



The Drug Rebate Equalization Act

The Lewin Group Assessment of Projected Impacts

Prepared for: Medicaid Health Plans of America

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Introduction

Medicaid Health Plans of America (MHPA) commissioned The Lewin Group to perform further analysis on the newest version of the Medicaid Prescription Drug Rebate Equalization Act, H.R. 904/S. 547, hereafter referred to as the DRE.

The DRE seeks to extend the discounts offered under the Medicaid Drug Rebate Program to Medicaid beneficiaries who receive prescription drugs through Medicaid MCOs. Currently, these Federal rebates are only provided for purchases made directly by the state (i.e., fee-for-service) for the Medicaid population.

The Medicaid Drug Rebate Program was created under the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). Under this program, brand name prescription drugs for the Medicaid population purchased by the state are subject to rebates from drug manufacturers based on the average manufacturer price (AMP) and best price. AMP represents the average price paid by wholesalers or retail pharmacies to manufacturers. Best price is the lowest price available from the manufacturer to any payer excluding certain federal government purchasers (e.g., Department of Defense, Department of Veterans Affairs).

For brand name drugs, the OBRA rebate has two components. The basic rebate component for brand name drugs is the greater of either: (1) 15.1 percent of AMP or (2) the difference between AMP and best price. The Congressional Budget Office estimated that the average basic rebate for brand name drugs at the end of 2007 was 23.1 percent of the AMP. For multi-source generic drugs, the rebate is equal to 11 percent of AMP; there is no best price provision. In addition to the basic rebate, there is an additional rebate paid by manufacturers on brand name drugs should the AMP of the drug increase faster than the overall inflation rate as measured by the Consumer Price Index .

In addition to the federally mandated OBRA rebates, many states have negotiated supplemental rebates with drug manufacturers on top of the OBRA rebates to ensure placement of particular drugs on the states' preferred drug lists.

At least four of the DRE's provisions were amended from the version introduced in the 110th Congress. Specific analyses were requested in response to seven questions. These seven questions are shown below in bolded text, with Lewin's response provided underneath each one.

Executive Summary

1. How will the DRE likely impact capitation rates and the rate-setting process? Will the rate setting process change depending on who (state or MCO) collects the OBRA rebate?

The DRE should not significantly change capitation rates or the rate-setting process. The DRE addresses Federal OBRA rebates only and does not apply to supplemental rebates. If states collect the OBRA rebates, as would occur under the 2009 version of the DRE, MCOs would submit drug utilization data to states quarterly, who would then submit combined FFS and MCO drug utilization data to drug manufacturers to obtain the OBRA rebates for both FFS and MCO drug volume.

Regardless of whether the OBRA rebates are captured by the state (as in the 2009 version) or the MCOs (as in the 2007 version), we do not anticipate a significant change in the MCOs' net revenue. The State would still pay the MCOs a capitation rate based on projected drug costs minus the estimated level of rebates. If the MCOs were to collect the OBRA rebate directly, the State would take this into account during the rate setting process and pay the MCOs less upfront in the capitation rate.

2. How would other Medicaid drug rebate policies being considered affect Medicaid MCOs under current law and how would they affect Medicaid MCOs were the DRE to be enacted simultaneously?

Two of the Congressional Budget Office budget options (Options 74 and 76) would raise the rebate amounts Medicaid receives, particularly for brand-name drugs. Should these two options be enacted along with the DRE (Option 75), the rebate dollars Medicaid receives from manufacturers should increase substantially, first by extending the rebates to a larger population, and second, by increasing the minimum level of rebates on brand drugs up to 22.1 percent of AMP. These options would benefit the State greatly, but should not have a large impact on the MCOs' net revenue in conjunction with the DRE provisions.

However, should these two options be enacted under current law – that is, the DRE does not pass – then both will put increasing pressure on states to carve-out the pharmacy benefit. With the increased rebates, it would be very difficult for a state to pay an MCO an actuarially-sound capitation rate that is equivalent to what net expenditures would be in the FFS setting (and for the MCOs to operate viably at such a rate).

3. What are the additional administrative costs to states of managing the rebates as outlined in the new legislation?

The 2009 DRE bill will likely impose few additional administrative costs on states. Most states currently receive MCO encounter data for use in the rate setting process, so submission and collection of the drug utilization data is already in place. Additionally, states already have oversight mechanisms in place, including federally required Drug Use Review Boards and MCO contracts that include formulary-related requirements.

4. What are the practical implications of the oversight language added to the 2009 version of the DRE bill and how does it differ from current law with regards to state oversight?

The additional oversight language will likely have little impact on states' current practices regarding oversight of MCO formularies. Most states currently use their MCO contracts to exercise oversight over MCO formularies and impose formulary requirements, such as allowing MCOs to use a restrictive formulary as long as it allows access to all drug products through a prior authorization process.

5. Is it possible for HHS/CMS and/or states to misinterpret the legislative language and intent and move to restrict MCOs from using drug utilization management tools?

The 2009 DRE bill allows MCOs to establish a formulary based on the positive inclusion of drugs selected by a formulary committee, as long as drugs excluded from the formulary are available through prior authorization. Under the DRE, MCOs would not be required to follow the same policies and practices as those established by the State. It is our understanding that MCOs would be able to impose quantity limits, step therapy, prior authorization, and other common utilization management practices. They would, however, not be able to completely exclude a drug from their formulary, without providing a prior authorization process, as described above.

6. What is the impact of the addition of language to the 2009 version of the DRE bill preventing "double-dipping" with 340B providers?

We believe that the change in the 2009 version was to bring the DRE provisions back in line with the original intent of the 340B program, as "double dipping" was prevented per the Veterans Health Care Act of 1992. It is our understanding that the intent of the DRE legislation is to disallow OBRA rebates for drugs purchased through the 340B program, regardless of whether the medications are provided through Medicaid MCOs or the FFS program.

MCOs will need to provide states with drug volume data in a manner that distinguishes drugs purchased through a 340B contract from non-340B medications. Overall, we do not anticipate a significant administrative burden for either the State or MCOs to separate the non-340B drugs for rebate submission.

7. How will this legislation affect the ability of MCOs to continue to negotiate supplemental rebates directly with pharmaceutical companies privately?

The DRE bill would not prohibit MCOs from negotiating supplemental rebates with pharmaceutical companies, as the DRE addresses Federal OBRA rebates only. Similar to what states do currently, we do not see any reason why the MCOs would not be able to continue to negotiate with manufacturers in order to ensure placement on the formulary or drive volume towards specific products. The dollar amount of the supplemental rebates negotiated would likely decrease under the DRE, but the opportunity to negotiate supplemental rebates should still be available.

With the State collecting the OBRA rebate directly, we do not anticipate a significant change in the capitation rates paid to the MCOs. While MCOs would not have to pass on their supplemental rebates directly to the states, some level of supplemental rebates that MCOs are expected to receive would be accounted for during the capitation rate development process, as they are currently.

Questions and Response

- 1. In the newest version of the DRE, states would collect the rebate instead of the health plans. What are the implications of this change in policy? How will this likely impact capitated payment rates and the rate-setting process? What are typical time periods for pharmaceutical rebates and how would the timing variations impact payments to health plans?**

Lewin Response:

Impacts of the DRE on Capitated Payment Rates and the Rate Setting Process

The current legislation language can be interpreted in various ways and perhaps should be refined and clarified. Our interpretations regarding the issues raised in this question are as follows:

First, we believe that the DRE addresses Federal OBRA rebates only. The DRE would therefore not apply to supplemental rebates (beyond the Federal rebates) that the State negotiates with drug manufacturers, nor would the DRE apply to the private rebates that managed care organizations (MCOs) negotiate with manufacturers. For naming convention, we refer to these private rebates to the MCOs as supplemental rebates throughout our responses as these rebates would serve a similar function under the DRE to the state supplemental rebates.¹

Second, there are two ways that rebate collection could occur when the pharmacy benefit is “carved-in,” both of which would be a change from current law, as shown in Exhibit A below. One option, depicted as Scenario 1 in Exhibit B below, is that the State would directly obtain all Federal rebates from manufacturers for prescriptions rendered to Medicaid MCO enrollees. This appears to be the approach put forth in the current version of the DRE legislation. In this scenario, MCOs would continue (as now occurs) to negotiate and collect any manufacturer rebates they are able to in order to ensure placement on the formulary or drive volume towards specific manufacturer products. Manufacturers would, however, know that they must pay the State the full Federal rebates in addition to whatever rebates are agreed to with the MCOs. For other (non-MCO) Medicaid medications paid for by the State in the fee-for-service (FFS) setting, the State would also not be prevented from negotiating additional, supplemental rebates with manufacturers as they do currently.

Exhibit A: Drug Rebate Dollar Flow Current Law

- State collects OBRA rebate for FFS Medicaid utilization through the following steps, which are performed on a quarterly basis:
 - 1) State Medicaid agency submits its own FFS Rx utilization data to the drug manufacturers quarterly

¹ The terms “private rebate” and “supplemental rebate” are often used interchangeably by the industry to refer to the rebates negotiated by MCOs.

- 2) Drug manufacturers provide OBRA rebates to the state Medicaid agency based on the FFS Rx volume only
- MCO receives a capitation payment for its covered services. The pharmacy component of the capitation rate is based on MCO Rx cost minus a discount for the supplemental rebates that the state estimates the MCO will receive in the upcoming period²

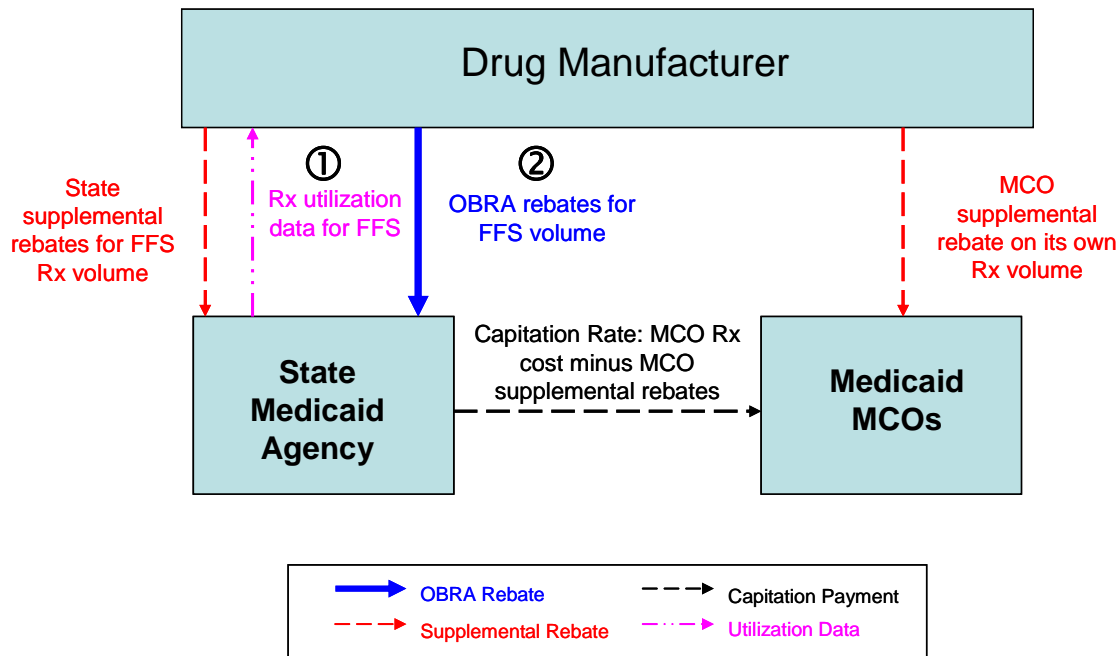
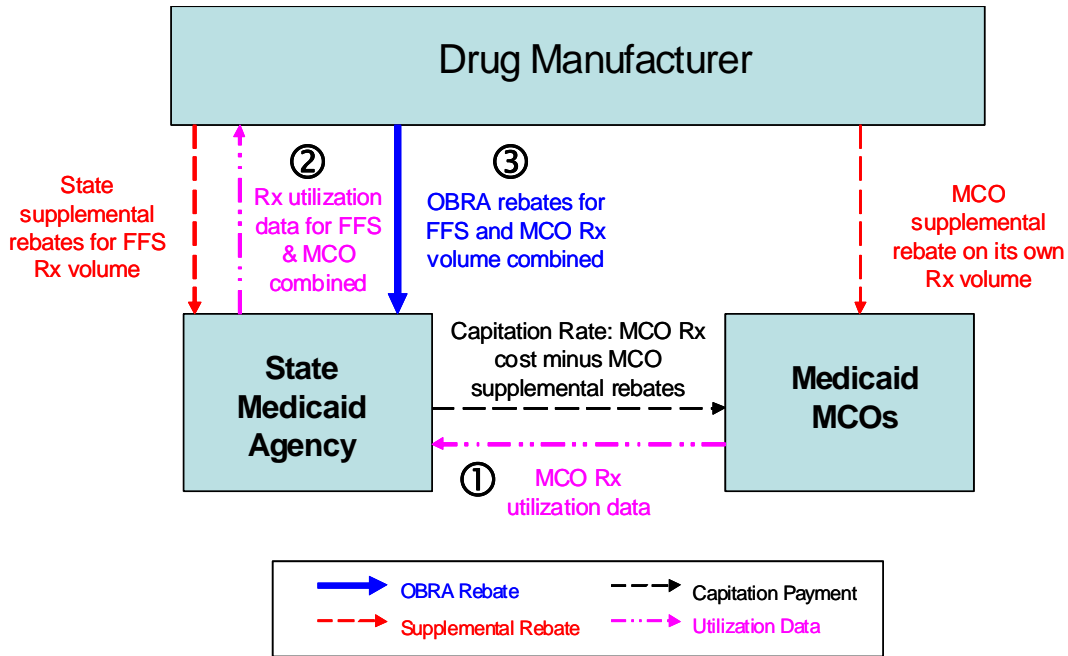


Exhibit B: Drug Rebate Dollar Flow Scenario 1

- State collects OBRA rebate for all Medicaid utilization (FFS and MCO experience is combined) through the following steps, which would be performed on a quarterly basis:
 - 1) Medicaid MCOs provide Rx utilization data to the state Medicaid agency quarterly
 - 2) State Medicaid agency combines its own Rx utilization data with the Rx utilization data received from its MCOs and reports it to the drug manufacturers
 - 3) Drug manufacturers provide OBRA rebates to the state Medicaid agency based on the combined FFS and MCO Rx volume
- The pharmacy component of the capitation rate continues to be based on MCO Rx cost minus a discount for the supplemental rebates that the state estimates the MCO will receive

² The pharmacy component of the capitation rate may be adjusted further for differences in utilization and brand/generic mix between the managed care and FFS environments.

in the upcoming period (this is the same as the current rate setting process without the DRE)



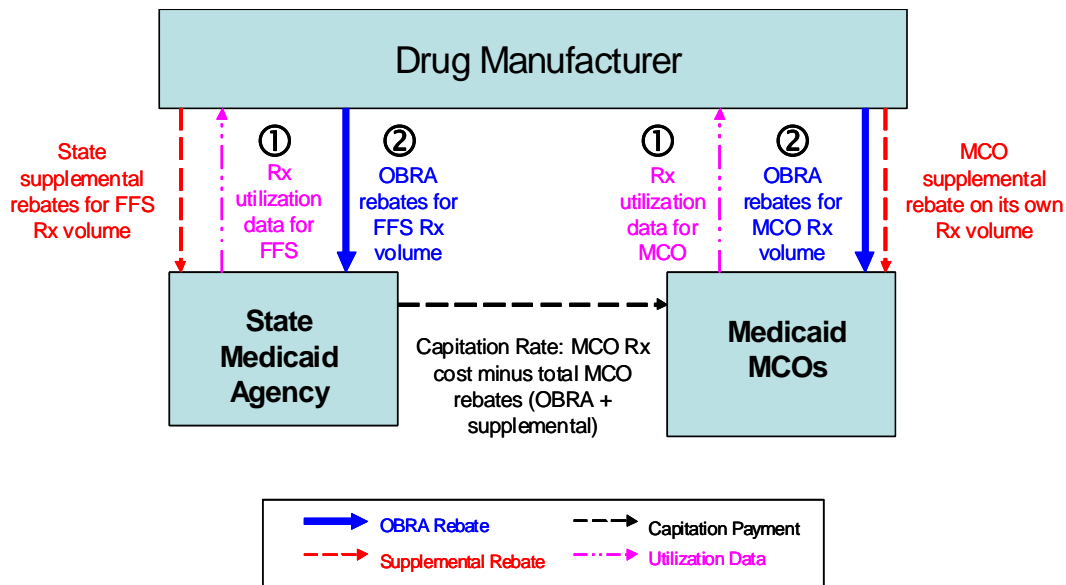
Under Scenario 2 in Exhibit C below, the state would not collect Federal rebates on Medicaid medications paid for by Medicaid MCOs – these rebates would be collected by the plans themselves. This scenario was envisioned in the original DRE language, although sentences were removed from the original DRE language (and other sentences were added to the 2009 version of the bill) that shift the rebate collection approach to Scenario 1.³ In a situation where the Federal rebates are collected by the MCOs, the states’ capitation rates to MCOs would need to be lowered by an actuarially appropriate amount, such that the state obtains the same net cost advantage as would occur under Scenario 1.

Exhibit C: Drug Rebate Dollar Flow Scenario 2

- MCOs collect OBRA rebates directly from the manufacturer on their Rx utilization through the following steps, which would be performed on a quarterly basis:
 - 1) State Medicaid agency reports its Rx utilization data to the drug manufacturers AND the Medicaid MCOs separately report their Rx utilization data to the drug manufacturers quarterly

³ The 2009 version of the DRE bill removed the following language shown in italics: “payment for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to *and that the State shall allow the entity to collect such rebates from manufacturers.*”

- 2) Drug manufacturers provide OBRA rebates to the state Medicaid agency based on its FFS Rx volume AND drug manufacturers separately provide OBRA rebates to the Medicaid MCOs based on their Rx volume
- During capitation rate development, the State discounts the MCOs' drug cost by an estimate of the total rebates (OBRA plus any supplemental) that the MCO will receive – essentially getting rebate dollars by paying the MCOs less in the capitation rate



Regardless of whether the OBRA rebate dollars are captured by the State or the MCOs directly, we do not anticipate a significant change in the MCOs' net revenue for the pharmacy benefit in either scenario over the current environment. As stated in the both the 2007 and 2009 versions of the DRE legislation, the "...capitation rates paid to the entity shall be based on actual cost experience related to rebates." Currently, the State and its actuaries typically build in a discount factor into the pharmacy costs to account for the supplemental rebates the MCOs obtain from the drug manufacturers. Under the 2009 DRE legislation (Scenario 1), we do not envision the capitation rate setting process changing. The State would still pay the MCOs based on projected drug costs minus some level of supplemental rebates. Under the 2007 DRE legislation (Scenario 2) where the MCOs would have collected the OBRA rebates directly, the State would have built in an additional discount factor to account for the OBRA rebates the MCOs would have received, essentially receiving the rebate dollars by reducing the capitation rate accordingly. Exhibits D, E, and F below display the flow of the pharmacy component of the capitation rate, rebate, and drug expenditure dollars for the managed care population and describe the net impact on the state, MCOs, and drug manufacturers using illustrative data.⁴

⁴ The cost and rebate dollars in these examples are hypothetical. The rebate percentages are representative of the experience of a couple of states and MCOs used in prior Lewin analyses, but actual rebate levels would vary by state and Medicaid MCO.

Exhibit D: Current "Carve-in" Model

- MCO Cash Flow:
 - Medicaid Cap Payment - \$105
 - Rx cost: \$100
 - 5% Supp. Rebate Factor: (\$5)
 - 10% Admin Load: \$10
 - Rx Expenditure - (\$100)
 - Drug Rebate - \$5
 - **Net: \$10 for admin/profit**
- Medicaid Cash Flow:
 - Medicaid Cap Payment - (\$105)
 - **Net: (\$105)**
- Drug Manufacturer Cash Flow:
 - Supp Rebate - (\$5)
 - **Net: (\$5)**

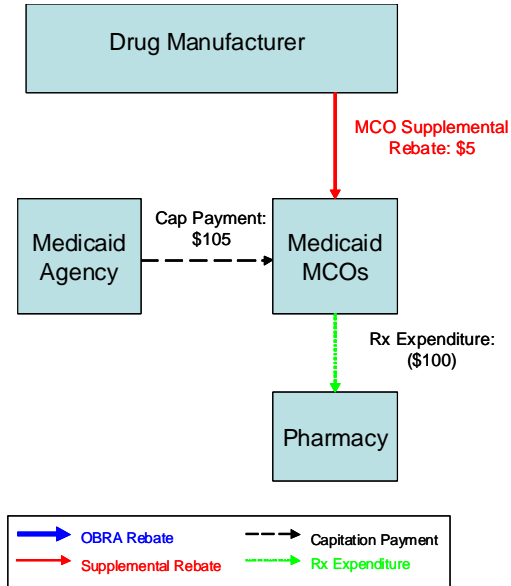


Exhibit E: State Collects OBRA Rebate (DRE 2009)

- MCO Cash Flow:
 - Medicaid Cap Payment - \$107
 - Rx cost: \$100
 - 3% Supp. Rebate Factor: (\$3)
 - 10% Admin Load: \$10
 - Rx Expenditure - (\$100)
 - Drug Rebate - \$3
 - **Net: \$10 for admin/profit**
 - **Change over Current: \$0**
- Medicaid Cash Flow:
 - Medicaid Cap Payment - (\$107)
 - 30% OBRA Rebate - \$30
 - **Net: (\$77)**
 - **Change over Current: \$28**
- Drug Manufacturer Cash Flow:
 - Supp. Rebate - (\$3)
 - OBRA Rebate - (\$30)
 - **Net: (\$33)**
 - **Change over Current: (\$28)**

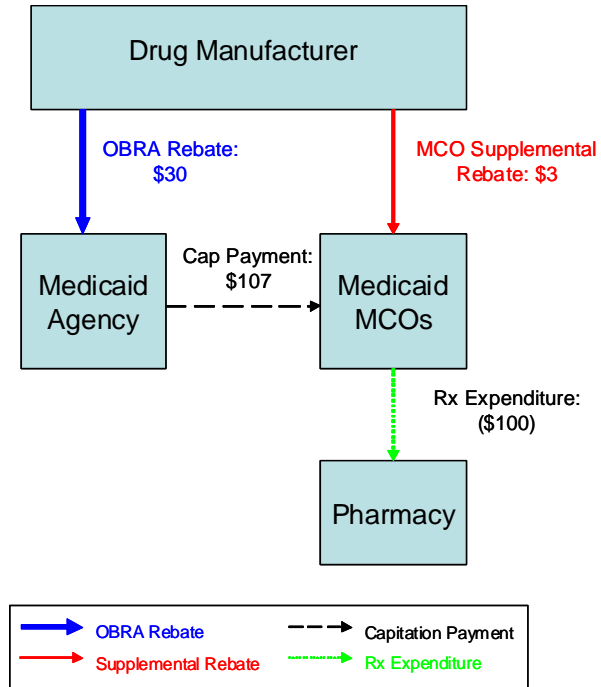
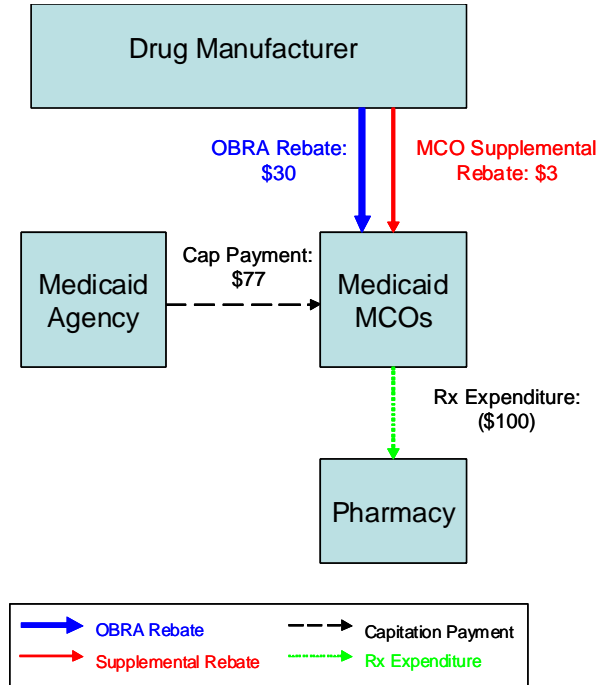


Exhibit F: MCO Collects OBRA Rebate (DRE 2007)

- MCO Cash Flow:
 - Medicaid Cap Payment - \$77
 - Rx cost: \$100
 - 3% Supp. Rebate Factor: (\$3)
 - 30% OBRA Rebate Factor: (\$30)
 - 10% Admin Load: \$10
 - Rx Expenditure - (\$100)
 - Drug Rebates - \$33
 - **Net: \$10 for admin/profit**
 - **Change over Current: \$0**
- Medicaid Cash Flow:
 - Medicaid Cap Payment - (\$77)
 - **Net: (\$77)**
 - **Change over Current: \$28**
- Drug Manufacturer Cash Flow:
 - Supp. Rebate - (\$3)
 - OBRA Rebate - (\$30)
 - **Net: (\$33)**
 - **Change over Current: (\$28)**



We anticipate that both DRE scenarios would create large-scale financial benefits for states and for the Centers for Medicare and Medicaid Services (CMS), and that the two scenarios should be roughly equivalent in terms of net Medicaid costs. Depending on how the negotiations between the various parties plays out, there could be situations in which the MCOs can better optimize the total rebate dollars for their actual drug mix should they collect the OBRA/DRE rebates directly. Conversely, net pharmacy costs might be minimized through the states directly collecting the rebates.

Overall, we do not anticipate that health plans will obtain a significant financial benefit from the enhanced rebates that occur through the DRE no matter which entity collects the OBRA rebate. If the MCOs receive these OBRA rebates (Exhibit F), the state is expected to recoup these savings through an appropriate capitation rate reduction. However, because states pay Medicaid MCO capitation rates on a prospective basis that does not exactly match the plan’s costs, there could be a net gain or loss to the State, and vice versa to the MCO, depending on how closely the capitation rate actually matches an MCO’s actual drug expenditures post rebate.⁵ While there might be a financial gain (or loss) to the MCO, we believe this would be

⁵ In Budget Option 75 (“Apply the Fee-for-Service Medicaid Drug Rebate to Drugs Purchased for Medicaid Managed Care Enrollees”), the Congressional Budget Office estimates that there would be smaller federal savings under our Scenario 2 because Medicaid MCOs would retain a portion of the higher rebate rather than pass on all savings to the Medicaid program. While we believe that the state would attempt to set capitation rates to recover the entire rebate, the overall impact could be either larger or smaller than that under Scenario 1, depending on how the prescription drug portion of the capitation rate matches the MCO’s actual net drug expenditures.

more a function of the prospective, at-risk model of capitation than a function of which entity collects the OBRA rebate dollars.

While the MCOs are not expected to see significant net financial gains under passage of the DRE, the plans will benefit from a total revenue perspective because the bill will strongly promote use of the carve-in model. (The pharmacy benefit accounts for roughly 20 percent of health plans' capitation revenue). Previous Lewin studies have found that MCOs will also benefit programmatically from having the pharmacy benefit included in – rather than pulled out of – their integrated system of coverage.⁶ Given the rebate levels that now exist, we view the DRE's passage as being a critical determinant as to whether the vast majority of states carve-in or carve-out the pharmacy benefit going forward.

In addition to the flow of funds and utilization data depicted in Scenarios 1 and 2 above, language in the 2009 version of the DRE bill requires states to report the total amount of rebates in dollars and volume received from manufacturers for drugs provided to Medicaid MCO enrollees to the Department of Health and Human Services on a quarterly basis. We believe that this provision will provide some transparency and accountability to the Medicaid program, but we do not anticipate it having a material effect on the capitation rate development process.

Time Periods for Pharmaceutical Rebates

Certain time periods associated with pharmaceutical rebates are governed by Section 1927 of the Social Security Act. According to 1927(b)(2)(A), states are required to report information on the total number of units of each dosage, form, strength, and package size for each of the covered drugs they paid for to each manufacturer no later than 60 days after the end of each quarterly rebate period. According to 1927(b)(1)(A), manufacturers are then required to pay the rebates to states no later than 30 days after they receive the above rebate information. There are audit and reconciliation processes that may delay the collection of all rebate dollars. For example, for drug expenditures incurred in the first quarter of the year, the utilization data would be reported to CMS and the manufacturers in the second quarter, with the majority of the rebate dollars being paid in the second and third quarters, but a small percentage of the rebates still remaining at the end of the third quarter.

Under the DRE, states would likely require MCOs to submit information on the total number of prescriptions, units, and reimbursed amount by NDC (i.e., labeler, product, and package size) for each of the drugs they covered within a reasonable period after the end of each quarter to allow the state enough time to combine the MCO utilization data with the FFS utilization data and send to the manufacturer within 60 days after the end of the quarter. We would expect that this information would be in a similar format to the data the states currently submit to the manufacturers and CMS.

⁶ Lewin Group studies include, "Programmatic Assessment of Carve-In and Carve-Out Arrangements for Medicaid Prescription Drugs" (October 2007), "Financial Assessment of Carve-In and Carve-Out Arrangements for Medicaid Prescription Drugs" (October 2007), "Analysis of Pharmacy Carve-Out Option for the Arizona Health Care Cost Containment System" (November 2003), and "Comparison of Medicaid Pharmacy Costs and Usage between the Fee-for-Service and Capitated Setting" (January 2003)

As MCOs would receive capitation payments on a prospective basis and OBRA rebate payments from manufacturers would go directly to the state under the 2009 version of the DRE, the timing of the rebate payments would likely not affect payments to the MCOs. Most states currently update rates annually, and we believe this would continue.

Should the MCOs collect the rebate directly as in the DRE legislation's 2007 version, we do not believe states would need to change their rate setting cycle. The state would review the MCOs' recent pharmacy utilization and rebate data during the rate setting process to make adjustments to the rebate assumptions to better match the capitation rates to the MCOs' net costs (i.e., post-rebate). Any substantial difference between the capitation rates and the MCOs' actual experience, both positive and negative, would be adjusted for in the next rate update. There is more uncertainty for the state and MCOs should the MCOs collect the OBRA rebate instead of the state; however, most of the pharmacy risk still lies in the MCOs' ability to control utilization versus their collection of OBRA rebates. Overall, there are so many components to rate setting, that the rebate assumptions built into the capitation rate would only be a small part as to whether a plan would gain or lose on the pharmacy benefit. The plan's ability to manage utilization would likely be a more significant factor in their profitability on the pharmacy line of service.

- 2. In the CBO Budget Options, Volume 1: Health Care, December 2008, Option 75, the CBO recognized significantly more savings to the state and federal governments with the states collecting the rebate. The CBO also outlined additional budget options (74-78) that impact the Medicaid Drug Rebate Program, some of which were later included in the President's Budget Proposal. How would these other Medicaid Drug Rebate policies – were they to be enacted – affect Medicaid health plans under current law and how would they affect Medicaid health plans were the Medicaid Prescription Drug Rebate Equalization Act to be enacted simultaneously?**

Lewin Response:

Of the budget options (74-78) that the CBO outlined in the CBO Budget Options, Volume 1: Health Care, December 2008, three of the options have been included in the President's Budget Proposal:

- Option 74: Modify the amount of the brand-name drug rebate in the Medicaid program. This option as defined in the President's Budget Proposal would increase the benchmark rebate amount on brand-name drugs from 15.1 percent of AMP to 22.1 percent. The best price provision would still apply.
- Option 75: Apply the Fee-for-Service Medicaid Drug Rebate to Drugs Purchased for Medicaid Managed Care Enrollees. This option is what has been proposed under the Drug Rebate Equalization Act.
- Option 76: Apply the Medicaid Additional Rebate to New Formulations of Existing Drugs. This option would not allow the AMP to be reset on new dosages or formulations – specifically extended-release versions – of existing drugs in respect to calculating the inflationary component of the OBRA rebate.

Both Option 74 and Option 76 would raise the rebate amounts Medicaid receives, particularly for brand-name drugs. Should these two options be enacted along with the DRE (Option 75), the rebate dollars Medicaid receives from manufacturers should increase substantially, first by extending the rebates to a larger population, and second, by increasing the minimum level of rebates on brand drugs up to 22.1 percent of AMP or increasing the inflationary component of the rebate. The increase in OBRA rebate dollars would likely create downward pressure on the supplemental rebates states and MCOs can negotiate. While the supplemental rebates may decrease, these two options should not create much of a change to the cash flow and operational processes described in the DRE scenario laid out in our answer to Question #1. Options 74 and 76 would benefit the state greatly, but should not have a large impact on the MCO's net revenue in conjunction with the DRE provisions.

However, should these two options be enacted under current law – that is, the DRE does not pass – then both will put increasing pressure on states to carve-out the pharmacy benefit. As many states with a carve-in model are already close to the tipping point, we believe that these two options, particularly the increase in brand drug rebates to at least 22.1 percent of AMP, would compel all states to implement a carve-out model for the pharmacy benefit. With the increased rebates, it would be very difficult for a state to pay an MCO an actuarially-sound capitation rate that is equivalent to what expenditures would be in the FFS setting (and for the MCO to operate viably at such a rate).

We feel that the most significant threat to the viability of the carve-in model under existing law is Option 74. The increase of the basic rebate portion on brand drugs to at least 22.1 percent of AMP would create substantial savings to Medicaid FFS programs. At the current level of 15.1 percent, the CBO estimates that the average basic rebate on brand drugs was 23.1 percent of AMP. This average basic rebate is higher than the 15.1 percent threshold due to some drugs having a “best price” that is substantially lower than AMP – 15.1 percent, raising the average rebate up considerably. Under Option 74, the average rebate for brand drugs should increase several percentage points, as the rebate dollars on numerous drugs currently at the minimum level would increase 7 percent. (Though the overall impact on total rebate dollars would be less than 7 percentage points as the “best price” on the drugs already below the AMP – 22.1 threshold would probably not change 7 percent as well). Many state FFS programs have reported total rebates (OBRA plus supplemental) that represent up to 30 to 35 percent⁷ of the state's initial (pre-rebate) Medicaid pharmaceutical claims expenditures. Without a substantial decrease in supplemental rebates, increasing the basic component of the brand drug rebate would likely drive the total rebate percentage close to 40 percent of initial pharmaceutical expenditures, making a carve-in model unsustainable from a state's budget perspective.

While not directly related to the Medicaid Drug Rebate program, the CBO Budget Options also include an option (Option 67) that would require manufacturers to pay a minimum rebate on drugs covered under Medicare Part D. This option would use Medicaid's rebate program as a model and would require manufacturers to pay a rebate on brand-name drugs

⁷ The Lewin Group. “Analysis of Drug Rebate Equalization Act's Savings to the Medicaid Program.” prepared for the Association for Community Affiliated Plans, September 2008.

equal to 15.1 percent of AMP, with an additional rebate for price increases that exceed inflation; however, the best price provision would not apply. These rebates would apply to all Medicare Part D beneficiaries.

For the dual-eligible population (about 6.3 million), this option would be a restoration of the rebate dollars manufacturers paid before the creation of Part D. Before the implementation of Part D in 2006, the pharmacy expenditures for these dual-eligibles were covered under Medicaid and received the OBRA rebates. We estimated this shift of the dual-eligible pharmacy benefit from Medicaid to Part D to have increased pharmacy spending by approximately \$3.2 billion in 2009⁸, as the rebates that Part D plans have received (estimated to be about 8.1 percent⁹) and utilization management techniques can not overcome the Medicaid rebates lost.

Due to the size and volume of pharmacy expenditures for the Medicare population, providing “Medicaid-like” rebates to the entire Medicare population (and not just the dual-eligibles) would likely reduce rebates to other payers such as Medicaid. As the OBRA rebate levels are prescriptive and would not change, supplemental rebates to the state and Medicaid MCOs would likely be reduced. As the Medicare rebate option would not lead to an increase in the Medicaid OBRA rebates such as Options 74 and 76, this option could result in an overall increase in drug spending for the states, as the Medicaid program could see their supplemental rebates decrease without an offsetting share in the increase rebates given to Medicare.

- 3. What are the additional administrative costs to states of managing the rebates as outlined in the new legislation? Was the additional cost of managing Medicaid MCO rebates factored into the CBO’s estimates of states’ savings? If CBO did include the rebate administration costs, do you believe their estimates and assumptions are accurate?**

Lewin Response:

The 2009 version of the DRE bill will likely impose a few additional administrative costs on states. Under Scenario 1 detailed in the response to Question #1 above, in which states collect the Federal OBRA rebates for all Medicaid prescription medication utilization, there would be no change to the capitation rate development process beyond collecting the MCOs’ drug utilization data to report to CMS and the manufacturers. Depending on the maturity of the managed care program, most states currently receive the MCOs’ encounter data for use in the rate setting process, so submission and collection of the drug utilization data is already in place for many states. There may be some administrative cost to ensure that the MCOs’ drug utilization data is submitted timely and in the correct format in order to be combined with the State’s FFS drug data; however, we don’t believe this would be a significant cost. Additionally,

⁸ The Lewin Group. “Analysis of Dual Eligible Pharmacy Costs Under Medicaid and Medicare Part D.” prepared for the Association for Community Affiliated Plans, September 2008.

⁹ US House of Representatives Committee on Oversight and Government Reform, Majority Staff; “Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage”; October 2007.

there may be some administrative burden in terms of the dispute resolution process with the drug manufacturers over the MCOs' utilization data. Depending on how this dispute process is operationalized, there could be some additional costs to the states but we do not view this to be a major factor in the overall financial impacts this legislation would create.

If MCOs are able to collect the OBRA rebates directly from manufacturers based on their prescription medication utilization (Scenario 2), then states would have the added step of accounting for OBRA rebates (in addition to the supplemental rebates) that an MCO receives as part of the capitation rate setting process. The process of adding an OBRA rebate discount into the capitation rate setting process would not be a significant burden to the state or its actuarial contractor.

Aside from administrative costs related to the data collection and the capitation rate development process, states could potentially have minor additional administrative costs due to increased oversight of MCO formularies, as allowed for in the 2009 version of the DRE bill. However, many states already have mechanisms in place to review prescription medication claims data and state-imposed formularies. For example, states are currently required to institute Drug Use Review (DUR) programs. Per Section 1927(g)(3) of the Social Security Act, states must establish a DUR Board composed of health care professionals with the appropriate knowledge and expertise in outpatient drugs. The DUR Board is charged with retrospective drug use review and assessment of data on drug use against predetermined standards (e.g., monitoring for therapeutic appropriateness, over and under utilization, appropriate use of generic products). As states already have this Board in place, its established review processes could be applied to the MCO program.

Furthermore, many states that currently carve-in prescription drugs already conduct oversight activities, ranging from including formulary-related requirements in their contracts with MCOs to reviewing prescription medication claims data. Because states are already engaged in some formulary and prescription drug claims review activities, there should not be a significant increase in administrative costs related to oversight of an MCO's formulary.

The CBO Budget Options report does not state whether the additional cost of managing Medicaid MCO rebates was factored into the its estimates of states' savings. It is therefore unclear whether the CBO considered this element in their estimate.

4. Language was added in the newest version to attempt to clarify or restate that states have oversight authority over managed care contracts and certifying formularies. What are the practical implications of this new language, if any, and how does it differ from current law with regards to state oversight?

Lewin Response:

The 2009 version of the DRE bill includes language related to state oversight that was not included in the 2007 version. This language is shown in italics below:

“A Medicaid managed care organization with a contract under section 1903(m) may exclude or otherwise restrict coverage of a covered outpatient drug on the basis of policies or practices of the organization, such as those affecting utilization management,

formulary adherence, and cost sharing or dispute resolution, in lieu of any State policies or practices relating to the exclusion or restriction of coverage of such drugs, *provided, however, that any such exclusions and restrictions of coverage shall be subject to any contractual requirements and oversight by the State. As contained in the Medicaid managed care organization's contract with the State, the State shall maintain approval authority over the formulary used by the Medicaid managed care organization.*"

This additional language will likely have little impact on states' current practices regarding oversight of MCO formularies. Most states currently use their MCO contracts to exercise oversight over MCO formularies and impose formulary requirements. For example:

- Michigan's MCO contract requires the MCO to have a process to approve physicians' requests to prescribe any medically appropriate drug that is covered under the Medicaid FFS program.
- Ohio's MCO contract requires MCOs to cover the same drugs covered by the Medicaid FFS program. Although the State allows the MCO to impose prior authorization requirements, MCOs must receive prior approval from the State for the medications that they wish to cover through prior authorization.
- Oregon's MCO contract allows MCOs to use a restrictive formulary as long as it allows access to other drug products not on the formulary through a process, such as prior authorization. The State requires MCO formularies to include FDA approved drug products for each therapeutic class that is sufficient to ensure the availability of covered drugs with minimal prior approval intervention and to include at least one item in each therapeutic class of over-the-counter medications.
- Virginia's MCO contract requires MCOs to report their formulary and pre-authorization requirements annually. The contract also requires MCOs to abide by the same requirements as the FFS program, responding to authorization requests within 24 hours and paying for at least a 72-hour supply of drugs prescribed for emergency medical conditions.

Additionally, some states have carved out certain classes of drugs from the MCO benefits package. Examples of these classes of drugs include mental health drugs, such as antipsychotics and antidepressants, HIV/AIDS drugs, and hemophilia drugs.

Because states currently exercise oversight and control over MCO formularies by imposing requirements in the MCO contract, the addition of the language to the 2009 version of the DRE bill is not likely to significantly affect current state practices. Furthermore, states would still retain the ability to exclude (i.e., carve-out) certain drug classes from the managed care program.

- 5. One of the key issues that was debated when the Medicaid drug rebate was first enacted was the issue of open formularies. Under the Medicaid Drug Rebate Program, states must have open formularies, but may manage utilization through prior authorization. Some have suggested that if rebates are extended to health plans, similar open formulary requirements should apply. However, it is our view – and we believe consistent with this version of the legislation – that plans would be permitted to manage their formularies using common drug utilization practices. Can you clarify the drug utilization management tools that would be**

permissible for health plans under this legislation? Would it be possible for HHS/CMS and/or states to misinterpret the legislative language and intent and move to restrict health plans from using common drug utilization management tools? Does the policy affect the incentives health plans have to lower pharmacy costs and find savings?

Lewin Response:

Under the Medicaid Drug Rebate Program, states are required to cover all FDA-approved drugs made by manufacturers that have a signed federal rebate agreement, with a few exceptions (e.g., barbiturates, agents used for anorexia, weight loss, or weight gain). However, states may impose prior authorization requirements on these drugs in order to manage utilization, as long as the state abides by requirements outlined in Section 1927(d)(5) of the Social Security Act:

“(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization;

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).”

Under the DRE bill, MCOs would be allowed to establish a formulary “based on the positive inclusion of drugs selected by a formulary committee consisting of physicians, pharmacists, and other individuals with appropriate clinical experience as long as drugs excluded from the formulary are available through prior authorization, as described in paragraph (5)” of Section 1927(d) outlined above.

Under the DRE bill, MCOs would be able to apply utilization management techniques to their formularies and would not be required to follow the “same such policies and practices as those established by the state.” It is our understanding that MCOs would be able to impose quantity limits, step therapy, prior authorization, and other common utilization management practices. They would, however, not be able to completely exclude a drug from their formulary, without providing a prior authorization process, as described above. Additionally, as discussed in the response to Question #4, MCOs would be subject to any contractual requirements imposed by states.

As several states that currently carve-in prescription drugs already impose requirements regarding MCO formularies through their MCO contracts, we do not believe that MCO practices regarding formularies would change dramatically with the passage of the DRE bill. Several states, including Oregon and Virginia, only allow MCOs to limit their formularies as long as they allow access to other drug products that are not on the formulary through a prior authorization process. Despite certain regulatory and contractual requirements, it is our view that MCOs would still be able to lower pharmacy costs and find savings by imposing common utilization management practices under the DRE bill.

Working with the pharmacy claims data from a state where all medications are paid for in the FFS setting, and with another state where claims were obtained from several carve-in MCOs, Lewin has analyzed the number of unique drug products being accessed in the FFS and MCO

settings.¹⁰ We found that Medicaid MCOs, with their current utilization management techniques, still provide substantial access to drugs that is comparable to a FFS setting (see Attachment 1). Based on these data and the contractual requirements already in place in many states, we believe that MCOs would be able to continue existing utilization management practices and still meet any of the access requirements already in place for Medicaid FFS programs under the Drug Rebate Program.

6. **Language was amended to prevent “double-dipping” with 340B providers, whereby pharmaceutical companies would potentially provide 340B pricing and be subject to the Medicaid Drug Rebate for pharmaceuticals provided through 340B pharmacies contracted with managed care organizations. What is the impact of this change on the ability of PBMs and/or health plans to collect rebates on 340B drugs? How would this affect discounts and price concessions health plans already get on 340B drugs? Describe the payment streams on 340B drugs under this legislation between states, pharmaceutical companies, 340B pharmacies, health plans and their PBMs, when applicable. Compare such payments with prior versions of the legislation. What are the operational implications for MCOs from the 340B change? Would MCOs need to track 340B claims separately from other pharmacy claims?**

Lewin Response:

The 2009 version of the DRE bill includes language that prevents states from receiving Federal OBRA rebates on 340B medications that are provided to Medicaid MCO enrollees. The 2009 version states that:

“Covered outpatient drugs are not subject to the requirements of this section if such drugs are-

- (A) dispensed by health maintenance organizations, *including* Medicaid managed care organization that contract under section 1903(m); and
- (B) subject to discounts under section 340B of the Public Health Service Act.”

The 2007 version of the DRE bill previously stated “other than” instead of “including” in paragraph (A), which would have given Medicaid MCOs the potential to “double dip” by obtaining OBRA rebates on drugs purchased at 340B prices. We believe that the change in the 2009 version was to bring the DRE provisions back in line with the original intent of the 340B program, as this “double dipping” was prevented for medications provided to Medicaid FFS enrollees per the Veterans Health Care Act of 1992. Section 602 of the Veterans Health Care Act of 1992 prohibits manufacturers from paying duplicate discounts or rebates for drug purchased through the 340B program - a duplicate discount would occur if an up-front 340B discount on the acquisition cost and a back-end transaction Medicaid rebate were provided on the same drug. We believe that the intent of the DRE legislation is to disallow OBRA rebates for drugs

¹⁰ The names of the states have not been disclosed, at the request of the organizations providing data for this comparison.

purchased through the 340B program, regardless of whether the medications are provided through MCOs or the FFS program.

The Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA) has developed guidelines for 340B entities on how to ensure that this “double dipping” does not occur on drugs provided to Medicaid beneficiaries. OPA has developed a Medicaid Exclusion File to be used by state Medicaid agencies and manufacturers to ensure that duplicate discounts are not paid on the same claim. The Medicaid Exclusion File identifies whether a 340B entity intends to fill Medicaid prescriptions with 340B-purchased drugs. A 340B entity may choose to dispense drugs to Medicaid beneficiaries outside of their 340B contract. 340B entities have two major options for billing Medicaid:

- 340B entity identifies itself as filling Medicaid prescriptions with 340B-purchased drugs in the Medicaid Exclusion File. The entity bills Medicaid at the 340B acquisition cost plus a dispensing fee. The State does not request a rebate on these 340B drugs.
- 340B entity “carves out” Medicaid drugs from the 340B program and bills Medicaid on the State’s pharmacy reimbursement fee schedule. The State collects rebates on these drugs as they are equivalent to all other outpatient drug purchases.

The HRSA Medicaid Exclusion Tutorial¹¹ mentions that generally 340B entities use the second option and do not include Medicaid prescriptions as part of the 340B agreement with their contract pharmacy. The Medicaid prescriptions are essentially “carved-out” and filled by the contract pharmacy, or any other pharmacy where the patient chooses to take the prescription, using non-340B inventory. Under this reimbursement option, any drug dispensed by a 340B entity would be treated like any other Medicaid prescription under FFS and would receive the OBRA rebates based on the process described in Exhibit B. For 340B entities that provide Medicaid prescriptions under their 340B purchasing contract (i.e., they are reimbursed at the 340B acquisition price), Medicaid drug claims would have to be identified as such using the Medicaid Exclusion File or another method. The volume of drugs from these providers should be excluded from the other Medicaid drug claims sent to CMS and the manufacturers to obtain the OBRA rebates. The 340B entity would bill Medicaid an amount that does not exceed the entity’s actual acquisition cost for the drug plus a dispensing fee.

Under the DRE, we believe that the MCOs would have similar reimbursement options as the State. The MCO could reimburse the 340B entity at the 340B acquisition price or at a price similar to what the MCO reimburses other retail pharmacies. If the MCO reimburses a 340B entity at the 340B acquisition price, then the drugs dispensed from that provider should be excluded from the drug volume reported to get the OBRA rebates. Depending on their contract arrangements with a 340B entity, some MCOs already remove the drugs purchased at 340B acquisition cost from their volume when negotiating supplemental rebates. On the assumption that the states will be collecting the OBRA rebates from manufacturers (as discussed in Question #1 above), all MCOs will need to provide states with drug volume data in a manner that distinguishes medications purchased through a 340B contract from non-340B medications.

¹¹ <http://www.hrsa.gov/opa/medicaidexclusion.htm>

As an established method for excluding the 340B-purchased drugs already exists for the state and some MCOs, only some MCOs may need to make an administrative change to ensure that 340B-purchased drugs are correctly identified and removed from their reported volume for the OBRA rebate. Overall, we do not anticipate a significant administrative burden for either party to separate out the non-340B drugs for the OBRA rebate submission.

- 7. How will this legislation affect the ability of health plans to continue to negotiate supplemental rebates directly with pharmaceutical companies privately? How would such rebates interact with the Medicaid Drug Rebate Program? How would the process likely work in the collection of supplemental rebates beyond best price with state collection of rebates? Is there even a possibility that health plans would have to pass their rebates to states? What is the potential impact of the extension of the Medicaid Drug Rebate Program on the Medicaid health plan's ability to negotiate supplemental rebates, if permitted? Would the rebates and any other permissible price concessions allowed on pharmacy benefits provided through health plans under this legislation match the rebates provided to states through fee-for-service to truly level the playing field?**

Lewin Response:

It is our understanding that the DRE bill would not prohibit the MCOs from negotiating supplemental rebates directly with pharmaceutical companies. As the DRE bill addresses Federal OBRA rebates only, it would not impose new regulations concerning supplemental rebates. As states currently negotiate supplemental rebates in addition to the OBRA rebates on their FFS drug volume, we do not see any reason why the MCOs would not be able to continue to negotiate in a similar manner and collect any manufacturer rebates they can in order to ensure placement on the formulary or drive volume towards specific manufacturer products. Manufacturers would, however, know that they must pay the State the OBRA rebates in addition to whatever rebates are agreed to with the MCOs, which may have the effect of reducing the level of supplemental rebates manufacturers provide in aggregate. The supplemental rebates to both the State and MCOs would likely decrease as drug manufacturers attempt to offset the overall increase in the rebate dollars they now must provide.

With the State collecting the OBRA rebate directly, we do not anticipate a major change in the capitation rate setting process. The pharmacy component of the capitation rate will still be based on some estimate of MCO drug cost minus any supplemental rebates. It is possible that the capitation rates would need to increase due to lower supplemental rebates collected by the MCOs under the DRE, but the gain in the OBRA rebates to the State on the MCO volume would handily outmatch any losses in supplemental rebates. While MCOs would not have to pass on their supplemental rebates directly to the states, some level of supplemental rebates that MCOs receive would be accounted for during the capitation rate development process. This is the current rate setting process and would not represent a change to the State or MCOs. Currently, the State applies a discount to the capitation rates to address the supplemental rebates that the State estimates the MCO would receive in the upcoming period. The capitation rates paid to the MCOs would reflect net pharmacy costs (i.e., post-rebate) plus some amount for administration of the program. We believe that states will not be able to double-dip on their supplemental rebates – that is, they will not be able to include both the FFS and MCO experience when negotiating their own supplemental rebates with manufacturers.

The DRE bill would level the playing field by treating each individual drug equally regardless if the drug was dispensed to a Medicaid FFS or MCO-enrolled beneficiary. However, as MCOs can better manage the benefit by reducing overall utilization and increasing the generic fill rate, the impact should create savings to both the State and CMS under a carve-in model compared to a carve-out model. In actuality, total rebate dollars collected may actually be less under a carve-in model under the DRE than a carve-out model but still produce savings due to a higher generic utilization rate and better overall management. As the rebates for brand drugs are substantially higher than for generic drugs, having a higher generic utilization rate will actually reduce rebates collected. But as the price of the generic is typically less than the price of the brand with a rebate (e.g., a \$20 generic is cheaper than a \$100 brand with a \$40 dollar rebate), this situation is advantageous to the State in terms of net expenditures.

Appendix 1

Analysis of Access to Drug Products Between Drugs Paid Via Fee-For-Service Medicaid Versus Medicaid Managed Care Organizations

The provisions of OBRA 1990 involved establishing Federal rebates to Medicaid medications paid for directly by the states. These Federal rebates have increased through the years to the point that they now typically represent more than 30% of the state's initial (pre-rebate) Medicaid pharmaceutical claims expenditures. The provisions of OBRA 1990 did not extend these rebates to medications paid for by Medicaid managed care organizations (MCOs). Currently, new legislation, known as the Drug Rebate Equalization Act (or DRE), would extend the same Federal rebates to medications purchased by Medicaid MCOs as occur in that state's Medicaid fee-for-service (FFS) program.

One of the premises for *not* extending the larger rebates to the MCOs is that the FFS setting ensures access to essentially all drug products. Thus, the larger FFS rebates correspond to the "strings" of providing more open access, whereas the MCOs receive much smaller rebates in return for having the ability to restrict access more aggressively.

Working with the pharmacy claims data from a state where all medications are paid for in the FFS setting, and with another state where claims were obtained from several carve-in MCOs, Lewin has analyzed the number of drug products being accessed in the FFS and MCO settings.¹ Several million prescriptions were obtained from each setting. The total prescription volume was approximately 20% lower in the MCO setting than the volume obtained from the Medicaid FFS setting. Thus, the tables below are slightly biased against the MCO setting; all other things equal, one would expect the MCOs to have used somewhat fewer drug products due to the smaller sample size of prescription volume.

Table 1 shows the unadjusted full number of products being accessed. We have tabulated the number of products being prescribed 1+ times, 10+ times, 100+ times, and 1,000+ times. These figures show that the MCOs paid claims for substantially more drug products than the FFS program whether the unit of measurement was the NDC code, the number of products with unique labels, or the number of drug names.

Table 1 also shows that the FFS program was paying for *heavy use* (defined as 1,000+ claims) of more pharmaceutical products than were the MCOs. This latter statistic could be misleading due to the smaller overall prescription volume occurring among the MCOs providing data relative to the FFS program being analyzed.

¹ The names of the states have not been disclosed, at the request of the organizations providing data for this comparison.

TABLE 1. COMPARATIVE TABULATIONS FOR ALL DRUG PRODUCTS

Table 1a. Number of NDC Codes With Claims by Claim Volume

	1+ Claim	10+ Claims	100+ Claims	1,000+ Claims
MCOs	17,596	9,856	4,070	913
FFS	13,521	9,336	4,456	1,085
MCOs as % of FFS	130%	106%	91%	84%

**Table 1b. Number of Label Names With Claims by Claim Volume
(excludes NDCs that did not match to standardized label name)**

	1+ Claim	10+ Claims	100+ Claims	1,000+ Claims
MCOs	7,471	4,334	2,100	701
FFS	5,543	4,016	2,169	794
MCOs as % of FFS	135%	108%	97%	88%

**Table 1c. Number of Brand Names With Claims by Claim Volume
(excludes NDCs that did not match to standardized brand name)**

	1+ Claim	10+ Claims	100+ Claims	1,000+ Claims
MCOs	3,986	2,288	1,143	453
FFS	2,733	1,998	1,124	490
MCOs as % of FFS	146%	115%	102%	92%

Some of the differences observed in Table 1 could be attributable to coverage differences. Specifically, we were concerned that the MCOs may be covering over-the-counter (OTC) medications to a much greater degree than was the Medicaid FFS program being analyzed. Table 2 controls for this issue by removing OTC medications from both sets of figures.

TABLE 2. COMPARATIVE TABULATIONS FOR NON-OTC DRUG PRODUCTS

Table 2a. Number of NDC Codes With Claims by Claim Volume

	1+ Claim	10+ Claims	100+ Claims	1,000+ Claims
MCOs	12,984	7,868	3,600	829
FFS	12,066	8,467	4,177	1,041
MCOs as % of FFS	108%	93%	86%	80%

**Table 2b. Number of Label Names With Claims by Claim Volume
(excludes NDCs that did not match to standardized label name)**

	1+ Claim	10+ Claims	100+ Claims	1,000+ Claims
MCOs	5,071	3,138	1,744	636
FFS	4,717	3,475	1,957	758
MCOs as % of FFS	108%	90%	89%	84%

**Table 2c. Number of Brand Names With Claims by Claim Volume
(excludes NDCs that did not match to standardized brand name)**

	1+ Claim	10+ Claims	100+ Claims	1,000+ Claims
MCOs	2,727	1,613	887	390
FFS	2,329	1,711	987	454
MCOs as % of FFS	117%	94%	90%	86%

The OTC-adjusted figures in Table 2 indicate that the MCOs provided access to 17% more unique products (focusing on the brand name) than did the FFS setting.² Similar to the unadjusted findings in Table 1, we also found that the FFS program used more drug products *heavily* than did the MCOs. Again, however, the fact that the MCO setting's overall volume was 20% lower may largely explain this finding regarding "heavy use" products.

Table 3 looks at the same information from one additional angle – the number of products (defined as brand names) being used in one setting but not in the other.

Table 3. # Of Brand Names Covered In One Setting But Not the Other (OTC Medications Excluded)

	1+ Claim	10+ Claims	100+ Claims	1,000+ Claims
Covered by FFS, but not MCO	569	437	251	135
Covered by MCO, but not FFS	954	339	150	71

Table 3 shows that both the FFS setting and the MCO setting had many instances where a product was prescribed only in one setting. Many of these occurrences are likely attributable to rarely used products where the patient need simply did not arise in the data year being assessed. Overall, there were 68% more instances (n = 954) where the MCO paid for at least one claim for a product but where FFS had no occurrence volume, relative to the number of products (n = 569) that were paid for at least once in the FFS program but never in the MCO setting. These statistics switched in the other direction as the claims volume threshold was increased.

Our key finding is that the MCO setting is providing access to as many – and in this case more – unique drug products than is the Medicaid FFS setting.³ This finding runs counter to perceptions about the restrictiveness of MCO formularies relative to Medicaid FFS. It can be inferred that the MCOs are permitting access to a very wide array of drug products when clinically indicated, although the MCOs may be steering volume more strongly towards certain products in general than does FFS (as suggested by the 1,000+ statistics in our tables). The generic fill rate in the MCO setting was 69.3%, well above that in the Medicaid FFS program (63.9%).⁴ Thus, the MCOs appear to be steering volume to lower-cost products while permitting access to a substantial array of products overall.

² The methodology for identifying and removing OTC products involved using a Generic Name Indicator field. Blank values suggested OTC products, as did "OTC-Other" in this field.

³ As the MCO and FFS experience are from different states, the formulary requirements and physician prescribing patterns within each state may account for some of this difference.

⁴ These generic fill rates exclude OTCs. The corresponding figures if OTCs are included in the calculation are 67.8% in the MCO setting and 62.6% in the FFS setting.