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PhRMA

VIA ELECTRONIC FILING

August 16, 2012

Ms. Donna Frescatore, Executive Director
New York State Health Exchange

Re: Selection of an Essential Health Benefits Benchmark Plan

Dear Ms. Frescatore:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on New York's selection of an Essential Health Benefits Benchmark Plan. PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

We appreciate the State's effort to engage stakeholders on this important subject. We offer the following comments for consideration:

- **Comprehensive prescription drug coverage is essential for delivering effective, high-quality care.** Although New York mandates that plans must cover prescription medicines, as does the Affordable Care Act, standards to ensure that qualified health plans (QHPs) offer comprehensive prescription drug coverage, including generic and brand medicines, are key to providing high quality, coordinated medical care. Comprehensive prescription drug coverage is particularly important for patients with chronic conditions and for reducing long-term health costs by avoiding unnecessary hospitalizations and medical care that could be prevented.
- **Assuring patient and provider choice of medicines is a pathway to avoiding discriminatory plan design.** The Center for Medicare and Medicaid Services (CMS) Center for Consumer Information and Insurance Oversight (CCIIO) Essential Health Benefits Bulletin issued on December 16, 2011 proposed that plans need only include one drug per therapeutic class. PhRMA believes requiring plans to include just one drug per therapeutic class is insufficient to ensure patient access to needed care—as is evident from a review of widely-agreed upon standards of care, such as those established by respected medical professional societies, or information on the face of a medicines Food and Drug Administration (FDA) label. Furthermore, this standard leaves open the potential for benefit designs that would discourage the enrollment of individuals with significant health care needs. Establishing such a low standard could potentially reset the market by encouraging new designs far below current standards of care and typical of employer coverage today.

- **New York should establish clear and meaningful standards for comparing qualified health plans to the benchmark plan.** In order to maintain quality health care, New York should develop a clear methodology for comparing QHPs to the selected benchmark plan. Actuarial equivalence will not be sufficient to ensure that plan coverage is clinically adequate. Therefore, New York should develop guidelines for qualified health plans that reflect multiple aspects of coverage, including the degree of choice available to patients and providers; processes for updating coverage to reflect newly available treatments; and protections for vulnerable populations.

I. Prescription Drug Coverage Is Essential for Delivering Effective, High-Quality Health Care.

The Affordable Care Act's (ACA's) requirement for qualified plans in the exchange to cover prescription drugs and vaccines[1] recognizes that coverage of prescription medicines is standard in commercial insurance products and, equally important, the role that medicines play in modern health care. Comprehensive prescription drug coverage—whether for medicines covered by the outpatient pharmacy benefit or as part of the medical benefit, such as drugs administered incident to a physician's service—is important to preventing, treating, and potentially curing serious and chronic medical conditions, as well as improving quality of life and reducing health care costs. Over the last several decades, new medicines have made it possible to prevent or slow the progress of many diseases, thereby reducing costly hospitalizations and other expensive medical and surgical procedures.

Recent medical advances, particularly those related to prescription medicines, have provided enormous clinical and economic value. As summarized by CBO, "Many examples exist of major therapeutic gains achieved by the industry in recent years…anecdotal and statistical evidence suggests that the rapid increases that have been observed in drug-related R&D spending have been accompanied by major therapeutic gains in available drug treatments."[2] For instance, the Centers for Disease Control and Prevention (CDC) identified "new drugs and expanded uses for existing drugs" as contributing to the decline in heart disease and stroke mortality.[3] Academic researchers associated new medicines with declines in mortality for breast cancer[4] and other

[1] Section 2713 of the ACA requires a group health plan or individual insurance issuer to provide coverage without imposing any cost sharing requirements for immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved.
[2] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006.
[3] Centers for Disease Control and Prevention, National Center for Health Statistics. "Health, United States, 2006: With Chartbook on Trends in the Health of Americans," Hyattsville, MD, 2006.
[4] SK Chia et. al, "The Impact of New Chemotherapeutic and Hormone Agents on Survival in a Population-Based Cohort of Women with Metastatic Breast Cancer," Cancer 2007; 110.

cancers,[5] reduced disability rates among elderly persons,[6] and increased productivity among workers with conditions like rheumatoid arthritis.[7]

In addition, it is crucial to recognize the role that prescription drugs can play in reducing long-term costs of care by avoiding unnecessary hospitalization and institutional costs.[8] For example, a recent study in the *American Journal of Cardiology* found that patients with high rates of adherence to statins had significantly lower total health care costs and lower risk of cardiovascular disease-related hospitalizations, relative to non-adherent patients. Authors estimated that increasing adherence rates to statin therapy could potentially save the U.S. healthcare system more than $3 billion annually.[9] Similarly, studies on diabetes show that adherent patients are half as likely to have a heart attack, undergo amputation or treatment for an ulcer, or experience an adverse renal event potentially leading to kidney disease.[10] Facilitating restricting access to medicines in the service of achieving short-term, line-item savings would lead to poorer utilization patterns, generating poor clinical outcomes, and higher costs on other services.

Assuring provider and patient choice of medicines is essential to ensuring that benefits meet patients' diverse health care needs. Patients often respond to medicines differently; maintaining broad access to medicines is essential to ensuring these patients have access to multiple treatment options as often multiple medicines must be tried before an adequate response is achieved.

It is important for quality health insurance to reflect the needs of patients with chronic conditions. A new study by economists at the University of Minnesota, the University of Wisconsin-Madison, and Indiana University found that employer-sponsored insurance for the chronically ill is less generous than insurance for those without a chronic condition, primarily due to higher cost sharing for prescription drugs.[11] The researchers conclude that "it is benefit design, not differences in the types of plans covering the [chronically ill and non-chronically ill], that explains the difference we observe in insurance generosity....the specific services used most by the chronically ill—prescription drugs—are, by design, reimbursed at a lower rate." It would be counterproductive, and inconsistent with the goals of achieving better access to care, improved quality and cost savings, and balance among categories of services, to establish standards such as the one drug per class rule that would result in systematically poorer coverage (including effectively no coverage of many needed medicines) for the many patients with

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[5] Lichtenberg, FR. "The Expanding Pharmaceutical Arsenal in the War on Cancer." National Bureau of Economic Research Working Paper 10328, February 2004.
[6] "Intensive Medical Care and Cardiovascular Disease Disability Reductions," forthcoming in David Cutler and David Wise, eds., Health at Older Ages: The Causes and Consequences of Declining Disability Among the Elderly, Chicago: University of Chicago Press, 2008 (with Mary Beth Landrum and Kate Stewart).
[7] Integrated Benefits Institute, "A Broader Reach for Pharmacy Plan Design," May 2007.
[8] J.M. McWilliams et al. "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage," Journal of the American Medical Association, 27 July 2011.
[9] D.G. Pittman et al. "Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations." American Journal of Cardiology, June 2011.
[10] T. Gibson et al. "Cost-Sharing, Adherence, and Health Outcomes in Patients with Diabetes." American Journal of Managed Care, August 2010.
[11] J.M. Abraham et al. "Gauging the Generosity of Employer-Sponsored Insurance: Differences Between Households With and Without A Chronic Condition." National Bureau of Economic Research, Working Paper 17232, July 2011.

chronic conditions. This large group of patients would, by definition, suffer the consequences of inadequate coverage year after year given the persistency of their conditions.

The challenges of developing essential health benefits and coverage in the insurance exchange will require drawing on best practices in and lessons from the employer sponsored market, FEHBP, and Medicare Part D, each of which offer successful models for recognizing the essential role of medicines, protecting beneficiaries, and promoting access to care, while maintaining affordability. Medicare Part D for example, has provided broad access to medicines, with high beneficiary satisfaction rates and at lower costs than originally anticipated.[12] Moreover, Part D has shown reductions in non-drug spending associated with gaining comprehensive drug coverage. Harvard researchers report savings in hospital and skilled nursing facility costs of about $1,200 per newly insured beneficiary,[13] or about $13.4 billion in 2007,[14] the first full year of the Part D program.

II. The Proposed "One Drug per Class" Rule Is Clearly Insufficient to Ensure Qualified Plans Are Comparable to Typical Employer Coverage or to the Chosen Benchmark, May Not Meet Patients' Clinical Needs, and Is Likely to Lead to Discriminatory Benefit Designs,

The Centers for Medicare and Medicaid Services (CMS) recently proposed that plans must offer at least one drug in each category or class offered by the benchmark plan, although specific drugs chosen for the formulary may vary.[15] This approach appears to assume that all drugs in each category or class are substitutable, and that patients do not require a choice of treatment options. However, the opposite is true. Drug classification systems place medicines into broad groupings in which medications are not generally substitutable. Inclusion of a single drug per therapeutic class is wholly inadequate to ensure access to necessary medicines and could lead to formulary designs that bear no resemblance to the level of coverage provided by the selected benchmarks, to typical employer coverage, or norms in the market today.

Further, the proposed standard would allow ample opportunity for benefit designs that would discourage enrollment of individuals with significant healthcare needs. The ACA non-discrimination requirement states that in order to be certified, QHPs must "not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs".[16] ACA also specifies that benefits must not be designed in ways that discriminate based on age, disability, or expected length of life, but must

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[12] KRC Survey for Medicare Today, "Seniors' Opinions About Medicare Rx: Sixth Year Update" October 2011; CBO Medicare baselines for 2004 through 2011 available at www.cbo.gov.
[13] J.M. McWilliams et al. "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage," Journal of the American Medical Association, July27, 2011.
[14] C.C. Afendulis and M.E. Chernew. "State Impacts of Medicare Part D." American Journal of Managed Care, October 2011.
[15] This is analogous to suggesting that plan networks need only include one hospital in a region, regardless of whether the hospital offers neonatal intensive care or a neurology intensive care unit. Applying this type of restrictive standard only to prescription drug coverage is inconsistent with the ACA requirement that benefits are not unduly weighted toward any category § 1302(4)(A) .
[16] ACA, § 1311(c) (1) (A) (emphasis added).

consider the health care needs of diverse segments of the population.[17] These non-discrimination standards are intended to help ensure that high-cost, sick, or otherwise unique patients are not pooled in a few plans, thereby protecting patient access to care while promoting competition and protecting the stability of exchanges and plans operating within exchanges.

By effectively setting a new, government-defined "floor" for pharmacy benefits that is well below the existing norm, such a standard could not only allow outlier plan designs to be offered, but could reset market expectations and incentives that drive health plans to restrict coverage to a single drug in a therapeutic class. For example, a plan following this standard to the letter could gain an advantage over its competitors by discouraging the enrollment of individuals with significant health care needs (and therefore, high health costs), since the coverage offered would be inadequate by any reasonable measure of a patient's needs. Moreover, such patients are likely to be attentive to their coverage, making a formulary in technical compliance with this new standard not derived from market experience a discouragement to their enrollment. Once one plan gains a competitive advantage by avoiding these high-risk individuals, other plans might have little choice but to follow suit and reduce their benefits to the same government-defined floor.

The following selected examples illustrate the serious risks to patients and the significant potential for discrimination against patients with particular high-cost conditions should this type of standard be adopted.

- ***For many conditions, the recognized standard of care includes combination therapy involving multiple medicines in the same class, by definition exceeding one drug per class.***

  For example, for adults and adolescents with HIV-1, clinical guidelines call for four different initial combination treatment regimens for treatment-naïve patients. These combination regimens have at least 2 drugs in the same USP class; if only one drug per USP class was available, HIV patients would not have access to the needed combination of drugs to treat their condition.[18]

  Likewise, in the instance of a patient being treated for diabetes, the standard of care often includes combination therapy with drugs that have complementary mechanisms of action in order to maintain a target blood glucose level, particularly as disease progression occurs.[19, 20] As all antidiabetic agents are grouped as a single class in the USP classification system, if any plan followed the government-created minimum and offered only one drug per USP

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[17] ACA, § 1302(b)(4).
[18] Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. http://www.aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/11/what-to-start
[19] Handelsman Y et al., "American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan." American Association of Clinical Endocrinologists. 2011. Accessed on January 3, 2012 at: https://www.aace.com/sites/default/files/DMGuidelinesCCP.pdf.
[20] Guiding Principles for Diabetes Care: For Health Care Professionals, National Diabetes Education Program. 2009. Accessed on January 3, 2011 at: http://www.ndep.nih.gov/media/GuidPrin_HC_Eng.pdf.

class, many patients would not have access to the needed combinations of drugs to treat their diabetes.

Similarly, clinical guidelines also recommend combination therapy for treatment of Hepatitis C. The standard of care has been to treat with ribavirin and peginterferon, with new data recommending the use of a direct-acting antiviral along with the other treatments.[21] Within the USP Model Guidelines, all of the antihepatitis treatments are grouped within one class making it possible that not all appropriate components of standard combination therapy would be available.

- ***Some drugs are approved by the FDA specifically for treatment of a condition after another drug in the class has been tried and failed.***

  For example, Sprycel (dasatinib) is a molecular target inhibitor specifically approved by the FDA for treatment of chronic myelogenous leukemia that is resistant to or intolerant to prior therapy with other chemotherapeutic treatments, including Gleevec (imaitinib), another molecular target inhibitor that may be treated as in the same class.[22] Afinitor (everolimus) is a molecular target inhibitor approved for treatment of advanced renal cell cancer after failure of Sutent (sunitinib) or Nexavar (sorafenib).[23] Again, if only a single drug were available in the class, patients whose cancer had progressed or proven to be resistant to the initial chemotherapy would not have access to appropriate care.

  Similarly, two new antivirals for treatment of HIV, Selzentry (maraviroc) and Isentress (raltegravir potassium) are indicated for use in patients who have been treated with other HIV medications and have evidence of viral resistance. Though these two antiretrovirals work differently, they are grouped together in the same USP class. With the one drug per class requirement, it is possible that patients with HIV would not have the benefit of advanced treatments that could halt viral replication.[24]

- ***Medical guidelines call for trying different agents to control conditions and recommend certain drugs not be used by certain patients.***

  The importance of providing choice of medicines for providers and patients is also evident in treatment guidelines. In treatment of high cholesterol, the patient's risk factors for coronary heart disease and lipid levels are evaluated as part of treatment selection. The National Cholesterol Education Program Adult Treatment Panel III guidelines for treatment of high cholesterol recommend that patients with high lipid levels and multiple risk factors for coronary heart disease, including diabetes, receive more intense treatment that will result in a larger percentage of lipid level reduction and result in coronary event risk reduction. Having

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[21] Ghany MG, Nelson DR, et al. An Update on Treatment of Genotype 1 Chronic Hepatitis C Virus Infection: 2-2011 Practice Guideline by the American Association for the Study of Liver Diseases. Hepatology. October 2011. http://s3.gi.org/physicians/guidelines/AASLDHepCUpdate.pdf
[22] Lexi-Comp, Inc. (Lexi-Drugs™). Lexi-Comp, Inc.; January 11, 2012
[23] Lexi-Comp, Inc. (Lexi-Drugs™). Lexi-Comp, Inc.; January 11, 2012
[24] Lexi-Comp, Inc. (Lexi-Drugs™). Lexi-Comp, Inc.; January 11, 2012

multiple treatment options available is necessary to provide appropriate medication selection and to reach proper treatment intensity[25], as lipid lowering agents within a therapeutic class vary significantly in their potency. Conversely, a plan electing not to provide coverage that meets this evidence-based standard—for instance, by providing only one statin that is not sufficiently powerful to achieve the level of lipid reduction required—could discourage enrollment of these patients who are, by definition, sicker and a higher cost than average.

Other treatment guidelines recommend that certain drugs not be used for certain patients. For example, monotherapy with beta-blockers, angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers is less effective at lowering blood pressure in African Americans than in Caucasians, and angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers are contraindicated for women who are or intend to become pregnant because of the risk of fetal developmental abnormalities.[26] Therefore, other blood pressure-lowering options should be available to meet the needs of these patients.[27] Statins also should not be used by women of child-bearing age because of the risk of fetal developmental abnormalities;[28] therefore, access to other cholesterol-lowering options should be available to meet the needs of these patients, yet all current options are grouped by USP into one class.

- ***Patients often respond to drugs in the same class differently, necessitating choice of medicines.***

  For example, a study in *Health Affairs* reported that "drugs might not be equally effective for an individual patient. Prior studies have shown that failure to respond to one SSRI or having severe side effects does not mean that the patient will have the same experience with another SSRI."[29] In fact, one study showed that 26% of the people who did not respond to fluoxetine did have a response to sertraline.[30] Conversely, another study demonstrated that 63% of patients who failed treatment with sertraline did have a response to fluoxetine.[31] Efficacy of nonsteroidal anti-inflammatory drugs (NSAIDs) also varies amongst patients. These medicines are used to treat arthritis and other painful inflammatory conditions. Often, multiple medicines within the class must be tried before an adequate response is achieved. One study showed that 49% of patients being treated with NSAIDs had to switch to a

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[25] Grundy SM et al. Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. Circulation. 2004; 110:227-239. Accessed on January 4, 2012 at: http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.pdf

[26] The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. National Institutes of Health, National Heart, Lung, and Blood Institute. August 2004. Accessed on January 4, 2012 at: http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf

[27] While we reference these particular groups, we note that a large body of research finds that (a) most patients with hypertension require treatment with multiple different types of anti-hypertensives, all of which fall under USP's cardiovascular category, to control their blood pressure and (b) there is significant variation in individual patients' response to particular anti-hypertensives, thus indicating the importance of choice among therapies. Gupta AK, Poulter NR, Dobson J, Eldridge S, Cappuccio FP, Caulfield M, Collier D, Cruickshank JK, Sever PS, Feder G on behalf of ASCOT investigators. Ethnic differences in blood pressure response to first and second-line antihypertensive therapies in patients randomized in the ASCOT Trial. *Am J Hypertens* 2010; 23:1023–1030.

[28] Lexi-Comp, Inc. (Lexi-Drugs™). Lexi-Comp, Inc.; January 11, 2012

[29] Huskamp HA. Managing Psychotropic Drug Costs: Will Formularies Work? *Health Affairs*. 2003;22(5):84-96.

[30] Zarate CA, Kando JC, Toben M, et al. Does Intolerance or Lack of Response with Fluoxetine Predict the Same Will Happen with Sertraline? *Journal of Clinical Psychiatry*. 1996;57:67-71.

[31] Thase ME, Blomgren SI, Birkett MA et al. Fluoxetine Treatment of Patients with Major Depressive Disorder Who Failed Initial Treatment with Sertraline. *Journal of Clincial Psychiatry*. 1997;58:16-21.

different NSAID; 20% of patients switched two or three times; and 7% received four or more different NSAIDs.[32]

III. New York Should Establish Clear and Meaningful Standards for Comparing Qualified Health Plans to the Benchmark Plan.

It will be important for health care quality reasons that New York develop a clear methodology for comparing QHPs to the selected benchmark plan. The types of safeguards that assure high quality coverage include, among others, the following protections and requirements:

- Independent Pharmacy and Therapeutic (P&T) Committee review of not only formularies, but also utilization management (UM) requirements and newly approved treatments and indications to be added to existing formularies.[33]

- Review of formularies to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes and considers the specific drugs, tiering, and utilization management strategies employed in each formulary.

- An exceptions and appeals process that provides enrollees with the opportunity to obtain an exception when a needed drug is excluded from a plan's formulary or placed on a higher cost-sharing tier.[34]

- Formularies must include a broad range of treatment options for conditions that disproportionately affect vulnerable individuals, for example patients with mental illness, HIV/AIDs, and cancer.[35]

In their totality, these types of requirements generally provide robust drug coverage while protecting patients' access to the medicines they need and offering plans the flexibility to develop different formularies, and manage utilization and costs. Of course, even a consumer with an adequate formulary should have access to an easy way to navigate the appeals process so that when medically necessary medicines are not available on the formulary, patients can access them. However, while an appeals process is an important backup safeguard, it is not a substitute for adequate coverage, as these systems place a significant burden on patients and physicians that can discourage their use.

We encourage New York to outline a process or set of criteria to be used to ensure that coverage in qualified health plans is actually comparable to that in the benchmark plan. To make a reasoned judgment about the comparability of coverage requires a set of criteria that address multiple aspects of coverage, including the degree of choice available to patients and providers;

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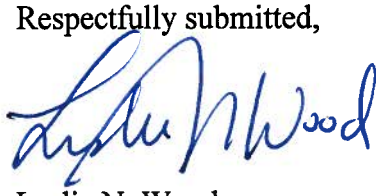
[32] Jacobs J, Bloom BS. Compliance and Cost in NSAID Therapy. Hospital Therapy. 1987;supplement:32-39.
[33] Medicare Prescription Drug Manual, Chapter 6, § 30.2.2.
[34] Medicare Prescription Drug Manual, Chapter 18, § 30
[35] Medicare Prescription Drug Manual, Chap. 6 § 30.2.5.

processes for updating coverage to reflect newly available treatments; processes for exceptions and appeals; and protections for vulnerable populations. Such a process should both allow for flexibility and draw on current best practices in the commercial and employer-sponsored insurance market.

In conclusion, we appreciate the opportunity to provide comments on essential health benefits. Please feel free to contact me with any questions.

Respectfully submitted,



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