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NCOIL National Office
Chair Asw. Pamela Hunter, NY and Vice Chair Rep. Deborah Ferguson, AR
Health Care Insurance and Long-Term Care Issues Committee
2317 Route 34 S, Suite 2B,
Manasquan, New Jersey 08736

Dear Chairwoman Hunter and Vice Chairwoman Ferguson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit feedback regarding NCOIL's proposed Accumulator Adjustment Program Model Act, as well as associated stakeholder input on the proposed Act. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. As a part of this mission, we support NCOIL's efforts toward the creation of a Model Act, which would help ensure that patients using cost-sharing assistance are able to access and adhere to the medicines they need. We are deeply concerned, however, that certain stakeholders are misrepresenting the purpose of cost-sharing assistance and disregarding its tremendous and immediate benefit to patients. We write now to provide clarity on this topic and to directly address stakeholders' specific misconceptions.

The proposed Model Act helps patients afford a medicine's out-of-pocket costs, which are set by the insurer.

In the commercial health insurance market, the amount that patients are responsible for paying out of pocket at the pharmacy counter for a prescription drug is determined by cost-sharing requirements (e.g., deductibles, coinsurance) that are set by health insurance companies and pharmacy benefit managers (PBMs). To help patients better afford their medicines, third-party entities, including pharmaceutical manufacturers, offer cost-sharing assistance, sometimes referred to as 'coupons.' Until recently, commercial health insurance plans have counted this assistance towards patients' deductibles and maximum out-of-pocket limits, making it easier for patients to get their medicines and stay adherent. Medication adherence is not only important for patients' health but also saves the health care system an estimated $213 billion per year.[i]

With an accumulator adjustment program (AAP) however, insurers employ electronic claims processing tools to block cost-sharing assistance from counting towards patient deductibles and out-of-pocket limits. This effectively means that patients continue to pay for their medicines

when they otherwise could have satisfied their deductible or out-of-pocket maximum had the cost-sharing assistance counted toward those requirements. This can have negative consequences, such as when patients face unexpected high costs in the middle of a plan year because the AAP has exhausted the value of the assistance, but the plan did not count the assistance to help the patient advance through their deductible or hit their maximum out-of-pocket limit for the year. This "copay surprise" is associated with medication abandonment, which is in turn associated with negative health outcomes: an analysis looked at three cost-sharing assistance programs and found that from 2018 to 2020, 25 to 36 percent of patients discontinued treatment when they faced an unexpectedly high out-of-pocket cost of $1,500 or more in the middle of the plan year due to an AAP.[ii]

By using AAPs, insurers shirk their responsibility to count patient cost sharing at the direct expense of the very patients whose interests they are supposed to serve. NCOIL's proposed Model Act will protect patients and ensure insurers are not able to operate AAPs at the expense of patients who rely on prescription medications to stay healthy or manage chronic conditions.

Health plans' increasing use of deductibles and coinsurance is shifting more of the cost of care to chronically ill patients taking brand medicines at a time when net prices and expenditures for innovative medicines are flat.

Patients who utilize cost-sharing assistance are often enrolled in plans that disproportionately expose them to high out-of-pocket costs for medicines.[iii] As a result, many patients with chronic conditions would be unable to afford their medicines without cost-sharing assistance counting towards their out-of-pocket accruals.[iv] For example, only 5 percent of patients abandoned newly prescribed brand medicines when using cost-sharing assistance in 2019, but analysis suggests that abandonment would have been 28 percent if not for cost-sharing assistance.[v]

IQVIA analyzed cost-sharing trends in seven therapeutic areas and found that anywhere from 44 to 95 percent of patients' total out-of-pocket spending for brand medicines in 2019 was due to deductibles and coinsurance. Compared to patients who only paid fixed-amount copays for brand medicines, patients with deductibles or coinsurance had significantly higher annual out-of-pocket spending across all seven therapeutic areas. In fact, for patients with complex conditions, like cancer and HIV, spending was as much as 25 to 30 times higher.[vi]

Growth of net price prices, which reflects rebates and discounts, has been in line with or below inflation for the past five years. In fact, net brand prices declined 2.9 percent in 2020.[vii] This, of course, does not necessarily comport with what patients are feeling at the pharmacy counter, which is why looking at the whole system is critical. According to research from the Berkeley Research Group (BRG), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2018 manufacturers retained only 54 percent of brand medicine spending while members of the supply chain retained 46 percent.[viii] Also, properly accounting for the share of spending that ultimately accrues to brand biopharmaceutical companies, as opposed to generic

manufacturers and supply chain intermediaries, brand medicines comprise just 10 cents of the premium dollar, or about half as much as what is spent on insurer administrative costs and profit.[ix]

AHIP is seeking to subvert the goals of the Model Act and advocating against patients' interests.

In addition to its misleading rhetoric in its comments to NCOIL about the sources of health care spending, AHIP is proposing amendments to NCOIL's model legislation that could dilute the positive benefit of the Model Act. At July's Health Care Insurance and Long-Term Care Issues Committee meeting in Boston, AHIP suggested that NCOIL's model legislation should include a requirement on manufacturers to provide certain information on the assistance they offer. The intent of such language is confusing and unclear, and it could have a chilling effect on cost-sharing assistance, which would be contrary to the intent of the Model Act – to help patients. Moreover, none of the twelve bills enacted in other states include such provisions.

NCOIL's proposed Model Act does not undermine insurers' ability to control health care costs.

When plans count cost-sharing assistance toward deductibles and out-of-pocket limits, it helps patients stay adherent to their medicines, which in turn can lower health care premiums by reducing emergency room visits and other medical spending driven by the negative health outcomes of nonadherence[x]. In fact, patients initiating treatment with brand medicines would be nearly three times more likely to abandon their medicines at the pharmacy counter if they were prevented from using cost-sharing assistance to lower their high out-of-pocket costs due to insurance benefit design.[xi]

Because nearly all drugs for which cost-sharing assistance is available are dispensed by prescription only, patients can only use cost-sharing assistance for medicines that prescribers deem to be medically necessary and that plans have already approved for coverage. Patients who use cost-sharing assistance are not bypassing a plan's utilization management policies. Prior authorization, step therapy, and other utilization management tools must be satisfied for the medicine to be approved by the insurer, which permits a pharmacy to fill a prescription under the insurer's plan. Furthermore, less than 1 percent of pharmacy claims filled with cost-sharing assistance are for products without generic alternatives,[xii] in contrast to claims suggesting that cost-sharing assistance steers patients toward brand products at the expense of generics.

The Model Act's intent is to keep patients healthy by allowing the assistance they use to count towards their deductibles and out-of-pocket maximums, which can lower overall health care costs without undermining plans' benefit design decisions.

The commercial health plan and federal health care program markets are structured and financed differently. This legislation will help commercially insured patients – who are

typically exposed to higher cost sharing than public program beneficiaries – afford their out-of-pocket costs to obtain the medicines they need.

Due to long-standing guidance issued by the federal government interpreting the federal Anti-Kickback Statute and certain other federal statutes, cost-sharing assistance may not be offered to patients covered under Medicare, Medicaid, or other federal health care programs. However, these federal laws do not extend to commercial health insurance plans, so cost-sharing assistance can be used by commercially insured patients when permitted under state law. Only a small number of states have limited the use of cost-sharing assistance, but recognizing the importance of this assistance, have limited assistance only when a generic equivalent is available for a brand product. In addition, a recent study of California's 2017 law banning use of cost-sharing assistance for brand-name drugs with a generic equivalent was associated with no significant increase in generic substitution in its first year.[xiii]

It is important to recognize Medicare and Medicaid are fundamentally different from commercial health insurance. Both have robust benefit design and formulary requirements that protect patient access to medicines. These benefit design specifications do not exist to the same extent for commercial insurance. Accordingly, in commercial insurance, manufacturer cost-sharing assistance can play a critical role in helping patients with access and adherence to critical medicines.

PhRMA again thanks NCOIL for considering these remarks and we hope that it is evident that manufacturer cost-sharing assistance counting on patients' behalf is a vital tool for patients and that AAPs are an obvious barrier to that goal. This is precisely why, since the first state legislation to prohibit AAPs emerged in 2019, twelve states have already enacted such laws, with many more likely to do so in the near term. To that end, we support NCOIL's effort to put forth a Model Act banning AAPs and oppose efforts to derail or dilute it. We stand ready to work with this committee to finalize the Model Act.

Sincerely,

Kipp Snider
National Vice President, State Policy

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[i] IMS Institute for Healthcare Informatics, *Avoidable Costs in US Healthcare: the $200 Billion Opportunity from Using Medicines More Responsibly* (Jun. 2013), available at: https://www.quotidianosanita.it/allegati/allegato4982969.pdf.

[ii] IQVIA analysis for PhRMA. Accumulator adjustment programs lead to surprise out-of-pocket costs and nonadherence, analysis finds. November 2020. https://catalyst.phrma.org/accumulator-adjustment-programs-lead-to-surprise-out-of-pocket-costs-and-nonadherence-analysis-finds.

[iii] IQVIA. Patient affordability and prescription drugs. https://www.iqvia.com/locations/united-states/library/white-papers/patient-affordability-and-prescription-drugs

[iv] National Hemophilia Foundation. Americans Across Political Parties Want the Federal Government to Require All Copay Assistance Be Applied Towards a Patient's Out-of-Pocket Costs, October 2020. https://www.prnewswire.com/news-releases/national-survey-americans-across-political-parties-want-the-federal-government-to-require-all-copay-assistance-be-applied-towards-a-patients-out-of-pocket-costs-301153527.html.

[v] IQVIA analysis of LAAD dataset for PhRMA. February 2021.

[vi] https://phrma.org/cost-and-value/commercially-insured-patients-with-chronic-conditions-face-high-cost-sharing-for-brand-medicines

[vii] IQVIA. "Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025." Published May 2021.

[viii] BRG: Revisiting the Pharmaceutical Supply Chain 2013-2018. January 2020.

[ix] Berkeley Research Group. "The Pharmaceutical Supply Chain; Addendum. "2020. Available at: https://www.thinkbrg.com/insights/publications/the-pharmaceutical-supply-chain/

[x] *See e.g.*, S Yermakov et al. Impact of Increasing Adherence to Disease-Modifying Therapies on Healthcare Resource Utilization and Direct Medical and Indirect Work-Loss Costs for Patients with Multiple Sclerosis. J Med Econ. 2015;18(9):711-20; G Carls et al. Impact of Medication Adherence on Absenteeism and Short-Term Disability for Five Chronic Diseases. J Occup Environ Med 54 no. 7 (2012): 792-805; S Devine, A Vlahiotis, H Sundar. A comparison of diabetes medication adherence and healthcare costs in patients using mail order pharmacy and retail pharmacy. Journal of Medical Economics. 2010;13(2):203-11.

[xi] IQVIA. Patient affordability part two. May 2018. https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-two.

[xii] IQVIA. An evaluation of co-pay card utilization in brands after generic launch. February 2018. https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization.

[xiii] Dafny L, Ody C, Schmitt M. When discounts raise costs: the effect of copay coupons on generic utilization. *Am Econ J Econ Policy*. 2017;9(2):91-123. doi:10.1257/pol.20150588Google ScholarCrossref