on December 30, 2015. CMS, *New Hampshire Building Capacity for Transformation*, 33 (Jan. 5, 2016), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/nh-building-capacity-transformation-orig-1115-appvl-01052016.pdf>; CMS, *California Medi-Cal 2020 Demonstration*, 70 *et seq.* (Dec. 30, 2015), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/nh-building-capacity-transformation-orig-1115-appvl-01052016.pdf>.

exploring prescription APM opportunities, rather than in simply applying VBP strategies to prescription drugs.

Section I of the report provides an overview of the MDRP and describes the growing use of VBP strategies and APMs by payers since enactment of the MDRP and the tools being used by payers. In Section II, we describe and analyze the wide array of federal and state laws, including those associated with the MDRP, that affect a state Medicaid agency's opportunity to establish an APM. An understanding of the content and interplay of these laws is essential for identifying viable APM options. Section III identifies and analyzes different legal pathways that would allow states to establish APMs. We conclude the report in Section IV with a summary of our analysis.

II. Background

This section provides an overview of the MDRP and describes the shift to value-based purchasing since enactment of the MDRP in 1990. We also identify various VBP and APM tools and payment incentive arrangements increasingly used by payers to control drug costs and utilization and to maximize favorable medication outcomes.

A. Overview of the MDRP

Under the Medicaid program, states have the option of providing coverage for outpatient drugs as part of their state plans.⁵ For states to receive federal matching funds for expenditures on a given covered outpatient drug, the manufacturer of the drug must have entered into a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) as part of the MDRP.⁶ In exchange for entering into a federal rebate agreement, manufacturers are assured Medicaid and Medicare coverage of their drugs, subject to certain limits.⁷ The MDRP directs state Medicaid programs to collect statutorily prescribed rebates from manufacturers on covered outpatient drugs, a portion of which is shared with the federal government.

The rebate amount under the MDRP is the greater of either: (1) a statutory discount off of the drug's AMP, or (2) the difference between AMP and Best Price. AMP is "the average price paid to the manufacturer for a drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer."⁸ Best Price is generally the lowest price at which a given drug is sold to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity.⁹ AMP and Best Price are both confidential and can only be disclosed in limited situations.¹⁰

The statutory discount off of AMP, called the rebate percentage, varies with the type of drug. The rebate percentage is currently set as 23.1% for a single-source or innovator drug (i.e., brand name drugs); 17.1% for single-source drugs, innovator blood-clotting factor, and drugs approved by the FDA only for pediatric care; and 13% for non-innovator or multisource (i.e., generic) drugs.¹¹ Congress increased the statutory discount percentages as part of the ACA.¹² The rebates attributable

⁵ Social Security Act (hereinafter "SSA", or "the Act") §§ 1905(a)(12), 1903(a).

⁶ SSA § 1927.

⁷ SSA § 1927(a),(d).

⁸ 42 C.F.R. § 447.504(a).

⁹ SSA § 1927(c)(1)(C)(i); See Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5,169, 5,252 (Feb. 1, 2016) (to be codified at 42 C.F.R. pt. 447); 42 C.F.R. § 447.505.

¹⁰ SSA § 1927(b)(3)(D).

¹¹ SSA § 1927(c)(1)(B), (c)(3)(B).

¹² Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 306-10 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

to the increase belong entirely to the federal government.¹³ Whether the rebate is provided as a percentage discount or as a difference between AMP and Best Price, manufacturers owe additional rebates if AMP increases faster than the consumer price index.¹⁴ The increased rebate manufacturers must pay when a drug's AMP increases faster than the consumer price index is often called the inflationary penalty. Rebates are calculated based on a drug's national drug code (NDC), an 11-digit number that identifies the drug's manufacturer, product type, and package size.¹⁵ Throughout this paper, we will refer to these required discounts as the statutory rebate.

Although states are entitled to receive significant rebates on the prescription drugs they cover under the MDRP, it is difficult for them to exclude any FDA-approved drug from Medicaid coverage. States are required to reimburse for all drugs from any manufacturer that has signed a rebate agreement, unless a state committee of pharmacists and physicians determines that a drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome... over other drugs in the formulary."¹⁶ States can also exclude coverage of drugs that have been prescribed for a use that is not a medically accepted indication or drugs in a class that Congress expressly excluded from coverage (e.g., benzodiazepines and hair growth drugs).¹⁷ States are also empowered to establish preferred drug lists (PDLs) and subject all non-preferred drugs to a prior authorization process. States can use this authority as leverage to negotiate rebates that supplement the statutory rebates required under the MDRP. Manufacturers are often willing to pay supplemental rebates for placement of their drugs on the state's PDL, which in turn protects them from prior authorization requirements and the related administrative burdens that tend to discourage providers from using non-preferred drugs. Prior authorization programs have broader applications as well. They can be used to guarantee evidence-based prescribing and to support patient adherence programs. For this reason, even drugs on a state's PDL can be subject to prior authorization.

The supplemental rebates referenced above evolved from a provision in the MDRP that sought to grandfather a California drug rebate program that predated the MDRP. The provision allowed for any state rebate agreement in effect when the MDRP was passed to remain in effect as long as the state was willing to share rebate information with HHS and the rebates totaled at least 10% of the state's prescription drug spending.¹⁸ Such agreements could be renewed if the resulting rebate

¹³ SSA § 1927(b)(1)(C).

¹⁴ SSA § 1927(c)(2).

¹⁵ SSA § 1927(a)(7). The 11-digit NDC contains three segments. The first five digits are the "labeler code", and reveal the manufacturer of the product. The next four digits are specific to the active ingredient, route of administration, and strength of the product. The last two digits correspond to the package size.

¹⁶ SSA § 1927(d)(4)(C).

¹⁷ SSA § 1927(d)(1).

¹⁸ SSA § 1927(a)(4).

would be at least as much as the rebate required under the MDRP.¹⁹ Following implementation of the MDRP, California began accepting the new statutory rebates established under federal law and shifted its attention to negotiating additional rebates that supplemented the MDRP.²⁰ Other states, which did not have rebate agreements in effect when the MDRP was created, followed California's lead and began seeking approval from CMS to enter into their own supplemental rebate agreements in the 2000s.²¹ Multistate supplemental rebate agreements were approved by CMS beginning in 2004.²² As of March 2016, 31 states have single-state supplemental rebate agreements and 28 are party to a multistate supplemental rebate agreement. Only four states—Hawaii, New Jersey, New Mexico, and South Dakota—have neither.²³

The MDRP is closely related to the federal 340B drug discount program, which takes its name from the federal law that established it, Section 340B of the Public Health Service Act. Under Section 340B, Congress established a statutory discount program for certain enumerated classes of safety net providers, called “covered entities,” to which manufacturers must sell covered outpatient drugs at no more than a statutory “ceiling price.”²⁴ The ceiling price is calculated by reducing the drug's AMP by its MDRP unit rebate amount.²⁵ In creating the 340B program, Congress recognized that when a 340B hospital or clinic dispenses a covered outpatient drug to a Medicaid patient, the manufacturer is at risk of giving two discounts on the same drug: an upfront 340B discount to the covered entity at the time of purchase, and a post-purchase rebate to the Medicaid program after Medicaid pays the covered entity for the drug and submits a rebate request to the manufacturer. This type of double price reduction is called a “duplicate discount.”²⁶ To protect manufacturers from this problem, Congress included a prohibition against duplicate discounts in Section 340B. The statutory provision states that “[a] covered entity shall not request payment under [Medicaid] with respect to a drug that is subject to an agreement under [Section 340B] if the drug is subject to the

¹⁹ *Id.*

²⁰ See Medi-Cal to Seek Supplemental Drug Rebates under Expedited, Two-Month Negotiating Period: Upcoming Letter to Ask for \$27 Mil. in Added Rebates, *The Pink Sheet* (Sept. 7, 1992), <https://www.pharmamedtechbi.com/publications/the-pink-sheet/54/036/medical-to-seek-supplemental-drug-rebates-under-expedited-twomonth-negotiating-period-upcoming-letter>.

²¹ CMS, State Medicaid Director Letter 02-014 (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>.

²² CMS, State Medicaid Director Letter 04-006 (Sept. 9, 2004), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd090904.pdf>.

²³ CMS, Medicaid Pharmacy Supplemental Rebate Agreements (SRA), <https://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf> (last visited June 16, 2016).

²⁴ Veterans Health Care Act of 1992, Pub. L. 102-585, § 602, 106 Stat. 4943, 4967 (1992).

²⁵ 42 U.S.C. § 256b(a)(2).

²⁶ HRSA, Medicaid Exclusion File/Duplicate Discount Prohibition, <http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/> (last visited June 16, 2016).

payment of a rebate to the State under [the Medicaid drug rebate program.]”²⁷ Congress tasked HHS with developing a mechanism to implement this provision.²⁸ The Health Resources and Services Administration (HRSA), the agency within HHS charged with administering the 340B program, responded to this mandate by establishing the 340B Medicaid Exclusion File.²⁹

A covered entity that chooses to bill Medicaid for a 340B drug after dispensing or administering the drug to a Medicaid recipient must submit its Medicaid billing number and/or national provider identifier (NPI) to HRSA for inclusion in the Medicaid Exclusion File.³⁰ HRSA requires covered entities that have submitted their billing identifiers for inclusion in the Medicaid Exclusion file to use 340B drugs whenever billing outpatient claims using those identifiers. Thus, by reviewing the Medicaid Exclusion File, states and manufacturers can identify the drug claims that must be excluded from state rebate requests. This is because any drug purchased under the billing numbers or NPIs listed in the Medicaid Exclusion File are not eligible for the MDRP statutory rebate.³¹ HRSA has clarified that the Medicaid Exclusion File is only intended to prevent duplicate discounts for Medicaid drugs reimbursed on a fee-for-service basis.³²

When drugs billed to Medicaid managed care organizations (MCOs) also became eligible for the MDRP through the ACA, Congress created a different solution. The MDRP statute eliminates the duplicate discount problem for MCO-billed 340B drugs by declaring that covered outpatient drugs purchased by a 340B covered entity and billed to an MCO are not subject to the MDRP.³³ To protect manufacturers against duplicate discounts on MCO-billed 340B drugs, the states need to be able to exclude 340B drug claims from their rebate requests.³⁴ In a December 2014 policy notice, HRSA indicated that it was working with CMS to develop such a mechanism.³⁵ In the first half of 2016, CMS promulgated two sets of regulations that address MCO duplicate discounts. The first rule, published in February, addressed the MDRP and the definition of a covered outpatient drug.³⁶ It clarified that states are responsible for ensuring that procedures are in place with their MCOs to

²⁷ 42 U.S.C. § 256(a)(5)(A)(i).

²⁸ *Id.* § 256(a)(5)(A)(ii).

²⁹ Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 – Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34,058 (Jun. 23, 1998); see also HRSA, 340B Drug Pricing Program Release No. 2014-1 (Dec. 12, 2014), <http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf>.

³⁰ HRSA, 340B Drug Pricing Program Release No. 2014-1, 1-2 (Dec. 12, 2014). The billing identifier used when submitting claims to Medicaid must be provided, but many covered entities provide both their NPI and any legacy Medicaid provider number.

³¹ *Id.*

³² *Id.* at 3.

³³ SSA § 1927(j)(1).

³⁴ The Medicaid Exclusion File is generally unsuitable for this purpose because a covered entity might choose to use 340B drugs for some MCOs but not others, or might choose to use non-340B drugs when billing fee-for-service Medicaid but 340B drugs when billing MCOs.

³⁵ HRSA, 340B Drug Pricing Program Release No. 2014-1, 3 (Dec. 12, 2014).

³⁶ Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5,170 (Feb. 1, 2016).

exclude 340B drug utilization from their MDRP rebate requests.³⁷ The second CMS rule,³⁸ issued in May, overhauls the regulations governing the Medicaid managed care program and clarifies that either states or their MCOs can collect 340B utilization data for purposes of avoiding duplicate discounts. HRSA might also weigh in on the issue when it issues omnibus 340B program guidelines in late 2016 or 2017.³⁹

B. Post-MDRP Shift to Value-Based Purchasing

Prior to enactment of the MDRP, state efforts to control the cost of drugs were focused on limiting utilization by patients and reducing reimbursement to pharmacies. Senator David Pryor (D-AR), who was widely regarded as the author of the MDRP, felt strongly that manufacturers must play a role in reducing Medicaid expenditures for prescription drugs. He made the case to Congress that state cost-control measures in the 1980s were misguided:

The most common state cost-cutting measures were to reduce pharmacy reimbursement, raise the coinsurance that must be paid by the poorest poor who qualify for Medicaid, limit the number of reimbursable prescriptions, and construct formularies or limited lists of approved drugs. Overall, twice as many states restricted prescription drug benefits as liberalized them in the 1980s.⁴⁰

Twenty-six years later, Senator Pryor's objective of shifting state drug cost-cutting efforts from Medicaid enrollees and pharmacies to manufacturers has been largely realized. Passage of the MDRP did not relieve states from the ongoing challenge of balancing the medication needs of their Medicaid enrollees with the budgetary demands of managing prescription drug expenditures. When it enacted the MDRP, Congress chose not to interfere with states' existing authority to reduce or freeze pharmacy reimbursement, to use formularies and preferred drug lists to control utilization, and to subject Medicaid patients to prescription limits and copayments. There was one area, however, where the MDRP did set limits. Namely, the MDRP made it very difficult for states to exclude coverage of drugs using a closed formulary. Under the original legislation, states were prohibited outright from excluding coverage of drugs sold by any manufacturer that had signed a rebate agreement with the Secretary.

Congress changed that provision three years later, and as a result, states may sometimes refuse coverage of a drug if it is therapeutically equivalent to another drug on the formulary.⁴¹ Under the supervision of a committee of pharmacists and doctors, the states can exclude from their formulary

³⁷ *Id.* at 5,273.

³⁸ Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27,498 (May 6, 2016).

³⁹ See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (Aug. 28, 2015) (proposing 340B program guidelines and soliciting comments).

⁴⁰ Pryor, D. (1990). A Prescription for High Drug Prices. *Health Affairs* 9.3, 101-109.

⁴¹ 42 U.S.C. § 1396r-8(d)(4).

any drug that “does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such populations over other drugs in the formulary.”⁴² With such a rigid test for denying coverage of therapeutically equivalent drugs, most states have adopted a fallback strategy for controlling drug costs. Namely, they establish PDLs and subject non-preferred drugs to a prior authorization procedure, which tends to discourage prescribing due to the administrative burdens placed on providers.

In a market in which coverage of Hepatitis C and other high-cost specialty drugs are straining Medicaid drug budgets, states are scrambling to find new strategies for giving patients access to new drug therapies in a cost-effective manner. A recent letter to Congress from the National Association of Medicaid Directors (NAMD) highlights the serious challenges that states face.⁴³ NAMD complained about how, under the MDRP, states are prohibited from using “closed formularies” and must rely instead on “traditional drug management tools,” such as prior authorization and generic substitution, which are “ineffective in addressing similarly situated drug therapies.”⁴⁴ Yet, even if states had broader authority to exclude coverage of drugs from their formularies, they could not exclude medically necessary drugs unless there are therapeutic alternatives available to patients.⁴⁵ States have to cover the drugs that the Medicaid population needs, no matter how expensive they might be.⁴⁶ As NAMD described in its letter, states “are unable to exert significant leverage” for negotiating rebates with manufacturers “without competitor products” on the market.⁴⁷ Ultimately, formularies and prior authorization strategies are only effective in controlling the cost of a drug for which there is a therapeutic or generic equivalent.

To address the competing challenges of covering medically necessary drugs and paying for them within the constraints of shrinking state Medicaid budgets, NAMD recommended a new approach that focuses on a drug’s broader value in improving health outcomes. NAMD proposed the following:

States must have the flexibility to incorporate pharmaceuticals into coverage and reimbursement models which encompass the whole person and the total cost of care. States have taken up the call for payment and delivery system reform. Pharmaceuticals, however, are noticeably absent from state Medicaid initiatives around value-based purchasing (VBP) and related work to encompass “whole

⁴² *Id.* § 1396r-8(d)(4)(C).

⁴³ Letter from Matt Salo, Exec. Dir., NAMD, to Senator Ron Wyden, Ranking Member, Senate Comm. on Fin., and Senator Charles Grassley, Member, Senate Comm. on Fin. (March 4, 2016) (hereafter “NAMD Letter”).

⁴⁴ NAMD Letter at 2.

⁴⁵ SSA § 1927(d)(1)(B), (d)(4)(C).

⁴⁶ CMS. *MDRP Notice Release No. 172* (Nov. 5, 2015), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf>.

⁴⁷ NAMD Letter at 2.

person care.” This situation is increasingly at odds with VBP pursued with other Medicaid providers, suppliers and vendors.⁴⁸

There are no pending efforts within Congress to give states the “flexibility” to pursue VBP strategies, as recommended by NAMD. However, whether Congress decides to take up pharmaceutical VBP legislation or not, there are areas where states can innovate through the use of value-based purchasing and manufacturer APM arrangements within existing legislation. Section III describes seven such pathways.

C. Alternative Payment Models and Value-Based Purchasing Tools

The fee-for-service methodology of reimbursing health care providers for services has been long criticized for driving overutilization of resources without creating incentives to deliver care more efficiently or with higher quality. In the past two decades, the movement away from fee-for-service models and toward value-based health care delivery models has accelerated. The “value-based” reform movement is difficult to define, but it generally refers to a shift away from paying for goods and services and toward paying for performance, effectiveness, and outcomes.

Although private payers were the first to begin evaluating VBP strategies, public payers were not far behind. California created quality performance measures as part of a Pay for Performance (P4P) program in 2001, and CMS began experimenting with P4P models in the late 2000s through its physician group practice demonstration program and inpatient quality measures initiative.⁴⁹

The ACA spawned a spectrum of VBP tools and demonstrations that include but are not limited to accountable care organization (ACO) initiatives,⁵⁰ health homes,⁵¹ and other care management models.⁵² These VBP tools and demonstrations recognize that prescription drugs can be a critical part of patient care, but they can be more likely to have their intended benefit when provided as part of a care model that addresses a Medicaid enrollee’s health care needs more comprehensively. A prescription drug VBP model can thus be one component of a larger whole-person health model.

Shared savings models and accountable care organization initiatives are becoming more common among state Medicaid programs.⁵³ CMS has indicated its support for such models in a letter to state

⁴⁸ *Id.*

⁴⁹ See *Nat’l Comm. for Quality Assurance, California Value Based Pay for Performance (VBP4P)*, <http://www.ncqa.org/hedis-quality-measurement/other-measurement-activities/pay-for-performance> (accessed June 13, 2016).

⁵⁰ See CMS, *State Medicaid Director Letter 13-005* (Aug. 30, 2013) (describing shared savings models), at <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-13-005.pdf>.

⁵¹ SSA § 1945

⁵² See, e.g., SSA § 1905(t)

⁵³ *Medicaid ACO’s: State Activity Map*, Center for Health Care Strategies, <http://www.chcs.org/resource/medicaid-aco-state-update/>.

Medicaid directors.⁵⁴ Minnesota’s integrated health partnership model represents an ACO-like model that incorporates drug costs by including pharmacy expenses in its total cost of care calculation.⁵⁵ Under the health homes state plan option created by the ACA, a state can establish health homes for Medicaid-eligible individuals suffering from chronic conditions.⁵⁶ The services provided under the health homes program are care management, coordination, and support services.⁵⁷ States receive a 90% federal match for health homes services for the first eight calendar quarters such services are provided, but the increased federal match only applies to health home services.⁵⁸ CMS has also authorized an expansive primary care case management (PCCM) approach to integrated care management.⁵⁹ In a 2012 letter to state Medicaid directors, CMS stated that “States may use the authority under section 1905(t) of the Act to offer coordinating, locating and monitoring activities broadly and create incentive payments for providers who demonstrate improved performance on quality and cost measures.”⁶⁰

Payers can work with manufacturers, providers, and pharmacies to create incentives for drug utilization consistent with the integrated care and patient outcome goals described above. They can also work solely with manufacturers to establish APMs that control drug utilization and drug costs independent of these goals. By borrowing from the various models being used in other countries, American payers can negotiate APM arrangements with the pharmaceutical industry that may or may not be tied to clinical outcomes. Whether they decide to engage in value-based purchasing, to establish one or more APMs with manufacturers, or to implement a combination of both approaches, public and private payers in the U.S. are increasingly interested in crafting new solutions for prescription drugs. There are different payment and utilization tools that payers, particularly commercial payers, are currently using when determining how to cover and pay for drugs, some of which are based upon a drug’s clinical value and others of which are based upon the volume of a drug’s use. These payment and utilization tools can be summarized briefly as follows:

- **Indication-Specific Pricing.** The value of a drug depends largely on why it is being prescribed. A single drug might be used for many different indications. Some indications might be approved by the Food and Drug Administration (FDA) based on the results of

⁵⁴ CMS, State Medicaid Director Letter 13-005.

⁵⁵ Minnesota Department of Human Services. *Integrated Health Partnerships Contract [2017 RFP version]*, Attachment A, p. 9, at http://www.dhs.state.mn.us/main/groups/business_partners/documents/pub/dhs-286917.pdf.

⁵⁶ SSA § 1945(a).

⁵⁷ *Id.* § 1945(c), (h)(4).

⁵⁸ Nineteen states currently have one or more approved health home state plan amendments. CMS. *Approved Health Home State Plan Amendments*, <https://www.medicaid.gov/State-Resource-Center/Medicaid-State-Technical-Assistance/Health-Homes-Technical-Assistance/Approved-Health-Home-State-Plan-Amendments.html>

⁵⁹ CMS. *State Medicaid Director Letter 12-002* (July 10, 2012), <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-12-002.pdf>.

⁶⁰ *Id.*

well-controlled clinical trials, while others might be supported by medical literature reporting on other kinds of empirical evidence. For example, Ritalin (methylphenidate) is perhaps best known as a treatment for attention deficit hyperactivity disorder in children. It is sometimes also prescribed to treat narcolepsy. It can also be a drug of abuse. Its value to a payer depends in large part on how it is being used. Payers can influence the use of drugs, by indication, through the use of formularies, PDLs, prior authorization, generic and therapeutic substitution, and related techniques.

- **Health Outcome-Based Arrangements.** In health outcome-based APMs, payments for the drugs are tied to clinical outcomes and are typically used when there is uncertainty or unclear value related to the benefits provided by the drug. Health outcome-based APMs can be categorized into two types: conditional coverage and performance-based. In conditional coverage arrangements, coverage is granted while data is being collected to make future coverage decisions or to determine whether a patient should continue on a treatment based on achieving certain outcomes. Performance-based arrangements help payers manage utilization of a drug by tying payment to a pre-specified measure or clinical outcome in the real-world setting. If the drug is unable to achieve the measure, the manufacturer compensates the payers, typically through a rebate.
- **Financial-Based Arrangements.** Financial-based APMs are structured to mitigate risks associated with the volume or utilization of a given product. These arrangements can be structured either at the population or patient level. An example of a population-level arrangement is a price-volume agreement under which the financial expenditure for a drug is controlled by setting an agreed-upon budget ceiling. If the total drug spending exceeds the threshold, the manufacturer would be responsible for the additional cost, often through a rebate back to the payer. Patient-level models, by contrast, tie financial benchmarks to individual patient drug utilization. These types of agreements can be in the form of a price cap, in which drugs are provided free of cost after patients reach a fixed financial utilization limit, or through a dosage cap, in which the manufacturer and payer agree on a predetermined level of consumption and anything beyond the agreed limit is paid for by the manufacturer.
- **Provider Value-Based Payment.** Provider value-based payment programs focus on evidenced-based use of pharmaceuticals and are similar to manufacturer health-outcome models. Providers are rewarded for prescribing and managing utilization of a drug effectively. Any bonuses or penalties can be tied to payment or other rewards, such as preferred provider status within the payer's provider network. Risk-based provider payment can also take the form of bundled payments, capitation, or risk corridors.
- **Patient-Centered Care Models and Services.** Payers can cover and pay for new patient-centered care models and enhanced services that improve clinical outcomes and manage costs. Examples of new models and services include medication therapy management,

disease management, case management/care coordination, transportation, housing, respite care, patient counseling or training, assistive devices, state-of-the-art diagnostic or therapeutic equipment, and genomic testing. By supplementing existing services with cutting-edge programs, payers can treat and manage the care of the “whole person” to ensure, among other things, that the patient’s medications are being prescribed and monitored as part of a larger system of care.

There are legal and operational limitations that prevent state Medicaid agencies from employing the full range of prescription drug tools and payment strategies described above. These limitations will be described in the following section, Section III. An understanding of these issues provides a foundation for identifying and evaluating different APM opportunities available to states. In Section IV, we describe seven legal pathways for establishing APMs, two of which rely on existing MDRP authority and the rest of which operate outside the scope of the MDRP.

III. Legal Framework for Establishing Medicaid Prescription Drug APMs

The U.S. pharmaceutical market is complex and its complexity largely stems from the wide array of federal and state laws that regulate the activities of prescription drug manufacturers, purchasers, and payers. Identifying and evaluating APM opportunities within the Medicaid program requires an understanding of Medicaid and MDRP laws and non-Medicaid federal and state laws that affect a state’s ability to engage in value-based purchasing or alternative payment of prescription drugs. The purpose of this section is to impart such an understanding and provide the necessary framework for understanding and analyzing the seven legal pathways for establishing APMs described in Section IV.

A. Constitutional Considerations

As states consider different pathways for establishing APMs for prescription drugs under Medicaid, they must be mindful of two important constitutional limitations. The first is imposed by the Commerce Clause, which prevents states from formulating payment systems in ways that regulate prices paid in out-of-state transactions. The second, imposed by the Supremacy Clause, bars states from establishing programs that conflict with federal law, known as federal preemption.

1. Commerce Clause

States need to ensure that their APM efforts do not violate the Commerce Clause, whether intentionally or not, by regulating out-of-state prices, tying in-state prices to out-of-state prices, or discriminating against out-of-state products. Recent case law has determined that the effect of MDRP’s Best Price requirement on state initiatives does not regulate out-of-state prices in violation of the Commerce Clause, but other aspects of a state’s APM program could implicate the Commerce Clause.

The Commerce Clause of the U.S. Constitution reserves for Congress the power “[t]o regulate commerce among the several states.”⁶¹ Courts have determined that the federal authority to regulate interstate commerce prevents individual states from acting in ways that regulate out-of-state transactions.⁶² Courts have interpreted the Commerce Clause to contain the implication that states cannot regulate out-of-state transactions, a doctrine known as the “Dormant” Commerce Clause.⁶³ The Dormant Commerce Clause is relevant to the interstate effects of MDRP’s Best Price requirement, because a state law feature that requires manufacturer to sell drugs at lower prices in one state could set a new manufacturer Best Price applicable in other states.⁶⁴ In the 2003 case *Pharmaceutical Research and Manufacturers of America [PhRMA] v. Walsh*, the Supreme Court analyzed a state statute implementing the Maine Rx program, which sought to reduce prescription drug prices for residents of Maine by enabling individuals to purchase drugs from retail pharmacies at a discount roughly equal to the rebate on Medicaid purchases.⁶⁵ The effect of this program would be to set a new manufacturer Best Price under the MDRP.

The Supreme Court found that, unlike the price control or price affirmation statutes analyzed in other cases, the Maine Rx statute “does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect.”⁶⁶ Specifically, the statute does not insist that “manufacturers sell their drugs for a certain price or tie the price of its in-state products to out-of-state prices.”⁶⁷ Therefore, the Supreme Court found the Maine Rx statute did not violate the Dormant Commerce Clause because it only regulates interstate commerce through its interaction

⁶¹ U.S. CONST. Art. I, § 8, cl. 3.

⁶² See, e.g., *Okla. Tax Comm’n v. Jefferson Lines, Inc.*, 514 U.S. 175 (1995); *Healy v. Beer Inst.*, 491 U.S. 324 (1989); *Hughes v. Oklahoma*, 411 U.S. 322, 326 (1979).

⁶³ Courts examine three factors to determine whether a state’s law has the unconstitutional effect of regulating out-of-state transactions and violates the Dormant Commerce Clause. First, courts consider whether the regulation is applied to commerce “wholly outside of the state’s borders.” Second, they examine whether the practical effect of the legislation is to control out-of-state transactions. Third, they consider what effect the regulation would have on other states’ regulations, and what would happen if other states adopted similar legislation. See *Beer Inst.*, 491 U.S. at 336. These three principles have been applied to strike down state regulations that affect prices charged outside of the state, laws that tie in-state prices to out-of-state prices, and pricing schemes that have a discriminatory effect on in-state versus out-of-state products. See *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935); *Schwegmann Bros. Giant Super Markets v. Louisiana Milk Comm’n*, 365 F. Sup. 1144, 1156 (M.D. La. 1973), *aff’d* 416 U.S. 922 (1974); see also *Dean Foods Co. v. Brancel*, 187 F.3d 609, 614–15 (7th Cir. 1999); *Beer Inst.*, 491 U.S. at 338; *West Lynn Creamery Inc. v. Healy*, 512 U.S. 186 (1994).

⁶⁴ The Dormant Commerce Clause has not been applied to any other aspects of the MDRP.

⁶⁵ ME. REV. STAT. tit. 22, § 2681. Specifically, the statute directed the Maine Commissioner of the Department of Health Services to enter into voluntary rebate agreements with drug manufacturers. *Id.* § 2681(4). Drug manufacturers who refused to enter into voluntary agreements would be subject to prior authorization. *Id.* § 2681(7).

⁶⁶ *PhRMA v. Walsh*, 538 U.S. 644, 669 (2003).

⁶⁷ In addition, the Supreme Court found that the program would not impose a disparate burden on out-of-state competitors because the statute applies equally to out-of-state and in-state pharmaceutical manufacturers and the in-state manufacturers receive no benefits from the statute. *Id.* (citing *PhRMA v. Concannon*, 249 F.3d 66, 81–82 (1st Cir. 2001)).

with MDRP and does not by itself affect interstate commerce or set a Best Price. The Supreme Court’s decision was applied in 2004’s *PhRMA v. Thompson*, where the D.C. Circuit found that Michigan’s Best Price Initiative did not violate the Dormant Commerce Clause because “any interstate effect on prices is the result not of provisions peculiar to the Initiative, but of the federal Medicaid rebate statute...”⁶⁸

These two seminal cases show that the impact of MDRP’s Best Price mechanism on the price of drugs in other states poses little risk of violating the Dormant Commerce Clause. Notwithstanding, in determining whether an APM arrangement with manufacturers may violate the Dormant Commerce Clause, it is crucial for states to ensure that the program does not by itself have the effect of regulating out-of-state prices, tie in- state prices to out-of-state prices, or discriminate against out-of-state products. If the program affects interstate commerce solely through its interaction with the MDRP, there is a low risk that it will constitute a violation of the Dormant Commerce Clause in light of *PhRMA v. Walsh*.

2. Supremacy Clause

States also have to avoid implementation of APMs that violate the Supremacy Clause. Specifically, states should ensure that their initiatives do not conflict with the MDRP or other federal law requirements.

The Supremacy Clause of the U.S. Constitution states “[t]his Constitution and the Laws of the United States which shall be made in Pursuance thereof ... shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”⁶⁹ Thus, federal law is supreme and supersedes or preempts provisions of state law that are contrary to it, making the contrary state law provision void. Preemption can occur in multiple ways:

1. Express preemption: federal law expressly supersedes state law;
2. Field preemption: federal regulation of the topic is so comprehensive that there is no remaining room for state regulation; and
3. Conflict preemption: the state law conflicts with the federal law such that it is an obstacle to the federal objectives.⁷⁰

⁶⁸ *PhRMA v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004). Under Michigan’s Best Price Initiative, if a drug manufacturer did not sign each of two specified rebate agreements with the state, one to provide rebates for drugs the state purchases for Medicaid recipients and the other to provide identical rebates for drugs that state purchases for two non-Medicaid state health programs, the drug would be covered under the programs subject to prior authorization.

⁶⁹ U.S. CONST. art. VI.

⁷⁰ *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990).

Determining which federal laws could affect a state Medicaid drug benefit program and whether or not an alternative purchasing arrangement under Medicaid violates congressional intent is a necessary prerequisite to designing an APM capable of withstanding a legal challenge.⁷¹ There is a lack of clarity regarding how federal preemption principles should be applied to state efforts to encourage discounts for non-Medicaid patients by conditioning Medicaid coverage of a company's drugs on providing those discounts. In *PhRMA v. Walsh*, a plurality of the Supreme Court, supported by six justices, agreed that PhRMA had not proven that the Maine Rx program violated the MDRP by imposing a state requirement that lacks a Medicaid purpose. Therefore, the Maine Rx program was not impliedly preempted by the MDRP.⁷² Yet, these six justices issued four opinions with differing reasons for this result. The Court left the conditions under which states can use their Medicaid purchasing power to benefit non-Medicaid patients as an open question.

Overall, seven justices agreed that a state should be allowed to leverage the MDRP to obtain discounts for non-Medicaid recipients if it can show a Medicaid purpose. The six justices who concluded that the MDRP did not preempt the Maine Rx program also asserted that CMS should review state plans to ensure that they are not preempted by the MDRP. This has turned out not to be much of a barrier as CMS has indicated its willingness to approve prior authorization programs to create an incentive for manufacturers to offer rebates for non-Medicaid patients. The appellate courts in the Eleventh and D.C. Circuits have explicitly held that preauthorization requirements do not violate the Supremacy Clause.⁷³

Regardless of this Supreme Court decision, states do not enjoy unfettered protection from potential Supremacy Clause challenges. In addition to receiving CMS approval for preauthorization requirements, states have applied for and received federal Medicaid waivers to provide benefits to non-Medicaid patients such as senior citizens and disabled persons who are low-income, but whose income is above Medicaid financial limits. Although prescription-only Medicaid coverage is not explicitly permitted by the MDRP, CMS has been willing to offer waivers for this purpose. An example of a prescription-only Medicaid proposal that violated the Supremacy Clause occurred in a federal Court of Appeals case concerning Vermont's prescription assistance program. In *PhRMA v. Thompson*, the court held that utilizing 1115 waivers (discussed in more detail below) to expand prescription-only Medicaid coverage is permissible only if the state contributes to the funding of the

⁷¹ If, for example, a state enacts legislation requiring manufacturers to disclose their AMP or Best Price for a given drug, such legislation would probably not withstand a preemption challenge because federal law explicitly protects the confidentiality of these provisions.

⁷² *PhRMA v. Walsh*, 538 U.S. 644, 669 (2003).

⁷³ In *PhRMA v. Thompson*, the D.C. Circuit upheld CMS' approval of Michigan's Best Price Initiative and its preauthorization requirement under the Supremacy Clause. 362 F.3d 817 (D.C. Cir. 2004). In *PhRMA v. Meadows*, the Eleventh Circuit found that Florida's preauthorization program, which allowed any manufacturer to have its products listed on Florida's Medicaid preferred drug list if the manufacturer was willing to give the state Medicaid program an additional 10% rebate, was not preempted by the MDRP. 304 F.3d 1197 (11th Cir. 2002).

expanded benefits because the MDRP requires that pharmaceutical manufacturers owe rebates only for drugs “for which payment was made under the state plan.”⁷⁴

The above case law shows that state efforts to reduce drug costs under the MDRP pose a low risk of violating the Supremacy Clause. Still, the Supremacy Clause sets some boundaries that states must observe. They must ensure that their programs do not directly conflict with or fail to meet requirements under the MDRP and the federal Medicaid statute generally. If a drug benefit plan does not meet MDRP requirements, such as a manufacturer rebate program in which a state does not make any “payments” under its state plan, a court could determine that the program is preempted by the MDRP.

B. MDRP Opportunities and Limits

The MDRP, in addition to reducing state Medicaid prescription drug costs since its introduction in 1990, established a framework for states to use in developing policies for covering prescription drugs under their state plans. Among other things, the MDRP statute established strict tests governing how and when states may limit coverage of a drug. These requirements must be carefully considered by states seeking to implement effective APM strategies, especially if they involve value-based purchasing. The following is a discussion of the provisions within the MDRP that impede, facilitate, or otherwise affect implementation of the coverage and payment tools described in Section I.

It is important to note that the MDRP-related rights and obligations described below generally apply with equal force and relevance to state managed care contracting. On May 6, 2016, CMS issued its long-awaited rule updating and modifying the agency’s prior Medicaid managed care regulations.⁷⁵ The rule explicitly addresses application of the MDRP to covered outpatient drugs reimbursed through the managed care contracts. The Medicaid MCO rule states, in relevant part:

(s) for MCOs ... that provide covered outpatient drugs. Contracts that obligate MCOs ... to provide coverage of covered outpatient drugs must include the following requirements:

⁷⁴ SSA § 1927(b)(1)(A); *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. June 8, 2001). The Vermont prescription assistance program required pharmaceutical manufacturers to rebate a portion of the price of drugs purchased by individuals who are not otherwise covered by Medicaid. The D.C. Circuit Court found that “[b]ecause Vermont’s [pharmacy discount program] payments are fully reimbursed by manufacturer rebates, and because the rebates produce no savings for the Medicaid program, the state’s payments to pharmacies are not “payments” within the meaning of the statute.” *Thompson*, 251 F.3d at 226.

⁷⁵ Medicaid and Children’s Health Insurance Program (CHIP) Programs. *Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability*, 81 Fed. Reg. 27,498 (May 6, 2016).

(1) The MCO ... provides coverage of covered outpatient drugs as defined in section 1927(k)(2) of the Act, that meets the standards for such coverage imposed by section 1927 of the Act as if such standards applied directly to the MCO...⁷⁶

CMS has therefore clarified by regulation that all of the MDRP requirements applicable to covered outpatient drugs subject to fee-for-service reimbursement are equally applicable to covered outpatient drugs subject to managed care contracting. Our discussion about the feasibility of implementing various coverage and payment mechanisms within the MDRP—including the use of formularies, prior authorization, rebates, generic and therapeutic substitution, patient cost-sharing, and prescription limits—is equally relevant to any Medicaid managed care program that includes prescription drug coverage.

1. Statutory Rebates

Congress has altered the formula for calculating statutory rebates on several occasions as recently as last year. The primary objectives of the original MDRP legislation were to ensure that for brand name drugs, Medicaid pays no more than a manufacturer's Best Price and does not pay for price increases in excess of the rate of inflation.⁷⁷ Although the current formula retains the Best Price limitation and inflationary penalty provisions, Congress substantially increased the size of the statutory rebates under the ACA and, more recently, under the Bipartisan Budget Act of 2015.⁷⁸ The former increased the minimum rebate percentage from 15.1% to 23.1% for brand name drugs (17.1% for factor products and pediatric drugs) and from 11% to 13% for generic drugs.⁷⁹ The latter extended the inflationary penalty to generic drugs.⁸⁰

The rebates that manufacturers pay under the MDRP are, on average, larger than the rebates they pay in the private sector.⁸¹ Given Congress' decision to keep increasing the statutory rebates payable under the MDRP, and given its explicit authorization for states to negotiate supplemental rebates, it is clear that Congress has not relied on commercial rebate benchmarks for determining the appropriate size of the MDRP statutory rebate. Congress apparently views manufacturers' rebate obligations, not through the prism of commercial fairness, but based on its perception that manufacturers have a unique responsibility to help support the Medicaid program. So, whereas the

⁷⁶ 42 C.F.R. § 438.3(s) (effective July 5, 2016). MCOs presumably will alter their prescription drug coverage policies to rectify any instances which do not meet the standards of the MDRP. For example, any MCOs that use closed formularies will have to evaluate whether they may continue to limit coverage.

⁷⁷ Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 101 Stat. 1388 (1990).

⁷⁸ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 306-10 (2010); Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 602, 129 Stat. 584, 596-97 (2015).

⁷⁹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 306-10 (2010).

⁸⁰ Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 602, 129 Stat. 584, 596-97 (2015).

⁸¹ See, e.g., Center for Health Care Strategies. (2003). *Comparison of Medicaid Pharmacy Costs and Usage between the Fee-for-Service and Capitated Setting*, 5-6

original rationale for the MDRP was to ensure that Medicaid pays no more than a manufacturer's Best Price and is protected from excessive price increases, it has evolved into an expectation that the drug industry has a deeper responsibility to do its part to keep the program solvent. Hence, just as providers generally have to accept below-market reimbursement rates, manufacturers have to pay above-market rebates.

The MDRP rebate is therefore a “double-edged” sword for states interested in implementing APM strategies. On the one hand, a manufacturer's existing responsibility to pay statutory rebates on a given product line will affect its approach and interest in negotiating supplemental rebates on those products. On the other, states are highly dependent on their statutory rebates to help offset the costs of covering prescription drugs for their respective Medicaid populations. States are not authorized to waive their right to collect statutory rebates and, even if they could, they have little incentive to do so. Fortunately, manufacturers have shown a willingness to enter into supplemental rebate agreements with states, and for this reason, states can be optimistic that manufacturers will be interested in entering into APM arrangements, notwithstanding their existing statutory rebate obligations.

2. Dependence on Prior Authorization Programs Instead of Closed Formularies

Under the MDRP, states cannot exclude drugs from coverage through the use of a formulary except under very narrow circumstances. Formularies, generic and therapeutic substitution, and step therapy are tools commonly used to control drug costs and steer utilization toward clinically effective drugs. They give payers leverage in negotiating favorable rebate arrangements with manufacturers while affording a certain level of control over the selection of drugs used by participating providers and pharmacies. Because state Medicaid agencies generally cannot use closed formularies, they must rely on other tools, primarily prior authorization, to maximize the value of covering and reimbursing prescription drugs.

The MDRP allows states to create formularies under a very narrow set of circumstances, specifically:

- The formulary must be developed by a committee of physicians, pharmacists, and other appropriate individuals appointed by the governor of the state or drug use review board;
- The formulary must include the covered outpatient drugs of any manufacturer that has entered into and complies with a rebate agreement unless the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome;
- Drugs excluded from the formulary but covered by the state plan must be available to beneficiaries through a prior authorization process, as described below; and

- The formulary must meet any other requirements provided for by the Secretary.⁸²

Essentially, there are only two ways that a drug may be excluded from a formulary. First, the drug can be completely excluded if a state committee finds that the drug has no “significant, clinically meaningful therapeutic advantage in terms of safety.” Second, states may implement what is in effect a partial exclusion from the formulary, meaning that the drug is technically included on the formulary but is only available to prescribers and patients through the prior authorization process described below. Formularies are therefore only nominally allowed under the MDRP because, in contrast to the commercial market, they cannot be used to completely exclude from coverage a drug otherwise covered by the state plan.⁸³

Although states have little authority under the MDRP to use closed formulary management strategies, they are empowered under the MDRP to establish prior authorization programs. In particular, “[a] State may subject to prior authorization any covered outpatient drug” so long as the prior authorization program: (1) “provides [a] response by telephone or other telecommunication device within 24 hours of a request for prior authorization;” and (2) “except with respect to [a statutory list of restricted drugs], provides for the dispensing of at least [a] 72-hour supply of a covered outpatient prescription drug in an emergency situation as defined by the Secretary.”⁸⁴ The program must also cover medically accepted indications.⁸⁵

In a letter to State Medicaid Directors, CMS clarified that it generally considers prior authorization programs to be a “significant component” of a state plan.⁸⁶ Therefore a state must submit a state

⁸² SSA § 1927(d)(4).

⁸³ *Id.*

⁸⁴ SSA § 1927(d)(1)(A), (5). The list of restricted drugs is as follows:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1396d(bb)(2)(A) of [title 42 of the U.S. Code], agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

⁸⁵ SSA § 1927(d)(1)(B)(i).

⁸⁶ CMS. *State Medicaid Director Letter 02-014* (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>. Material changes in state law, policy or a state’s Medicaid program must be submitted to CMS for review as part of a state plan amendment. 42 C.F.R. § 430.12(c)(1)(ii).

plan amendment (SPA) before implementing these programs.⁸⁷ In a separate letter, CMS provides additional guidance on preferred drug lists and prior authorization programs, including what to include in a SPA request submitted to CMS by the state for approval.⁸⁸

The prior authorization requirements described above also apply to drugs provided through managed care organizations. The Medicaid managed care regulation specifically states that “[c]ontracts that obligate MCOs ... to provide coverage of covered outpatient drugs must” require the MCO to “conduct a prior authorization program that complies with the requirements of [42 USC § 1396d(5)], as if such requirements applied to the MCO ... instead of the state.”⁸⁹ Therefore, CMS directs MCOs to follow the prior authorization provisions in the MDRP. CMS also clarifies that, with respect to formularies, “[t]he MCO ... may be permitted to maintain its own formularies for covered outpatient drugs, but when there is a medical need for a covered outpatient drug that is not included in their formulary but that is within the scope of the contract, the MCO ... must cover the covered outpatient drug under a prior authorization process.”⁹⁰

3. Opportunity to Negotiate Supplemental Rebates

The MDRP statute expressly allows states to “enter directly into agreements with a manufacturer” with permission from the Secretary.⁹¹ CMS has interpreted this provision to allow states to negotiate supplemental rebate agreements with manufacturers, with CMS approval, and therefore potentially capture additional discounts.⁹²

⁸⁷ CMS, *State Medicaid Director Letter 02-014* (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>.

⁸⁸ CMS, *State Medicaid Director Letter 04-006* (Sept. 9, 2004) <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd090904.pdf>. According to the letter, the SPA request must include information explaining how the state will maintain “appropriate access to needed medications,” consistency of the preferred drug list with the goals and objectives of the Medicaid program, information on how the state will maintain continuity of care, information on vendor contracting, a description of state-specific supplemental rebate agreements, a description of annual evaluations that must be adopted for multistate pooling agreements, and a description of how the program will maintain the goals and objectives of the Medicaid program if tied to non-Medicaid programs.

⁸⁹ 42 C.F.R. § 438.3(s) (effective July 5, 2016).

⁹⁰ Medicaid and Children’s Health Insurance Program (CHIP) Programs. *Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability*, 81 Fed. Reg. at 27,544.

⁹¹ SSA § 1927(a)(1); CMS, *State Medicaid Director Letter 02-014* (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>.

⁹² CMS, *State Medicaid Director Letter 02-014* (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>.

Any supplemental rebates negotiated by states must be split with the federal government based on the state's federal medical assistance percentage, in the same way that states must split the statutory MDRP, such that it is to the advantage to both the state and CMS to allow states to negotiate these agreements.⁹³ Although states can only keep part of the supplemental rebates they negotiate, most state Medicaid agencies have negotiated supplemental rebate agreements with drug manufacturers.⁹⁴

There are multiple ways that state Medicaid agencies can structure their supplemental rebate programs:

- Creating incentives for manufacturers to agree to a supplemental rebate for each of their drugs in exchange for placement on a preferred drug list and coverage without prior authorization.
- Using their supplemental rebate authority to negotiate manufacturer health outcome-based arrangements.
- Negotiating rebates as part of a larger purchasing pool established by multiple states working together to increase their negotiating power.

The state's authority under the MDRP to subject a particular drug or product line to prior authorization gives states the leverage they need to negotiate supplemental rebate agreements with manufacturers. States use placement on their PDLs as a negotiating strategy. Drugs included on a state's PDL are typically reimbursed without prior authorization or are subject to less restrictive prior authorization requirements. Preferred drugs are defined as:

- [D]rugs that the state has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost-effective drug within each therapeutically equivalent or therapeutically similar class of drugs, or all drugs

⁹³ See Dept. of Health & Human Services Office of Inspector General, OEI-03-12-00520, *States' Collection of Offset and Supplemental Medicaid Rebates* (Dec. 2014). According to the HHS Office of the Inspector General report, as of 2013 there were 44 states with supplemental rebate programs. When the federal government increased the MDRP rebates under the Affordable Care Act (ACA), the supplemental rebates for 41 of these states experienced a corresponding decrease in size in the same amount as the federal government's increased rebates. The decrease is the result of how the rebates were negotiated with manufacturers originally because they were based on a guaranteed price to manufacturers. Three states based their rebates on a percentage of wholesale acquisition cost instead and did not see a decrease in rebates after the ACA. In many cases, even if states do not already have supplemental rebate programs, these may need to be renegotiated.

⁹⁴ Nat'l Conference of State Legislatures. *Recent Medicaid Prescription Drug Laws and Strategies*, <http://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx> (last updated Jan. 2016). Please note, if a state Medicaid program wishes to tie its supplemental rebate program to a non-Medicaid supplemental rebate program, CMS also believes that the state should seek approval through the SPA process. See CMS. *State Medicaid Director Letter 02-014* (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>.

within such a class if the agency does not differentiate between preferred and non-preferred drugs.⁹⁵

Non-preferred drugs continue to be available to beneficiaries, as required by the MDRP's open formulary rules, but are generally subject to stricter prior authorization procedures than preferred drugs. Because the increased prior authorization steps applicable to non-preferred drugs might have a dampening effect on providers prescribing such drugs, prior authorization programs serve as an incentive for manufacturers to work with the state to make sure their drugs are included on the PDL.

States can also maximize leverage in negotiating supplemental rebate agreements by pooling their Medicaid purchasing with other state Medicaid agencies.⁹⁶ State Medicaid agencies typically do not combine their Medicaid and non-Medicaid drug purchasing, however. Rebates attributable to non-Medicaid drug spending (e.g., universities, correctional, employee health plans) are included when determining a manufacturer's Best Price for a given drug.⁹⁷ Therefore, for the reasons discussed below, manufacturers are wary of extending price concessions when non-Medicaid drugs are included.

4. Adjusting Manufacturer Rebate Obligations

Payers, including state Medicaid programs, generally do not purchase and take possession of pharmaceuticals in the same way as a hospital or clinic. Rather, they pay for drugs after the drugs have been purchased, used, and billed. For this reason, the most common strategy for negotiating drug prices with manufacturers—and certainly the focus of the MDRP—involves the payment of a rebate by the manufacturer to the payer. In an alternative payment arrangement, whether health outcome-based or financial-based, the payer and manufacturer need a certain level of flexibility to adjust the rebate obligation so that the payments, or other forms of consideration, can flow in both directions. The parties also need the ability to evaluate the value of a drug, and to structure the APM to maximize that value, based on how the drug is used. Drugs are often approved by the FDA for different uses, called indications, and they could be more effective for one indication than another. Manufacturer rebate arrangements, besides being adjustable, may need to be indication-specific. As explained below, state opportunities to adjust manufacturer rebate obligations based on performance and/or the drug's indication are possible with supplemental rebates but not with statutory rebates.

⁹⁵ 42 C.F.R. § 447.51.

⁹⁶ Krause, B. (2004). State Purchasing Pools for Prescription Drugs: What's Happening and How Do They Work? NGA Center for Best Practices, <http://www.nga.org/files/live/sites/NGA/files/pdf/0408PRESCRIPTION.pdf>; see also, *State Medicaid Director Letter 04-006* (Sept. 9, 2004), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd090904.pdf>.

⁹⁷ See 42 C.F.R. § 447.505.

The statutory rebates that manufacturers must pay under the MDRP are calculated according to a formula that only Congress can change. The MDRP gives state Medicaid agencies absolutely no discretion to increase or reduce the statutory rebate amount that manufacturers must pay them. The MDRP statutory rebates collected by state Medicaid agencies are shared between the states and the federal government according to the proportional federal medical assistance percentage.⁹⁸ Under the ACA, Congress significantly increased the size of the statutory rebates but gave the increased rebate amounts entirely to the federal government.⁹⁹ States and CMS must therefore accept their portion of the existing statutory percentage rebate and cannot vary that amount to create an incentive for the use of a clinically effective drug or discourage the use of a less effective one. Adjustable rebates are possible, by contrast, if built into state supplemental rebate arrangements. The MDRP allows states to enter into supplemental rebate arrangements but does not limit or otherwise address the size and variability of the supplemental rebates negotiated by states.¹⁰⁰

Likewise, supplemental rebates offer an opportunity for states to negotiate APM arrangements with manufacturers at the indication level. Nothing in the MDRP precludes a supplemental rebate agreement from making indication-level determinations, as long as the base rebate is at least as high as the MDRP statutory rebate.¹⁰¹ Moreover, the MDRP gives states the explicit right to require prior authorization in order to limit the use of a covered outpatient drug to only medically accepted indications.¹⁰² States therefore have the legal tools to establish indication-specific supplemental rebate arrangements with manufacturers. Because clinical outcomes can vary depending on a drug's indication of use, the opportunity to negotiate indication-specific supplemental rebates provides a platform for value-based purchasing with manufacturers. Where states find reliable indication-specific clinical data and how they use such data to establish effective outcome-based APM arrangements is another matter.

The FDA approves drugs based on their indications for use.¹⁰³ Unfortunately, drugs are identified less granularly under the MDRP. The critical statutory variables—AMP and Best Price—are determined on a National Drug Code (NDC) basis. A drug's NDC only identifies the manufacturer of a drug, its active chemical and strength, and its package size.¹⁰⁴ It does not specify the relevant indication for which it should be prescribed. Thus, states need to look deeper in order to tie rebates to the actual purpose for which a drug is being used. To be able to make indication-level decisions, a

⁹⁸ SSA § 1927(b)(1)(B).

⁹⁹ SSA § 1927(b)(1)(C).

¹⁰⁰ SSA § 1927(a)(1); CMS. *State Medicaid Director Letter 02-014* (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>.

¹⁰¹ See SSA § 1927(a)(1); CMS. *State Medicaid Director Letter 02-014* (Sept. 18, 2002), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf>.

¹⁰² SSA § 1927(d)(4)(C).

¹⁰³ 21 C.F.R. § 314.50.

¹⁰⁴ SSA § 1927(a)(7).

state must be able to identify whether a drug is effective for a particular indication or whether a clinically effective drug has been used. States could encounter operational barriers in gathering and analyzing data to assess whether the use of a drug for a particular indication is more or less successful than other potential uses. These are logistical rather than legal challenges, though. There are alternative ways for states to obtain the utilization and efficacy data needed to apply indication-specific measures.

5. Manufacturer Best Price Concerns

The amount of the statutory rebate that a manufacturer must pay for a particular drug is determined in large part by either the drug's AMP or Best Price. The Best Price component of the statutory rebate formula is often invoked by manufacturers as a reason why they cannot engage in negotiations of price discounts or rebates. They argue that a single transaction can set a new Best Price, which in turn can increase the statutory rebates they must pay to every state Medicaid agency across the country. Best Price is thus often the “floor” for any drug price negotiations because manufacturers will not want to set a new Best Price. Manufacturers are not required to disclose their Best Price to states, so the manufacturer holds the upper hand in negotiating rebates and any other arrangement that could lower a drug's price. AMP, by contrast, is a nationwide average, so negotiations affecting a drug's AMP will only have a small incremental impact on the statutory rebates payable to states.

Best Price is not only the lowest selling price of a drug. It also includes all discounts, rebates and payments applicable to a given sales transaction, even if those discounts and payments are provided after the drug's purchase date.¹⁰⁵ For example, Best Price includes any rebates or other price concessions negotiated by a PBM if that rebate or discount relates to a single drug transaction and reduces the price paid by the purchaser.¹⁰⁶ On the other hand, not all sales or price concessions are taken into account in determining a drug's Best Price. The MDRP statutory rebate is excluded from Best Price calculations.¹⁰⁷ Best Price also excludes nominal prices,¹⁰⁸ 340B discounts, and other price concessions extended to safety net providers as defined by the Secretary.¹⁰⁹

Best Price exclusions are vitally important to the success of a proposed APM-based rebate arrangement. States can leverage the existence of a Best Price exclusion in their rebate negotiations with manufacturers because it removes one of the most powerful reasons manufacturers can cite for opposing a rebate proposal, namely, the risk of establishing a new Best Price. For example, supplemental rebates paid to state Medicaid agencies by manufacturers pursuant to “CMS-

¹⁰⁵ 42 C.F.R. § 447.505(b).

¹⁰⁶ *Id.* § 447.505(b), (c)(17).

¹⁰⁷ *Id.* § 447.505(c)(7).

¹⁰⁸ See *Id.* § 447.508.

¹⁰⁹ *Id.* § 447.505(c)(1)-(19).

authorized” supplemental rebate agreements are excluded from Best Price calculations.¹¹⁰ Manufacturers might resist paying supplemental rebates for a variety of reasons, but the risk of setting a new Best Price cannot be one of them. For states that deputize their MCO contractors or PBM subcontractors to negotiate rebate arrangements on their behalf, another Best Price exemption applies. Discounts or rebates provided to MCOs or PBMs are only included in Best Price if “the rebates are designed to adjust prices at the retail or provider level and discounts to a retail community pharmacy’s final drug price.”¹¹¹ If the rebates are passed through to the state, which would be the objective of an APM rebate arrangement negotiated by an MCO or PBM, then the rebates are excluded from Best Price. They could not be viewed as adjusting the drug’s purchase price at the retail or provider level.

6. Prescription Limits

States are subject to two types of prescription limits under the MDRP: (1) limits on the number of prescriptions that a patient can receive each given month; and (2) limits on the number of pills or volume of a drug dispensed per each prescription or the number of refills. Specifically, the MDRP allows “[a] State [to] impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under the Act.”¹¹² Medicaid regulations further clarify that states must include details as to “the amount, duration, and scope of each service that it provides for (1) [t]he categorically needy; and (2) [e]ach covered group of medically needy” in their state plans.¹¹³

State Medicaid agencies are therefore allowed to adopt prescription limits in their drug coverage policies. Such limits, however, must be consistent with the MDRP, including the requirement that

¹¹⁰ 42 C.F.R. § 447.505(c)(4), (7). A supplemental rebate agreement is not authorized by CMS until it has been expressly approved. See CMS, *MDRP Release No. 11* (Apr. 11, 1994), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-011.pdf>; and CMS, *MDRP Release No. 102* (Nov. 15, 2000), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-102.pdf>. This means that unapproved rebates paid to a state are included in Best Price calculations.

¹¹¹ Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,252–53; see also 42 C.F.R. § 447.505(c)(17); CMS, *State Medicaid Director Letter 04-006* (Sept. 9, 2004), <https://www.medicare.gov/Federal-Policy-Guidance/downloads/smd090904.pdf>; CMS, *MDRP Release No. 28* (Apr. 28, 1997), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-028.pdf>; CMS, *MDRP Release No. 29* (Jun. 5, 1997), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-029.pdf>; CMS, *MDRP Release No. 30* (Sept. 17, 1997), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-030.pdf>.

¹¹² SSA § 1927(d)(6).

¹¹³ 42 C.F.R. § 440.230(a).

they apply to all drugs within a therapeutic class and are only used for purposes of discouraging waste or addressing fraud and abuse. States have generally taken advantage of their right to establish prescription limits, including limits on the number of prescriptions a beneficiary can fill each month in practice.¹¹⁴ Therefore, although limits as to the number of prescriptions a beneficiary can fill per month are not explicitly addressed in the statute, CMS is allowing them under the MDRP.

7. Confidentiality of AMP and Best Price

The MDRP statute specifies that AMP, Best Price, and unit-level sales information shared by manufacturers or wholesalers with HHS are confidential.¹¹⁵ The information cannot be disclosed in a form that identifies specific manufacturers or wholesalers and the prices charged by them.¹¹⁶ There are exceptions that allow HHS and state Medicaid agencies to exchange information as necessary to implement the program.¹¹⁷ States have access to AMP data but not Best Price.

These confidentiality provisions could complicate state efforts to establish rebate or other APM arrangements with manufacturers. A state, for example, would be prohibited from sharing confidential pricing data with MCOs, PBMs, or hospitals. If the state relies on these organizations to negotiate discounts with manufacturers on its behalf, the lack of information could put the organizations at a disadvantage in their negotiations. Even if the state takes the lead in negotiating discounts or rebates with manufacturers, manufacturers could refuse to enter into such negotiations, or offer only modest concessions, on the grounds that such concessions would adversely affect their AMP and Best Price calculations. The state would not have access to Best Price data for the drugs at issue, so it would have no way of evaluating whether the manufacturer's unwillingness to negotiate is reasonable. Because the risk of setting a new Best Price is so dire, manufacturers can legitimately cite that risk as a basis for being uncooperative. Of course, if the proposed discounts or rebates are exempt from Best Price, as described above with respect to supplemental rebates, for example, this obstacle disappears.

C. Non-MDRP Medicaid Limitations

We have described how the MDRP, either directly or indirectly, affects APM strategies for enhancing medication therapy patient outcomes and managing drug costs. There are additional features of the Medicaid program outside of the MDRP that might affect a state's ability to establish a prescription drug APM. Medicaid limits the cost-sharing responsibility that can be imposed on beneficiaries. CMS's recent covered outpatient drug rule, which requires states to reimburse retail

¹¹⁴ Health Mgmt. Assocs. for KCMU. (2012). Medicaid Benefits: Prescription Drugs. *Kaiser Family Foundation*, <http://kff.org/medicaid/state-indicator/prescription-drugs/>.

¹¹⁵ SSA § 1927(b)(3)(D).

¹¹⁶ *Id.*

¹¹⁷ SSA § 1927(b)(3)(D)(i-v).

drugs at actual acquisition cost (AAC), affords states little flexibility to adjust drug reimbursement amounts to pharmacies based on performance or to facilitate pharmacy incentive arrangements in a fee-for-service environment. Last, states might need a federal waiver or approval of a SPA to address coverage and payment limitations that stifle APM innovation. These non-MDRP considerations are addressed below.

1. Patient Cost-Sharing

The broader Medicaid statute governs state options for cost-sharing outside of the MDRP.¹¹⁸ CMS regulations governing beneficiary cost-sharing include provisions that specifically address cost-sharing for drugs¹¹⁹ and sets maximum allowable cost sharing amounts. The maximum allowable cost sharing amount for “preferred” drugs is currently \$4.00 for all Medicaid beneficiaries, regardless of income level.¹²⁰ Preferred drugs are defined as:

[D]rugs that the state has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost effective drug within each therapeutically equivalent or therapeutically similar class of drugs, or all drugs within such a class if the agency does not differentiate between preferred and non-preferred drugs.¹²¹

Based on this definition, a state Medicaid agency that does not establish a preferred drug list cannot set cost-sharing for beneficiaries at more than \$4.00.¹²² A state Medicaid agency could adopt larger cost-sharing amounts if approved through a Medicaid waiver.¹²³

For non-preferred drugs, the maximum cost sharing amount is \$8.00 for Medicaid beneficiaries with incomes at or below 150% of the poverty line or 20% of the cost that the agency pays for families with income above 150% of the poverty line.¹²⁴ Finally, total cost sharing across all services “may not exceed 5% of the family income of the family involved,” such that states must consider their cost-sharing programs across all services provided under the state plan before setting the cost-sharing amount for drugs and must have some mechanism for determining when a family meets the 5% of family income threshold.¹²⁵ Tiered copays and patient cost-sharing are therefore allowed

¹¹⁸ SSA § 1916A.

¹¹⁹ 42 C.F.R. § 447.50 *et seq.*

¹²⁰ *Id.* § 447.53. CMS does not allow cost-sharing for preferred drugs for anyone under the age of 18, services for pregnant women, services for the terminally ill, services provided to inpatients and other categories of persons. CMS also caps cost sharing in states that do not have FFS payment rates for all income levels at \$4. *Id.*

¹²¹ *Id.* § 447.51.

¹²² *Cf. id.*

¹²³ Nat'l Conference of State Legislatures. *Recent Medicaid Prescription Drug Laws and Strategies*, <http://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx> (last updated Jan. 2016).

¹²⁴ 42 C.F.R. § 447.53(b).

¹²⁵ SSA § 1916A.

under the Medicaid program, but their effectiveness is limited by the strict caps on the amount of cost-sharing that can be imposed on beneficiaries.

As previously stated, the recently released Medicaid managed care rule applies the provisions of the MDRP to Medicaid MCOs. The final rule also extends the MDRP provisions applicable to patient cost-sharing to Medicaid managed care contracting:

(h) Services furnished by a managed care organization (MCO). Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the cost sharing specified in the state plan and the requirements set forth in [the Medicaid Premiums and Cost Sharing provisions].¹²⁶

The provisions on cost-sharing for drugs therefore would apply to both fee-for-service and managed care arrangements.

2. Actual Acquisition Cost Reimbursement

Under the covered outpatient drug final rule, states must base reimbursement of covered outpatient drugs for pharmacies on the drug's AAC plus a professional dispensing fee.¹²⁷ The rule also specifies that dispensing fees must be reimbursed at actual cost.¹²⁸ Notably, retail drugs dispensed to Medicaid managed care enrollees do not have to be reimbursed based upon AAC, because the covered outpatient drug rule only applies to drugs reimbursed on a fee-for-service basis.

AAC is defined as “the agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.”¹²⁹ The costs that can be included in the dispensing fee include, but are not limited to, “a pharmacist’s time in checking the computer for information about an individual’s coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.”¹³⁰

Because the AAC requirement is tied to invoice pricing, it does not allow flexibility for adjusting fee-for-service reimbursement rates to pay more for clinically effective uses of drugs or less for clinically ineffective uses of drugs. States do have the flexibility to adopt benchmarks and can employ a variety of pricing methodologies to calculate AAC, but all of the methodologies that can be

¹²⁶ 42 C.F.R. § 447.52.

¹²⁷ *Id.* § 447.512(b).

¹²⁸ Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,294.

¹²⁹ 42 C.F.R. § 447.502.

¹³⁰ *Id.*

used must be based on invoice pricing.¹³¹ In the preamble to the covered outpatient drug final rule, CMS listed several sample methodologies for calculating AAC. For example, a state can utilize a state survey of a retail pharmacy provider’s pricing or a national survey, such as the National Average Drug Acquisition Cost.¹³² States must submit a SPA describing the reimbursement methodology they will use to establish AAC and the processes the state will use to obtain and update the methodology.¹³³ States can use alternative pricing methodologies only when AAC is not available for a specific drug for a limited time period, and must detail the alternative methodology that will be used in the SPA.¹³⁴

The scope of the AAC reimbursement rule is somewhat different for specialty drugs. The requirement clearly applies to specialty drugs purchased through retail pharmacies, but does not apply when those drugs are dispensed through mail-order pharmacies.¹³⁵ The rule does permit states to develop separate and presumably higher professional dispensing fees for the costs of handling specialty drugs.¹³⁶

In some situations, drugs administered by non-pharmacy providers are governed outside of the MDRP entirely, and therefore states could have much more flexibility in implementing VBP programs to influence decision making at the point of care. There could also be opportunities with pharmacists. Payments to pharmacists other than drug reimbursement and dispensing fees—for example, payment for medication therapy management or other professional services—fall outside the scope of the AAC reimbursement requirement. The opportunities available for state Medicaid agencies to create pharmacy and non-pharmacy-provider VBP programs are addressed further in Section IV.

3. Service Expansions to Address “Whole-Person” VBP Strategies

When considering APM opportunities, a state Medicaid agency may need to consider the scope of the state’s Medicaid program itself. The Medicaid statute defines a series of mandatory benefits that must be included in a Medicaid State Plan.¹³⁷ The benefits include hospital services, physician services, screening and testing services for children, nursing facility services, laboratory and X-ray services, and others. Many other benefits are optional, including prescription drug coverage

¹³¹ A State Medicaid agency must set a reimbursement amount that is “consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available.” SSA § 1902(a)(30)(A).

¹³² Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,175.

¹³³ 42 C.F.R. § 447.518.

¹³⁴ *Id.*

¹³⁵ Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,313. Although the covered outpatient drug rule was ambiguous on whether mail order specialty drugs are subject to AAC reimbursement, CMS has since clarified that states do not have to pay for such drugs at AAC. See presentation by John Coster, Director of CMS Division of Pharmacy, 340B Coalition Annual Summer Conference, Washington, DC (July 13, 2016).

¹³⁶ Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,293.

¹³⁷ SSA § 1902(a).

(although all 50 states currently provide it) and case management services. Many VBP strategies include services that are not reimbursed by traditional Medicaid. If a state provides a service that is not included in its Medicaid State Plan, it will not be able to claim the federal matching share of the costs of the services provided.¹³⁸ Medicaid MCOs have more leeway to provide additional services, but must provide at least the Medicaid covered services that are within the scope of the MCO's contract with the state.¹³⁹ Fortunately, the federal Medicaid statute provides states with several state plan and waiver authorities to expand coverage and/or adjust reimbursement to meet the pharmacy-related needs of Medicaid patients.

Drug treatment of the HIV population serves as a good example of how coverage and payment limitations can adversely affect health outcomes. The National HIV/AIDS Strategy focuses on a “treatment cascade” model that aims to identify HIV-positive individuals, link them to care, retain them in care, ensure medication adherence, and eventually achieve viral suppression.¹⁴⁰ Viral suppression occurs when serum levels of HIV are so low that transmission of the disease is highly unlikely. Traditional Medicaid, for example, only pays for some steps in the cascade. It will pay for the initial testing, reimburse for the care provided, cover the drugs prescribed, and provide for the follow-up monitoring.

The success of the strategy, however, depends on the services provided between reimbursable events. Newly-diagnosed individuals might need social support services, nutritional therapy, assistance with transportation, and help navigating byzantine assistance programs. Linkage to care involves identifying providers who the individual can regularly see, not only providing a list of names. Retention in care and medication adherence might only occur if a case manager is actively following up on the individual to ensure that he or she goes to scheduled appointments and fills prescriptions.

There are provisions in federal law that a state can use to meet the needs of special populations, like those described above. A few provisions (including the Social Security Act's section 1915(i) home and community-based services program and section 1932 primary care management by MCOs, as well as the ACA section 2703 health homes program) do not require a formal waiver and can be implemented with an approved SPA.¹⁴¹ Broader reforms, by contrast, entail requesting and obtaining a federal waiver under sections 1115, 1115A, 1915(b), or 1915(c) of the Social Security Act.¹⁴² MCOs also have some flexibility to provide services “in lieu of” traditional Medicaid services

¹³⁸ SSA § 1903(a)(1); *see also* SSA § 1915(c).

¹³⁹ SSA § 1903(m)(1)(A)(i).

¹⁴⁰ See Office of Nat'l AIDS Policy, National HIV/AIDS Strategy for the United States: Updated to 2020 (July 2015), <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf>.

¹⁴¹ SSA § 1915(i), § 1932(a), § 1945.

¹⁴² SSA § 1115, 1115A, 1915(b), 1915(c).

when the replacement service is less costly and equally effective, or to reinvest savings into services not covered under the State Plan.¹⁴³

D. Other Federal Issues

Stakeholders within the pharmaceutical industry have raised questions regarding whether other areas of federal law might have a chilling effect on APM opportunities. Two issues in particular have been raised: the prohibition against “off-label” marketing of prescription drugs and the anti-kickback statute.¹⁴⁴ Both are addressed in this section.

1. Off-Label Promotion

Some have alleged that APM strategies that focus on the indication for which a drug is being used could implicate prohibitions against “off-label” promotion of a drug.¹⁴⁵ Off-label promotion is a form of “misbranding,” treated as a criminal violation under the Food, Drug, and Cosmetic Act.¹⁴⁶ The FDA approves drugs for specific indications, and the required labeling information addresses only those indications. When a manufacturer promotes a drug for any use that is not on the label, the drug is “misbranded” because its labeling or advertising is thereafter misleading.¹⁴⁷ When off-label drugs are billed to Medicaid, the manufacturer can face False Claims Act prosecution.¹⁴⁸

It is well-established that doctors have the right to prescribe drugs for off-label uses and payers have the right to pay for such uses.¹⁴⁹ The risk of violating federal law arises, however, if a

¹⁴³ Medicaid and Children’s Health Insurance Program (CHIP) Programs. *Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability*, 81 Fed. Reg. at 27,856; 42 C.F.R. § 438.3(e) (effective July 5, 2016).

¹⁴⁴ See, e.g., Young, K. Medicare Plan Draws Calls for Marketing, Kickback Rule Changes. *The Commonwealth Fund*, (June 1, 2016), <http://www.commonwealthfund.org/publications/newsletters/washington-health-policy-in-review/2016/jun/june-6-2016/medicare-plan-draws-calls-for-marketing?omnicid=WHPR1047279&mid=pinson@ohsu.edu>.

¹⁴⁵ See, e.g., Pearson, S.D. et al. (2016). Indication-Specific Pricing of Pharmaceuticals in the United States Health Care System. *Institute for Clinical and Economic Review*, 4, (http://icer-review.org/wp-content/uploads/2015/03/Final-Report-2015-ICER-Policy-Summit-on-Indication-specific-Pricing-March-2016_revised-icons-002.pdf).

¹⁴⁶ 21 U.S.C. § 331(a).

¹⁴⁷ *Id.* § 321(n).

¹⁴⁸ CMS, Off-Label Pharmaceutical Marketing: How to Recognize and Report It (Oct. 2015), <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf>.

¹⁴⁹ The FDA has stated that “once a drug or medical device has been approved or cleared by FDA, generally, health care professionals can lawfully use or prescribe that product for uses or treatment indications that are not included in the product’s approved labeling.” FDA, Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Draft) (Dec. 2011), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf> “FDA recognizes that these off-label uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care.” *Id.*

manufacturer seeks to promote its drug for that off-label use. A manufacturer might be concerned that it is “promoting” an off-label use of a medication if it negotiates terms specific to such an indication. Private negotiations might not constitute off-label promotion if they have no impact on prescriber or patient decision-making. Indication-specific terms that focus only on competing FDA-approved indications would not raise off-label misbranding concerns. Similarly, if no specific off-label use is discussed (i.e., all off-label use is treated the same), then the manufacturer likely could not be viewed as “promoting” any off-label use.

To date, off-label prosecutions and related False Claims Act cases have focused on allegations that pharmaceutical manufacturers actively encouraged off-label uses of approved drugs. Many forms of “promotion” have led to off-label and related prosecutions, including making incentive-based payments to sales representatives based on off-label sales, offering kickbacks to physicians who prescribe for off-label uses, disseminating misleading posters, publicizing studies supporting off-label uses while suppressing studies questioning efficacy, and giving billing coding advice to prescribers.¹⁵⁰ It is relatively rare, however, for an off-label prosecution to involve statements made to a state Medicaid agency. One prosecution, involving Merck’s promotion of the pain reliever Vioxx, included allegations that the manufacturer made false statements to state Medicaid agencies regarding the cardiovascular safety of the drug.¹⁵¹ Citing that prosecution, CMS described “[m]aking false representations directly to Medicaid to influence decisions about payment for drugs used off-label” as an example of unlawful off-label promotion.¹⁵²

For the above reasons, manufacturers need to be truthful when negotiating indication-specific APM arrangements with states, especially if one or more of the indications encompassed in the arrangement is off-label. If they make a false representation that influences a state’s decision about payment, they have committed a textbook violation of the False Claims Act, whether an off-label indication is involved or not.¹⁵³ Manufacturers that are truthful during their negotiations with states are at little risk of violating the prohibition against off-label promotion. The government would be unlikely to pursue an off-label prosecution centered on an agreement negotiated between a state Medicaid agency and a truthful manufacturer, especially if the agreement is approved by CMS. A state can reduce the risk further if it relies on independent clinical data, rather than manufacturer representations, to support an APM arrangement involving an off-label indication.

Moreover, truthful discussions of off-label uses between a drug manufacturer and a state Medicaid agency might be constitutionally protected. The government’s right to prosecute off-label promotion

¹⁵⁰ CMS. *Fact Sheet, Off-Label Pharmaceutical Marketing: How to Recognize and Report It*, <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf>.

¹⁵¹ See Department of Justice. *U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx* (Apr. 19, 2012), <https://www.justice.gov/opa/pr/us-pharmaceutical-company-merck-sharp-dohme-sentenced-connection-unlawful-promotion-vioxx>.

¹⁵² CMS. *Fact Sheet, Off-Label Pharmaceutical Marketing: How to Recognize and Report It*.

¹⁵³ See 31 U.S.C. § 3729.

is the subject of several pending legal challenges. At least two courts have opined that off-label restrictions can result in an unconstitutional restraint on commercial free speech. In *United States v. Caronia*, the United States Court of Appeals for the Second Circuit questioned whether the government is really prosecuting illegal conduct (misbranding) or restricting speech, which warrants much stricter constitutional scrutiny.¹⁵⁴ The United States District Court for the Southern District of New York went a step farther and concluded in *Amarin Pharma v. FDA* that the FDA's off-label regulations have an unconstitutional chilling effect on commercial speech.¹⁵⁵ The FDA and Amarin entered into a proposed settlement under which the FDA would not appeal the decision.¹⁵⁶ *Caronia* and *Amarin* both used a four-part balancing test established by the Supreme Court for when commercial speech is protected by the First Amendment.¹⁵⁷ The first three parts establish whether free speech is implicated: (1) is it speech? (2) does it concern lawful activity? (3) is it not misleading?¹⁵⁸ The fourth part asks whether the governmental interest is substantial, whether the restriction advances the governmental interest, and whether the restriction is no more extensive than necessary to achieve the interest.¹⁵⁹ While other federal courts have not yet applied the First Amendment commercial speech tests to the FDA's off-label enforcement activities, there is reason to be optimistic that truthful speech regarding the lawful activity of prescribing drugs for off-label uses is protected.

Off-label discussions between a state and manufacturer are particularly likely to meet the test described above. If a manufacturer and state enter into a dialogue in an effort to establish an APM arrangement, and if the manufacturer is not being misleading and the off-label use is lawful, there is a good case to be made that such discussions would be protected because (1) there is a strong governmental interest in establishing the underlying APM arrangement (including ones that involve off-label uses of a drug); (2) the government is in an excellent position to ensure that the arrangement, and discussions surrounding the arrangement do not cross the line into unnecessary promotion because the arrangement must be approved by both the state and CMS; (3) the state can rely on independent clinical data, rather than claims by the manufacturer, to support the APM arrangement.

For the above reasons, a state Medicaid agency evaluating an APM can likely avoid exposing a manufacturer to potential off-label promotion problems. First, the agency would need to determine whether the APM involves off-label uses as a threshold matter. If it does, the state Medicaid agency

¹⁵⁴ 703 F.3d 149 (2d Cir. 2012).

¹⁵⁵ 119 F. Supp. 3d 196, 224–28 (S.D.N.Y. 2015).

¹⁵⁶ *Amarin Pharma, Inc. v. FDA*, Case No. 15-CIV-3588, Proposed Stipulation and Order of Settlement (S.D.N.Y. Mar. 8, 2016); see also Amarin Corp. PLC, Amarin's Right to Promote Vascepa® Off-Label Affirmed under First Amendment Litigation Settlement Terms (Mar. 8, 2016), <http://investor.amarincorp.com/releasedetail.cfm?ReleaseID=959511>.

¹⁵⁷ See *Caronia*, 703 F.3d at 164; *Amarin*, 119 F. Supp. 3d at 225 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980))

¹⁵⁸ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

¹⁵⁹ *Id.*

could perform its own research to determine whether there is sufficient clinical data to support the off-label indication. If it is satisfied, and it chooses to proceed with the APM, it could seek CMS approval of the mechanism, through a SPA, supplemental rebate approval, or otherwise, depending on the APM. Any manufacturer “speech” regarding the off-label use identified by the Medicaid agency, if truthful, would likely be protected.

2. Anti-Kickback Statute

The federal Anti-Kickback Statute (AKS) has also been raised as a possible hurdle to negotiating prescription drug APMs. The AKS is a criminal statute that prohibits the knowing and willful exchange of, or offer to exchange, anything of value in an effort to induce or reward the referral of federal health care program business.¹⁶⁰ The AKS is broadly drafted and establishes penalties for those who solicit and receive remuneration and those who offer or pay remuneration for prohibited transactions. The AKS prohibits the solicitation, offer, payment, or receipt of remuneration in exchange for referrals of federal health care business and remuneration for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under a federal health care program.¹⁶¹ Theoretically, anything of value provided by a manufacturer to a party in a position to increase the Medicaid and Medicare business of that manufacturer could be an AKS violation.

Because of concern about the breadth of the AKS, Congress explicitly excludes ten types of arrangements.¹⁶² Congress also gave the Secretary of HHS the authority to promulgate safe harbors

¹⁶⁰ 42 U.S.C. § 1320a-7b(b). States may also have their own state anti-kickback laws that influence whether APM arrangements constitute an illegal inducement.

¹⁶¹ *Id.*

¹⁶² The AKS does not apply to:

1. Discounts or reductions in price obtained by a provider of services or other entity under Medicare or Medicaid, including a State health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity;
2. Payments made between an employer and a bona fide employee;
3. Payments between a vendor of goods and services to a purchasing agent for a group of individuals or entities if the agent has a written contract with the individual or entity which specifies the amount to be paid and, if the entity is a provider, the agent discloses the amount received from the vendor with respect to purchases made by or on behalf of the entity;
4. Medicare Part B co-insurance waivers by federally qualified health centers;
5. Certain transactions that fit within safe harbors established by the Secretary of HHS;
6. Remuneration between an organization and an individual or entity, if the organization is a health maintenance organization under 42 U.S.C. 1395mm and entered into a written agreement 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 items or services;
7. Pharmacy waivers or Medicare Part D cost sharing;
8. Remuneration between a federally qualified health center and a Medicare Advantage organization pursuant to a written agreement;
9. Remuneration between a health center entity and an individual or entity providing support to each health center entity; and
10. Discounts furnished under the Medicare coverage gap discount. 42 U.S.C. § 1320a-7b(b)(3).

to the AKS that protect specific business and financial relationships and to interpret the statutory exceptions.¹⁶³ There are currently twenty-five safe harbors, and all requirements of a safe harbor must be met to qualify for protection from AKS liability.¹⁶⁴ Failure to meet the terms of a safe harbor or statutory exclusion does not render the arrangement per se illegal. Rather, it means that the arrangement will be evaluated on a facts and circumstances basis that takes into account various attributes of the payment arrangement to determine whether payments were made with the intent to induce referrals, and therefore are impermissible.

The discount exception in the AKS statute is the most relevant exception to APM arrangements, as it excludes discounts or reductions in price obtained by a provider or other entity under Medicare or Medicaid, including state health care programs, as long as the reduction in price is disclosed and reflected in the costs claimed or charges made by the provider or entity.¹⁶⁵ The HHS Office of the Inspector General (OIG) also promulgated a regulatory discount safe harbor, which interprets the statutory exception. Under this safe harbor, a discount is “a reduction in the amount a buyer (who buys either directly or through a wholesaler or a GPO) is charged for an item or service based on an arms-length transaction.”¹⁶⁶ A rebate is a type of discount that has terms that are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.¹⁶⁷ Another safe harbor applies to discounts offered to MCOs and arrangements between MCOs and their first-tier contractors that have substantial financial risk, but the parties must have a written agreement for at least one year, among other requirements, to provide these price reductions.¹⁶⁸

As noted above, an arrangement that does not meet an exception or safe harbor is not per se improper under the AKS, but rather is evaluated on a case-by-case basis using a facts and circumstances approach. The OIG looks at a number of factors when examining an arrangement.

¹⁶³ See 42 C.F.R. § 1001.952.

¹⁶⁴ *Id.*

¹⁶⁵ 42 U.S.C. § 1320a-7b(b)(3)(A). This exception was included to “ensure the practice of discounting in the normal course of business transactions would not be deemed illegal.” H.R. REP. NO. 95-393(ii), at 53 (1977).

¹⁶⁶ 42 C.F.R. § 1001.952(h)(5). “Discount” does not include:

- (i) Cash payment or cash equivalents (except that rebates may be in the form of a check);
- (ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;
- (iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;
- (iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;
- (v) Warranties;
- (vi) Services provided in accordance with a personal or management services contract; or
- (vii) Other remuneration, in cash or in kind, not explicitly described in this section. *Id.*

¹⁶⁷ *Id.* § 1001.952(h)(4).

¹⁶⁸ *Id.* § 1001.952(t), (u).

For example, OIG has instructed pharmaceutical manufacturers to ask specific questions to determine whether an arrangement might create undue risk:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?¹⁶⁹

Application of the above factors suggests that some APM arrangements pose greater AKS risk than others. For example, an APM strategy that involves risk-sharing payments between a state Medicaid agency and manufacturer is not likely to be problematic, but remuneration paid by a manufacturer to a provider is inherently suspect, especially if the remuneration can be linked to inclusion of the company's drugs on the provider's formulary. Other arrangements, like those between manufacturers and PBMs or MCOs, likely only pose significant risk if the intent behind them is improper. Because the OIG has never issued regulatory guidance addressing APM arrangements, and to date no advisory opinions have been published on the subject, no one can say with certainty how the OIG would view a particular APM established within a state Medicaid program.

Regardless of the uncertainty, there is a low risk that the OIG would consider any APM to violate the AKS. APM arrangements have two potential levels of protection from the AKS. First, when a manufacturer negotiates directly with a state rather than a commercial entity, the risk is negligible. Second, when an arrangement is reviewed and approved by CMS, this creates a stamp of federal approval. The risk might be slightly elevated when an arrangement is negotiated between a manufacturer and a private party, such as a PBM or MCO, because a government actor is not directly involved. However, these private parties would be acting as agents of the state, and therefore this type of negotiation would still pose a low risk of violating the AKS.

E. State Legislation

State law can add another layer of requirements that either impede or facilitate the development of prescription drug APMs within the Medicaid program. Examples include state "any willing provider" laws and laws governing generic substitution, PDL exclusions, PBMs, MCOs, and freedom of information.

¹⁶⁹ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,734 (May 5, 2003).

Although there are undoubtedly other kinds of state legislation that could affect a state's APM efforts, we address below the ones that are most likely to be relevant.

1. Generic and Other Substitution Laws

Many states have enacted generic substitution laws that require pharmacies to automatically substitute the generic version of a drug that is chemically and therapeutically equivalent to the brand name drug for which the prescription was written.¹⁷⁰ Often a provider may only need to write “dispense as written” or similar language to require the pharmacy to dispense the drug listed on the prescription instead, and therefore these traditional generic substitution laws do not limit the drugs available to state Medicaid beneficiaries in a way that would violate the MDRP's open formulary rules.¹⁷¹ We do not anticipate that traditional state generic substitution laws will undermine state efforts to create prescription drug APM and VBP arrangements, but state Medicaid agencies should take care that they do not structure these arrangements in a way that would conflict with other kinds of state substitution laws.

Some states are implementing therapeutic substitution laws or laws that allow for the substitution of biosimilars for their biologic equivalents that could limit more significantly the types of drugs that are available under a state Medicaid program.¹⁷² These laws are controversial because the drug being substituted does not share the same biochemical composition of the drug prescribed and therefore, when applied to the Medicaid program, may require CMS approval through the submission of a SPA.¹⁷³

Further, some state laws restrict certain classes of drugs from generic or therapeutic substitution programs. For instance, under North Carolina law, “[a] prescription for a narrow therapeutic index drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product, and the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product.”¹⁷⁴ In

¹⁷⁰ Nat'l Conference of State Legislatures, *Recent Medicaid Prescription Drug Laws and Strategies*, <http://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx> (last updated Jan. 2016). Drug substitution laws combined with prior authorization programs are covered under Sections II(B)(b).

¹⁷¹ *Id.*

¹⁷² See, e.g., Wash. Admin. Code § 182-530-4150; Nat'l Conference of State Legislatures, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx> (last updated May 31, 2016). Please note, the Washington State therapeutic interchange program only applies to “endorsing practitioners,” meaning that a physician must opt-in to the program before a therapeutic substitution is allowed.

¹⁷³ Nat'l Conference of State Legislatures, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx> (last updated May 31, 2016).

¹⁷⁴ N.C. GEN. STAT. ANN. § 90-85.28(b1).

Hawaii, a “pharmacist shall not substitute an equivalent generic drug product for any prescription for an anti-epileptic drug, except upon the consent of the practitioner and the patient or the patient’s parent or guardian.”¹⁷⁵ State Medicaid agencies should be mindful of these laws when designing and implementing prescription drug APM programs.

2. PDL Exclusions

As previously mentioned, most state Medicaid agencies utilize PDLs and prior authorization to manage their pharmacy programs.¹⁷⁶ Some state laws exclude certain classes of drugs from state Medicaid PDLs and the prior authorization requirements typically applied to non-preferred drugs. These states have exclusions for drugs that treat mental illness, HIV/AIDS, cancer, and immunosuppressive drugs for organ transplant patients, among other conditions.

Two illustrative examples come from Michigan and Hawaii. Michigan state law explicitly excludes from its state PDL those drugs classified as anticonvulsants, antidepressants, antipsychotics, or non-controlled substance antianxiety drugs and drugs for treating mental illness, HIV/AIDS, cancer, organ replacement therapy, and epilepsy or seizure disorders. The law also states that the Michigan Department of Community Health is prohibited from requiring prior authorization for these classes of drugs.¹⁷⁷ Hawaii exempts from state prior authorization requirements physicians or physician assistants treating a Medicaid recipient who is living with HIV/AIDS or hepatitis C or is in need of immunosuppressives for an organ transplant.¹⁷⁸

3. “Any Willing Provider” Laws

Many states have “any willing provider” laws that require payers to accept health care providers as part of their network as long as the provider is willing to comply with the terms of participation set by the payer.¹⁷⁹ These laws may be written broadly or may be specific to a payer’s acceptance of a pharmacy provider as part of its network.¹⁸⁰ Any willing provider laws could adversely impact an APM proposal in which the state seeks to establish a limited provider network in an attempt to manage more closely the care provided to beneficiaries who need the services of those providers. For example, a state may be interested in directing populations affected by a certain disease state to seek care from a limited network of pharmacies and/or providers that are specially equipped to

¹⁷⁵ HAW. REV. STAT. ANN. § 328-92(c).

¹⁷⁶ Smith, V.K. et al. (2014). *Medicaid in an Era of Health & Delivery System Reform: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2014 and 2015*, <http://kff.org/report-section/medicaid-in-an-era-of-health-delivery-system-reform-prescription-drug-utilization-and-cost-control-initiatives/>.

¹⁷⁷ MICH. COMP. LAWS ANN. § 400.109h.

¹⁷⁸ HAW. REV. STAT. ANN. § 346-352.

¹⁷⁹ Nat’l Conference of State Legislatures, *Recent Medicaid Prescription Drug Laws and Strategies*, <http://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx> (last updated Jan. 2016).

¹⁸⁰ *Id.*

treat and manage that disease. The success of such an approach often depends on recruiting a limited number of highly qualified professionals to staff these centers of excellence. Any willing provider laws could require Medicaid MCOs to accept all pharmacies, or even potentially all provider types, that are willing to meet the qualification requirements to become a center of excellence.

4. Laws Regulating PBMs and MCOs

Many states have enacted laws regulating the practices of PBMs and Medicaid MCOs that could affect the implementation of APM arrangements for prescription drugs.¹⁸¹ Some states have enacted laws aimed at curbing provisions that require patients to use mail-order pharmacy services.¹⁸² There are also state laws regulating PBM registration and licensure and addressing formulary and drug interchange requirements for PBMs.¹⁸³ Because PBMs utilize various fee arrangements, some states have passed laws governing PBM payment structures.¹⁸⁴ For instance, in Vermont, PBM quotations for an administrative-services-only contract must “include a reasonable fee payable by the health insurer which represents a competitive pharmacy benefit profit.”¹⁸⁵ Some states have laws intended to increase drug pricing and reimbursement transparency. In Maryland, a PBM, before entering into a contract with a purchaser, must inform the purchaser that the PBM may “pass through or retain the manufacturer payments depending on the contract terms with a purchaser.”¹⁸⁶ Another Vermont law, which was recently enacted, requires pharmaceutical manufacturers to provide a justification for price increases for certain prescription drugs.¹⁸⁷ Drug pricing transparency laws could have the unintended consequence of hindering PBM-manufacturer negotiations that a state might want to encourage as part of its APM initiative.

¹⁸¹ PBM Watch. *Pharmacy Benefit Manager Legislation*, <http://www.pbmwatch.com/pbm-legislation.html> (accessed June 13, 2016).

¹⁸² Nat'l Comm. Pharmacists Ass'n. *State Laws Reforming the Practices of Pharmacy Benefit Managers (PBMs)*, 1, 13, 15 (Working Paper), http://www.ncpanet.org/pdf/leg/nov12/pbm_enacted_legislation.pdf (accessed June 13, 2016); Pharmacists United for Truth and Transparency, *State Regulations in Pharmacy Benefit Management*, 1, http://www.approx.com/media/documents/PUTT_State%20Regulations_061713a.pdf (accessed June 13, 2016).

¹⁸³ PBM Watch. *Pharmacy Benefit Manager Legislation*, <http://www.pbmwatch.com/pbm-legislation.html> (accessed June 13, 2016); Pharmacists United for Truth and Transparency. *State Regulations in Pharmacy Benefit Management*, 2-3, http://www.approx.com/media/documents/PUTT_State%20Regulations_061713a.pdf (accessed June 13, 2016); GA. CODE ANN. § 33-64-2.

¹⁸⁴ Pharmacists United for Truth and Transparency. *State Regulations in Pharmacy Benefit Management*, 3, http://www.approx.com/media/documents/PUTT_State%20Regulations_061713a.pdf (accessed June 13, 2016).

¹⁸⁵ VT. STAT. ANN. tit. 18, § 9421(b).

¹⁸⁶ MD. CODE ANN., INS. § 15-1623.

¹⁸⁷ Journal of the Senate 1,986, 2,250-51 (May 6, 2016), <http://legislature.vermont.gov/assets/Documents/2016/Docs/JOURNAL/sj160506>.

It is also common for states to enact legislation related to managed care. State managed care laws establish licensure requirements and address prescription drug benefit design, drug utilization management and review, pharmacy freedom of choice, continuity of care, quality assurance, grievance and appeals, liability, use of mail-order services, and fees arrangements/rates.¹⁸⁸ For instance, Nebraska law states that a medical benefit contract by a health maintenance organization or preferred provider organization providing reimbursement for prescription drugs cannot “require a person to obtain prescription drugs from a mail-order pharmacy as a condition to obtaining reimbursement for such drugs.”¹⁸⁹ As states increasingly rely on MCOs to furnish services to Medicaid beneficiaries, it is vital that state Medicaid agencies understand and structure their prescription drug APM models in accordance with existing state managed care laws.

5. Freedom of Information Laws

Many, if not all, states have freedom of information laws that make certain records available to the public for inspection, unless an exemption or exception applies.¹⁹⁰ These exemptions and exceptions vary by state.¹⁹¹ State freedom of information laws could potentially affect a state APM initiative built around manufacturer supplemental rebates. Manufacturers consider pricing information proprietary and, for this reason, consistently insist on strong confidentiality provisions in their supplemental rebate agreements.¹⁹² Many states provide broad exemptions or exceptions that would protect such information from public disclosure.¹⁹³ For instance, Connecticut clarifies that nothing in its freedom of information act “shall be construed to require disclosure of ... [c]ommercial or financial information given in confidence, not required by statute.”¹⁹⁴ Some states have enacted laws specifically addressing the confidentiality of supplemental rebate agreements.¹⁹⁵ For example, in Florida, the “rebate amount, percent of rebate, manufacturer's pricing, and

¹⁸⁸ Nat'l Conference of State Legislatures. *Managed Care State Laws and Regulations, Including Consumer and Provider Protections*, <http://www.ncsl.org/research/health/managed-care-state-laws.aspx> (last updated Sep. 2011);

Tobin, A.E. (1995). *Pharmacy Managed Care*. *American Health Lawyers Association*;

Acad. of Managed Care Pharmacy. *Pharmacy Practice in Managed Care*, <http://www.amcp.org/slidedecks/> (last updated Dec. 2015).

¹⁸⁹ NEB. REV. STAT. ANN. § 44-513.02.

¹⁹⁰ See, e.g., ALASKA STAT. ANN. § 40.25.110; CAL. GOV'T CODE § 6253; Francis M. Dougherty et. al., *State Freedom of Information Acts*, 15 FED. PROC., L. ED. § 38:21 (last updated June 2016); Patricia E. Salkin, *Sunshine Acts: Open Meetings and Freedom of Information Laws*, 1 AM. L. ZONING § 3A:20 (5th ed.)(last updated May 2016).

¹⁹¹ Patricia E. Salkin, *Sunshine Acts: Open Meetings and Freedom of Information Laws*, 1 AM. L. ZONING § 3A:20 (5th ed.)(last updated May 2016).

¹⁹² See e.g., Sections 7.1-7.4 of the National Medicaid Pooling Initiative (“NMPI”) Supplemental Drug Rebate Agreement between the State of Michigan, Department of Community Health, Manufacturers, and Magellan Medicaid Administration, Inc, available at http://www.providersynergies.com/services/documents/NMPI_2015_Supplemental_Drug_Rebate_Agreement.pdf

¹⁹³ See generally Nat'l Freedom of Info. Coal., *State FOI Resources*, <http://www.nfoic.org/state-foi-resources> (accessed June 13, 2016).

¹⁹⁴ CONN. GEN. STAT. ANN. § 1-210(b)(5)(B).

¹⁹⁵ See, e.g., W. VA. CODE ANN. § 9-5-15.

supplemental rebate, and other trade secrets as defined in [a Florida statute] that the agency has identified for use in negotiations, held by the Agency for Health Care Administration... are confidential and exempt from” Florida’s public record disclosure law.¹⁹⁶ Notwithstanding, state freedom of information laws might be drafted so broadly to encompass non-pricing terms in supplemental rebate agreements that manufacturers consider to be propriety.

F. Multiple Discounts

Manufacturers might have rebate or discount obligations to multiple parties simultaneously. Those obligations might be tied to a specific drug, payer, patient group, provider, pharmacy, or combination. If a drug is already subject to one rebate or discount, a manufacturer might be loath to agree to additional discounts or rebates on the same drug unless there are assurances that it will not be subject to multiple discounts.

Manufacturers routinely encounter some known duplicate discount scenarios. A duplicate discount might occur any time a drug is subject to a Medicaid rebate and some other rebate or discount simultaneously. As described in Section I, a discounted drug bought by a 340B covered entity and billed to Medicaid would result in a duplicate discount if the state sought a rebate on the drug. Congress recognized this risk and established statutory safeguards for drugs billed to fee-for-service Medicaid and those billed to Medicaid MCOs.¹⁹⁷ If a drug covered by a PBM is also covered by Medicaid as a secondary payer, and if the PBM has negotiated rebates with the manufacturer of that drug, a drug would be subject to duplicate discounts. In this case, one of the two discounts was negotiated voluntarily rather than mandated by law.

The duplicate discount risk is not limited to the MDRP. If a 340B drug is billed to a state AIDS Drug Assistance Program (ADAP), which can be eligible for its own retrospective 340B rebate, the manufacturer could be subjected to two 340B discounts. Vaccines are outside the scope of the MDRP, but could still be subject to PBM rebates, state-negotiated rebates, or voluntarily given 340B discounts.

One state appears to have encountered a situation in which existing manufacturer rebate obligations to PBMs prevented it from negotiating its own supplemental rebate agreements. In April 2015, New York passed a law that authorized the state to enter into supplemental rebate negotiations with manufacturers of hepatitis C virus and HIV/AIDS retroviral treatments.¹⁹⁸ The law simultaneously barred manufacturers of such products from paying supplemental rebates to an

¹⁹⁶ FLA. STAT. ANN. § 409.91196.

¹⁹⁷ See 42 U.S.C. § 256b(a)(5)(A); SSA § 1927(j)(1).

¹⁹⁸ N.Y. SOC. SERVS. LAW § 367-a(7)(e).

MCO or its agents when the state is collecting rebates on the same drugs.¹⁹⁹ Because the state has inherent authority to enter into supplemental rebate negotiations, the statute’s primary purpose was presumably to remove the risk of duplicate discounts to create more favorable negotiating conditions for the state.

G. Practical Constraints

There are also multiple practical constraints that state Medicaid agencies might encounter when structuring APMs, especially if they involve changes in payment or participation requirements with providers, pharmacies, and MCOs. These constraints relate to a state’s ability to solicit stakeholder cooperation and access clinical effectiveness and outcomes data.

1. Stakeholder Cooperation

Not unlike other delivery system or payment reform initiatives, in order to implement an APM or to engage in value-based purchasing, state Medicaid agencies must work with relevant stakeholders and may need to obtain statutory authorization to proceed from their legislature. States will need to negotiate with the pharmacies, hospitals, and MCOs that would need to adjust their operations to accommodate an APM or VBP initiative. States also might be venturing into fields in which other stakeholders already have complicated arrangements among themselves. A state Medicaid agency likely cannot control the interparty relationships that exist prior to the implementation of a new prescription drug program. When such arrangements exist, as in the New York supplemental rebate example described above, the agency might need legislative or administrative action to take a seat at the table. If a state has an “any willing pharmacy” or “dispense as written” law that prevents certain APM or VBP arrangements, it may need to go through the legislative process in order to relax implementation barriers.

The Medicaid program is jointly administered by states and the federal government. Depending on the APM approach, implementation will likely require varying levels of federal oversight and/or approval. Most APM strategies will need approval from CMS through the submission of a SPA or waiver. Prior authorization programs, purchasing pools, payment changes, and manufacturer risk-sharing arrangements generally need approval from CMS through a SPA.²⁰⁰

¹⁹⁹ *Id.*

²⁰⁰ See CMS, *State Medicaid Director Letter 04-006* (Sept. 9, 2004), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd090904.pdf>; CMS, *State Medicaid Director Letter 16-001* (Feb. 11, 2016), <https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf>.

2. Access to Clinical Data and Other Information

States are also constrained by challenges related to accessing clinical effectiveness and outcomes data needed to implement some of the health outcome-based arrangements described in Section I. These are the same challenges encountered when implementing other initiatives, such as clinical performance measures for primary care medical home programs, when clinical information is needed that is not normally included in fee-for-service claims or managed care encounter data. CMS requires states to cover all drugs under their State Plans, which includes all drugs for which a manufacturer has entered into a rebate agreement with CMS, without regard to clinical effectiveness for particular indications except as to whether the drug has a “significant, clinically meaningful therapeutic advantage in terms of safety.”²⁰¹ To effectuate health outcome-based APMs, clinical data must be available to make determinations for which drugs are more effective at treating particular conditions for Medicaid patients.

Medicaid agencies also might operate at an information deficit compared to other stakeholders. The confidentiality of AMP and Best Price is protected by statute, but other business terms might be made confidential by contract. For example, a PBM rebate agreement might include heavy penalties if the PBM discloses the terms of the agreement to any outside parties. Manufacturer rebate and risk-sharing agreements will undoubtedly include strong nondisclosure provisions. These contract restrictions could, for example, prevent states from learning the precise supplemental rebates negotiated by other states.

IV. State APM Opportunities: Seven Legal Pathways

CMS is clearly a proponent of prescription drug value-based purchasing programs and has signaled its support for their use in the Medicaid program. For example, in the preamble to the covered outpatient drug rule, CMS stated:

*[C]ertain arrangements, such as VBP agreements, may benefit patients and these and others can adjust prices available from the manufacturer. CMS is considering how to provide more guidance on these arrangements.*²⁰²

More recently, CMS issued an MDRP release devoted entirely to VBP arrangements and their impact on Best Price.²⁰³ The notice encourages states to enter into VBP arrangements to address high-cost prescription drug treatments and, more specifically, to consider negotiating supplemental rebates

²⁰¹ SSA § 1927(d)(4)(C).

²⁰² Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,253.

²⁰³ CMS. *Medicaid Drug Rebate Program Notice, Release No. 176* (July 14, 2016), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-176.pdf>

with manufacturers on both fee-for-service and managed care drugs because such arrangements would be excluded from Best Price determinations.²⁰⁴

These communications reflect an awareness that prescription drug VBP arrangements can play an important role in the Medicaid program, and they begin to provide guidance to states on how to take advantage of VBP opportunities. It is unclear whether the agency will allow further innovation within the MDRP and the Medicaid program more generally to facilitate value-based purchasing and APM arrangements in the future. However, like other innovative initiatives that state Medicaid agencies have undertaken, a request for a SPA or waiver can begin a discussion with CMS that eventually leads to a new model of prescription drug coverage and payment that both the state and CMS can support.

In the preceding sections, we identified commonly used tools for managing prescription drug costs, tying payment to drug performance and enhancing clinically effective utilization of medications. We also identified provisions within the MDRP and other factors that could facilitate or impede state efforts to implement APMs. In this section, we evaluate the opportunities and obstacles that states encounter in trying to use these APM and VBP tools to advance alternative purchasing practices. We have identified seven legal pathways for developing APMs that appear to offer significant opportunities for states:

1. Supplemental rebate arrangements;
2. MCO contracting;
3. MCO/340B covered entity partnerships;
4. Hospital-dispensed covered outpatient drugs;
5. Physician administered drugs that fall outside the definition of a “covered outpatient drug”;
6. Section 1937 alternative benefits plans; and
7. Section 1115 waivers.

In addition to describing each pathway, we assess the pathway’s strengths and weaknesses. The approach taken in each of the legal pathways described below varies significantly. Pathway One builds upon existing state authority to negotiate supplemental rebates, an MDRP tool currently used

²⁰⁴ *Id.* Likewise, in March 2015, CMS described the launch of biosimilars as a “unique opportunity to achieve measurable cost savings and greater beneficiary access” by providing “biologics that achieve desirable, cost-effective clinical outcomes for beneficiaries using the various drug utilization and cost management tools they have available (e.g., step therapy, prior authorization, preferred drug lists) to the extent such tools are consistent with the state plan.” Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,253.

by almost every state Medicaid program to gain additional rebate revenue from drug manufacturers. Based on the above CMS release encouraging states to negotiate supplemental rates as part of a VBP initiative, CMS would likely support a state's use of Pathway One to establish an APM. A state's right to negotiate supplemental rebates under the MDRP is also the basis of Pathway Two, although the task of negotiating with manufacturers is outsourced by the state to its managed care contractors. In states that include their prescription drug benefit in managed care contracts, the ability to implement prescription drug APM opportunities under Pathway Two depends heavily on the ability of the state's MCO and PBM partners to bring manufacturers to the negotiating table. Pathways One and Two can be used together if a state chooses to carve one or more therapeutic drug classes out of their managed care contracts in order to negotiate directly with manufacturers. The remaining five pathways take a different approach. They are structured to allow states to negotiate alternative payment arrangements outside of the MDRP, either in whole or in part. Pathways Three and Four are based on explicit statutory exceptions to the MDRP. The MDRP statute only applies to "covered outpatient drugs," so Pathway Five focuses on opportunities relating to prescription drugs that fall outside the statute's definition of a "covered outpatient drug."²⁰⁵ Pathway Six relies on the Secretary of HHS's authority to approve differing benefit packages for certain groups of Medicaid enrollees, and Pathway Seven relies upon the Secretary's authority to waive MDRP requirements and other Medicaid provisions.

It is worth noting that the seven pathways are not necessarily mutually exclusive. Some are more appropriate for a narrow class of drugs and others can be used more broadly. For example, Pathways One and Seven could be applied to virtually any group of drugs covered by a state plan, whereas Pathways Two and Three are limited to MCO-covered drugs, and Pathway Five applies only to physician-administered drugs. In designing a specific prescription drug APM, a state could choose to combine two or more of the pathways presented below or limit its APM to only one of the pathways.

A. Pathway One: Supplemental Rebate Arrangements

We have described how states, either individually or through multistate purchasing groups, are expressly authorized under the MDRP to enter into supplemental rebate agreements with manufacturers and how supplemental rebates are excluded from Best Price determinations. These agreements require manufacturers to pay rebates that supplement the statutory rebates they are obligated to pay under their MDRP rebate agreements with the Secretary. Apart from being subject to CMS approval, supplemental rebate arrangements are largely unregulated, allowing states and manufacturers to negotiate terms and conditions designed to implement the health outcome-based and financial-based APM arrangements described in Section I. Pathway One seeks to take advantage of this opportunity by using the tools underlying supplemental rebate arrangements

²⁰⁵ SSA § 1927(a), (k)(2)-(3).

(prior authorization, PDLs, generic and therapeutic substitution, etc.) to negotiate broader and more creative supplemental rebate agreements. It is premised on the notion that states would do better by using their supplemental rebate authority to develop strategic and collaborative APM relationships with manufacturers rather than using such authority for the sole purpose of procuring more rebate revenue.

Ever since enactment of the ACA, states have been entitled to receive MDRP statutory rebates on covered outpatient drugs paid for by Medicaid MCOs, not only those reimbursed on a fee-for-service basis. Extension of the MDRP to drugs purchased through MCOs, most of which are reimbursed by PBMs on behalf of MCOs, means that states now have an opportunity to negotiate supplemental rebates on such drugs. Challenges arise, however, in trying to take advantage of this opportunity. Most PBMs have existing manufacturer rebate arrangements for their various lines of business, including their Medicaid managed care business. Manufacturers paying rebates under those arrangements might be reluctant to pay supplemental rebates to state Medicaid programs. Already obligated to pay an above-market statutory rebate under the MDRP, and contractually bound to pay the PBM rebate, manufacturers might have little appetite to negotiate another rebate on the same drug. In an effort to launch an MCO supplemental rebate program, states can try to prevent PBMs from collecting rebates on Medicaid MCO drugs, similar to what the New York legislature did last year for hepatitis C and HIV drugs. New York used a legislative approach to address the multiple discount problem that arises when a state seeks supplemental rebates on MCO drugs, but states can try using the MCO contracting process to achieve the same goal.

It is important to point out that the APM approach reflected in Pathway One is focused on alternative purchasing arrangements with manufacturers rather than on alternative payment arrangements with health care providers. States' supplemental rebate authority does not afford new and innovative ways for states to structure drug coverage and payment to pharmacies that they, in turn, can use to improve patient outcomes and to control costs. Under CMS's recent covered outpatient drug rule, covered outpatient drugs reimbursed on a fee-for-service basis must be reimbursed at AAC and state AAC rates must be based on invoice data. So, states that pay for drugs on a fee-for-service basis have little discretion to adjust drug ingredient reimbursement to pharmacies in an effort to incentivize pharmacies to engage in medication therapy management, patient compliance and other outcome-based programs. There is no room to experiment with pharmacy dispensing fees either because they too must be based on actual cost. The only potential area for innovation is if the state is permitted under the state plan to pay pharmacists separately for their professional services. Otherwise, the areas of opportunity for APMs are limited to mail-order specialty drugs, drugs administered by physicians in hospitals and clinics, or drugs covered through a Medicaid MCO. The AAC reimbursement rule does not apply to these three categories of covered outpatient drugs, so state APM initiatives would have to focus on one or more of them for prescription drug purchasing.

Assuming the state can work with its MCOs and their PBMs to navigate the aforementioned multiple discount risk, we do not believe there are any significant federal impediments to establishing an

APM based on Pathway One. Rebates paid under supplemental rebate agreements are expressly excluded from Best Price determinations if they are “CMS-authorized.”²⁰⁶ Supplemental rebate arrangements pose little AKS risk because the only party that a manufacturer could potentially induce is the state Medicaid agency itself. Similarly, it is unlikely that supplemental rebate discussions, even when the rebates are indication specific, would constitute “promotion” of an off-label use of a drug. Certain state laws like those exempting one or more categories of drugs from prior authorization or the state Medicaid PDL or requiring disclosure of negotiated rebate terms that manufacturers might consider to be proprietary could have a chilling effect on negotiations, but most state laws are not so intrusive. Ultimately, the most significant question is whether the state has the requisite tools and leverage to negotiate an APM supplemental rebate arrangement that manufacturers will find sufficiently attractive to support making payments above and beyond the MDRP rebate.

B. Pathway Two: MCO Contracting

Pathway Two is similar to Pathway One but is designed to take advantage of the greater flexibility and experience that Medicaid MCOs offer in negotiating alternative payment arrangements with manufacturers and providers. Because AAC reimbursement under the covered outpatient drug rule does not apply to drugs purchased through MCOs, MCOs have more flexibility than states to reimburse covered outpatient drugs in a manner that rewards pharmacies for engaging in outcome-based best practices. Such authority allows them to establish alternative value-based payment models for retail drugs that states are precluded from pursuing in the fee-for-service setting. Pathway Two is also structured to take advantage of the significant experience that PBMs have in negotiating APM arrangements with manufacturers on behalf of private non-Medicaid payers. Under Pathway Two, states would delegate to the PBMs the task of negotiating the states’ supplemental rebates in lieu of the PBMs’ own rebates. Of course, this approach would require delicate negotiations in contracting with the MCOs because the terms of an MCO-based supplemental rebate program would have to be incorporated into the MCO’s subcontract with the PBM.

In considering the viability of an APM based on Pathway Two, a state must consider at the outset how to structure the PBM’s supplemental rebate arrangement in a manner that does not adversely affect a manufacturer’s Best Price. PBM rebates are historically included in a manufacturer’s Best Price calculations, so it would be understandable if most manufacturers hesitated to entertain a PBM supplemental rebate proposal for fear of setting a new Best Price. In this case, though, the rebates would be passed through to the Medicaid program, either directly to the state Medicaid agency or indirectly through the MCO. They would therefore qualify for the explicit Best Price exemption applicable to PBM rebates that are not designed to adjust prices at the retail or provider

²⁰⁶ 42 C.F.R. § 447.505(c)(7).

level.²⁰⁷ The PBM would stand to lose money by forfeiting its own rebates in order to negotiate rebates for the state, but the PBM's increased costs could presumably be addressed through the managed care rate-setting process. The state could adjust the per member per month (PMPM) prescription drug cost estimates to account for the PBM's lost rebates.

PBMs have significant experience working with Medicaid managed care populations. When operating in the Medicaid program, PBMs are subject to the same legal restrictions applicable to state Medicaid agencies, and therefore are unable to employ many of the negotiating tools available to them in the private sector. For example, they cannot establish a closed formulary or implement a prior authorization program that deviates from the MDRP requirements governing coverage and reimbursement of fee-for-service drugs.²⁰⁸ They have to adhere to Medicaid regulations setting limits on patient cost-sharing.²⁰⁹ Although the MDRP statute permits limits on the number of prescriptions that a patient can receive in a given month, the number of pills that can be dispensed, and the number of refills per prescription, such limits can only be established for purposes of discouraging waste or preventing fraud and abuse.²¹⁰ PBMs would have to comply with the same standards.²¹¹ Given these restrictions, and given the inherent difficulty of convincing a manufacturer to make a payment in addition to a statutory rebate that already exceeds in size most commercial PBM rebates, PBMs might not be able to deliver the same kinds of APM arrangements that they are accustomed to negotiating for themselves.

It is unclear whether supplemental rebate agreements established under Pathway Two are subject to CMS approval. Neither the MDRP statute nor its implementing regulations address whether CMS must review, let alone approve, a supplemental rebate agreement negotiated by a PBM on a state's behalf. Given that CMS could seek to exert its regulatory authority over such agreements, and to that end threaten to include PBM-negotiated supplemental rebates in a manufacturer's Best Price calculations unless the underlying agreement is "CMS-authorized," states interested in Pathway Two should try to clarify the impact of Best Price by initiating a dialogue with CMS as early as possible.

Like Pathway One, we see minimal risk under the federal AKS and FDA's off-label promotion regulations. The relevant risks are somewhat elevated due to the private status of the PBM and MCO, compared to the governmental status of a state Medicaid agency, although the PBM and MCO are negotiating with manufacturers as agents of the state. Last, states regulate MCOs and PBMs in a wide range of ways that might make an APM supplemental rebate arrangement less attractive to manufacturers. Laws affecting PBM pricing transparency and permissible fee arrangements serve

²⁰⁷ *Id.* § 447.505(c)(17).

²⁰⁸ *Id.* § 438.3(s)(1).

²⁰⁹ *Id.* § 438.108.

²¹⁰ SSA § 1927(d)(6).

²¹¹ 42 C.F.R. § 438.3(s)(1).

as good examples. Pathway Two is generally more susceptible to state law interference and enjoys less protection under the Supremacy Clause because it is more of a private sector solution than Pathway One.

C. Pathway Three: MCO/340B Covered Entity Partnerships

Section 1927(j) of the Social Security Act establishes two explicit MDRP exemptions for covered outpatient drugs that, in the absence of the exemptions, would be subject to the full range of MDRP requirements. The first exemption, found in 1927(j)(1) ((j)(1) Exemption), was created to protect drug manufacturers from providing both a discount and an MDRP rebate on a drug purchased through the federal 340B drug discount program. It provides that manufacturers are not required to pay an MDRP rebate on drugs purchased through the 340B program and paid for by an MCO.²¹² The (j)(1) Exemption covers the entire MDRP statute, not only the rebate requirements.²¹³ The second exemption was established under Section 1927(j)(2) ((j)(2) Exemption) and serves as the basis of Pathway Four, which is discussed in the next section.

The (j)(1) Exemption only applies to drugs purchased through the federal 340B drug discount program. The 340B program allows certain types of safety net providers, called “covered entities,” to purchase covered outpatient drugs at substantially discounted prices.²¹⁴ Often these providers pay less than the amount state Medicaid agencies pay, even after the MDRP rebate is factored in. 340B program covered entities include federally qualified health centers, disproportionate share hospitals, children’s hospitals, clinics funded by the Ryan White HIV/AIDS Program, and hemophilia treatment centers, among other safety net providers. Some of these providers treat large and diverse Medicaid populations, some focus on specific conditions, and some do both.

Congress included language in the 340B and MDRP statutes to protect manufacturers from providing a 340B discount and paying an MDRP rebate on the same drug. When fee-for-service Medicaid pays for the drug, the covered entity cannot bill Medicaid for a drug purchased through the 340B program unless the state has a mechanism for ensuring that it will not seek a rebate on the drug.²¹⁵

²¹² SSA § 1927(j)(1).

²¹³ *Id.*

²¹⁴ The MDRP and the 340B program are intertwined because both define “covered outpatient drug” by reference to the MDRP statute.

²¹⁵ 42 U.S.C. § 256b(a)(5)(A).

If a Medicaid MCO is paying for the drug, the drug is not subject to the MDRP statute if it was purchased through the 340B program.²¹⁶ Congress added the (j)(1) Exemption to the MDRP statute to perform the latter function (i.e., to protect manufacturers from giving both the MDRP statutory rebate and a 340B discount on Medicaid MCO drugs).

Besides protecting manufacturers from the duplicate discount risk associated with 340B drugs paid for by MCOs, the (j)(1) Exemption entirely removes such drugs from regulation under the MDRP. The (j)(1) Exemption therefore creates an opportunity for state Medicaid agencies to experiment with APMs outside of the MDRP's constraints. The (j)(1) Exemption is triggered when two events coincide: (1) a covered entity purchases a drug through the 340B program; and (2) the drug is "dispensed" by a Medicaid MCO.²¹⁷ CMS has interpreted the word "dispensed" to mean "paid for."²¹⁸ If the exemption is triggered, the drugs in question "are not subject to the requirements" of the MDRP statute.²¹⁹

Perhaps the most significant advantage of Pathway Three is that the drugs in question are already purchased at discounted prices that approximate, and in many cases are less than, the prices the state pays after receiving the MDRP rebate. Thus the pathway is less dependent on replacing the MDRP rebate revenue. This means that states can focus their APM negotiations with the manufacturers on patient outcome and quality of care measures and worry less about the size of their rebates. It should also reduce the state's administrative costs in seeking the rebate and managing manufacturer rebate disputes.²²⁰ The state and the MCO would have to exercise some discretion, however, when deciding how much of the 340B discount covered entities must pass through to the MCOs. If the 340B drugs are paid at AAC or at a rate deemed unsatisfactory to the 340B covered entities, they might choose to "carve out" Medicaid and use non-340B drugs when treating Medicaid MCO enrollees. Except in limited circumstances, 340B covered entities may choose when to use 340B drugs to treat a patient. States and MCOs would need to establish

²¹⁶ SSA § 1927(j)(1). State Medicaid agencies have a responsibility to identify 340B drugs billed to MCOs and ensure that they do not seek a rebate on those drugs. The agency must require the MCO to identify 340B claims in its utilization data. Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. at 27,545-48. Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,273-74. States are grappling with how to best accomplish this, with proposed solutions including requiring the 340B entities to use non-340B drugs for MCO enrollees, having 340B entities identify 340B drugs retrospectively so the state can remove them from rebate claims, using third party clearinghouses to identify 340B claims, and mandating the use of certain point-of-sale or point-of-billing modifiers to indicate that 340B drugs were used.

²¹⁷ SSA § 1927(j)(1).

²¹⁸ See Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. at 27,546.

²¹⁹ SSA § 1927(j)(1).

²²⁰ Note that some administrative burden would remain to remove the 340B claims from the other rebate claims. Also, the availability of the pathway would be both payer-dependent (only when an MCO is the payer) and drug-dependent (only when 340B drugs are used).

reasonable 340B payment rates because the (j)(1) Exemption only applies when 340B drugs are used.

Pathway Three offers several additional advantages. MCO 340B drugs are not regulated under the MDRP as a result of the (j)(1) Exemption. States are therefore liberated from the MDRP requirements preventing them from establishing closed formularies, setting different prescription limits, varying rebate amounts based on indication or linking payment to a drug's clinical performance. States and manufacturers have broader latitude to negotiate creative and mutually beneficial APM agreements. There is an explicit Best Price exemption for 340B drugs, so the risk of establishing a new Best Price should not interfere with negotiations.²²¹ Pathway Three also allows for innovative pharmacy payment models because the drugs would not be subject to AAC reimbursement standards. Last, CMS approval would not be required unless the state chooses to couple its APM initiative with broader reforms requiring a SPA or waiver.

Opportunities under Pathway Three can only be implemented in a managed care environment, so the pathway is likely to be attractive in only those states that operate, or plan to establish, large managed care programs. Manufacturers would be at higher risk of violating AKS or FDA off-label promotion requirements because the manufacturer's negotiations would be with commercial entities rather than the state itself. The risk would nonetheless be quite low because the MCOs and the PBMs would be acting on behalf of the state. CMS review and approval of APM agreements with manufacturers would reduce the risk even further. The previously discussed state law and contract drafting risks applicable to MCOs and PBMs would apply equally to Pathway Three arrangements. In addition, states would benefit from having a strong working relationship with the 340B provider community. Toward that end, the state and MCOs might want to concentrate their APM and VBP efforts on a subset of the 340B community and try to recruit a targeted group of hospitals and clinics to establish one or more centers of excellence. This strategy would trigger CMS review to address patient freedom-of-choice limitations and could be affected by state any willing provider laws.

D. Pathway Four: Hospital-Dispensed Covered Outpatient Drugs

Just as Pathway Three is built around the (j)(1) Exemption, Pathway Four is based on the (j)(2) Exemption. It applies to hospitals that dispense covered outpatient drugs using formulary systems, and bill Medicaid at no more than the hospital's purchasing cost for the drug.²²² The statute states that the state's Medicaid plan "shall provide" that a hospital billing such drugs "shall not be subject to the requirements of this section."²²³ Although the statute could be read to exempt hospitals from the MDRP rather than the drugs billed by those hospitals, CMS has interpreted the (j)(2) Exemption

²²¹ Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,256.

²²² SSA § 1927(j)(2).

²²³ *Id.*

to mean that the drugs themselves are not subject to the rebate requirement.²²⁴ Virtually every hospital buys drugs using a formulary, so as long as they bill the drugs at no more than their purchasing costs, a requirement states could add to their state plans, such drugs would appear to fall within the (j)(2) Exemption.

The scope of the (j)(2) Exemption is not entirely clear, and CMS has only interpreted it in the face of litigation.²²⁵ On the one hand, the (j)(2) Exemption is a clean slate, and CMS is not restricted by how it has looked at the provision previously. On the other hand, the public has no way of knowing whether CMS might be willing to allow states to employ the exemption. There are several issues in need of clarification:

- What constitutes a “formulary system?”
- Can the pathway be implemented through an MCO? The exemption refers to billing under the Medicaid state plan, which could be read to include both fee-for-service and managed Medicaid.
- Is “purchasing cost” the same as AAC? The term suggests that Congress intended to include not only the ingredient cost of the drug, but also the costs associated with acquiring the drug.
- Does the reference to “hospitals” mean that only physician-administered medications could be exempted, or does the exemption extend to drugs dispensed by in-house retail pharmacies?
- How are “hospitals” defined? States may want to include in that term integrated delivery systems built around a hospital.

Pathway Four has the potential of offering many of the advantages of Pathway Three described above. Because the manufacturer rebate arrangements would not be governed under the MDRP, rebates could be indication specific and adjustable. Value-based provider payment innovation would also be possible for hospital physician-administered drugs. Importantly, most of the hospitals serving a large numbers of Medicaid beneficiaries are likely to be enrolled in the 340B Program. By only having to pay hospital purchasing costs, states would have an opportunity to reduce their drug expenditures to levels comparable to or below their current expenditures under the MDRP. This, in turn, would free them to pursue health outcome-based APM arrangements that do not involve

²²⁴ See CMS. *MDRP Release No. 153* (Oct. 16, 2009), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-153.pdf>; see also Safety Net Hospitals for Pharm. Access (now known as 340B Health), *CMS Clarifies NDC Reporting Requirements* (Nov. 3, 2009), http://www.340bhealth.org/files/ndc_packet.pdf.

²²⁵ Safety Net Hospitals for Pharm. Access (now known as 340B Health), *CMS Clarifies NDC Reporting Requirements* (Nov. 3, 2009), http://www.340bhealth.org/files/ndc_packet.pdf.

payment of large rebates. Relief from the pressure of having to negotiate deep rebates is especially important for the drugs billed by non-340B hospitals because, for reasons discussed in connection with Pathway Two, the state-negotiated rebates associated with such drugs might be included in a manufacturer's Best Price.

If CMS clarifies the (j)(2) Exemption in a manner that allows for its use in a managed care environment, Pathway Four could be attractive to all states, not only those with large fee-for-service programs. It might also complement use of Pathway Three so that a state can capitalize on alternative purchasing and payment opportunities for all hospital drugs (both 340B and non-340B), and 340B clinic drugs covered by an MCO. As with the other pathways, dependence on MCOs and PBMs to negotiate and implement alternative payment relationships with manufacturers and providers carries risks. The same risks, both federal and state, would apply here.

E. Pathway Five: Physician Administered Drugs That Fall Outside the Definition of "Covered Outpatient Drug"

The MDRP, and the restrictions it imposes on drug coverage, only apply to "covered outpatient drugs." The definition of covered outpatient drugs is broad, encompassing all prescription drugs, biologics (other than vaccines), and insulin.²²⁶ The definition is narrowed by a "limiting definition," which provides that the term:

...does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

- Inpatient hospital services.
- Hospice services.
- Dental services.
- Physicians' services.
- Outpatient hospital services.
- Nursing facility services and services provided by an intermediate care facility for the mentally retarded.
- Other laboratory and x-ray services.
- Renal dialysis.

²²⁶ SSA § 1927(k)(2).

The term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication.²²⁷ The limiting definition provides a potential opportunity for Medicaid agencies to experiment with APM arrangements, free of the constraints of the MDRP.

The scope of Pathway Five is narrower than that of the other seven pathways because it only applies to drugs that are not separately billed and reimbursed within a state's Medicaid program. Virtually every drug dispensed in the retail setting is separately billed and paid for by Medicaid, so Pathway Five would be limited to drugs administered by a physician or a nurse or other professional operating under a physician's supervision. States have a strong incentive to consider these physician-administered drugs to be covered outpatient drugs because they become rebatable under the MDRP if they have covered outpatient drug status. For this reason, we suspect that Pathway Five would only be appealing for a narrow category of physician-administered drugs. The state would have to be willing to surrender its MDRP statutory and supplemental rebates in exchange for the right to negotiate an APM arrangement outside the limitations of the MDRP. State officials would have to feel confident that, by applying a closed formulary and using other promising APM strategies not permitted under the MDRP, they could negotiate rebates comparable to those available through the MDRP and/or establish attractive health outcome-based arrangements justifying lower rebate amounts.

As far as we know, Pathway Five is untested, probably because it runs counter to the prevailing wisdom among states and CMS of trying to qualify as many drugs as covered outpatient drugs as possible in order to apply clinical prior authorization criteria and to maximize rebate revenue under the MDRP. The approach works if the drugs can be paid for as part of a broader set of services. Among these drugs, the most suitable would be those for which the value of the forfeited MDRP rebates is outweighed by the potential benefits of improving patient outcomes, avoiding waste, reducing utilization of costly health services such as hospitalizations, or achieving other kinds of value-based goals. It therefore lends itself to use in conjunction with provider payment models built around specific disease states or episodes of care that involve the administration of drugs that generally have low rebate value but high patient outcome potential. Provider payments could themselves be structured to create incentives for value-based patient care because they would not be subject to AAC limitations. The AAC reimbursement rule only applies to covered outpatient drugs.

The novelty of Pathway Five also has its disadvantages. There is no clear Best Price exemption for payments made by manufacturers under a Pathway Five approach. In fact, drugs that would otherwise be covered outpatient drugs if not for the limiting definition "shall be treated as a

²²⁷ SSA § 1927(k)(3).

covered outpatient drug for purposes of determining the best price...for such drug.”²²⁸ Any rebates negotiated for such drugs would be included in Best Price unless an exemption applies. If the rebates are negotiated by a PBM rather than the state, they would appear to qualify for the exemption applicable to PBM rebates since they would not be used to adjust drug prices at the provider level.²²⁹ The same line of reasoning should exempt rebates negotiated directly by the state. APM negotiations undertaken by PBMs and MCOs would be in their capacity as agents of the state, so it would make no sense if a Best Price exemption applies to the APM rebates when negotiated by the PBM or MCO but not by the state itself. CMS might be willing to exempt state-negotiated rebates if the underlying rebate agreement is “CMS-authorized,” similar to a supplemental rebate agreement.²³⁰ So the need for CMS support for a Pathway Five approach seems inevitable, either because the state would need CMS to clarify that manufacturer payments negotiated under the pathway are exempt from Best Price or because the APM agreements with the manufacturers would need formal CMS approval.

It is also unclear whether a Pathway Five APM strategy could be implemented in a managed care environment. Presumably, for a physician-administered drug to fall outside of the covered outpatient drug definition, it should not matter whether the bundled disease state or episode-of-care payment is made by an MCO or the state. To ensure that the physician-administered drug is not separately billed and reimbursed by the MCO, the state would have to include clear directives in its MCO contract.

Implementing this approach through MCOs could be affected by state laws regulating MCOs and PBMs, as previously discussed. Alternatively, the states could choose to carve out the relevant services and payments from their MCO contracts. That way, the benefit would be administered by the states rather than the MCOs. Regardless, APM negotiations could be affected by state prior authorization or freedom of information laws similar to Pathways One and Two.

Manufacturers of drugs targeted for a Pathway Five APM could be receptive to entering into risk-sharing contracts and other kinds of alternative payment arrangements because they would be relieved of their rebate obligations under the MDRP. The parties would be free to negotiate rebates that are indication specific and adjustable based on whether the drugs improve outcomes or otherwise perform well according to APM benchmarks. Moreover, by paying for services in a way that includes payment for the drugs provided incidental to those services, states give themselves an additional opportunity to create incentives for providers to coordinate the range of services

²²⁸ *Id.*

²²⁹ See Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,253; 42 C.F.R. § 447.505(c)(17); CMS, MDRP Release No. 28 (Apr. 28, 1997), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-028.pdf>; CMS, MDRP Release No. 29 (Jun. 5, 1997), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-029.pdf>.

²³⁰ See 42 C.F.R. § 447.505(c)(7).

furnished to the patient, to use clinically effective drugs, and to ensure patient compliance with treatment and drug regimens. Manufacturers might be encouraged to pursue Pathway Five APM arrangements for the same reasons. On the other hand, such drugs also could be subject to multiple discounts if, for example, they have been purchased through the 340B program or a group purchasing organization or are eligible for a commercially negotiated PBM rebate, which in turn could dampen a manufacturer’s enthusiasm to pursue an APM arrangement with the state.

F. Pathway Six : Section 1937 Alternative Benefit Plans

Enacted under the Deficit Reduction Act of 2005, and amended in 2010 by the ACA, section 1937 of the Social Security Act provides states flexibility to develop Medicaid benchmark or benchmark equivalent coverage, now referred to by CMS as “alternative benefit plans” (ABPs).²³¹ States are required to provide Medicaid expansion populations with a benefit package in accordance with ABP standards²³² and can develop ABPs for targeted populations or geographic regions of a state.²³³

Among the required benefits, ABPs must cover essential health benefits (EHBs) defined to include ten categories of health care services, including prescription drugs.²³⁴ For prescription drugs,

²³¹ SSA § 1937(a); CMS. *State Medicaid Director Letter 12-003* (Nov. 20, 2012), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf>; CMS, *Alternative Benefit Plan Coverage*, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/alternative-benefit-plans.html> (last visited June 20, 2016). The following coverages are considered to be benchmark coverage: (1) The standard Blue Cross/Blue Shield preferred provider option service benefit plan offered under the Federal Employee Health Benefits program; (2) a coverage plan that is offered and generally available to the state’s employees; (3) a health insurance coverage plan that is offered by an health maintenance organization (HMO), and “has the largest insured commercial, non-Medicaid enrollment of covered lives of such coverage plans offered by such a [HMO] in the State involved”; and (4) a “Secretary-approved” plan. SSA § 1937(b)(1); 42 C.F.R. § 440.330.

²³² SSA § 1902(k)(1).

²³³ CMS. *State Medicaid Director Letter 12-003* (Nov. 20, 2012), <https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf>; CMS, *Alternative Benefit Plan Coverage*, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/alternative-benefit-plans.html> (last visited June 20, 2016).

²³⁴ SSA § 1937(b)(5). The ten categories of health care services are:

- (1) Ambulatory patient services;
- (2) Emergency services;
- (3) Hospitalization;
- (4) Maternity and newborn care;
- (5) Mental health and substance use disorders, including behavioral health treatment;
- (6) Prescription drugs;
- (7) Rehabilitative and habilitative services and devices, except that such coverage shall be in accordance with § 440.347(d);
- (8) Laboratory services;
- (9) Preventive and wellness services and chronic disease management; and
- (10) Pediatric services, including oral and vision care, in accordance with section 1905(r) of the Act.

42 C.F.R. § 440.347; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1302(b), 124 Stat. 119, 163-65 (2010). The state must also adhere to other applicability and coverage requirements. SSA § 1937(a)(2)(B), (4), (6), (7); 42 C.F.R. §§ 440.315, 440.320, 440.335, 440.345, 440.350, 440.360, 440.365, 440.390, 440.395.

Medicaid ABP EHB standards are defined in reference to EHB standards for health insurance exchange plans requiring coverage of the greater of (1) one drug in every United States Pharmacopeia category and class; or (2) the “same number of prescription drugs in each category and class as the EHB-benchmark plan.”²³⁵ In addition, to the “extent states pay for covered outpatient drugs under their [ABP’s] prescription drug coverage, states must comply with the requirements under section 1927 of the [Social Security] Act.”²³⁶ In the comment and response preamble to the final Medicaid EHB rule, there is a lengthy discussion of the application of section 1927 of the Social Security Act to Medicaid ABPs and EHB coverage standards for prescription drugs.²³⁷ Initially, in the proposed Medicaid EHB rule, CMS suggested a blanket application of Medicaid section 1927 outpatient drug requirements to Medicaid ABPs.²³⁸ In the final rule, however, CMS retracted this position, explaining that it was “over-inclusive,” and clarified that “section 1927 requirements do not apply to ABPs to the extent that they conflict with the flexibility under section 1937 of the Act for states to define the amount, duration, and scope of the benefit for covered outpatient drugs.”²³⁹

Therefore, unlike traditional Medicaid, Medicaid ABPs are not required to cover all drugs from manufacturers that have signed a federal rebate agreement. The flexibility for ABPs allowed under section 1937 trumps section 1927 requirements, and ABPs can design a formulary in compliance with the EHB standards noted above for health exchange plans. To the extent that drugs are included within an ABP formulary, such coverage must comply with section 1927.

The advantage of Pathway Six is that, in general, Medicaid ABPs allow states to define benefit packages that do not follow traditional Medicaid benefit standards. States are afforded flexibility in developing benefit packages for ABPs. “While this flexibility permits states in some instances to limit prescription drug coverage based on the coverage offered under other public employee or commercial plans, it also includes the ability to exceed the amount, duration, and scope of prescription drugs covered under those plans.”²⁴⁰ Further, states can impose certain restrictions

²³⁵ 42 C.F.R. § 440.347(a); 45 C.F.R. § 156.122(a)(1).

²³⁶ 42 C.F.R. § 440.345(f).

²³⁷ Medicaid and Children’s Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment, 78 Fed. Reg. 42,160, 42,219-24 (Jul. 15, 2013).

²³⁸ Medicaid, Children’s Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 Fed. Reg. 4,594, 4,631 (Jan. 22, 2013).

²³⁹ Medicaid and Children’s Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment, 78 Fed. Reg. at 42,219.

²⁴⁰ *Id.*

such as prior authorization.²⁴¹ Additionally, section 1927 of the Social Security Act permits a PDL if it is under a prior authorization program that meets the requirements set forth in section 1927(d)(5) of the Social Security Act.²⁴² In designing ABPs, states “must include prescription drug coverage to at least reflect the EHB- benchmark plan standards, including the requirement to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered.”²⁴³

G. Pathway Seven: Section 1115 Waivers

Section 1115 of the Social Security Act grants the Secretary of HHS the authority to approve experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the Medicaid and children’s health insurance programs.²⁴⁴ Under section 1115 authority, the Secretary can waive federal Medicaid requirements set forth in section 1902 of the Social Security Act governing the state plan.²⁴⁵ This authority also allows the Secretary to provide federal financial participation for costs of the demonstration project which would not otherwise be included as matchable expenditures under section 1903 of the Social Security Act.²⁴⁶ CMS has emphasized that the purpose of section 1115 demonstrations is to “demonstrate and evaluate policy approaches such as: [e]xpanding eligibility to individuals who are not otherwise Medicaid or CHIP eligible; [p]roviding services not typically covered by Medicaid; or [u]sing innovative service delivery systems that improve care, increase efficiency, and reduce costs.”²⁴⁷

Section 1115 demonstration waivers have historically been used to waive provisions of federal law to cover additional low-income families or to engage in broader managed care and payment reform efforts. For instance, Arizona has longstanding 1115 waiver authority to operate its statewide Medicaid managed care system, Arizona Health Care Cost Containment System (AHCCCS).²⁴⁸ More recently, states such as New York, New Jersey, Kansas, Massachusetts, Texas, and California have used section 1115 waivers to implement innovative payment and delivery system reform models—

²⁴¹ *Id.* at 42,223. However, “states must continue to adhere to the requirements that states must respond within 24 hours for pre- authorization requests, except for excluded drugs listed at section 1927(d)(2) of the Act, and that at least a 72-hour supply of a covered outpatient prescription drug must be dispensed in an emergency situation.” *Id.*

²⁴² *Id.*

²⁴³ SSA § 1115(a)(1).

²⁴⁴ SSA § 1115

²⁴⁵ SSA § 1115(a)(1).

²⁴⁶ SSA § 1115(a)(2)(A).

²⁴⁷ CMS, Section 1115 Demonstrations, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/1115/section-1115-demonstrations.html> (last visited June 19, 2016).

²⁴⁸ CMS, Arizona Medicaid Section 1115 Demonstration, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/az/az-hccc-ca.pdf> (amended Dec. 15, 2014).

called Delivery System Reform Incentive Payment Waivers—to improve the health of their Medicaid enrollees, enhance patient experience and outcomes, and manage health care costs.²⁴⁹

Pathway Seven seeks to take advantage of the opportunities authorized under section 1115 of the Social Security Act to implement various APM initiatives. The most significant advantage of Pathway Seven is that the states are afforded considerable flexibility in designing an APM that furthers both their overall value based purchasing goals and the objectives of the Medicaid program. Notably, section 1115 authorizes the Secretary to waive section 1902(a)(54) of the Social Security Act, which provides that any state providing medical assistance for covered outpatient prescription drugs through its Medicaid program must comply with the applicable requirements of section 1927 of the Social Security Act.²⁵⁰ The reference to section 1927 provides the authority for HHS to waive provisions of the MDRP in Medicaid demonstration projects.

To date, HHS waivers of section 1927 through section 1115 demonstration waivers have been limited. A March 2016 search of state section 1115 demonstration waivers identified only six states—Arizona, Arkansas, Iowa, Michigan, New Hampshire and Tennessee—whose waivers extended to a provision within section 1927. The waivers include the following:

- Section 1927(d)(4) of the Social Security Act: This subsection of section 1927 sets out requirements related to state prescription drug formularies, including coverage of outpatient drugs.²⁵¹ However, to date, CMS has approved only modest relaxation of MDRP formulary restrictions. Tennessee’s waiver of this provision allows it to establish a more limited drug formulary in terms of covered medications and limits on the number of prescriptions allowed per month.²⁵² It came about because the state had few limits on drugs before and the cost of prescriptions caused significant concern.²⁵³ After a 25% increase in prescription drug cost in 2004, CMS approved and the state implemented the section 1115

²⁴⁹ Gates, A., Rudowitz, R., & Guyer, J. (2014). An Overview of Delivery System Reform Incentive Payment (DSRIP) Waivers, *KCMU*, <http://kff.org/report-section/an-overview-of-delivery-system-reform-incentive-payment-waivers-issue-brief/>.

²⁵⁰ SSA § 1902(a)(54).

²⁵¹ SSA § 1927(d)(4).

²⁵² See CMS, Demonstrations & Waivers: TennCare II, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/waivers_faceted.html?filterBy=Tennessee (last visited June 19, 2016).

²⁵³ Cleaveland, C. Tennesseans Must Rein in Prescriptions. *Times Free Press* (Mar. 12, 2009), <http://www.timesfreepress.com/news/life/entertainment/story/2009/mar/12/cleaveland-tennesseans-must-rein-prescriptions/211061/>.

waiver amendment to TennCare in 2005,²⁵⁴ limiting clients to five prescription drugs per month subject to certain exceptions.²⁵⁵

- Section 1927(d)(5) of the Social Security Act: This subsection of section 1927 allows a state plan to require the approval of a drug before dispensation for any medically accepted indication only if the system “provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization.”²⁵⁶ Certain waivers permit states to require that requests for prior authorization for drugs be addresses within 72 hours, rather than 24 hours.²⁵⁷ However, a 72-hour supply of the requested medication must be provided in an emergency.²⁵⁸
- Section 1927(g) of the Social Security Act: This subsection of section 1927 requires each state to establish a drug use review program for covered outpatient drugs to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse

²⁵⁴ Division of Health Care Finance & Administration, TennCare Timeline, <https://www.tn.gov/tenncare/article/tenncare-timeline> (last visited June 19, 2016).

²⁵⁵ Cleaveland, C. Tennesseans Must Rein in Prescriptions. Times Free Press (Mar. 12, 2009), <http://www.timesfreepress.com/news/life/entertainment/story/2009/mar/12/cleaveland-tennesseans-must-rein-prescriptions/211061/>.

²⁵⁶ SSA § 1927(d)(5).

²⁵⁷ Arkansas: CMS, Arkansas Health Care Independence Program (Private Option Section 1115 Demonstration), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ar/ar-private-option-ca.pdf> (amended Jan. 1, 2015); Iowa (currently suspended): CMS, Iowa Marketplace Choice Plan Section 1115 Demonstration, <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ia/ia-marketplace-choice-plan-ca.pdf> (amended July 31, 2015); Michigan: CMS, Healthy Michigan Section 1115 Demonstration, <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/mi/mi-healthy-michigan-ca.pdf> (amended Dec. 17, 2015); New Hampshire: CMS, New Hampshire Health Protection Program Premium Assistance (June 23, 2015), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/nh-health-protection-program-premium-assistance-ca.pdf>.

²⁵⁸ Arkansas: CMS, Arkansas Health Care Independence Program (Private Option Section 1115 Demonstration), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ar/ar-private-option-ca.pdf> (amended Jan. 1, 2015); Michigan: CMS, Healthy Michigan Section 1115 Demonstration, <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/mi/mi-healthy-michigan-ca.pdf> (amended Dec. 17, 2015); New Hampshire: CMS, New Hampshire Health Protection Program Premium Assistance (June 23, 2015), <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/nh-health-protection-program-premium-assistance-ca.pdf>; also see CMS, Iowa Marketplace Choice Plan Section 1115 Demonstration, <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ia/ia-marketplace-choice-plan-ca.pdf> (amended July 31, 2015).

medical results.²⁵⁹ Arizona is relieved from this requirement²⁶⁰ because it has contracted with Medicaid MCOs from the inception of its Medicaid program to carry out this function.

Another advantage of Pathway Seven is that it may complement other pathways presented in this report. As previously mentioned, states are often innovators with respect to their Medicaid programs, and these pathways are not mutually exclusive. For instance, a state may consider incorporating a partnership under Pathway Three into a broader managed care payment reform effort in which MCOs are contractually obligated to increase the use of value-based payment methodologies in their payment relationships with their network providers. Further, a section 1115 waiver of section 1927 to allow indication specific pricing or rebates, as an alternative to the fixed statutory rebate, for certain classes of drugs might be paired with an accountable care organization-like model that includes incentives for improved performance on outcomes for patients with chronic illnesses or diseases that can be treated with the requested drug classes. Assuming a state preserves its right to the MDRP statutory rebate and is authorized to negotiate supplemental rebates, the state's receipt of either kind of rebate would not present a Best Price risk for manufacturers because both are explicitly excluded from Best Price calculations.²⁶¹

To obtain an 1115 waiver, a state must first apply for and obtain CMS approval. The state must ensure that its demonstration application contains all the required elements.²⁶² Further, the proposed demonstration must be budget neutral, so that “during the course of the project Federal Medicaid expenditures will not be more than Federal spending without the waiver.”²⁶³

States also must solicit meaningful input from the public in the development of the application,²⁶⁴ and there will also be public input at the federal level after the state submits the application.²⁶⁵ To determine whether the waiver would promote the objectives of the Medicaid program, CMS utilizes specific criteria, including whether the demonstration would:

- Increase and strengthen overall coverage of low-income individuals in the state;

²⁵⁹ SSA § 1927(g)(1)(A).

²⁶⁰ CMS, Demonstrations & Waivers: Arizona Health Care Cost Containment System, https://www.medicare.gov/medicaid-chip-program-information/by-topics/waivers/waivers_faceted.html?filterBy=Arizona (last visited June 19, 2016).

²⁶¹ 42 C.F.R. § 447.505(c)(7).

²⁶² *Id.* § 431.412; CMS, *State Medicaid Director Letter 12-001* (Apr. 27, 2012), <https://www.medicare.gov/federal-policy-guidance/downloads/sho-12-001.pdf>.

²⁶³ CMS, Section 1115 Demonstrations, <https://www.medicare.gov/medicaid-chip-program-information/by-topics/waivers/1115/section-1115-demonstrations.html> (last visited June 19, 2016).

²⁶⁴ 42 C.F.R. § 431.408.

²⁶⁵ *Id.* § 431.416; CMS, *State Medicaid Director Letter 12-001* (Apr. 27, 2012), <https://www.medicare.gov/federal-policy-guidance/downloads/sho-12-001.pdf>. The state must also comply with post approval requirements.

- Increase access to, stabilize, and strengthen providers and provider networks available to serve Medicaid and low-income populations in the state;
- Improve health outcomes for Medicaid and other low-income populations in the state; or
- Increase the efficiency and quality of care for Medicaid and other low-income populations through initiatives to transform service delivery networks.²⁶⁶

State cooperation with CMS is vital, because the terms of the section 1115 demonstration waiver (which presumably would dictate the state's ability to take advantage of APM opportunities) must be approved by CMS.

V. Conclusion

Alternative and value-based purchasing and payment experimentation in the private sector has yielded exciting strategies for payers, manufacturers, and providers to work as partners in meeting the daunting challenge of ensuring that patients have access to medications that improve health outcomes and are cost effective. Propelled by enactment of the ACA, interest in and implementation of prescription drug VBP arrangements have grown rapidly in the U.S. Assimilation of such arrangements into the Medicaid program has been slow, though. The ability of state Medicaid agencies to take advantage of APM and VBP opportunities for prescription drugs is limited in large part because states are legally obligated to comply with the MDRP, a federal program established more than a quarter century ago and focused more on reducing drug costs than facilitating outcome-based partnerships. States are guaranteed statutory rebates under the MDRP but, in return, they must operate within a strict legal framework that complicates efforts to implement alternative or value-based payment strategies. With the introduction and increasing availability of high cost specialty drugs, the challenges are even greater.

Notwithstanding the difficulties inherent in implementing a drug benefit with a set of tools developed by Congress in 1990, states have more latitude than commonly thought to establish APMs that advance one or more health system reform goals. The research and analysis reflected in this report were performed to help elucidate legal pathways for establishing prescription drug APMs within the Medicaid program. We present seven pathways for establishing APMs, which used alone or in combination, provide potential opportunities for state Medicaid programs to enhance their ability to tie prescription drug coverage and payment to clinical effectiveness, to improve patient health outcomes, and to manage prescription drug spending. The pathways vary in approach with respect to the use of managed care contracting versus fee-for-service payment, the use of

²⁶⁶ CMS, Section 1115 Demonstrations, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/1115/section-1115-demonstrations.html> (accessed June 19, 2016).

supplemental rebates versus piggybacking on the discounted pricing available to 340B providers and hospitals, and the need for formal CMS approval versus the absence of any CMS review process.

The seven legal pathways described in this report are not APMs themselves. The pathways merely provide different legal avenues for establishing a specific APM. For example, in Pathway One, a state would probably want to focus its APM efforts on a subset of the drugs in its supplemental rebate program for which the benefit of a financial-based or health outcome-based arrangement looks particularly promising. In Pathway Two the state would essentially outsource to its MCOs and their PBMs the task of negotiating APM supplemental rebate arrangements, so the state would have to work with its contracted MCOs and their PBMs, and in some instances defer to their experience, when identifying product lines and manufacturers for inclusion in the APM initiative. Pathways Three and Four entail partnering with 340B providers and hospitals, respectively, so the nature of the APM, in addition to the drugs, manufacturers, and providers included in the APM, would largely depend on the outcome of state negotiations with the 340B provider and hospital communities.

Each state Medicaid program and health care delivery system is unique. This means that some APM strategies are more appropriate to some states than others, which in turn means that some legal pathways described in this report are more suitable to some states than others. The hope is that by presenting seven pathways and explaining the legal basis for them, states will be able to match one or more of the pathways with their prescription drug coverage and payment goals.