STATEMENT

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Testimony of the Pharmaceutical Research and Manufacturers of America

January 25, 2016

Submitted to the New York State Joint Legislative Budget Hearing on the 2016-17 Executive Budget Proposal on Health

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MEMORANDUM

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New York State Fiscal Year 2016-2017 Budget

January 21, 2016

In the 2016-2017 State Fiscal Year (SFY) New York State Executive Budget, Governor Cuomo proposes several policies that will negatively impact patient access to prescription drugs. Onerous proposals include disclosure provisions and price controls that could be ruinous to the current competitive market, and that could lead to higher drug prices and would do nothing to improve patient access to needed medicines.

PhRMA opposes the provisions of the Governor's proposal that would:

1) Require prescription drug manufacturers to report proprietary pricing information
2) Create the ability for the State to impose price controls
3) Repeal a prescriber's "dispense as written" authority (prescriber prevails) in both fee-for-service and managed care Medicaid
4) Provide authority to directly negotiate supplemental rebates in fee-for-service Medicaid for certain classes of drugs
5) Allow prior authorization of fee-for-service drugs in the Clinical Drug Review Program (CDRP) **before** the Drug Utilization Review Board (DURB) has evaluated a medicine

Implementing these proposals will limit patient access to needed medicines and will negatively impact biopharmaceutical research in New York, which benefits patients, jobs, and New York's economy.

PhRMA continues to support the extension of prescriber prevails to all drug classes in Medicaid managed care to help ensure that all patients have appropriate access to the prescription medicines that their provider determines is best suited to treat their health conditions. We also support statutory changes to ensure that a prescriber's determination is final.

1. **Require prescription drug manufacturers to report proprietary pricing information. This provision will not help patients, could threaten the innovation of future treatments, and may violate certain trade secrets and other privacy protections.**

The amendments to subdivision 7 of Section 367-a of the social services law are exploiting Medicaid patients to advance the agenda of insurers in the State of New York and nationally. Insurers, led by their trade association, American Health Insurance Plans (AHIP), have been creating a bait and switch by claiming that the disclosure of proprietary information about drug research and development and the business practices of America's biopharmaceutical companies will provide benefits to patients and state governments, which it will not. This rhetoric is aiming to take the spotlight off of the insurance industry, which is struggling to uphold its end of the bargain in health reform. Biopharmaceutical companies have been upholding their end of the Affordable Care

Act (ACA), which greatly increased the amount of Medicaid rebates the industry pays[1], which has increased from $652 million in FY 2010 for medicines used by New York Medicaid patients to nearly $1.1 billion in FY 2014; fills in the donut hole for Americans who receive their drug benefit through Medicare Part D at a cost to the biopharmaceutical industry of $41 billion over 10 years, and supports other elements of the ACA through an annual fee ranging from $2.5 billion to upwards of $4 billion yearly.

Revealing Proprietary Information Can Ruin a Competitive Market and Lead to Higher Prices for All.

The Governor's budget would require biopharmaceutical manufacturers to reveal a significant amount of proprietary and trade secret information related to specific pricing, sales and marketing costs, and research and development (R&D) information to the State. In many cases, this information is highly confidential because it helps companies compete, and contracts often prohibit companies from disclosing such information. Neither the U.S. Department of Health and Human Services (HHS) nor the Food and Drug Administration (FDA) is permitted to disclose this type of information, even if requested.

In addition, the biopharmaceutical industry is one of the most heavily regulated industries in the U.S. Companies already report extensive information on costs, sales, clinical trials, and total research and development (R&D) expenditures. Requiring information on production and distribution costs for individual products may not be even feasible because the R&D process is long-term and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Accounting for these related discovery costs could be nearly impossible. Further, the collection of requested information could result in misleading assumptions because it does not take into account the cost of medicines and incremental advances that do not make it through the clinical trial process. The reality is that only 12% of medicines entering clinical trials make it to market, with 88% of the compounds researched failing late in the process. Not recognizing the expense associated with these failures results in an inaccurate calculation of the risky investments these biopharmaceutical companies are making. Also, it is clear that the State has not assessed the budget it would take to design and staff a system to collect this information from manufacturers.

The language seems to speculate that disclosing proprietary information will lower the State's prescription drug costs—this could not be further from the truth. In fact, the Federal Trade Commission's (FTC) Office of Policy and Planning, Bureau of Competition and Bureau of Economics cautioned the New York legislature in 2009 that disclosure of similar information would jeopardize the competitive market and remove incentives to provide discounts and additional rebates and "...may increase pharmaceutical prices".

The Budget Focuses on One Line Item and Ignores the Inherent Value of the Industry in Improving the Quality of Patients' Lives and Reducing Costs in Much Larger Areas of the Medicaid Budget.

This language singles out the biopharmaceutical industry—spending on which is less than 5 percent of TOTAL spending on Medicaid services and benefits in New York. In fact, there are a variety of stakeholders involved in determining what state Medicaid programs pay for a medicine including insurers, pharmacy benefit managers and wholesalers. The important role that these entities play in setting drug prices and in setting utilization management for the Medicaid program is overlooked by the requirements in this language. The irony is that insurers and pharmacy benefit managers oppose disclosure of their own similar information.

[1] The Affordable Care Act increased 1) the base Medicaid rebate from 15.1% of Average Manufacturer Price (AMP) to 23.1% of AMP, 2) applied the rebate to lives in Medicaid Managed Care (the rebate only applied to lives in fee-for-service Medicaid prior to ACA) 3) allowed for the expansion of Medicaid and 4) changed the calculation of AMP which also increased the rebate.

It is important to note that medicines are the *only* part of the healthcare system where costs decrease over time for patients and states. When brand name medicines face brand competition within a therapeutic class or when a brand's patent expires and generic drugs immediately enter the market, prices drop, often significantly. Today, nearly nine out of ten prescriptions are filled with a generic medicines that often cost pennies on the dollar, saving money for both patients and the healthcare system overall—we do not see savings like this anywhere else in the healthcare system.

What this proposal does not account for is the value provided by innovative therapies. It is important to remember that these advances help control healthcare spending. Greater patient access to prescription medicines means fewer doctor visits and hospital stays and a decrease in costly medical procedures, all of which translate into lower healthcare costs overall. In fact, if patients took their medicines exactly as prescribed, $213 billion could be saved annually in the United States.[2]

The State Should Focus on Collecting Millions of Dollars in Rebates It Is Already Authorized to Collect Rather Than Implementing Onerous Policies

The Department of Health reported last year that "Over the course of the last four years, DOH has collected more than **$8 billion** in pharmacy rebates and has saved an additional **$400 million** from transitioning pharmacy benefits from fee-for-service to managed care."[3] Moreover, Comptroller DiNapoli's audit of the 2015 Medicaid program found that the State did not collect an estimated $95.1 million from drug manufacturers due to inaccuracies in provider billing and invoicing processes. The findings in this audit mirror those of a report released in February 2015 that found DOH did not collect nearly $120 million in available rebates over a 33-month period because of ineffective policies and processes.[4]

PhRMA respectfully requests that the State focus on correctly collecting the significant rebates it claims it has not collected before implementing new and onerous policies that could have the perverse effect of raising prices, harming patient access to prescription medicines, and harming the biopharmaceutical industry in New York.

PhRMA cautions New York to not cut off the nose to spite the face by taking action on the advice of the insurance industry which would only result in higher costs for the State and will have grave effects on an industry that is a key component of the State's economy. Simply put, revealing competitors' pricing and discount information removes incentives to provide discounts in the marketplace, resulting in higher costs for the health care system.

2. **Creates the Ability for the State to Impose Price Controls**

Under the guise of so-called "transparency," the Governor's budget proposal allows the Department of Health to employ actuaries, analyze proprietary information, assess "value" and set a ceiling price for drugs. The State would then attempt to collect rebate penalties if the price of the drug increases more than an arbitrary ceiling price set by the State. First, the idea that an actuary would be able to conduct a full and respectable value analysis from the proprietary information submitted is deplorable. The idea of value includes *value to the*

[2] IMS Institute for Healthcare Informatics. Avoidable Costs in US Healthcare: The $200 billion Opportunity from Using Medicines More Responsibly.
[3] http://blog.timesunion.com/capitol/archives/245020/dinapoli-state-doh-failed-to-collect-more-than-95-million-in-drug-rebates/
[4] Ibid.

patient as well as value to the healthcare system. Value is not something that can be merely assessed by the price of a medicine. A drug may cost more in the short-term, but the long-term value to the patient and the healthcare system can be immense. But, these dividends may not be fully realized in the health plan year that the drug is administered. The Budget's proposal of a ceiling price based on some arbitrary definition of value and the further assessment of a tax based on this capricious design is shortsighted. This policy is a wolf in sheep's clothing and is nothing more than an attempt to cap and control prices at the expense of the Medicaid patient and New Yorkers in general. Any proposal to arbitrarily cap prescription drug prices would have a devastating impact on medical innovation, threatening to turn back the clock on progress that is being made against some of the most challenging and debilitating diseases of our lifetime. This proposal could result in fewer new medicines for patients, many of which are researched and developed in New York, and cost countless jobs in an industry that is vital to New York's economy and our nation's economic competitiveness.

The Medicaid Rebate Program, Enacted and Governed by Federal Law

The prices that state Medicaid programs pay for covered outpatient drugs, and the process by which these prices are determined, are established by federal law (Social Security Act §1927, "Payment for Covered Outpatient Drugs"). Medicaid rebate amounts are determined by a federal statutory formula and calculated by the Centers for Medicaid and Medicare services. <u>There is no State role in this pricing determination, and the State's attempt to insert itself in a matter of federal law and regulation conflicts with federal law</u>.

Federal law always preempts state law, and as a result, the federal Medicaid pricing arrangement – determined by statute and implemented by the federal government – will remain in place, as-is. A state attempt to impose a ceiling price on Medicaid drugs *cannot succeed* due to its inherent conflict with this federal structure. Even if the State were to impose Medicaid ceiling prices, in practice such a restriction would be meaningless, as Medicaid programs are required by federal law to cover medically necessary outpatient drugs – regardless of their price.

Currently, four major pharmacy benefit programs negotiate steep discounts on prescription drugs for MORE than 80 percent of all prescriptions filled in the United States—Express Scripts alone covers 90 million Americans. Each time a pharmacy benefit manager or other entity achieves a larger discount on drug purchased in the commercial market than the federal minimum rebate of 23.1% of AMP, state Medicaid programs immediately benefit without having to do anything—because by federal law, states must receive the best price that any commercial entity receives for a drug. In addition, state Medicaid programs are insulated from prices that increase faster than inflation. Specifically, the Centers for Medicare and Medicaid Services charges an additional rebate called the "inflation penalty" any time the price percent of increase is greater than the percent increase of the Consumer Price Index-Urban (CPI-U). All of this happens automatically for the State, and the State would be penny-wise and pound foolish to expend all of the resources to collect this <u>PROPRIETARY data</u> and employ actuaries who would not have the full data needed to make a "value assessment" that would fairly capture the value of a drug.

Rather than pursue short-sighted policies that would thwart medical innovation and threaten an industry that employs more than 55,564 people across the State, and likely would only cost the State money and will not bring the State the "savings" earmarked in this Budget, policymakers should focus on efforts that would enable patients to access existing treatment options while encouraging the development of the next generation of medicines that will improve and extend the lives of even more patients.

New York Needs to Be Careful When Comparing Medicine Costs to Those Abroad – Patients Abroad Have Diminished Access to Medicines

Several industrialized nations seek cost containment through price controls, which restrict access to medicines and discourage the research and development of new treatments. The U.S. relies on its competitive marketplace to control costs, while encouraging the development of new therapies. Because of the ecosystem that exists in the U.S., patients enjoy access to innovative medicines far earlier than patients in countries with centralized price controls, and the U.S. leads the world in drug discovery and development.

For example, in the U.K. the National Institute for Health and Clinical Excellence (NICE) considers not only the benefit, but also the cost in deciding what medicines will be covered by the U.K.'s National Health Service. As a result, patients are often denied access to innovative therapies. Specifically, between 2007 and 2013, almost 80 percent of cancer medicines reviewed by NICE have been given some kind of access restriction. In 2013, NICE rejected all six cancer medicines it reviewed.

In addition, U.S. cancer patients have higher survival rates than patients in Europe. The 5-year survival rate for all cancers is 40 percent higher for men and 13 percent higher for women in the U.S. than in Europe. Researchers have attributed the higher cancer survival rates in the U.S. to the greater availability of advanced treatment options. Also, a study by Tufts University found that between 2000 and 2005, 73 percent of medicines launched in the U.S. before becoming available in Europe – which was attributed to our nation's market-based system.

Further, price comparisons fail to acknowledge the effect of a competitive market in controlling costs. High generic utilization rates, competition among brand-name medicines, and, aggressive tactics by insurers to negotiate prices all help to control how much the U.S. health care system spends on medicines. Currently, nearly 90 percent of all medicines prescribed to U.S. patients are generics, which are typically up to 80 percent less than that of the brand medicine. In contrast, between 50-60 percent of all medicines prescribed in countries with strict price controls are generics and these medicines are more expensive. In addition, cross-country comparisons focus solely on the list prices of medicines and exclude from calculations the steep discounts that are required in U.S. public programs such as Medicaid and the additional discounts negotiated by insurers and pharmacy benefit managers.

Also, according the Ed Schoonveld, author of The Price of Global Health, "Many EU countries use tough rules and monopsony powers to exert low prices. These prices may not fairly cover research and development cost, but competing drug companies have no choice but to accept the price as it still gives some contribution to their cost of development and commercialization. Forcing these price levels to all higher income countries would seriously hamper innovation."

3. **Stripping "Dispense as Written" through Prior Authorization and Prescriber Prevails Processes**

The budget would prevent a prescriber from invoking "Dispense as Written", or prescriber prevails, for prescription medicines in Medicaid fee for service and in seven classes of drugs in managed care (the budget retains prescriber prevails for atypical antipsychotics and antidepressants). This requirement revokes a prescriber's right under current New York law to seek an exception for a patient to receive a particular medicine if, in a prescriber's best judgment, a specific medicine is the best choice to treat a patient's condition. In some cases, a patient may have an allergy to an inactive, generic ingredient or a specific-medical need (e.g., epilepsy) where a brand medicine must be used instead of the equivalent generic, for example.

Prescribing a medicine through the "prescriber prevails" process allows a practitioner's reasonable professional judgment to prevail. There are still many hurdles that a prescriber must go through to prevail and allow the patient to receive the prescriber's choice of medicine rather than the State's preferred medicine that is not custom-picked for the patient. It is a time consuming process, since prescribers must make the case for medical necessity by navigating through a health plan's prior authorization processes. In addition, according to Cornell Professor Sean Nicholson's analysis, prescriber prevails is only successful 0.1% of the time. Prescribers will only spend the time to go through a prior authorization process when they truly believe that a patient needs a certain, non-preferred medicine. Furthermore, prescriber prevails is an important tool in achieving overall reductions in health costs, across all disease states, including mental illness, cancer, diabetes, cardiovascular disease, and HIV/AIDS. To be effective, the drugs must work and patients must adhere to their drug regimens. Health care providers are in the best position to decide which drugs are most effective and to which are most likely to be adhered. These are not decisions that should be entrusted to health plan bureaucrats.

PhRMA Supports Extending Prescriber Prevails to All Drug Classes in Managed Care and Supports Strengthened Statutory Provisions to Ensure that a Prescriber's Determination Is Final.

It is vital that health care providers have discretion in drug treatment regimens. They are the most qualified to make decisions that will result in optimal patient compliance and the reduction of adverse events. Providers know that drug effectiveness, dosage needs, and risks of toxicity can vary by patient and can also be influenced by factors such as race, ethnicity and genetic makeup. For patients with serious, chronic or multiple illnesses, drug interactions are a serious problem that requires extreme caution. When health care decisions are made by non-providers and are based largely on cost, patient adherence is compromised and can result in increased health care costs, hospitalizations and emergency room visits. This runs counter to what the State is trying to achieve in Medicaid reform.

Health care providers grapple with 18 different managed care plans, all of which have varied drug formularies. Prescriber prevails is a clear policy that translates across all plans and helps ensure that all patients, regardless of diagnosis, have equal access to prescriptions drugs that are best suited to treat their conditions. For these reasons, PhRMA supports extending prescriber prevails to all drug classes in Medicaid managed care. Furthermore, we support statutory changes that will ensure that a prescriber's determination is final in Medicaid managed care.

4. **Providing the Authority to Directly Negotiate Supplemental Rebates on Fee-for-Service Enrollees**

PhRMA opposes giving the State the authority to directly negotiate supplemental rebates for certain classes of drugs on fee-for-services enrollees. The intent of this proposal is to further tax the biopharmaceutical industry without providing sufficient access to patients, which is the intent of the Medicaid drug rebate program. The state already has authority to negotiate supplemental rebates in fee for service, making this provision superfluous.

5. **Instituting Prior Authorization in the CDRP without DURB Review Undermines Longstanding Expert Assessment Process**

Once again, the Department of Health is seeking unilateral authority to make prior authorization decisions without review by the Drug Utilization Review Board in the Medicaid fee-for-service program. According to the Department's DURB website, the Board is charged with reviewing drug appropriateness, safety and if drugs are medically necessary. This independent body is comprised of doctors, pharmacists, disease experts and consumers who provide expert counsel to the Department of Health (DOH) regarding the Preferred Drug

Program. As part of the Board's decision-making process, it accepts information from the Department, patients, advocates, manufacturers and practicing physicians. The Department has sole discretion to convene a DURB meeting at any time. Meetings are accessible to the public. The DURB is a longstanding model program that has helped to ensure that patients enrolled in the Medicaid program have timely access to safe, effective medicines. The legislature should reject this attempt to usurp this open and informed process.