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Name of the respondent: Marissa Watkins
Affiliation/Organization: The Pharmaceutical Research and Manufacturers of America (PhRMA)
Email and phone number: mwatkins@phrma.org – (202) 835-3515

The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully submits comments to the Colorado Commission on Affordable Health Care (CCAHC) on cost drivers in the health care system.

PhRMA represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $51.2 billion in 2014 alone.

1. What do you think are the fundamental cost drivers and why?

Recently, there has been a significant amount of conversation around the cost and value of innovative medicines, especially those intended for patients who suffer from chronic, debilitating diseases such as HIV, Hepatitis C and cancer. What has not been reported is that retail prescription medicines have consistently accounted for just ***10% of U.S. health care spending***. Spending on prescription drugs was ***.10 cents of every dollar spent on health care***. In fact, the most recent national health spending projections show that it is expected to grow at rates in line with overall health care spending through 2023. What is more, according to National Health Expenditure, in 2014, about 5% of Medicaid projected spending was prescription drugs.

To put this in context, private insurers spent roughly as much on drugs as they did on administrative costs in 2013. Furthermore, the U.S. will spend $13.6 trillion on hospital care over the next decade, more than three times total spending on prescription medicines.

Hospital spending would be even higher than it is if it were not for the beneficial impact of prescription medicines. For example, from 2000 to 2012, research conducted by the Altarum Institute showed total inpatient hospitalizations for cancer treatment declined by 15%, in favor of shifting cancer care to lower cost free-standing or outpatient hospital cancer care clinics. On a per capita basis, that decline was 25% over that same time period. More effective prescription cancer medicines helped to enable that shift in the site of care to occur, which resulted in an overall reduction in health care costs. Even as new retail oral oncologic agents coming on to the market in recent years, and the expansion of prescription drug coverage due to Medicare Part D and the Affordable Care Act (ACA), prescription drug spending has remained fairly stable.

Innovative medicines developed by biopharmaceutical companies have been transforming patient care for over a century – helping patients live longer, healthier and more productive lives. Prescription medicines are often the most cost-effective means of preventing and treating disease. A 2013 study by IMS Institute for Healthcare Informatics estimated that the U.S. health care system could save $213 billion annually if medicines were used properly. An article in Health Affairs echoed this sentiment and found that just an extra $1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol can generate $3 to $10 in savings on emergency room visits and inpatient hospitalizations.

A recent article in the Health Affairs journal, "Increased Use of Prescription Drugs Reduces Medical Costs In Medicaid Populations" cites the positive impact of prescription drugs on reducing other medical costs in the

Medicaid program. The article found that when prescription drugs are taken appropriately as prescribed by a physician, there is a reduction in other medical costs for certain Medicaid populations. The authors looked at data on more than 1.5 million Medicaid enrollees to examine the impact of changes in prescription drug use on medical costs. The researchers found a 1% increase in overall prescription drug use was associated with decreases in non-prescription drug medical costs for three distinct groups of Medicaid beneficiaries. Among blind or disabled adults, a 1% increase in drug usage was associated with a 0.108% decrease in total non-drug costs; for other adults there was a 0.167% decrease; and for children, there was a 0.041% decrease.[1]

What is more, many innovative new medicines eventually become generics and are available to patients for years to come at low cost. About 90% of all prescriptions filled are generics. Prescription drugs are the only sector of the health care system that eventually costs less and has a built-in savings mechanism.

When considering the cost of "specialty" medicines, it is important to realize they are used by less than 5% of U.S. patients who typically have severe or rare health conditions. These medicines are often subject to greater cost sharing, which makes them appear to be more expensive than they are, particularly compared to other health care services – and patients bear that burden. Further, for hepatitis C medicines, payers are receiving discounts of up to 40% for commercial members and 55%-65% for Medicaid/VA members. In a September 2, 2015 editorial, *The New York Times* Editorial Board concluded that "competitive market forces and hard-nosed bargaining" make "tremendously effective" new hepatitis C medicines not just more accessible to ailing patients – but also offer good value to the U.S. health care system. Additionally, a recent actuarial analysis of pharmacy benefit manager drug trend reports show that trends for "specialty" medicines are frequently misleading, and often use inconsistent definitions and methods which can inflate and bias reported trends.

Clearly, medicines are an important part of the solution to the cost challenges facing the nation's health care system, not the cause. Without new medicines to treat Alzheimer's disease, Parkinson's, cancer and other conditions, the cost to treat these diseases could bankrupt our health care system. Medicines have helped raise average U.S. life expectancy from 47 years in 1900 to 78 years. Since its peak in 1991, the cancer death rate in the U.S. has fallen 22% and 2 out of 3 patients diagnosed with cancer are now living at least 5 years following diagnosis. And new hepatitis C therapies have cure rates above 90% and dramatically decrease the burden of the disease on the U.S. health care system and the economy into the future.

2. What are the barriers to reducing cost?

As more Americans gain access to health care, it is important that they also have access to the medicines they need. Currently, suboptimal use of prescription medications remains a challenge and can result in major costs downstream. There is a large opportunity for patients and their healthcare providers to enhance the quality and efficiency of our healthcare system by improving adherence to medicines. However, patients are being forced to pay far more out of pocket for their medicines than for other health care interventions. In the current marketplace, patients are required to pay more out of pocket for the medicines they need – to help manage disease and prevent complications – than for hospital and physician visits. Commercially insured patients are typically required to pay on average 20% of the cost of their medicines compared to 4% for other health care services such as inpatient, hospital care.

High cost-sharing for prescription drugs in the Exchanges reduces patients' access to life-saving medicines and drives up health care costs. According to new research from Milliman, silver plans, the most popular coverage in

[1] http://www.pharmacytimes.com/association-news/health-affairs-issue-features-nacdsphrma-research-on-impact-of-prescription-utilization-on-medicaid-costs

the health insurance exchanges, are four times more likely to require patients to meet a combined deductible – often exceeding $2,000 – before any prescription drug coverage takes effect. Moreover, silver plans require patients to pay on average more than twice as much out-of-pocket for prescription medicines than they would under a typical employer plan. These barriers to accessing medicines increase other costs in the health care system.

3. Can you list up to three things that you are doing to address cost that are unique?

1. Curing, treating and managing some of the most serious diseases such as Cancer, Cystic Fibrosis, asthma, arthritis, and HIV: Through the continued development of new treatments and cures, each discovery improves patients' lives, advances medical innovation and fuels economic growth. Medicines allow patients to avoid expensive hospital care by slowing, treating and curing diseases. For example, if non-adherent patients with diabetes were to become adherent and follow their doctor's treatment plan, hospitalizations and emergency room visits could be avoided and yield nearly $5 billion in medical savings. In addition, a wide range of studies have shown that taking medicines exactly as directed is associated with reduced total health care costs. For example:

    - Preventing Hospitalizations: Poor medication adherence is associated with increased hospitalizations, nursing home admissions, and physician visits. For instance, research demonstrates that patients who did not consistently take their diabetes medicine were 2.5 times more likely to be hospitalized than were patients who took their medicine as directed more than 80% of the time.
    - Preventing Disease: Non-adherent patients were 7%, 13% and 42% more likely to develop coronary heart disease, cerebrovascular disease, and chronic heart failure, respectively, over three years than patients who took antihypertension medicine as directed.
    - Preventing Adverse Events: Providing counseling to patients to clarify their medication regimen following hospital discharge can dramatically reduce the likelihood of adverse drug events.

2. Prescription medicines are the only product or service of the health care industry that actually decreases in cost over time: This is because innovator companies produce medical advances that lead to low-cost generic copies. Currently, nearly 90% of all medicines prescribed to U.S. patients are generics. Because significant research and development resources are not required for the manufacturing of generic medicines, the cost of a generic medicine is typically up to 80% less than that of the brand medicine.

3. Prescription Assistance Programs: America's biopharmaceutical research companies are on a mission to improve patient health, advance medical innovation, and fuel economic growth. The medicines they create provide hope that a cure can be found, treatment will be effective, and patients' lives can be lived to the fullest. The Partnership for Prescription Assistance is one way to help connect qualifying patients with the assistance program that is right for them. PPA has helped millions of qualifying patients get the medicines they need by connecting them with a patient assistance program that is right for them. Through PPA, many patients get their medications free or nearly free. Since its launch in April 2005, the PPA has connected nearly 9.5 million people to patient assistance programs.

4. Is there any supporting data that demonstrates a reduction in cost?

Many medicines shift the treatment paradigm toward prevention by allowing patients to avoid expensive hospital stays and long-term care. And every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generated $3 to $10 dollars in savings on emergency room visits and inpatient hospitalizations. Researcher findings from University of Chicago establish that a 10% decrease in the cancer death rate is worth roughly $4.4 trillion in economic value to current and future generations. By preventing the need for expensive hospital, emergency, or long term care, medicines can reduce the growth in health care spending, and in some cases, result in savings. For example, based on a large body of research showing that better use of medicines can reduce spending on other medical services, the Congressional Budget Office (CBO) now credits Medicare policies that increase use of medicines with savings on other Medicare costs.

5. Where do you see waste in the system?

Waste, Fraud and Abuse: There is a significant amount of waste, fraud and abuse within the health care setting. According to the Centers for Medicare & Medicaid Services (CMS), over $21.9 billion has been paid improperly by Medicaid during 2011. This figure is a little over 5% of the total cost of the program. Colorado should assess the extent of fraud and abuse in Medicaid and partner with health care professionals so they may put themselves in a better position to help prevent and detect fraud.

Too Little Preventive Care: According to the Centers for Disease Control (CDC), nationally, Americans use preventive services at about half the recommended rate. Cost-sharing such as deductibles, co-insurance, or copayments also reduce the likelihood that preventive services will be used, thus preventing more costly complications in the future. One study found that the rate of women getting a mammogram went up as much as 9% when cost-sharing was removed. Eliminating cost-sharing (e.g., deductibles, co-insurance, or copayments) for certain preventive services increases the likelihood that preventive services will be used. The government is making strides to broaden private health plan access to recommended preventive services with no cost or low cost-sharing. PhRMA supports preventive medicine and wellness. Whether through the support of various other programs focused on medication adherence, preventive care, and wellness services or their collaboration with the Partnership to Fight Chronic Disease (PFCD), America's pharmaceutical companies realize that preventive care is an essential step in saving lives.

Not Managing Chronic Diseases: According to the PFCD, "Chronic diseases are the most prevalent and costly health care problems in the United States. Nearly half (45%) of all Americans suffer from at least one chronic disease. More than two-thirds of all deaths are caused by one or more of five chronic diseases: heart disease, cancer, stroke, chronic obstructive pulmonary disease, and diabetes. Many chronic diseases are life-long conditions, and their impact lessens the quality of life not only of those suffering from the diseases, but also of their family members, caregivers, and others. Properly managing these diseases will help reduce overall health care spending and have a positive economic impact because chronic diseases reduce economic productivity by contributing to increased absenteeism, poor performance, and other losses." According to PFCD, a Milken Institute analysis determined that "treatment of the seven most common chronic diseases, coupled with productivity losses, costs the U.S. economy more than $1 trillion dollars annually. The same analysis estimates that modest reductions in unhealthy behaviors could prevent or delay 40 million cases of chronic illness per year."

6. What are the principal barriers to transparency?

Health insurance plans can vary dramatically in benefits, cost sharing, and breadth of provider networks. Consumers can face significant difficulties when trying to identify these variations and assess the consequences of choosing one plan over another. Therefore, transparency regarding a plan's benefit design is critical to enabling consumers to make an informed decision when selecting a plan.

There continue to be challenges for consumers trying to select a plan. For example, a recent study of 2015 marketplace websites found that direct formulary links were not always available on many of the state marketplace websites and healthcare.gov. Additionally, this study found that it was not always clear which services were subject to the plan's deductible. It is particularly important for consumers to understand whether they will have to reach their plan's deductible before receiving coverage for medicines because most employer plans provide first-dollar coverage for medicines and therefore consumers may not be expecting their prescriptions to be subject to a deductible.

Ideally insurer websites will include a robust calculator that estimates total out-of-pocket costs—including both premiums and expected cost sharing based on anticipated medical needs. The Medicare Part D Plan Finder provides such estimates and helps inform consumers about their plan choices.

7. What would you change to make things better related to cost?

Allow Access to Medicines

As more Americans gain access to health care, it is important that they also have access to the medicines they need. Suboptimal use of prescription medications remains a challenge, and there is a large opportunity for patients and their healthcare providers to enhance the quality and efficiency of our healthcare system by improving the use of medicines.

Innovative medicines are preventing costly complications of chronic diseases, reducing the number of visits to the emergency room, length of hospital stays, and helping patients avoid major surgeries. Towards this end, expanded implementation of Value Based Insurance Designs (VBIDs) developed by the competitive market place, that allow patients access to prescription medications for chronic conditions at low or no cost sharing levels would be a step in the right direction. The very premise of these innovative insurance designs concedes that better adherence to prescription drug regimens result in a decrease in medical costs.

Despite these major advances, patients are being forced to pay far more out of pocket for their medicines than for other health care interventions. In the current marketplace, patients are required to pay more out of pocket for the medicines they need – to help manage disease and prevent complications – than for hospital and physician visits. High cost-sharing for prescription drugs in the Exchanges reduces patients' access to life-saving medicines and drives up health care costs. Allowing access to innovative medicines can enable more people than ever before to live longer, healthier lives and save money by reducing chronic diseases and preventing emergency room or hospital stays.

Consumer Transparency

PhRMA supports protections for patients as they select a health plan to ensure they are aware of all the cost obligations the plan includes. Colorado residents are choosing health plans based on premiums and a summary description of benefits, without complete and accurate information about their own cost-sharing responsibilities, especially for medicines. Consumer cost-sharing obligations including deductibles, copayments, coinsurance, and excluded out of pocket expenses may be significantly greater than the total premium paid for a

health benefit plan. Consumers may not be budgeting for significant costs outside of the premium. Further, patients with ongoing medical conditions are unable to determine if the medication and physicians and health care they rely on will be covered by the plan in which they are enrolling.

The State should ensure that enrollees are given all relevant information about all the costs and benefits a health care plan offers by providing detailed information about cost sharing for specific items and services. This can be done by requiring insurers to provide clear, accurate information on out of pocket costs, copayments and coinsurance, any exclusions or restrictions from coverage, and drug formulary and prior authorization process information. These protections will allow consumers to consider all costs and restrictions so they can select a plan that best meets their needs.

Prevent Negative Mid-Year Formulary Changes

Prohibit insurers from moving a prescription drug to a tier with a larger deductible, copayment, or coinsurance after the formulary is approved by the Commissioner except under specified circumstances. For example, a generic coming into the market would be exempted this requirement. It is critical for patients who are currently undergoing a course of therapy with one or more prescription drugs to continue to be able to access those drugs throughout the plan year.

Currently, plans can move drugs to higher cost-sharing tiers at any point during a year, or worse, remove drugs from their formularies entirely. Mid-year formulary changes impose a tremendous burden on enrollees, as well as on physicians and pharmacists—the administrative burden on healthcare providers is significant. These types of changes can result in major costs downstream, in the form of emergency room visits, corrective treatments.