Extending the Federal Drug Rebate Program to Medicaid MCOs:

Analysis of Impacts

Prepared for:

Association for Health Center Affiliated Health Plans and

National Association of Urban-Based HMOs (NAUHMO)

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Executive Summary

A coalition of Medicaid Focused Health Plans[1] contracted with the Lewin Group to analyze the impacts of allowing Medicaid managed care organizations (MCOs) to have access to the Medicaid drug rebate on a voluntary basis. Since its inception in 1991, the federal rebate program has applied only to Medicaid fee-for-service programs. Currently, Medicaid MCOs must enter into separate negotiations with drug manufacturers, either directly or through their contracting pharmacy benefits managers (PBMs), in order to obtain rebates. The proposal being explored would allow participating health plans to continue to pay for the ingredient costs of drugs as they do currently, but rebates would no longer be a negotiable item with the manufacturers or with the health plans' pharmacy benefits managers (PBMs). Instead, Medicaid health plans would receive the same level of rebate available to state Medicaid fee-for-service programs.

Another recent report by the Lewin Group and funded by the Center for Health Care Strategies[2] demonstrated that the approaches taken by the Medicaid managed care industry in the pharmacy arena have been highly effective in containing costs vis-à-vis the fee-for-service (FFS) environment. That is, even though the Medicaid MCOs are at an ingredient price disadvantage of approximately 15 percentage points as a result of the larger rebates available to FFS Medicaid, they generally are managing the mix and usage of prescription medications such that overall TANF per member per month costs of the pharmacy benefit are 10 to 15 percent lower in the capitated (Medicaid MCO) setting than in FFS Medicaid. Thus, the fundamental question is whether Medicaid MCO participation in the federal rebate program would create cost advantages that would be entirely additive, or whether there would be trade-offs and/or mitigating factors associated with such participation.

The Coalition/Lewin report described the following potential trade-offs of the policy:

- Many if not most MCOs would be able to participate in the federal rebate with their current utilization management policies largely intact.

- Plans would be more likely to collect the rebates from manufacturers in a timely manner if they were able to collect them directly and not to have to go through the state.

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[1] The Coalition includes the Association for Health Center Affiliated Health Plans (AHCAHP), the National Association of Urban HMOs (NAUHMOs) with support of Schaller-Anderson, Inc., and AMERIGROUP, Inc.

[2] www.ahcahp.org/publications

- Most MCOs interviewed felt that their participation in the federal rebate program definitely would result in changes to their PBM relationships, as PBMs would not longer be responsible for negotiating the rebates for the plans.

- While it is impossible to predict the precise reaction of the pharmaceutical industry, or its ultimate success in fighting any change to current rebate law, it is safe to assume that the industry will fight such changes and that Medicaid MCO time and resources may be consumed in a potentially lengthy battle.

- Given the budgetary situation in which most state Medicaid programs find themselves, states may expect to share in at least part of the savings that resulted from any change in the federal rebate policy.

The report also looked at the potential financial impact of the proposal. The PMPM dollar value and total dollar value of the additional rebates that would be available if the federal rebates were extended to Medicaid MCOs are significant. The Lewin Group has produced a range of estimates and sensitivity analyses that provide an "order of magnitude" sense of the potential annual and cumulative savings over a ten-year period. Nationwide, annual savings growing to more than $100 million, and cumulative 10-year savings exceeding $700 million, are clearly possible—even if one assumes that only half of the total potential savings will be realized due to the voluntary nature of the proposal.

I. INTRODUCTION

This report provides an analysis of a change to the federal Medicaid Drug Rebate Program that would give Medicaid managed care organizations (Medicaid MCOs) access to the federal rebates. Since its inception in 1991, the federal rebate program has applied only to Medicaid fee-for-service programs. Medicaid providers, including MCOs, hospitals, nursing homes and other entities that purchase prescription drugs provided to Medicaid recipients, have been ineligible to receive these mandated rebates. These rebates create a Medicaid "best price," i.e., the lowest price paid for a prescription product by any purchaser, other than Federal discount programs and state pharmaceutical assistance programs. Currently, Medicaid MCOs must enter into separate negotiations with drug manufacturers, either directly or through their contracting pharmacy benefits managers (PBMs), in order to obtain rebates. The amount that is negotiated may affect the amount of the rebate that the manufacturer is obligated by law to pay Medicaid state agencies under the Medicaid best price rules.

The change being explored by several Medicaid-focused health plans is to allow Medicaid managed care plans access to the federal rebate program on a voluntary basis. Participating health plans would continue to pay for the ingredient costs of drugs as they do currently, but rebates would no longer be a negotiable item with the manufacturers or with the health plans' pharmacy benefits managers (PBMs). Instead, Medicaid health plans would receive the same level of rebate available to state Medicaid fee-for-service programs.

Multiple reasons lie behind the keen interest among Medicaid MCOs in re-examining the federal rebate policy, after more than 10 years since the rebate program's inception:

- First, both the number and nature of MCOs serving the Medicaid population have changed considerably. A decade ago only 10 percent of the total Medicaid population was enrolled in managed care plans, most of which had large commercial lines of business as well. The large majority of Medicaid recipients were covered by state FFS programs, which had access to the federal rebate program. However, during the past ten years the rebate has applied to a shrinking percentage of the Medicaid population; by 2001, about 36 percent of Medicaid recipients were enrolled in capitated managed care. Further, among the health plans serving the Medicaid population today, the smaller, Medicaid-focused health plans with more limited financial resources are becoming the norm.

- Second, capitated Medicaid health plans, like Medicaid FFS programs, are experiencing double-digit growth rates in their pharmaceutical benefits costs and—like state Medicaid agencies—are exploring a variety of mechanisms to control drug spending.

- Finally, the "strings" attached to the rebate program have loosened somewhat since commencement of the program and are currently being tested further by a number of state Medicaid agencies. The Omnibus Budget Reconciliation Act of 1993 (OBRA '93) permitted the creation of formularies, although the most restrictive types of formularies are still prohibited. Recently, a number of states including Florida, Michigan, Georgia and Oregon have pushed the limits of the federal rebate statute, e.g., through preferred drug lists tied to supplemental rebates, reference pricing, and the like. In other words, a

growing number of Medicaid agencies appear to be pursuing strategies that will allow them to benefit from "the best of both worlds" to the greatest extent possible—the rebate program available to fee-for-service programs *and* the utilization management/cost containment strategies employed by private insurers. As a result, there is a possibility that the trade-offs associated with the federal rebate versus greater flexibility in utilization and cost management strategies may be less significant now than heretofore for MCOs.

The remainder of this report is divided into three sections:

1. A brief overview of the federal rebate program, including utilization and cost management strategies precluded and those allowed;

2. Issues surrounding the extension of the federal rebate to MCOs, including factors that might work to mitigate savings to MCOs and/or the federal government; and

3. Potential financial impact of extending the federal Medicaid rebate to MCOs, including total potential financial impact and a presentation of cost estimates that include sensitivity analyses.

II. OVERVIEW OF THE FEDERAL REBATE PROGRAM

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) established the Medicaid Drug Rebate Program, designed to tap Medicaid's purchasing power by giving the program the same types of volume discounts generally afforded to other large purchasers of health care services. Under this program, drug manufacturers must have a signed rebate agreement with the Secretary of the Department of Health and Human Services in order for payment to be made for Medicaid-covered outpatient drugs. Drug manufacturers participating in the drug rebate program provide quarterly rebates to states for drugs dispensed to state Medicaid recipients.[3] These rebates result in "best price" to Medicaid, i.e., Medicaid pays the lowest price paid for a prescription product by any purchaser, other than Federal discount programs and state pharmaceutical assistance programs.

In exchange for getting the manufacturers' "best price," state Medicaid fee-for-service programs must maintain a relatively open drug list. With the exception of a few drugs or classes of drugs (e.g., barbiturates, agents used for anorexia, weight loss, or weight gain) that may be excluded from coverage altogether, states that choose to include outpatient drugs in their Medicaid

[3] Each state Medicaid agency must provide to each manufacturer with a rebate agreement, within 60 days after each rebate period (generally quarterly), information on number of units, dosage form, strength and package size of each outpatient covered drug dispensed and paid for during the rebate period. Manufacturers are to pay the rebate within 30 days following receipt of the information. In practice, however, rebate payments often are not made for 9 months or longer, as a result of disputed items, inadequate state accounting systems, and so forth.

benefit packages[4] must provide coverage of all FDA-approved drugs made by drug manufacturers that have a signed federal rebate agreement. While OBRA '90 prohibited the use of restrictive formularies entirely, OBRA '93 amended the law to allow states to create a formulary if the formulary meets certain requirements:

- The formulary must be developed by a committee comprising physicians, pharmacists and other appropriate individuals;

- Coverage of an outpatient drug may be limited only if it does not have "a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome…over other drugs included in the formulary;" and

- The state permits coverage of the excluded drug pursuant to a prior authorization program, which must provide a response within 24 hours of the request and must provide for the "dispensing of at least a 72-hour supply of a covered prescription drug in an emergency situation."

In short, under the federal rebate agreement, states may not employ "closed" formularies—a common approach used by private insurers—as a method to manage utilization and costs, i.e., they cannot exclude coverage of a drug outright.

However, the federal rebate agreement does not preclude states from engaging in various other pharmacy benefit management approaches, most notably the following:

- **Prior authorization** – The statute specifically states that "a prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph." That is, states may subject *any* covered outpatient prescription drug to prior authorization, without the type of rigorous justification and special committee deliberation process required for formularies. A letter from CMS to State Medicaid Directors, issued September 18, 2002, sought to clarify and confirm the flexibility states have with respect to prior authorization and its use in negotiating supplemental rebates with drug manufacturers. A copy of the letter is included in Appendix A.

  As discussed above, prior authorization *must* be available in conjunction with formulary restrictions. However, prior authorization programs can also be used in conjunction with preferred drug lists (PDLs), mandatory generic substitution, step therapy, or as a stand-alone utilization control mechanism. In all cases, however, prior authorization programs must meet the 24-hour response and 72-hour supply requirements noted above. It appears that these requirements, perceived by many states to be quite onerous, have limited the application of prior authorization in most states to a rather proscribed set of drugs. However, a recent national survey of state Medicaid agencies commissioned by the Kaiser Family Foundation (KFF)[i] found that, of 44 respondents to

[4] All states and the District of Columbia include outpatient prescription drugs in their Medicaid benefit packages.

the survey, 35 states and the District of Columbia had some prior authorization requirements in the year 2000.

- **Quantity limits** – States may impose limits on the quantity per prescription, number of prescriptions or number of refills allowed in a time period. According to findings from the survey cited above, 41 of 44 responding Medicaid agencies had at least one such limit in place in 2000.

- **Generic substitution** – States may encourage or require the substitution of generic drugs for brand-name drugs through mechanisms such as the following: a) requiring a higher level of cost-sharing for brand-name drugs; b) paying higher dispensing fees to pharmacies for generic versus brand-name drugs; and c) mandating the use of generics unless the prescribing physician overrides the substitution (i.e., by writing "brand medically necessary" or "dispense as written" on the prescription or unless prior authorization is obtained). All respondents to the KFF survey employed at least one of these mechanisms in 2000.

- **Step therapy** – States may require trial and failure with a first-line agent prior to approval of a second-line agent. Twelve of the 44 respondents to the KFF survey had such requirements for certain drugs or drug classes in 2000.

- **Patient cost-sharing** – States are quite limited in the cost-sharing they may impose upon Medicaid recipients. Copay requirements may range from $.50 per prescription to $3.00 per prescription, and differential copays may be applied to generic versus brand-name drugs. Twenty-nine Medicaid agencies responding to the KFF survey reported requiring patient copays.

It is important to note that while the approaches described above theoretically have been permissible for many years, only recently have states begun to implement them in large scale and/or ground-breaking ways. Thus, what is permissible in practice is yet to be determined. The initiation in Florida and Michigan of PDLs linked to supplemental rebates, for instance, has led to challenges by the pharmaceutical industry, with the final outcome still in the balance.[5]

III. ISSUES SURROUNDING THE EXTENSION OF THE FEDERAL REBATE PROGRAM TO MEDICAID MCOS

The Lewin Group recently completed a study, funded by the Center for Health Care Strategies, in which we analyzed the differences between pharmacy costs, drug mix, and utilization in the capitated Medicaid setting versus FFS Medicaid.[ii] This study demonstrated that the approaches taken by the Medicaid managed care industry in the pharmacy arena have been highly effective

[5] In the case of Michigan, the pharmaceutical industry filed two separate lawsuits, one against the Michigan Department of Community Health (MDCH) and one against the Centers for Medicare and Medicaid Services (CMS). The Michigan State Court of Appeals ruled in favor of MDCH in late 2002. The federal suit is still outstanding.

in containing costs vis-à-vis the FFS environment. That is, even though the Medicaid MCOs are at an ingredient price disadvantage of approximately 15 percentage points as a result of the larger rebates available to FFS Medicaid, they generally are managing the mix and usage of prescription medications such that overall TANF per member per month costs of the pharmacy benefit are 10 to 15 percent lower in the capitated (Medicaid MCO) setting than in FFS Medicaid.

Thus, the fundamental question is whether Medicaid MCO participation in the federal rebate program would create cost advantages that would be entirely additive, or whether there would be trade-offs and/or mitigating factors associated with such participation.

This section presents brief discussions of five key factors likely to affect the impact of a change to the federal rebate policy:

- potential restrictions on Medicaid MCO utilization and cost management approaches;
- timing of rebates;
- MCOs' relationships with their pharmacy benefits managers (PBMs);
- pharmaceutical industry reaction; and
- dynamics of capitation rate development and its potential impact on sharing of savings between MCOs and states.

A. Utilization Management Approaches

Understanding the current state-of-the-art in Medicaid MCO pharmacy management is important in assessing the "trade-offs" that might be part and parcel to an extension of the federal rebate to these entities. It is not the purpose of this section to include an exhaustive discussion of the various strategies Medicaid MCOs are using in their efforts to contain the rising costs of their drug benefit, but rather to elucidate an issue around which there often is some degree of confusion, i.e., the degree of flexibility Medicaid MCOs, vis-à-vis state FFS programs, have in managing their pharmacy benefit.

It is often thought that Medicaid MCOs have free rein in establishing and implementing their prescription benefit management approaches—that they may, for instance, develop their own formularies without being bound by the requirements specified for formularies in the federal rebate agreement. In fact, however, many states do hold their contracting Medicaid MCOs to those requirements. A recent study conducted by the Center for Health Service Research and Policy at the George Washington University Medical Center[iii] reported that 18 states (of 39 reporting states with risk-based managed care agreements) permit drug formularies in their contracts with Medicaid MCOs. Among these 18 states, there is wide variability with regard to the restrictions that apply to the MCO formularies. For example:

- The District of Columbia's contract requires that, "[i]n developing a drug formulary and making prescribed drug-related coverage determinations, Provider shall comply with 42 U.S.C. Section 1396r-8(d) with respect to formularies, prior authorization, and other permissible limitations." That is, MCOs are subject to the formulary requirements set forth in the federal rebate law.

- The Oregon contract provides that the "Contractor may use a restrictive formulary as long as it allows access to other drug products not on the formulary through some process such as prior authorization. The formulary must include FDA approved drug products for each therapeutic class sufficient to ensure the availability of covered drugs with minimal prior approval intervention by the provider of pharmaceutical services."

- Michigan's contract states simply that "[t]he Contractor may have a prescription drug management program that includes a drug formulary."

For MCOs already held to most or all of the requirements set forth in federal rebate law, then, participation in the federal rebate program would create few new restrictions in the area of utilization management.

For MCOs not held to these requirements, the issue is somewhat more complicated. In interviews The Lewin Group has conducted with Medicaid MCOs—both in our recent study funded by the Center for Health Care Strategies and as part of our current engagement—varying perceptions have surfaced regarding Medicaid MCOs' flexibility in applying drug utilization management strategies vis-à-vis the flexibility of State FFS programs. Some MCO pharmacy directors believe that the difference between what a FFS program can do and what MCOs have at their disposal is minimal. Others, however, view the differences as more significant. Several MCOs felt that they would need to change their current pharmacy benefit/utilization management practices if allowed to participate in the federal rebate program.

> "There's been a big breakthrough with how aggressive states can be in managing drug costs. The restrictions that go hand-in-hand with access to the rebate program have been loosened significantly, such that the difference between a closed formulary and an open formulary with strict prior authorization is largely a matter of semantics. MCOs probably wouldn't lose much in the way of utilization management ability if they were to gain access to the federal rebate."
>
> - MCO Pharmacy Director

> "The prerequisite conditions to receiving these rebates preclude formulary management and the use of utilization management programs. It is the Plan's belief that the increased rebate dollars received would not offset the additional expenditure incurred due to increased inappropriate utilization of pharmaceutical products."
>
> - Health Plan Representative

It is not surprising that such divergent views exist. As described in Section II, the boundaries of the federal rebate law are indeed in a state of flux, and it is difficult to predict where the lines will finally be drawn. It appears, however, that the answer may lie somewhere in the middle. That is, many (but not all) Medicaid MCOs have somewhat more flexibility than do state FFS programs in managing prescription drug utilization, but the advantage may not be so large as to be the driving factor in an MCO's assessment of the benefits of participating in the rebate program. Based on the work Lewin has performed in this study and the CHCS study, it appears that numerous states are employing the same techniques used by many Medicaid MCOs, but are not pursuing the strategies that are available to them as aggressively as are the

MCOs we spoke with, for a number of reasons. These include concern about the pharmaceutical industry's reaction as well as the administrative challenges of complying with the requirements for prior authorization programs.

In short, it is quite possible that many if not most MCOs would be able to participate in the federal rebate with their current utilization management policies largely intact, particularly if the pharmaceutical industry is unsuccessful in challenging the aggressive initiatives being waged in Florida, Michigan and other states. Further, the administrative burden of the federal rebate's prior authorization requirements do not appear to be as problematic for MCOs as they are for state FFS programs, whether the MCOs operate their prior authorization programs internally or contract out this function to their PBMs.

However, other issues may act to mitigate the advantages to MCOs of participating in the federal rebate program, as discussed below.

B. Timing of Rebates

As noted previously, drug manufacturers are required to pay rebates on undisputed items to state Medicaid agencies within 30 days following receipt of the necessary information from the state. However, it was the understanding of many of those we interviewed that rebates are generally not received by state agencies for nine months or more, while MCOs receive rebates from drug manufacturers more quickly, usually within three to five months.

It was beyond the scope of this study to survey states in order to assess more specifically their effectiveness in collecting rebates in a timely fashion. However, a brief web search did confirm that the collection of drug manufacturer rebates has been a problem in at least some states. For instance, an October 2001 press release issued by the Office of the New York State Comptroller stated that "nearly $20 million in Medicaid drug rebates owed by manufacturers have gone uncollected by the State" during the 30-month period audited, and that "the state does not properly track or pursue rebate revenues…and there is little done to resolve disputes with drug manufacturers when rebates are challenged." Similarly, a 1999 management letter from the Office of the Legislative Auditor of the State of Minnesota included a finding that the Minnesota Department of Human Services "did not have an adequate system of accounting for the Drug Rebate Program during fiscal year 1999," and that "the department had outstanding unpaid rebate billings dating to 1995."

It is unclear whether the timing of rebates to MCOs would be affected by their participating in the federal rebate program. Much depends upon whether the MCOs would be able to continue their current rebate collection processes. It is possible that all rebate reports would need to be funneled through the states to the drug manufacturers, in which case the MCOs would experience delays in receiving rebates compared to current time frames.

Even if MCOs were not required to go through the states to collect rebates, current rebate accounting practices might have to change. For many if not most MCOs, their PBMs are performing the rebate accounting function for them now. If the MCO-PBM relationship changes as a result of MCO participation in the federal rebate agreement, MCOs might need to establish their own internal rebate accounting and follow-up systems. Under any scenario,

MCOs might also need to develop new formats for reporting rebatable expenditures to drug manufacturers and/or to their sate Medicaid agency.

C. MCO Relationships With Their PBMs

Most MCOs contract with PBMs to perform some or all of the health plans' pharmacy benefits management functions. In some cases, the PBMs perform only the claims processing and basic drug utilization review functions, but more often they play a much larger role, with responsibility for contracting with pharmacies, operating prior authorization programs, helping to develop and maintain the formulary, and negotiating rebates with drug manufacturers and collecting them. However, decision-making about such pharmacy benefit management strategies continues to rest with the MCOs, through processes they establish to independently identify the formulary decisions and management strategies that are consistent with their goals.

The payment methodology used by MCOs to pay PBMs for the services they provide generally includes one or some combination of the following: (a) a flat fee per claim; (b) a fee per prescription, e.g., for prior authorizations or non-formulary exceptions administered; (c) a per-member-per-month fee; and (d) retention by the PBM of some portion of the rebate that the PBM has negotiated on behalf of the MCO.

In addition to the rebate that the PBM negotiates on behalf of the MCO (which is disclosed to, and agreed to by, the MCO), most PBMs also negotiate additional rebates with drug manufacturers that accrue solely to the PBM. The details of these rebate arrangements are not disclosed to the MCOs, but they represent a significant source of revenue to the PBMs and help the PBMs keep their administrative fees relatively low.

Most MCOs interviewed felt that their participation in the federal rebate program definitely would result in changes to their PBM relationships, which in turn would lead to increases in pharmacy benefits management costs. The box below summarizes the potential impacts raised by several MCO pharmacy directors.

Sample Quotes from Interviewed MCOs Regarding Impact on PBM Relationship

"There would no longer be a relationship with the PBM for the Plan's Medicaid membership. The Plan's remaining small commercial membership would result in dramatically increased PBM costs due to the loss in volume."

"For those health plans who use an external PBM, the majority source of PBM profitability is still rebate dollars received from manufacturers. Those health plans may end up looking for just a claims processor, since traditional PBMs may be less interested in doing business with them."

"This would also result in increased operational costs by requiring additional Plan pharmacy personnel to review prior authorization requests and perform other functions that are currently covered by the PBM."

D. Pharmaceutical Industry Reaction

With Medicaid and other purchasers seeking strategies to control drug spending, pharmaceutical manufacturers' profits are being targeted. Certainly, many of the new initiatives states are implementing—from supplemental rebates tied to preferred drug lists as in Florida and Michigan, to strong generic substitution programs as in Massachusetts—will have a direct negative impact on the revenues of the industry's major manufacturers. Thus, the

lawsuits filed by PhaRMA against Florida, Michigan and others are not surprising. For the same reason, there is little doubt that new challenges would be waged by the pharmaceutical industry in the face of an extension of the federal rebate program to Medicaid MCOs, as any savings to MCOs and/or states would come directly from the drug manufacturers' bottom lines.

It is impossible to predict the precise reaction of the pharmaceutical industry, or its ultimate success in fighting any change to current rebate law. However, it is safe to assume that the industry will, indeed, fight such changes and that Medicaid MCO time and resources may be consumed in a potentially lengthy battle. Given that this is a time when a multitude of public policy and payer efforts to reduce pharmacy costs are taking place, it can be expected that the manufacturers will be particularly aggressive in minimizing the impact of a policy change that, from the manufacturers' perspective, is simply a forced price cut.

Two scenarios seem the most likely. First, the pharmaceutical industry may argue that they agreed to a certain level of rebates based on the size of the population for whom the rebates would apply; they would likely press for a lower rebate percentage should the law be changed to broaden the size of the rebate population. Counter-arguments exist that the number of capitated enrollees has grown substantially, and that changes in welfare rules have further reduced the number of persons for whom the rebates apply. However, if the pharmaceutical industry's lobbying efforts proved successful, they would eliminate some or all of the added rebate savings at the Medicaid-wide level. The health plans might still come out advantaged in this scenario since they would receive some added rebates, but the offsetting costs would be spread across the entire Medicaid program.

If the pharmaceutical industry is unsuccessful in recouping its additional rebates through the above approach, the industry could raise prices more sharply for all payers than would otherwise be the case. In effect, this would create a "cost shift" to the private sector. Such an approach would reduce or eliminate any system-wide savings, but would still create sizable savings for the Medicaid program.

E. Dynamics of Capitation Rate Development

A primary concern of Medicaid MCOs has been the manner in which states have developed their capitation rates, and whether the methodology has resulted in unfairly low payment to MCOs for the pharmacy benefit. While the rate-setting methodology has recently changed from one based on the upper payment limit (UPL) to one based on "actuarial soundness," it is useful to briefly summarize the UPL methodology and its impact.

When states were bound by the UPL regulations, they included their *net* costs for prescription drugs, i.e., after rebate, in calculating their UPL —a rebate to which MCOs are not entitled. As a result, there was a general perception that the capitation rates MCOs received included payment for pharmaceutical costs that were well below the MCOs' expenditures, since MCO rebate percentages are significantly smaller. In fact, however, while all states calculated their UPLs in this fashion, many states did not discount their *capitation rates* to account for the effect of the federal drug rebate program. For example, in translating UPLs to capitation rates, some states added back the rebate amounts received by the state, and then subtracted an amount to

account for the effects of the MCO-specific rebates and utilization management programs. Thus, some MCOs were not at the disadvantage that was often thought, although others were.[6]

With the switch to the "actuarial soundness" methodology, states are reexamining the way in which they calculate their capitation rates. It is likely that an extension of the federal rebates to MCOs would cause states to scrutinize how they account for the pharmacy portion of the rate. Given the budgetary situation in which most state Medicaid programs find themselves, it is certainly conceivable that states would expect to share in at least part of the savings that resulted from any change in the federal rebate policy.

IV. POTENTIAL FINANCIAL IMPACT

The Lewin Group has produced a series of estimates of the total financial impact of extending the federal rebates to Medicaid MCOs. Four "base" scenarios are presented, each encompassing a ten-year time frame, that vary according to different penetration assumptions reflecting the percentages of SSI and TANF recipients who receive their pharmacy benefits through a capitated program. All other assumptions used to derive the base scenarios—total Medicaid enrollment growth, the PMPM value of the additional rebate, and pharmacy cost trends—are held constant across each of the scenarios.

Each of the base scenarios provides an estimate of the total annual and cumulative savings across the ten-year time period **if the proposal were fully enacted, all Medicaid MCOs elected to participate, and none of the potential mitigating factors discussed in Section III came into play.** Below we present the base scenario estimates, followed by a summary of the assumptions used in deriving the base scenarios and, finally, sensitivity analyses that take into account the voluntary nature of the proposal and the likely sharing of savings between health plans and states.

A. Presentation of Base Scenario Estimates

Table 1 below presents the total potential annual and ten-year cumulative savings for each of the base scenarios. The penetration assumptions used to generate the scenarios are outlined in Section IV.B, below. Again, the savings shown in the base scenarios represent the total dollar value of the additional rebates if the federal rebates became available to Medicaid MCOs. How these savings might be constrained and/or apportioned have not been factored in.

[6] The pharmacy component of the capitation rate is, of course, just one facet of the broader issue of capitation rate adequacy. In many sates, the MCO rates are determined through a bidding and negotiation process with the state Medicaid agency.

Table 1. Savings Estimates Assuming Varying Penetration Growth Percentages

Penetration Grwoth Assumptions		Total Savings (in millions)	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
	No Change	Total Savings	$ -	$ 49.4	$ 56.1	$ 63.6	$ 72.2	$ 81.9	$ 91.8	$ 102.9	$ 115.4	$ 129.3	$ 145.0
		Cumulative Savings	$ -	$ 49.4	$ 105.4	$ 169.0	$ 241.2	$ 323.2	$ 415.0	$ 518.0	$ 633.3	$ 762.7	$ 907.6
	Low	Total Savings	$ -	$ 50.0	$ 57.5	$ 66.1	$ 76.0	$ 87.3	$ 99.0	$ 112.4	$ 127.4	$ 144.5	$ 163.9
		Cumulative Savings	$ -	$ 50.0	$ 107.5	$ 173.6	$ 249.6	$ 336.9	$ 435.9	$ 548.3	$ 675.7	$ 820.2	$ 984.2
	Mid	Total Savings	$ -	$ 53.5	$ 65.5	$ 79.7	$ 96.5	$ 116.5	$ 138.3	$ 163.8	$ 193.3	$ 227.7	$ 267.5
		Cumulative Savings	$ -	$ 53.5	$ 119.0	$ 198.7	$ 295.3	$ 411.8	$ 550.1	$ 713.8	$ 907.2	$ 1,134.8	$ 1,402.4
	High	Total Savings	$ -	$ 58.5	$ 76.8	$ 98.9	$ 125.6	$ 157.8	$ 194.0	$ 236.6	$ 286.7	$ 345.4	$ 414.3
		Cumulative Savings	$ -	$ 58.5	$ 135.3	$ 234.2	$ 359.8	$ 517.6	$ 711.6	$ 948.2	$ 1,234.8	$ 1,580.2	$ 1,994.6

As Table 1 clearly indicates, the nationwide savings potential is quite large in all of the scenarios. Even under the most conservative assumptions regarding capitated pharmacy penetration (i.e., no growth from current penetration levels over the next ten years), annual savings start at approximately $50 million in the first year and grow to almost $150 million in year 10, for a cumulative savings of more than $900 million over the ten years. The most aggressive assumption (i.e., high growth in capitation pharmacy penetration) results in cumulative savings of almost $2 billion over the 10-year period.

While it is impossible to know which of these scenarios will play out, the "mid" scenario represents Lewin's best estimate of the degree to which Medicaid pharmacy costs will be capitated. This scenario is based on a growth in capitated pharmacy penetration over the next 10 years from approximately 32 percent to 55 percent for TANF, and from 13 percent to 25 percent for SSI. The annual savings generated in this scenario grow to $267 million by year 10, with cumulative savings of $1.4 billion.

B. Assumptions Used in Deriving Base Scenario Estimates

1. Medicaid Enrollment

According to CMS estimates, the total Medicaid population as of June 30, 2001, was 35.5 million. To trend the Medicaid population forward 10 years, annual trend rates of 2 percent for the SSI population and 1 percent for the TANF population were used, per CMS' 2000 Medicaid Chartbook.

It is assumed that 75 percent of the Medicaid population is in the TANF and TANF-related eligibility categories, with the remaining 25 percent in the SSI and SSI-related categories. While some percentage of Medicaid recipients are in other eligibility categories, we were unable to produce PMPM savings estimates for these categories within the scope of this study. However, some of these recipients do receive their pharmacy benefits through capitated programs, and we did not want to assume that there would be no savings associated with these groups. Therefore, we have assumed that these "other" eligibility categories will be similar to the combined TANF and SSI categories with respect to financial impact and simply subsumed them within the TANF and SSI categories for purposes of this study.

2. TANF and SSI Capitated Pharmacy Enrollment

While the number of Medicaid managed care enrollees nationally is generally available, it is difficult to obtain reliable and consistent data on enrollment in the various types of managed care (e.g., capitated programs versus primary care case management programs). It is even more challenging to pinpoint the number of capitated managed care enrollees who receive their pharmacy benefits through the capitated program versus through a FFS carve-out. The Lewin Group estimated June 2001 TANF and SSI capitated pharmacy enrollment from various data sources, on a state-by-state basis. We then calculated the penetration rates resulting from these estimates and created four base scenarios of capitated enrollment for the upcoming 10 years. The first and most conservative scenario assumes that capitated penetration will remain constant over the next 10 years, and thus capitated enrollment in this scenario grows only as a result of general growth in the Medicaid population. Each of the other three scenarios projects additional growth in capitated enrollment based on different assumed penetration rates at the end of the 10-year period, with smooth annual growth rates. The penetration rates assumed at the end of the 10-year period in each of the scenarios are presented below.

Table 2. Penetration Rate Assumptions for Year 2012

Penetration Growth Scenario	TANF	SSI
No Growth	31.8%	13.1%
Low	35.0%	15.0%
Mid	55.0%	25.0%
High	80.0%	40.0%

Note: All figures reflect estimated proportion of population whose pharmacy costs will be paid for through capitation payments to managed health care organizations.

3. PMPM Value of Additional Federal Rebate

Per-member-per-month ingredient costs for the 2002 base year were estimated at $14.45 for the TANF capitated population and $158.96 for the SSI capitated population, using data collected during Lewin's previous CHCS study and additional data not available at the time of that study. Ingredient cost savings resulting from an extension of the federal rebate to Medicaid MCOs had been estimated at 14.2 percent in the previous CHCS study, based on an average rebate percentage of 5.2 percent for Medicaid MCOs versus 19.4 percent for FFS Medicaid. This savings percentage was applied to the TANF and SSI PMPM ingredients costs, resulting in an estimated PMPM value of $2.05 for TANF and $22.57 for SSI.

These PMPM savings estimates were projected forward 10 years based on the pharmacy cost trend assumptions described below.

4. Pharmacy Cost Trend

Lewin used a pharmacy cost trend taken from "Health Spending Projections for 2001-2011: The Latest Outlook" by Heffler et al. from CMS' Office of the Actuary. The average annual increases in spending nationally on prescription drugs projected by CMS are outlined in the table below. As CMS's projections did not extend to the year 2012, Lewin simply continued the annual trend CMS projected for years 2008 through 2011 for an additional year.

Table 3. CMS Projection of Annual Increases in National Spending on Prescription Drugs

Annual Periods	Percentage Increase
2002	13.5%
2003-2007	11.7%
2008-2011	10.3%

All of the assumptions described above and their incorporation into the savings calculations may be viewed in Appendix B.

C. Sensitivity Analyses

The sensitivity analyses that follow address the likely sharing of savings between states and MCOs, and the voluntary nature of the proposal:

- First, we split the PMPM savings 50/50 between the states and the MCOs, as we believe that the states will retain at least some of the savings themselves. Tables 4 and 5 show the distribution of the TANF PMPM savings and the SSI PMPM savings, respectively.

Table 4. TANF PMPM Savings: Sensitivity Analysis

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Total Potential PMPM Savings - Base Scenarios	$ 2.05	$ 2.29	$ 2.56	$ 2.86	$ 3.19	$ 3.57	$ 3.94	$ 4.34	$ 4.79	$ 5.28	$ 5.83
PMPM Savings Cut to MCOs Assuming 50/50 Share Between MCOs and States	$ 1.03	$ 1.15	$ 1.28	$ 1.43	$ 1.60	$ 1.78	$ 1.97	$ 2.17	$ 2.39	$ 2.64	$ 2.91
PMPM Savings to States Assuming 50/50 Share Between MCOs and States	$ 1.03	$ 1.15	$ 1.28	$ 1.43	$ 1.60	$ 1.78	$ 1.97	$ 2.17	$ 2.39	$ 2.64	$ 2.91

Table 5. SSI PMPM Savings: Sensitivity Analysis

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Total Potential PMPM Savings - Base Scenarios	$ 22.57	$ 25.21	$ 28.16	$ 31.46	$ 35.14	$ 39.25	$ 43.29	$ 47.75	$ 52.67	$ 58.10	$ 64.08
PMPM Savings Cut to MCOs Assuming 50/50 Share Between MCOs and States	$ 11.29	$ 12.61	$ 14.08	$ 15.73	$ 17.57	$ 19.63	$ 21.65	$ 23.88	$ 26.34	$ 29.05	$ 32.04
PMPM Savings to States Assuming 50/50 Share Between MCOs and States	$ 11.29	$ 12.61	$ 14.08	$ 15.73	$ 17.57	$ 19.63	$ 21.65	$ 23.88	$ 26.34	$ 29.05	$ 32.04

- Second, the voluntary nature of the proposal would certainly result in some health plans electing to participate and others electing not to participate in the federal rebate program. In modeling this impact, we reduced the projections incorporated in the base scenarios by 50 percent. That is, we have modeled the savings that would accrue if roughly half of the country's Medicaid managed care enrollment was in health plans that elected to participate in the federal rebate.

Table 6. Impact of Voluntary Nature of Program on Total Dollar Savings

Penetration Grwoth Assumptions		Total Savings (in millions)	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
	No Change	Total Savings	$ -	$ 24.7	$ 28.0	$ 31.8	$ 36.1	$ 41.0	$ 45.9	$ 51.5	$ 57.7	$ 64.7	$ 72.5
		Cumulative Savings	$ -	$ 24.7	$ 52.7	$ 84.5	$ 120.6	$ 161.6	$ 207.5	$ 259.0	$ 316.7	$ 381.3	$ 453.8
	Low	Total Savings	$ -	$ 25.0	$ 28.8	$ 33.0	$ 38.0	$ 43.6	$ 49.5	$ 56.2	$ 63.7	$ 72.3	$ 82.0
		Cumulative Savings	$ -	$ 25.0	$ 53.8	$ 86.8	$ 124.8	$ 168.4	$ 218.0	$ 274.1	$ 337.8	$ 410.1	$ 492.1
	Mid	Total Savings	$ -	$ 26.8	$ 32.7	$ 39.8	$ 48.3	$ 58.2	$ 69.2	$ 81.9	$ 96.7	$ 113.8	$ 133.8
		Cumulative Savings	$ -	$ 26.8	$ 59.5	$ 99.4	$ 147.6	$ 205.9	$ 275.0	$ 356.9	$ 453.6	$ 567.4	$ 701.2
	High	Total Savings	$ -	$ 29.3	$ 38.4	$ 49.5	$ 62.8	$ 78.9	$ 97.0	$ 118.3	$ 143.3	$ 172.7	$ 207.2
		Cumulative Savings	$ -	$ 29.3	$ 67.6	$ 117.1	$ 179.9	$ 258.8	$ 355.8	$ 474.1	$ 617.4	$ 790.1	$ 997.3

To illustrate the effect of apportioning the PMPM savings equally between the state Medicaid programs and the Medicaid MCOs, and assuming 50 percent MCO participation in the federal rebate, we show total dollar savings and cumulative dollar savings, as well as the Medicaid program and MCO shares, for the "mid" scenario in Table 7, below.

Table 7. Impact of Sensitivity Analysis on Total Dollar Savings, Mid Scenario

Mid Scenario	Total Savings (in millions)	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
	Total Savings	$ -	$ 26.8	$ 32.7	$ 39.8	$ 48.3	$ 58.3	$ 69.2	$ 81.9	$ 96.7	$ 113.8	$ 133.8
	Medicaid Program Share	$ -	$ 13.4	$ 16.4	$ 19.9	$ 24.1	$ 29.1	$ 34.6	$ 40.9	$ 48.3	$ 56.9	$ 66.9
	MCO Share	$ -	$ 13.4	$ 16.4	$ 19.9	$ 24.1	$ 29.1	$ 34.6	$ 40.9	$ 48.3	$ 56.9	$ 66.9
	Cumulative Savings	$ -	$ 26.8	$ 59.5	$ 99.4	$ 147.6	$ 205.9	$ 275.0	$ 356.9	$ 453.6	$ 567.4	$ 701.2
	Medicaid Program Share	$ -	$ 13.4	$ 29.8	$ 49.7	$ 73.8	$ 102.9	$ 137.5	$ 178.5	$ 226.8	$ 283.7	$ 350.6
	MCO Share	$ -	$ 13.4	$ 29.8	$ 49.7	$ 73.8	$ 102.9	$ 137.5	$ 178.5	$ 226.8	$ 283.7	$ 350.6

Any number of additional sensitivity analyses can be applied to the savings estimated in the base scenarios to address the other potential mitigating factors described in Section III. For instance, the pharmaceutical industry's reaction to the proposal would almost certainly be powerful and at least partially successful, and could very well constrain significantly the PMPM projections incorporated in the base scenarios. Changes in MCO-PBM relationships potentially resulting from health plan participation in the federal rebate program might lead to increased administrative fees to the MCOs, which would partially offset savings. Further, MCOs might encounter additional costs that partially offset the savings achieved, e.g., as a result of added administrative burden to the extent they operate prior authorization programs internally, revise rebate report formats, etc. We have not modeled such impacts here, but they are potentially significant and should be kept in mind.

V. CONCLUSIONS

The PMPM dollar value and total dollar value of the additional rebates that would be available if the federal rebates were extended to Medicaid MCOs are significant. The Lewin Group has produced a range of estimates and sensitivity analyses that provide an "order of magnitude" sense of the potential annual and cumulative savings over a ten-year period. Nationwide,

annual savings growing to more than $100 million, and cumulative 10-year savings exceeding $700 million, are clearly possible—even if one assumes that only half of the total potential savings will be realized due to the voluntary nature of the proposal.

However, there are a number of factors that could limit the level of savings that occurs, chief among them the almost certain reaction of the pharmaceutical industry. At best, the industry's crusade would delay the implementation of any policy change and consume state and Medicaid MCO time and resources and, at worst, succeed in preventing such a policy shift altogether. In addition, while the trade-offs may not be as significant as once thought, Medicaid MCOs stand to jeopardize some of their current successes in managing the pharmacy benefit—for example, they may have to give up effective relationships with their PBMs for their Medicaid lines of business, wait longer to receive rebates, or incur new administrative costs. For some MCOs, the potential benefits may clearly outweigh the potential costs. Other MCOs may conclude that, as one health plan representative put it, "The Plan's primary focus [in controlling pharmacy costs] is driven by coordination of prescribing patterns. Rebate initiatives are a secondary or tertiary level approach and have minor impact on how the Plan manages drug costs." Such MCOs may determine that their efforts to manage the pharmacy benefit are better spent in areas other than extension of the federal rebate.

In assessing whether to push for a change in existing rebate policies, MCOs need to assess the degree to which the rather lucrative potential of additional rebate amounts will be realized, as well as the degree to which new costs will emerge that offset the added rebate revenue.

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[i] The Henry J. Kaiser Family Foundation, "Medicaid Outpatient Drug Benefits: Findings From a National Survey and Selected Case Study Highlights," October 2001.

[ii] Center for Health Care Strategies, "Comparison of Medicaid Pharmacy Costs and Usage between the Fee-for-Service and Capitated Setting," January 2003.

[iii] Center for Health Services Research and Policy, The George Washington University Medical Center, "Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts," Fourth Edition, 2001.