NASHP’s Proposal for a State Purchasing Pool for Prescription Drugs

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I. Overview

States have passed dozens of bills to reduce prescription drug prices and provide more regulatory oversight and transparency for the pharmaceutical supply chain, including prescription drug review boards, drug importation laws, and regulation of pharmacy benefit managers (PBMs).\(^1\) The National Academy for State Health Policy (NASHP) has analyzed and designed model legislation, and closely tracked these state efforts.\(^2\) Among the variety of approaches to curtail rising prescription drug costs, states are seeking ways to leverage public purchasing power to reduce prescription drug spending.\(^3\)

In this vein, NASHP sets forth this proposal for states to consider: Establish a State Purchasing Pool for Prescription Drugs that expands the purchasing power of state employee prescription drug plans (SEPDP) to non-state employers and insurance carriers, such as self-funded employers or insurance carriers providing coverage to small groups or individuals. In the 2019 legislative session, one state included expanding the reach of state employee prescription drug plans as one of a range of options for a newly enacted prescription drug affordability board to pursue.\(^4\) Other states are exploring a way to leverage the purchasing power of their state employee prescription drug plan to offer a public purchasing pool to other employers, small groups, and individuals.

As part of their health benefit plans, states provide their employees prescription drug coverage usually through a contract with a PBM that administers the drug benefit, including negotiating discounts with manufacturers, paying pharmacy claims, and establishing drug formularies (a list of covered drugs). Allowing other public employers, private employers, and health insurers to participate in a prescription drug purchasing pool with the SEPDP could address a number of policy concerns by leveraging the unique position of the SEPDP:

- **Leveraging the state’s purchasing power to bring down costs.** State governments are often one of the largest employers in the state and possess considerable bargaining power to negotiate favorable prescription drug prices with manufacturers, wholesalers, and PBMs. Allowing non-state public employers (e.g., municipalities, counties, state universities, public schools, etc.), private employers, insurers, or individuals to participate in the a common purchasing pool with the SEPDP allows more members to benefit from greater economies of scale and purchasing power; it also would benefit the SEPDP by expanding its negotiating base.

- **Streamlining administration of pharmacy benefits.** Expanding the purchasing power of SEPDP to non-state employers and insurers can streamline administration of prescription drug benefits by using a common formulary or preferred drug list and favorable contractual terms with a single PBM.
• **No risk pooling.** Unlike medical coverage, prescription drug plans do not pool risk. Instead, prescription drug plans negotiate drug price discounts and rebates based on the number of covered lives they represent. The larger the number of covered lives, the greater the discounts. Without risk pooling, there is less concern about adverse selection causing the costs of coverage for state employees to increase by adding new populations or members to a state purchasing pool for prescription drugs.

• **Access to coverage.** A State Rx Purchasing Pool can offer more favorable prescription drug prices and plan terms for segments of the private market without competitive prescription drug plan options. By combining their covered lives with those in the SEPDP, the collective purchasing power can drive better prices and terms of coverage than may otherwise be available.

• **Enhanced competition.** The State Rx Purchasing Pool can compete with existing prescription drug plan products, encouraging carriers and PBMs to offer competitive benefits and prices in these markets.

II. Proposal for a State Rx Purchasing Pool

A. Leveraging State Employee Prescription Drug Plans

This brief describes two target populations for a State Rx Purchasing Pool to expand the purchasing power of the SEPDP:

1. **Self-Funded Employers.** This version of the State Rx Purchasing Pool allows self-funded employers to purchase prescription drugs for their employees and covered dependents at the prices and the terms of the State Rx Purchasing Pool. Participating employers would only have to be self-funded for prescription drug coverage; they would not have to be self-funded for medical coverage.

   An example is Connecticut’s File No. 297 (2019), a bill that proposed a allowing self-funded employers to purchase prescription drug via a public purchasing pool, providing that “[t]he Comptroller shall offer nonstate public employers and qualified private employers the option to purchase prescription drugs for their employees, employees’ dependents and retirees under the purchasing authority of the state . . .” where “qualified private employer means a self-insured private employer doing business in this state.”

2. **Insurance Carriers.** This version of the State Rx Purchasing Pool allows health insurance carriers providing fully insured prescription drug coverage, such as to small employers or individuals, to purchase prescription drugs under the prices and terms of the State Rx Purchasing Pool. Insurance carriers offering individual coverage could offer the State Rx Purchasing Pool both to individuals purchasing comprehensive coverage in the ACA marketplaces as well to otherwise uninsured individuals on a standalone basis.

   An example is Maine’s L.D. 1499, which was enacted in 2019 and authorizes the state’s Prescription Drug Affordability Board to “Allow […] health insurance carriers providing coverage to small businesses and individuals in the State to participate in the public payor prescription drug benefit for a fee . . .”

A state could pursue either or both approaches to create a State Rx Purchasing Pool. Together, the two approaches would expand participation in State Rx Purchasing Pool’s as an option to the entire private market: self-funded employer plans and fully insured plans in the large, small, and individual markets. The two different target populations for a State Rx
Purchasing Pool built on the SEPDP implicate different legal issues, as discussed in Part III, below.

B. **State Rx Purchasing Pool Design Choices: Administrative Separation and PBM Services**

Two critical design features of State Rx Purchasing Pool proposals are, first, the degree of administrative separation between the existing SEPDP and the State Rx Purchasing Pool and, second, the extent to which the State Rx Purchasing Pool functions as a PBM or merely represents a set of contract provisions that may be adopted by other entities.

(1) **Degree of Administrative Separation.** Keeping an existing SEPDP distinct from the State Rx Purchasing Pool is advantageous, even where the State Rx Purchasing Pool is designed to provide pharmacy benefits for the SEPDP. That is because a SEPDP is an employee benefit program to which employment-related regulations attach. A separate State Rx Purchasing Pool based on the SEPDP (in that it contracts with the same PBM, features the same formulary, pharmacy network, and cost sharing structure) avoids the regulatory difficulties detailed below in Part III. There is little downside to maintaining a separate State Rx Purchasing Pool for administrative purposes because prescription drug benefit plans do not pool risk, unlike medical benefit plans where pooling is necessary to generate the cost-savings. The two variations are illustrated in **Figure 1** (depicting a direct SEPDP buy-in) and **Figure 2** (depicting a separate State Rx Purchasing Pool).

**Figure 1.** State Employee Prescription Drug Plan Buy-In*

* May cause SEPDP to lose ERISA government-exemption, create a MEWA subject to state regulation (e.g., unable to self-fund without an exception)
State’s PBM Contract Terms vs. State-Operated PBM. The second consideration is whether the state proposes (a) to negotiate with the existing SEPDP’s PBM on behalf of participating employers or insurers, where participating employers’ or insurers’ may access the State Rx Purchasing Pool’s PBM contract terms and discounts for a fee, or (b) to assume the functions of a PBM, and provide those services to self-funded employers or private insurance carriers directly.

To the extent the state wants to extend its PBM contract terms to non-state employers, private employers, and insurers, state oversight and regulation of PBMs is helpful. Generally, a State Rx Purchasing Pool relies on the strength of the SEPDP’s contractual terms with its PBM and the extent to which the PBM negotiates and passes through discounts and rebates to the SEPDP and other plan members. Thus, a State Rx Purchasing Pool may be strengthened if the state has favorable PBM contract terms and greater oversight over PBMs, limits on spread pricing, formulary management, creation fiduciary duties, etc., whether through state PBM regulation or contractually.\(^8\) Many states have passed PBM regulations and dozens more are pursuing bills to oversee PBMs.\(^9\)

Alternatively, the state authority administering the State Rx Purchasing Pool could undertake to perform some or all of the functions of a PBM itself. If the state were to assume the PBM functions for its State Rx Purchasing Pool, it could foster competition in the highly consolidated PBM market and alter employers’ options for PBM plan terms and rates. Legislators in at least one state have considered taking this idea a step farther, proposing to prohibit entities other than the state from delivering PBM services entirely.\(^10\)

Regardless of form, for maximum impact, a State Rx Purchasing Pool should be explored in conjunction with PBM regulation either by state law or contractually.\(^11\)
C. Comparison to State Prescription Drug Discount Card Programs

According to the National Conference of State Legislatures, 19 states are currently operating drug discount card programs available to individuals, typically with lower incomes. These state drug discount card programs share some similarities to State Rx Purchasing Pool in that they both leverage the state’s large-volume purchasing power and are typically administered by a PBM to negotiate price discounts. Drug discount cards have been used to provide drug discounts to populations not eligible for Medicare Part D, such as uninsured or underinsured residents under the age of 65. Having survived early legal challenge, these state prescription drug discount card programs are largely voluntary and are not subject to federal regulation.

One distinction between state prescription drug discount card programs and the State Rx Purchasing Pool is to whom the program is offered. State prescription drug discount cards are typically offered to individuals, while the State Rx Purchasing Pool would be offered to private self-funded employers and/or insurance carriers offering coverage to individuals and small groups. Alternatively, states could adopt or amend their prescription drug discount card programs to offer a prescription drug discount card to individuals to directly purchase drugs with the discounts negotiated for the State Rx Purchasing Pool.

Despite similarities to the State Rx Purchasing Pool, the state prescription drug discount card programs are more limited. Under most discount card programs, the state’s bargaining power to negotiate discounts is based on its purchasing power for its Medicaid program. Although the Medicaid program must receive the lowest prices under the Medicaid Best Price Rule, the state prescription drug discount card programs do not necessarily offer card members Medicaid prices, but whatever discounts the state can negotiate under the threat of requiring prior authorization for a drug under Medicaid if the manufacturer refuses to grant a discount for the program. But Medicaid doesn’t allow closed formularies and all drugs must be covered, so other than prior authorization or step therapy, the state has less leverage on the Medicaid program to negotiate prices for the drug discount card program because it cannot threaten to remove a drug from the approved formulary if the manufacturer does not cooperate.

For the State Rx Purchasing Pool, whether targeting non-state government, self-funded, or fully insured populations, the state would derive its bargaining power from the SEPDP, potentially combined with other non-state purchasers, not the Medicaid program. The state has more options in administering its SEPDP than its Medicaid prescription drug coverage, including tiering, utilization management techniques (such as prior authorization or step therapy), and formularies that need not cover all FDA-approved drugs. Thus, leveraging the SEPDP may provide states with additional negotiating options with prescription drug manufacturers to secure discounts and participation.

III. Legal Issues for a State Rx Purchasing Pool

Using the SEPDP as a basis to expand access to prescription drug coverage raises legal and administrative considerations, regardless of which model a state pursues. Most of these legal issues can be avoided through the design of the State Rx Purchasing Pool to maintain
some degree of administrative separation between it and the SEPDP as discussed in Part II, above.

The primary legal considerations for offering the Public Purchasing Pool to **Self-Funded Employers** are that allowing non-state employers to buy into the SEPDP could cause it to lose its government exemption under the Employee Retirement Income Security Act of 1974 (ERISA) and could create a multiple employer welfare arrangement (MEWA) subject to state regulation. These legal concerns can be avoided if the State Rx Purchasing Pool is organized as a distinct entity through which both the state and non-state employers could purchase prescription drugs for their employees and dependents.

The primary legal considerations for offering the State Rx Purchasing Pool to **Insurance Carriers** are complying with the Affordable Care Act’s requirements for small-group and individual health plans, including that they cover the “essential health benefits” and meet standards for “qualified health plans” to be sold on the ACA marketplaces.

A. **Legal Issues for Self-Funded Employer State Rx Purchasing Pool**

1. **ERISA exempt status.** A principal consideration whenever employer-sponsored benefits are at issue is the effect of ERISA on the proposal. The main issue under ERISA is that allowing non-state employers to buy in to the SEPDP would cause the SEPDP to lose its ERISA-exemption. But the SEPDP’s exempt status can be maintained if the state creates a separate but coordinated State Rx Purchasing Pool in which the SEPDP and self-funded employers can participate.

   ERISA regulates welfare benefit plans offered by employers to their employees. ERISA defines “employee welfare benefit plan” as plans, funds, or programs established or maintained by an employer or employee organization to provide specified benefits, through insurance or otherwise.\(^{17}\) The Department of Labor (DOL) considers prescription drug benefits to be medical care, whether offered as a stand-alone benefit or part of a group health plan, and thus prescription drug plans are regulated as employee welfare benefit plans under ERISA.\(^{18}\) ERISA sets a single nationwide regulatory standard that preempts state regulation of self-funded employee welfare benefit plans. However, states have retained their traditional power to regulate insurance;\(^ {19}\) so, when a welfare benefit plan offers health insurance (under a fully insured plan), as is typically the case where the employer is not large enough to self-insure, the health insurance products offered are subject to state insurance regulation and benefit mandates. When the plan does not offer health insurance, as is the case with self-funded plans, the plan is subject to ERISA regulation only.

   The health plans\(^ {20}\) that public employers offer to their employees are exempt from nearly all ERISA regulations whether or not they are self- or fully-insured because they are governmental plans. The DOL has determined that in addition to plans limited to state and municipal employees and their dependents, plans covering non-state employee member of quasi-public entities, like advisory boards, qualify for governmental exemption. Enrolling non-public employees into the state plan does not automatically forfeit governmental status so long as the number is *de minimis*. In advisory opinions, DOL has consistently maintained that a categorical
inclusion of non-public employees in a state health benefit plan would not be considered *de minimis*. Consequently, allowing non-public employers to directly buy-in to the SEPDP will likely cause the SEPDP to lose its ERISA-exempt status. Losing this exemption may impose new or duplicative reporting burdens on the state, change the legal remedies available to existing state employee beneficiaries, and alter plan funding and disclosure requirements.\textsuperscript{21}

If, however, the state was to create a State Rx Purchasing Pool in which both the SEPDP and non-state employers could participate, the SEPDP could retain its ERISA exemption while still combining the purchasing power of the state with non-state employers to negotiate prescription drug discounts.

(2) Creation and state regulation of MEWAs. A second consequence of allowing private, non-governmental employers to buy in to the SEPDP directly would be the creation of a *multiple employer welfare arrangement* (MEWA). The significance of creating a MEWA is that state laws may limit a SEPDP from self-funding if it is a MEWA.

A MEWA is any arrangement providing welfare benefits to the employees of two or more employers.\textsuperscript{22} The DOL considers MEWAs to be distinct arrangements, legally separate from each participating employer, that sponsor either fully insured or self-funded plans. While self-funded plans usually enjoy ERISA protection, a history of fraud led Congress to expressly except MEWAs from ERISA’s preemption provisions, allowing states to apply their insurance laws even to self-funded MEWAs.\textsuperscript{23} Thus, both MEWAs offering insurance and those providing self-funded health benefits are regulated jointly by both states and DOL.\textsuperscript{24} Because ERISA only applies to welfare benefit plans that employers provide for the benefit of their employees, a MEWA offers an ERISA plan only when the MEWA is itself considered an employer. Allowing non-state employers to participate in the SEPDP or State Rx Purchasing Pool would not create an ERISA-covered plan because neither would meet the definition of an “employer” under ERISA.\textsuperscript{25} Thus, the MEWA created by allowing private employers to buy into the SEPDP directly would not create an ERISA-covered plan, and each participating employer would still maintain a benefit plan covered by ERISA for compliance and reporting purposes. Regardless of type of plan it sponsors or its status under state insurance law,\textsuperscript{26} a MEWA is required to file certain forms with DOL, including Form 5500 and Form M-1.\textsuperscript{27}

Because of the operational similarities of self-funded MEWAs to traditional insurers, in many states, MEWAs are not permitted to self-fund or, if so, they must meet the state’s licensure and financial requirements for commercial insurers.\textsuperscript{28} Allowing non-state employers to “buy-in” to the SEPDP and creating a MEWA could also mean that the SEPDP may not be able to self-fund under state insurance laws. Nevertheless, many states expressly or implicitly exempt any welfare benefits plan administered by the state from their state insurance laws. Thus, a self-funded MEWA that included the state as one of the employer-members might also be exempt from the state’s MEWA restrictions, and, depending on the state, such an arrangement may be permissible without any legislative action. In contrast, other states’ statutes disfavoring self-funded MEWAs may not allow exceptions when a public employer is a plan sponsor. In such cases, some regulatory exception, such as rules or advisory opinions from the state attorney
These difficulties regarding creation of a MEWA, federal reporting requirements to DOL, and state limits on self-funded MEWAs can largely be avoided by keeping separate the administration of the SEPDP and a State Rx Purchasing Pool in which employers, including the state, could participate. The administrative separation need not be so extreme as to eliminate the savings, expertise, and efficiencies of a single plan. For example, the SEPDP and Public Rx Purchasing Pool could share overlapping staff and negotiate as a whole with a PBM for common contract terms and prices. The lack of risk pooling further simplifies the administration of the State Rx Purchasing Pool.

B. Legal Issues for Offering a State Rx Purchasing Pool to Insurance Carriers

(1) Mandatory pharmacy benefits. The Affordable Care Act requires all health insurance products offered in the individual and small group markets and all qualified health plans (QHPs) available on the exchange to cover the essential health benefits (EHB). The EHB package includes prescription drugs. These requirements mean that states must avoid crafting a State Rx Purchasing Pool that operates to carve out prescription drug benefits from insurer’s existing products. Allowing insurers to adopt the state’s plan design and PBM terms, participate in a State Rx Purchasing Pool, or contract with the state as a PBM are unlikely to raise carve-out concerns. Simply allowing insurance carriers an option to arrange for the required prescription drug benefits under the same terms as the SEPDP or to participate in the State Rx Purchasing Pool would likely comply with the Affordable Care Act’s EHB requirements.

IV. Implementing a State Rx Purchasing Pool

NASHP’s proposed State Rx Purchasing Pool builds on State Employee Prescription Drug Plans, leveraging the state’s purchasing power and PBM terms to offer non-state employers, small groups, and individuals the state’s negotiated discounts and favorable terms to reduce prescription drug costs for a larger population. NASHP developed the following checklist of considerations and steps for implementation of a State Rx Purchasing Pool.

- **Identify the intended population.** Decide whether the state wants to extend the State Rx Purchasing Pool to self-funded employers, insurance carriers offering coverage to small group market and/or individual market.

- **How to reach uninsured individuals?** If the state wants to reach uninsured individuals, the state could rely on insurance carriers to offer the State Rx Purchasing Pool on a standalone basis with individual premiums or adopt a (or adapt an existing) state prescription drug discount card program to allow otherwise uninsured individuals to purchase drugs under the discounts negotiated by the State Rx Purchasing Pool.

- **Identify the administrative body.** The state should identify and engage the administrative body that will be empowered to establish and administer a State Rx Purchasing Pool. This may be the administrators who run the state employee health benefit plan, the state’s financial officer (Comptroller, Treasurer, etc.), or it
may also entail the creation of a new administrative body such as Prescription Drug Review Board.

- **Develop authorizing legislation and regulations.** The state should explore authorizing legislation to delegate the authority required for the administrative body to pursue a State Rx Purchasing Pool, including the authority to promulgate implementing regulations. Consider how much to specify in legislation or regulation to maintain flexibility.

- **Explore PBM regulation or review/renegotiate SEPDP contract terms.** As discussed above in Part II, the attractiveness of the State Rx Purchasing Pool derives from the strength of the state’s contractual terms with and oversight over its PBM. To strengthen the state’s oversight over its PBM, the state may pass PBM regulations, renegotiate or re-procure its PBM contract, or even consider assuming the functions of the PBM itself.

- **Keep administrative separation between the State Rx Purchasing Pool and the SEPDP.** To avoid the legal issues described above (losing the SEPDP’s ERISA exemption, establishing a MEWA) the State Rx Purchasing Pool should be established as a separate entity from the SEPDP, under common PBM terms, which would offer prescription drug coverage to both the SEPDP and the State Rx Purchasing Pool participants, such as self-funded employers and insurance carriers offering prescription drug coverage to individuals and small groups.

NASHP is presenting this option for state review and comment and will work through NASHP’s Center for Prescription Drug Pricing and State Rx Work Group to develop more specific guidance and to share experiences among states.
Notes
4 L.D. 1499, 129th Leg., 1st Reg Sess. (Me. 2019); 2019 Me. Laws Ch. 471 (to be codified at Me. REV. STAT. tit. 5, ch. 167)
6 As discussed below, the state could also develop or adapt a state prescription drug discount program to offer the State Rx Purchasing Pool directly for individual purchase.
7 L.D. 1499, 129th Leg., 1st Reg Sess. (Me. 2019); 2019 Me. Laws Ch. 471 (to be codified at Me. REV. STAT. tit. 5, ch. 167)
11 For example, in 2019, Maine passed legislation to create a Drug Affordability Board with the authority, among other things, to create a State Rx Purchasing Pool by allowing private insurance carriers to participate in the public prescription drug benefit. During the same session, Maine also passed legislation to regulate PBMs, including creating fiduciary duties for PBMs, eliminating spread pricing. Maine LD 1504, Ch. 469 Pub. L., http://legislature.maine.gov/bills/getPDF.asp?paper=SP0466&item=4&snum=129.
13 Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 669, 123 S. Ct. 1855, 1871, 155 L. Ed. 2d 889 (2003) (concluding that Maine’s prescription drug discount card program, MaineRx, was not preempted by the Medicaid statute and did not violate the dormant commerce clause of the Constitution).
15 Another reason a state might have less leverage to negotiate under Medicaid is that in states with large Medicaid Managed Care programs, the Medicaid population can be split up among several managed care organizations and pharmacy benefit managers, so state control over Medicaid drug purchasing may be less direct or centralized.
16 Additional legal considerations may be raised if the state wants to allow any individual to buy in to the SEPDP, rather than just small employers. This brief only examines the legal factors raised by allowing employers or insurance carriers to participate in the SEPDP.
18 See U.S. Dep’t of Labor, Employee Benefit Security Administration, Benefit Claims Procedure Regulation FAQs, A-7: Do the requirements applicable to group health plans apply to prescription drug benefit programs offered as a stand-alone plan or as part of a group health plan?, https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/benefit-claims-procedure-regulation.
19 Medical benefit plans can include health insurance but, in the context of ERISA, insurance generally means “fully insured”---where a third-party insurer assumes the risk in a contract to pay future benefits. For convenience, this brief will refer to “medical benefit plans” using the more contemporary term, “health plan,” with the caveat that “health plan” is still be distinguished from “health insurance” and does not comprise plans that only include “health” benefits (such as gym memberships) with no medical component.
21 29 U.S.C. § 1002(40)(a) (providing, “The term “multiple employer welfare arrangement” means an employee welfare benefit plan, or any other arrangement (other than an employee welfare benefit plan), which is established or maintained for the purpose of offering or providing any benefit described in paragraph (1) to the employees of two or more employers (including one or more self-employed individuals), or to their beneficiaries . . .”) For fully insured MEWAs, states may apply and enforce any state insurance laws requiring the maintenance of reserves designed to ensure that the MEWA will be able to satisfy its benefit obligations in a timely fashion. In
addition, states may subject MEWAs to licensing, registration, certification, financial reporting, examination, audit and any other requirement of State insurance law necessary to ensure compliance with the State insurance reserves, contributions and funding requirements. See U.S. Dep’t of Labor, Employee Benefits Security Administration, Multiple Employer Welfare Arrangements under the Employee Retirement Income Security Act (ERISA): A Guide to Federal and State Regulation (August 2013), at 28 [hereinafter DOL MEWA Guide].


25 ERISA defines “employer” to mean “any person acting directly as an employer, or indirectly in the interest of an employer, in relation to an employee benefit plan; and includes a group or association of employers acting for an employer in such capacity.” 29 U.S.C. § 1002(5) (emphasis added). DOL’s interpretative rulings have established that an “association of employers” meets the definition of “employer” only when it is a bona fide group of employers acting in the interests of its employer members. Among other factors, where participating employer members do not exercise control over the plan, there is no bona fide association, and the MEWA would not be considered an ERISA-covered plan. See DOL MEWA Guide, supra note 23, at 8.

26 DOL MEWA GUIDE, supra note 23, at 5.


29 42 U.S.C. § 300gg-6(a).


