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Client Alert

FDA & Life Sciences Practice Group

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New York Institutes New Medicaid Drug Price Control Measures

State Budget Includes Medicaid Drug Expenditure Cap

On April 20, 2017, New York Governor Andrew Cuomo signed into law certain cost-control measures that attempt to cap the state's Medicaid drug spending, making New York the first state to pass such sweeping legislation. The law could have a significant impact on pharmaceutical manufacturers' New York Medicaid rebate liability.

New York's Fiscal Year 2018 budget (available here) includes a Medicaid drug expenditure cap provision that allows the state Department of Health ("DoH") to (a) set an annual projected spending target for pharmaceuticals, and (b) demand additional rebates of drug manufacturers to meet that target.[i]

If, based on quarterly projections for individual drug expenditures or all drugs covered under New York's Medicaid program, the DoH determines that Medicaid drug spending is projected to exceed the target, DoH officials are now empowered to negotiate additional supplemental Medicaid rebates ("Target Rebates") for specific drugs from drug manufacturers. The measure also permits the DoH to require that manufacturers submit extensive business and pricing information to the state. If a manufacturer does not agree to an additional rebate, then its drugs may be subject to prior authorization or other restrictions.

New York will need to obtain federal permission to change its Medicaid program. Specifically, a state is required to submit a State Plan Amendment ("SPA") to the Centers for Medicare & Medicaid Services ("CMS") for review and approval when there is a material change in state law, organization, or policy, or in the state's operation of its Medicaid program.[ii] New York's Medicaid drug cost control legislation appears to meet the material change threshold, thus arguably requiring that New York submit and obtain an SPA to effectuate the changes.

NEW YORK MEDICAID DRUG SPENDING GROWTH TARGET

The legislation requires the DoH to establish a Medicaid Drug Spending Growth Target ("Growth Target") each year using a methodology tied to the Consumer Price Index ("CPI"). For the years 2017-2018, the Growth

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Target is calculated using the 10-year rolling average of the medical component of the CPI plus 5%, less a pharmacy savings target of $55 million. For 2018-2019, the spending growth target is calculated using the 10-year rolling average of the medical component of the CPI plus 4%, less $85 million. The base amounts (that is, those amounts to which the percentage increases and millions in savings are to be applied) are oddly not specified in the legislation.

A key feature of the new law is the state's application of the Growth Target to individual drugs, principally to identify candidates for additional rebate demands. The law, however, fails to convey how the Growth Target will be reduced to drug-specific amounts, information that is critical to fully understand the practical impact of the law. Moreover, there is also no distinction between expenditure growth due to manufacturer price increases, on the one hand, or increased utilization, on the other, a difference that strikes us as important from a policy perspective.

SUPPLEMENTAL REBATE DEMANDS AND NEGOTIATIONS

Quarterly Expenditure Projections and Initial Department of Health Negotiations

Each quarter, the DoH must project the annual Medicaid expenditures for each covered drug and for all drugs covered under New York's Medicaid program, including both fee-for-service and Medicaid Managed Care utilization, *taking into account all manufacturer rebates received by the Department*. Based on those projections, the DoH may take action to curb expenditure growth beyond the annual Growth Target. If drug-specific spending is expected to exceed the annual target, the state will contact individual manufacturers and attempt to negotiate additional rebates. If the state and manufacturer come to an agreement (or earlier agreed to a supplemental rebate under the terms of the 2016 Budget amendments), then the manufacturer is sheltered from review by the New York DoH Drug Utilization Review Board ("DURB") for the remainder of the Growth Target period. If no agreement is reached regarding rebates for a particular drug, then the drug is referred to the DURB for review, further negotiations, and potential imposition of formulary and prior authorization sanctions.

The law does not clarify how drugs might be singled out for review and action by the DoH. There are factors that the DoH must consider—such as a "drug's actual cost to the state, including current rebate amounts," and "whether the manufacturer of the drug is providing significant discounts relative to other drugs covered by the Medicaid program"—but it is unclear how the DoH will prioritize specific drugs for additional supplemental rebate action.

Drug Utilization Review Board Action

If a drug is referred to the DURB for review, the DURB must first determine ***whether*** to recommend an additional supplemental rebate for the drug ("Target Rebate"), and, if one is called for, the DURB must set the ***amount*** of the Target Rebate.

In determining whether a Target Rebate should be established, the DURB must consider the actual cost of a drug to the state, net of federal and state rebates. The DURB is given the discretion to consider: (1) the drug's impact on the Growth Target; (2) the adequacy of capitation rates of participating Medicaid managed care plans; (3) the drug's affordability and value to the Medicaid program; (4) any significant and unjustified increase in the price of the drug; and (5) whether the drug may be priced disproportionately to its therapeutic benefits.

Once the DURB has determined that the imposition of a Target Rebate is appropriate, it will formulate a recommendation for the amount of the Target Rebate based on the following factors:

- Publicly available information relevant to the pricing of the drug;

- Information supplied by the DoH relevant to the pricing of the drug;
- Information relating to value-based pricing;
- The seriousness and prevalence of the disease or condition that is treated by the drug;
- The extent of utilization of the drug;
- The effectiveness of the drug in treating the conditions for which it is prescribed, or in improving a patient's health, quality of life, or overall health outcomes;
- The likelihood that use of the drug will reduce the need for other medical care, including hospitalization;
- The Average Wholesale Price ("AWP"), Wholesale Acquisition Cost ("WAC"), retail price of the drug, and the cost of the drug to the Medicaid program minus rebates received by the state;
- In the case of generic drugs, the number of manufacturers that produce the drug;
- Whether there are pharmaceutical equivalents to the drug; and
- Information supplied by the manufacturer, if any, explaining the relationship between the pricing of the drug and the cost of development of the drug and/or the therapeutic benefit of the drug or information that is otherwise pertinent to the manufacturer's pricing decision.

Any information provided by the manufacturer to the DURB during its assessment will be treated as confidential and will not be disclosed in a form that identifies a specific manufacturer or the prices charged by the manufacturer.

Given that one of the key considerations of the DURB is the cost of the drug to the Medicaid program, *net of rebates received by the state*, we do not anticipate that products for which the Medicaid Unit Rebate Amount ("URA") equals or is close to its Average Manufacturer Price ("AMP") will be subject to additional rebates. This is because products for which a significant part of the AMP is rebated to New York will, in general, be less of a net expenditure to the state than will drugs with smaller URAs. However, New York Medicaid's ingredient cost reimbursement rate is AWP minus 17% for brand drugs, or AWP minus 25% for generic drugs, subject to a MAC. For this reason, drugs with large AMP to AWP deltas may not be shielded from scrutiny even if their URAs equal or approach AMP.

Negotiating a Target Rebate

Based on the DURB Target Rebate recommendation, the DoH will engage in a second round of negotiations with each targeted manufacturer to agree on a rebate amount. If the DoH cannot negotiate a supplemental rebate of at least 75% of the DURB's Target Rebate, the Department may waive certain protections enjoyed by the drug under New York's Medicaid laws:

(1) Waive provisions relating to New York's Medicaid Managed Care programs that require Managed Care Organizations to cover medically necessary atypical antipsychotic, anti-depressant, anti-retroviral, anti-rejection, seizure, epilepsy, endocrine, hematologic, and immunologic therapies regardless of formulary status;[iii] and

(2) Waive the provision of the Medicaid Preferred Drug Program that allows prescribers to independently justify coverage of a pharmaceutical for a patient that fails to meet statutory prior authorization criteria.[iv]

The Department, however, is not permitted to implement one of these waivers if doing so would prevent a Medicaid recipient from accessing a drug that is the only treatment for a particular disease or condition.

The law provides, without explanation, that "under no circumstances shall the Commissioner be authorized to waive such provisions with respect to more than two drugs in a given time." We speculate that this language is intended to prevent waiver with regard to more than two drugs *in a therapeutic class* at one time, but it could also mean two drugs manufactured by a single company, or simply two drugs.

Further, if negotiations fail, the DoH would be permitted to subject drugs to prior approval. The DoH may also direct its eighteen Medicaid Managed Care plans to remove drugs from their formularies if a manufacturer fails to agree to a supplemental for those drugs.

Any supplemental rebate negotiated pursuant to this process in 2017 would be backdated to apply as of April 1, 2017. Supplemental rebates apply to Medicaid utilization regardless of whether it arises out of the state's managed care program or under fee-for-service. A small silver lining is that once the state changes are approved by CMS, any additional rebate amounts paid by manufacturers will be Best Price exempt.

While a supplemental rebate agreement is in place—which may be in addition to existing rebate agreements entered into by the manufacturer with respect to the same drug—no additional rebates shall be required to be paid to a managed care provider or any of a managed care provider's agents (*e.g.*, PBMs) while the Department is collecting the supplemental rebate. This is a tricky provision to interpret, but it appears to bar the imposition of *new* rebate obligations. One could read it, however, to suggest that the law pauses all "additional rebate" payments to MCOs during the time the supplemental is in place. This ambiguity will have to be addressed.

Data Disclosure Requirements If Negotiations Fail

If a manufacturer and the DoH cannot agree to a supplemental rebate based on the DURB recommendation, the manufacturer may be required by DoH to submit extensive information regarding its drug product, including:

- Actual cost of developing, manufacturing, producing (including cost per dose of production), and distributing the drug;
- Research and development costs for the drug, including payment to predecessor entities conducting research and development (*e.g.*, biotech companies, universities and medical schools, private research institutions);
- Administrative, marketing, and advertising costs for the drug, apportioned by marketing activities
    - Directed to consumers,
    - Directed to prescribers, and
    - Total cost of all marketing and advertising directed primarily to consumers and prescribers in New York (including, detailing, copay discount programs, and direct-to-consumer marketing);

- Extent of utilization of the drug;
- Prices charged for the drug to purchasers outside the U.S.;
- Prices charged to typical purchasers in the state, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers;
- The average rebates and discounts provided per payer type in the state; and
- The average profit margin of each drug over the prior five-year period and the projected profit margin anticipated for such drug.

Manufacturers are not currently required to provide this type of sensitive information to any other jurisdiction in the U.S. Although other states have pending bills that would require manufacturers to provide this type of information, New York is the first state to pass a transparency provision that requires reporting to state authorities such detailed cost and pricing information about particular products.

The New York legislation does not articulate how the DoH will *use* this information. One interpretation is that the data disclosure requirement is simply intended to be punitive, and therefore leverage in the negotiation process. Another is that the data could be used as the basis for imposing penalties under the additional formulary controls permitted under amended New York Public Health Law § 280(7)(A). Given that much of the required information would be useful to the DURB in formulating/improving its negotiating position, the state may attempt to leverage production with the threat of an all-out demand even before negotiations fail.

ADDITIONAL TOOLS TO PREVENT EXCEEDING THE ANNUAL GROWTH TARGET

If, after attempting to negotiate Target Rebates for all targeted pharmaceutical products, the total Medicaid Drug expenditures are nonetheless still projected to exceed the Growth Target, the Commissioner of Health may take a number of other actions. The DoH may subject to prior approval *all* drugs produced by a manufacturer that has refused to enter into a Target Rebate agreement, as well as direct the state's eighteen Medicaid Managed Care plans to remove those drugs from their formularies. Additionally, the Department may promote the use of cost effective and clinically appropriate drugs other than those subject to a failed Target Rebate negotiation. Manufacturers may be "permitted" to accelerate rebate payments under existing rebate contracts in an effort to meet short-term Growth Target goals (an interesting tactic to say the least).

Before the DoH takes advantage of any of these additional tools, it must first provide thirty days written notice to the Legislature, unless such action is necessary in the fourth quarter of a fiscal year to prevent Medicaid drug expenditures from exceeding the Growth Cap. In that case, thirty days written notice is not required. Given that the DoH is permitted to take a number of these actions unilaterally, we interpret this notice provision as a check on the agency, as well as a potential tracking mechanism to determine the effectiveness of such measures.

ADDITIONAL REBATES AND REQUIREMENTS FOR GENERIC DRUGS

New York also enacted specific provisions to limit the state's expenditures on generic drugs. The DoH may require manufacturers of generic drugs to pay additional rebates on utilization of any generic drug that has had significant price increases in a short period of time (specifically, increases of more than 75% of its state maximum acquisition cost ("SMAC") on or after April 1, 2017 in comparison to its SMAC at any time during the preceding twelve months).

This amendment makes significantly more onerous the state's pre-existing rule, which provided for additional rebates only for generic drugs with price increases greater than 300% of SMAC.

The Legislature also established *DoH reporting requirements* for generic price increases. The DoH must to submit a report to the Legislature by February 1 of each year detailing:

- The number of generic drugs that exceeded the price increase threshold (*i.e.*, an increase of greater than 75% SMAC) during the preceding year in comparison to the number of drugs that exceeded the price increase thresholds in specified baseline years (*i.e.*, 300% SMAC during 2014 and 2015 or at least 75% SMAC during 2015 and 2016);

- The average percentage amount by which the reported drugs exceeded the price increase threshold in the preceding year as compared to in baseline years;

- The number of generic drugs available to New York Medicaid beneficiaries, by fiscal quarter, in the preceding year in comparison to the drugs available by fiscal quarter during 2014, 2015, and 2016; and

- The total drug spend on generic drugs for the preceding year in comparison to the total drug spend on generic drugs during 2014, 2015, and 2016.

MEDICAID STATE PLAN AMENDMENT REQUIREMENTS

New York will need federal approval to effectuate the cost control legislation. A state is required to submit a State Plan Amendment ("SPA") to CMS for review and approval when there is a material change in state Medicaid law, organization, or policy, or in the state's operation of its Medicaid program.[v] New York State's Medicaid drug cost control measures appear to meet the material change threshold, thus arguably requiring that New York submit and obtain an SPA.

In general, if an SPA does not violate federal requirements and the SPA submission is complete, CMS is likely to approve it. Once CMS approves an SPA, the changes can take effect retroactively to the first day of the quarter in which the state submitted the SPA to CMS.[vi] Thus, if New York submits an SPA to CMS on or before June 30, 2017, the change would have a retroactive effective date of April 1, 2017 if approved.

The only federal public notice requirements for SPAs apply when a state proposes a significant change to its methods and standards for setting payment rates for services (which do not appear to be implicated in this law).[vii] States may have their own public notice requirements for SPAs, and New York appears to post state plan amendments on its Medicaid website, but only after they are filed with CMS.[viii] If New York submits an SPA and CMS approves it, notice will be published in the New York State Department of State's State Register prior to the effective date of the change.

As of the date of publication of this Client Alert, New York has not published notice of a filed SPA for the Medicaid drug expenditure cap provision of the state's Fiscal Year 2018 budget.

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We will continue to analyze the impact of this novel and complex legislation, and will continue to monitor state legislatures for additional price control legislation. We will be happy to assist you and your company with any and all pricing and transparency questions.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

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[i] N.Y. Senate Bill 2007B

[ii] *See* 42 C.F.R. § 430.12(c)(ii).

[iii] *See* 42 C.F.R. § 430.12(c)(ii).

[iv] *See* 42 C.F.R. § 447.256(c).

[v] *See* 42 C.F.R. § 430.12(c)(ii).

[vi] *See* 42 C.F.R. § 447.256(c).

[vii] *See* 42 C.F.R. § 447.205.

[viii] *See* New York State Department of Health, New York State Medicaid State Plan, Proposed and Approved State Plan Amendments, at www.health.ny.gov/regulations/state_plans/status/.