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February 19, 2019

The Honorable Alex M. Azar II
Secretary of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: **Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 (CMS-9926-P)**

Dear Secretary Azar:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Department of Health & Human Services' (HHS's) proposed rule, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020[1] (the proposed rule). 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.

The requirements in the Patient Protection and Affordable Care Act (ACA) for health plans to cover prescription drugs[2] and vaccines[3] recognize that coverage of prescription medicines is standard in commercial health insurance products and, equally important, that medicines play an important role 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 costs of other health care services.[4]

PhRMA supports HHS's efforts to maintain a strong commercial health insurance market and to provide clarity to health plans and patients across a range of policies. We urge HHS to keep the patient experience in mind as it finalizes this rule and to do so in a way that recognizes

[1] 84 Fed. Reg. 227 (Jan. 24, 2019).
[2] Plans subject to essential health benefit requirements must cover ten benefit categories, including prescription drugs. ACA § 1302(b)(1)(F).
[3] Section 2713 of the Public Health Service Act (PHSA), as added by the ACA, requires a group health plan or individual health 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.
[4] Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (2012), https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf.

that cost sharing can be a formidable barrier for patients seeking to remain adherent to the medicines their doctors prescribe.

PhRMA has the following recommendations:

- *Manufacturer Coupons*. Cost-sharing support from manufacturers is an important source of financial assistance for patients and improves adherence to medicines. That improved adherence is threatened by health insurers' and group health plans' increasing use of accumulator adjustment programs, which ignore cost sharing paid by coupons when calculating whether a patient has reached the out-of-pocket maximum. In this regard, accumulator adjustment programs have a material and detrimental financial impact on patients. We believe the ACA intended to include coupons as cost sharing on behalf of an enrollee. Nevertheless, we do not oppose HHS allowing the use of these accumulator adjustment programs in the narrow instance where there is an available AB-rated[5] generic equivalent of a brand medicine with a coupon as long as there are appropriate patient protections. We ask HHS to confirm that plans and issuers may not use accumulator adjustment programs when coupons are applied outside of the narrow instance described in the proposed rule.
- *Cost-Sharing Requirements for Generic Drugs*. HHS should not permit plans and issuers to exclude the cost sharing for brand drugs from the annual limitation on cost sharing when an AB-rated generic is available. Under those circumstances, plans and issuers already have the flexibility not to cover the brand drug at all, and creating special carve-outs from the annual limitation on cost sharing would be unnecessarily confusing.
- *Midyear Formulary Changes*. We agree that midyear formulary changes are generally prohibited in individual and group health insurance coverage, but that issuers may reasonably adjust their formulary to reflect the market entry of an AB-rated generic for a brand drug already on formulary.
- *Therapeutic Substitution*. We disagree with HHS's suggestion that it might promote therapeutic substitution, which interferes with the professional judgment of prescribers. Therapeutic substitution ignores the important clinical differences among drugs in the same class. We do not believe the health communication infrastructure exists to facilitate such substitution.
- *Reference Pricing.* HHS should also not promote reference-based pricing, which ignores the different clinical benefits of drugs within the same category or class and would inappropriately shift costs to patients when a price exceeds an arbitrary threshold.
- *Premium Adjustment Percentage*. HHS should not change the methodology for recalculating the premium adjustment percentage. HHS is not obligated to change

[5] For simplicity, PhRMA uses the term "AB-rated" to refer to the various types "A ratings" (e.g., AA, AN, AO, AP, and AT) that FDA assigns to reflect a determination of therapeutic equivalence depending on the relevant dosage form.

the methodology, or even reconsider it, and doing so now will increase costs for patients and cause thousands of people to lose access to care.

- *Risk Adjustment Methodology*. PhRMA supports the existing risk adjustment methodology and recognizes that updates will be necessary. We caution that HHS may be overemphasizing the risk that the risk adjustment methodology could affect prescribing patterns.
- *Direct Enrollment Entities*. PhRMA urges HHS to monitor the use of direct enrollment entities to ensure that consumers are not inappropriately steered towards short-term, limited-duration insurance plans.

We discuss each in detail below:

Annual Limitation on Cost Sharing (§ 156.130): Manufacturers' Coupons

HHS proposes to limit manufacturer cost-sharing support programs, which provide an important source of financial support for eligible patients and improve medication adherence. When cost sharing rises, patients are more likely to abandon their medicines. In 2017, 69 percent of commercially insured patients did not fill their new prescriptions when they had to pay more than $250 out of pocket, while only about 11 percent of patients with out-of-pocket costs of less than $30 abandoned their prescriptions at the pharmacy.[6] Thus, higher patient out-of-pocket costs frequently lead to medicines that have been prescribed by a health care provider—and which a health plan has agreed to cover—never reaching the patient because a financial barrier was erected around appropriate treatment.

Troublingly, the out-of-pocket burden for patients is only growing because of rapidly increasing patient cost sharing for brand medicines, a result of the increased use of deductibles and coinsurance in the commercial market.[7] From 2006 to 2016, commercial enrollee spending on deductibles increased over 175 percent, exposing patients to higher out-of-pocket costs, which vastly outpaced wage growth.[8] In addition to increasing deductibles, plans rely more heavily on coinsurance than copays, which impairs out-of-pocket spending predictability for patients. For the first time ever in 2016, coinsurance overtook copays as the preferred form of cost sharing on commercial plans for specialty drugs.[9] For these reasons, cost-sharing support is an important protection for patients to access prescribed medications that both prescribers and plans agree is appropriate. Multiple studies report that manufacturer cost-sharing support is associated with

[6] Katie Devane, et al., IQVIA, Patient Affordability Part Two (2018), https://www.iqvia.com/locations/united-states/patient-affordability-part-two.
[7] Katie Devane, et al., IQVIA, Patient Affordability Part One, https://www.iqvia.com/locations/united-states/patient-affordability-part-one.
[8] Gary Claxton, et al., Peterson-Kaiser, Increases in cost-sharing payments continue to outpace wage growth (2018), https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/#item-start
[9] Pharmacy Benefit Management Institute, Trends in Specialty Drug Benefits Report, 2017 edition (2017), https://www.pbmi.com/ItemDetail?iProductCode=SPECIALTY_2017&Category=SPECIALTY

higher adherence and lower rates of therapy discontinuation.[10] For patients at risk of prescription drug abandonment due to high cost sharing, another study found that cost-sharing support programs typically reduced patients' monthly out-of-pocket costs to a level where they were much less likely to abandon therapy.[11]

Ignoring the harms to patient adherence and well-being, health plans and pharmacy benefit managers (PBMs) have begun to institute "accumulator adjustment programs," under which patients are penalized for using cost-sharing support and end up paying more out-of-pocket than is ordinarily permitted under their plans. These programs can leave patients with thousands of dollars in unexpected costs at the pharmacy, resulting in exactly the problems that cost-sharing support is designed to solve: prescription abandonment, poor health outcomes, and unnecessary medical spending that could have been avoided with appropriate prescription drug access and use.

HHS suggests that its proposal to permit plans to exclude manufacturer coupons for certain drugs from the annual limitation on cost sharing faces no statutory roadblocks, stating that "[w]hile the PPACA does not speak directly to the accounting and use of drug manufacturer coupons to the annual limitation on cost sharing, we believe that the overall intent of the law was to establish annual limitations on cost sharing that reflect the actual costs that are paid by the enrollee."[12] We disagree with this statement for several reasons:

- First, the statute *does* speak to the issue of counting third-party assistance toward the annual limitation on cost sharing, and (as discussed below), it provides that costs paid for by third parties count toward the annual limitation on cost sharing when they help pay a patient's deductible, coinsurance, or copayments—meaning that HHS's coupon proposal contravenes the statute.
- Second, HHS's assertion "that the overall intent of the law was to establish annual limitations on cost sharing that reflect the actual costs that are paid by the enrollee" is inaccurate. If HHS's assertion was correct, then HHS would not have defined the term "cost sharing" for purposes of the annual limitation on cost sharing as costs paid by "*or on behalf of an enrollee*."[13] Costs that are paid "on behalf of" enrollees are costs paid by third parties, not "actual costs that are paid by the enrollee." Even today, HHS has not proposed to limit this definition of cost sharing to costs that are "paid by the enrollee."
- Third, HHS's proposal would undercut the whole purpose of coupons – to help patients reduce their out-of-pocket cost and better afford their medicines.

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[10] Jonas B. Daugherty, Matthew L. Maciejewski & Joel F. Farley, *The Impact of Manufacturer Coupon Use in the Statin Market*. 19 J. Managed Care Pharmacy 765-772 (2013); Matthew Daubresse et al., *Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study*, 37 Pharmacotherapy 12-24 (2016).

[11] Catherine I. Starner et al., *Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums,* 33 Health Affairs 1761-1769 (2014).

[12] 84 Fed. Reg. at 290.

[13] 45 CFR § 155.20 (emphasis added); *see also* 45 CFR §§ 156.20, 156.130.

To turn to the statutory roadblock faced by HHS's proposal, the ACA's annual limitation on cost sharing provision provides that "[t]he cost-sharing incurred under a health plan with respect to self-only coverage or coverage other than self-only coverage for a plan year. . . shall not exceed [specified amounts].[14] The statute then expressly defines "cost sharing" for this purpose:

> (A) In general. The term "cost-sharing" includes— (i) *deductibles, coinsurance, copayments, or similar charges*; *and* (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of title 26) [i.e., amounts paid by a beneficiary for medical care for the beneficiary and his or her spouse and dependents, "*but only to the extent such amounts are not compensated for by insurance or otherwise*"] with respect to essential health benefits covered under the plan.
> (B) Exceptions. Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.[15]

The "cost sharing" definition that applies for annual limitation on cost sharing purposes clearly includes two distinct categories: (1) deductibles, coinsurance, copayments, and similar charges (whoever pays for them); and (2) "qualified medical expenses" (provided that those particular expenses are not compensated by insurance "or otherwise"). Accordingly, the statute does not permit HHS to exclude from the annual limitation on cost sharing deductibles, coinsurance, copayments, or similar charges for any essential health benefits – whether paid for by a coupon or not. We understand that HHS believes its policy goals would be advanced by placing such a limit on the cost sharing that counts toward the annual limitation on cost sharing. However, HHS must seek to advance its policy goals only through means that are consistent with the statute.

Nevertheless, if HHS does move forward with its proposal, PhRMA does not oppose HHS allowing plans to exclude cost sharing paid by a manufacturer coupon for the brand drug from the plan's annual limitation on cost sharing in the case when a health plan covers both a brand drug and the AB-rated generic equivalent for the brand, as long as the generic is both available and medically appropriate for the patient.

In the interest of ensuring that this proposed change is not misconstrued to permit health insurance issuers and group health plans to sharply increase out-of-pocket responsibility for drugs for which there is no generic equivalent available, we urge HHS to provide additional detail in the final rule. We ask HHS to confirm that the term "generic equivalent" was used in its conventional meaning (including as it is used in state generic substitution laws) to refer to a drug that FDA has determined to be therapeutically equivalent (that is, AB-rated in the FDA Orange Book) to a brand drug that is on the plan's formulary.

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[14] ACA § 1302(c)(1).
[15] ACA § 1302(c)(3) (emphasis added).

Accordingly, PhRMA concludes that a plan or issuer *must allow* the value of manufacturer cost-sharing support for a brand drug to count towards the annual limitation on cost sharing when there is *not* an AB-rated generic version of that same drug on the plan's formulary. PhRMA understands this to be HHS's intent and is concerned that, without confirmation, plans and issuers may misinterpret HHS's policy. Although plans are permitted to use utilization management techniques, the annual limitation on cost sharing is central to the ACA's guarantee that no patients—including participants and beneficiaries in self-insured and large group health plans—should be underinsured, and risk bankruptcy, despite having minimum essential coverage.

It is likewise important that health plans be permitted to exclude cost-sharing support from the annual limitation on cost-sharing *only* if the AB-rated generic is on formulary and is *medically appropriate for the enrollee*. To satisfy this requirement, HHS should require that any health plan that chooses to implement this exclusion also have an exception process that applies the standards in 45 CFR § 156.122(c) to permit an enrollee to use the brand drug—and have cost-sharing support apply to the annual limitation on cost sharing—if the AB-rated generic is not medically appropriate for the enrollee. HHS proposes to require an exception process in connection with its related proposal to permit exclusion of a portion of the brand drug cost sharing, when a generic is available on formulary, and there is no reason not to provide the same protection in the corresponding situation when cost-sharing support is applied. There remain situations where a generic would not be medically appropriate, but the brand would. For example, a generic product might include a different preservative or other excipient (e.g., sulfite) to which the patient is allergic. Generic manufacturers may also have production issues affecting safety or quality that could lead a prescriber to conclude a generic is not medically appropriate.[16] Therefore, HHS should permit plans to exclude cost-sharing support from the annual limitation on cost sharing for brand drugs when an AB-rated generic is on formulary only if the plan has an exception process that allows the support to be applied to the annual limitation on cost sharing when the generic would not be medically appropriate. Otherwise, patients will face an impossible choice between an inappropriate medicine and potentially unaffordable cost sharing.

The determination of medical appropriateness should also consider the risk of medication nonadherence posed by high out-of-pocket costs for some generic drugs. This is particularly concerning in health plans with high deductibles where a patient must meet the deductible before paying the lower cost-sharing amount. Therefore, the exceptions process should also allow patients to receive an exception if the cost to the patient for the generic will be higher than the cost sharing level assigned by the generic tier. For example, if a patient were in a plan with a $10 generic tier but was taking a $200 generic drug on the generic tier that was subject to the deductible, that patient would be eligible for this exception until reaching the deductible. In these cases, a coupon could be used for either a brand or a generic—depending on what kind of support was available—and the cost-sharing support would have to count towards the plan's out-of-pocket maximum.

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[16] Anna Edney, Bloomberg News, *America's Love Affair with Cheap Drugs Has a Hidden Cost* https://www.bloomberg.com/news/features/2019-01-29/america-s-love-affair-with-cheap-drugs-has-a-hidden-cost (Jan. 29, 2019).

If HHS finalizes this proposal with these clarifications, *cost-sharing support for a brand drug on the formulary would always count toward the annual limitation on cost sharing if there is no medically appropriate and affordable AB-rated generic for that specific drug available on the formulary*. We urge HHS to state so clearly. As discussed above, PBMs have widely implemented "accumulator adjustment programs" in recent years, including in group health plans covered by the ACA's maximum annual limitation on cost sharing. It is important for HHS to confirm that such programs undercut the intent of the annual limitation on cost sharing requirements.

Assuming HHS adopts the provision as proposed and as described here, it should apply to all non-grandfathered individual health insurance coverage and all non-grandfathered group health plans.[17] The annual limitation on cost sharing applies to all non-grandfathered health coverage, and there is no rational basis to limit these clarifications to qualified health plans.

Annual Limitation on Cost Sharing (§ 156.130): Cost Sharing Requirements for Generic Drugs

PhRMA opposes HHS's proposal to permit plans to exclude from the annual limitation on cost sharing some or all cost sharing attributable to a brand drug when a generic equivalent is available, because it will generate confusion among enrollees, undermine HHS's definition of essential health benefits (EHB), and is unnecessary to achieve HHS's stated goal of promoting use of cost-effective generic drugs. Under HHS's existing definition of prescription drugs required to be covered in the EHB package, a health plan will rarely, if ever, be required to cover a brand drug when it also has a corresponding generic equivalent on formulary. This is because the primary HHS requirement for formularies is that each category and class of drugs has a minimum number of drugs covered on formulary.[18] For the purpose of these counts, two chemically indistinct drugs, such as a brand and a corresponding generic, count as a single drug.[19] Therefore, this proposed change is entirely unnecessary, because any plan that seeks to discourage use of brand drugs when a generic is available, can choose to cover only the generic on formulary and thereby not be required to count the cost of the brand toward the annual limit on cost sharing. Under both current law, and the proposed rule, if only the brand were medically appropriate, the patient would be entitled to access the drug through a formulary exception and the cost sharing would be applied to the annual limit on cost sharing.

We are even more concerned that HHS has proposed to allow issuers not to consider brand drugs EHB if a generic is available. We acknowledge HHS's goal of "incentivizing the use of lower-cost drugs" while maintaining the "consumer protection provided by the annual limitation on cost sharing," but we do not see how HHS's proposal achieves this balance.

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[17] Pursuant to PHSA § 2707.
[18] 45 CFR § 156.122(a).
[19] CMS, *Letter to Issuers on Federally-Facilitated and State Partnership Exchanges* 54 (Apr. 5, 2013), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

Changing EHB requirements would deprive patients prescribed these drugs from protections under both the annual limitation on cost sharing and the prohibition on annual or lifetime dollar limits.[20] Moreover, consumers would be deprived of this protection not only for individual and small group health plans, but also for all other group health plans, including large group and self-insured plans.[21] Such a policy change would also generally undermine the role that states have traditionally had in establishing EHB-benchmark plans.[22]

Consumers should not have to fear that a certain subset of drugs, despite being on formulary, are subject to an entirely different set of rules than those that apply to every other formulary drug. As HHS notes, this change would also require a new, complicated calculation of drugs that can or cannot be paid for using premium tax credits (which can be applied only to EHB). This would undermine HHS's long-held position that any drug covered by plans is an EHB.[23] Upsetting this straightforward standard is unnecessary given the flexibility plans already have to exclude these drugs from the formulary.

Regardless of whether HHS finalizes its proposed regulation text at 45 CFR § 156.130(h)(1)(iii), we encourage the agency to clarify that there continues to be a "general rule that all prescription drugs covered by . . . a plan are considered EHB."[24] This general rule, that all covered prescription drugs are considered EHB for the purposes of the annual limitation on cost sharing, necessarily applies across the market, to effectively apply to all non-grandfathered health plans, encompassing not only all non-grandfathered individual and small group market health insurance coverage under PHSA § 2707(a), but also non-grandfathered group health plans –whether insured or self-insured, and whether small or large – under PHSA § 2707 (b).

Guaranteed Renewability of Health Insurance Coverage (§§ 146.152, 147.106, 148.122)

PhRMA appreciates HHS's reaffirmation of its interpretation of the federal guaranteed renewability requirement that requires health insurance issuers to modify their coverage only at renewal, and, therefore, generally prohibits issuers from removing a drug from the formulary, or changing its tier, in the middle of a policy year. Prescription drug coverage is often a basis upon which patients select a health plan, and it undermines guaranteed renewability—and fundamental fairness—for issuers to weaken their formularies after individuals have made their plan selection for the year. However, we agree with HHS that a limited exception is appropriate only when an AB-rated generic is added to a formulary midyear and a change is made to the corresponding brand drug. If a plan makes such a change, an exception process should be available, as HHS proposes, for enrollees to access a medically-appropriate off-formulary drug. We previously discuss (under the "Manufacturers' Coupons" section of this letter) circumstances in which an

[20] PHSA §§ 2707(b); 2711; ACA § 1302(c).
[21] As HHS recognizes in the proposed rule, the obligation for large group and self-insured plans to institute annual cost-sharing limitations and prohibitions against annual/lifetime limits extends only to drugs that are EHB.
[22] See 78 Fed. Reg. at 12843 ("As stated previously, the Secretary structured the EHB regulations to maintain state flexibility in defining benefits within the categorical parameters set out by Congress.").
[23] *See* 80 Fed. Reg. 10817 (Feb. 27, 2015); *see also* proposed rule at 289.
[24] Proposed 45 CFR § 156.130(h)(1)(iii). Subject to HHS's proposed exception, if finalized.

AB-rated generic may not be medically appropriate for a patient prescribed a brand drug. As in other sections of the proposed rule, HHS has not defined "generic" for this purpose, and we recommend HHS confirm that it means a generic drug that FDA has determined to be therapeutically equivalent to the brand (*i.e.*, AB-rated in the FDA Orange Book).

Prescription Drug Benefits (§ 156.122)

Therapeutic Substitution

PhRMA strongly opposes any new policy that would encourage therapeutic substitution within the prescription drug benefit required as part of the EHB package. PhRMA is concerned that this could be harmful to patient health and add unintended costs to the health care system. Differences in how therapeutic substitution is understood among different stakeholders in the health care system create significant potential for flawed implementation of any such policy. Patients would be put at risk through inappropriate and inadvertent therapeutic substitutions. Finally, health care communication systems are far from being developed, tested, and ready to support even limited patient-centric options for therapeutic substitution.

In the proposed rule, HHS defines therapeutic substitution as the substitution of chemically different compounds within the same drug class for one another. HHS believes that therapeutic substitution of drugs within a drug class could potentially improve the efficiency of the pharmaceutical market. HHS solicits comments on whether therapeutic substitution and generic substitution should be pursued as options within the EHB prescription drug benefit.

First, HHS is mistaken in its belief that brand drugs are the key element of health care inflation. Prices for drugs remain a relatively stable component of overall health care spending. In health insurance premium rate filings studied in nine states, brand and generic prescription drugs were responsible for only 14 percent of premium growth in the individual and small group markets in 2017, whereas inpatient and outpatient hospital care represented 45 percent of premium growth.[25] In addition, drug spending trend is decreasing, with Express Scripts reporting 0.4 percent growth for 2018, the slowest rate of growth in the 25 years Express Scripts has been reporting this number.[26] Similar low and declining drug trend spend has been reported by other PBMs and actuaries.[27]

Therapeutic Substitution is Unsafe

HHS's focus on therapeutic substitution unnecessarily increases the likelihood that patients could receive inappropriate and potentially unsafe medication therapy. Therapeutic substitution is very different than commonly practiced generic substitution. PhRMA believes in the appropriate use of generic drugs (i.e. AB-rated drugs). AB-rated generics are copies of drugs

[25] Avalere Health, *Outpatient Services Are the Largest Driver of 2017 Premium Increases* (2016).
[26] Express Scripts, Drug Trend Report (2018).
[27] Milliman Medical Index; Prime Therapeutics, Focus on Trend: Commercial (2018); CVS Health, Drug Trend Report (2017).

that were developed by research-based pharmaceutical companies and were the subject of full applications with FDA. For many patients, generic drugs can provide the appropriate therapy.

Therapeutic substitution assumes that each drug product in the same class is an identical product, whether brand or generic. A therapeutic class may have many different prescription drugs to treat a similar clinical indication. However, drugs in the same class may have significant differences in their chemical formulas and mechanisms of action to provide the drug's benefits. Switching drugs in a class can pose significant danger to patient health if there are possible side effects or a patient has additional health conditions.

Many patients suffer from multiple conditions that are being managed by prescription drugs; therefore, switching to another medication within the same therapeutic class could upset the stability of their ongoing treatment plan. The treatment plan is a result of the prescriber's knowledge of possible drug interactions, drug-disease interactions, and the patient's current illnesses. A change to any element of the therapy plan can have adverse results on patient health.

A recent literature review of findings on non-medical switching (i.e., switching to a chemically distinct but similar medication for reasons other than lack of clinical efficacy/response, side effects or poor adherence), which appears to be precisely the type of therapeutic substitution HHS is considering, found that "[n]on-medical switching was more often associated with negative or neutral effects than positive effects on an array of important outcomes. Among patients with stable/well-controlled disease, non-medical switching was associated with mostly negative effects."[28] Thus, PhRMA reiterates its opposition to therapeutic substitutions, which are not made by prescribers for the explicit clinical benefit of the patient.

Therapeutic Substitution Can Increase Costs

Appropriate prescription-drug therapy enhances the quality and cost-effectiveness of medical treatment. Therapeutic substitution can lead to unintended patient health outcomes, resulting in additional health care expenditures such as added physician visits or hospitalizations.

Therapeutic substitution is cost-driven, rather than patient-driven, and it jeopardizes patient safety. Each medication within a therapeutic category has its own unique clinical and chemical characteristics; consequently, forcing patients to switch between medications can trigger drug interactions, side effects, and treatment failures—all of which could harm patients and add costs to the medical system. Policies like therapeutic substitution are promoted in the economic interest of insurers, not the interest of patients.

Different drugs within a class are associated with different side effects. Additionally, different health factors outside of the condition that the medicine is prescribed for can impact which medication is best for an individual patient. A patient, who, for example, experiences

[28] E Nguyen et al., "Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review." 32 Current Medical Research and Opinions 1281 (2016), *available at* https://www.ncbi.nlm.nih.gov/pubmed/27033747.

nausea with one drug in a class, may have to try several different drugs in a class before the one that does not cause them nausea. If the drug has been therapeutically substituted at the pharmacy level, the burden on the patient to determine if a drug is working well for them is significantly greater than when a physician chooses the exact medicine a patient will take and oversees a patient's entire treatment regimen.

Allowing pharmacists to dispense medication not prescribed by a treating physician for cost purposes alone is not good for patient safety, is bad policy, and could lead to a conflict of interest.

Reference-Based Pricing

PhRMA strongly opposes reference-based pricing of prescription drug benefits. The proposed rule solicits comments on the opportunities and risks of implementing or incentivizing reference-based pricing (reference pricing) for prescription drugs. Reference pricing for prescription drugs is a blunt instrument that would result in a host of negative consequences because it prioritizes cost over all other considerations, including clinical appropriateness, drug efficacy, and/or patient and prescriber preferences.

Implementing a reference-pricing system that covers drugs within a therapeutic class only up to an arbitrary reference value ignores the medical needs of patients and current clinical recommendations. Although medicines in the same class may have the same basic mechanism of action, small differences at the molecular level and the site of action mean that medicines within the same class can have variances that may impact how a medicine works. Each patient is unique, with genetic and molecular variations that may affect how he or she responds to or tolerates any given medication. For autoimmune conditions, such as rheumatoid arthritis, multiple sclerosis, or inflammatory bowel disease, there is no one-size-fits all approach to treatment, and finding the right therapy for patients often involves a frustrating series of trial and error before identifying the appropriate product that will work for them. Reference pricing would penalize patients who, for reasons outside of their control, only tolerate or respond to a medication whose cost is higher than the reference price.

Having a broad range of treatment options is fundamental to providing good care to all patients. It is critical that patients who are stabilized and well-managed on a therapy maintain access to the appropriate products to prevent further complications, poorer disease outcomes, and greater utilization of other health care services such as emergency department visits and hospitalizations. Evidence on the effects of high-deductible health plans shows that haphazardly increasing patient cost sharing can cause patients to skip necessary care.[29] By similarly shifting costs to patients, reference pricing will impede access for patients who happen to need a medication that costs more than the reference price thereby worsening health outcomes and increasing total health spending for that individual.

[29] Rajender Agarwal, Olena Mazurenko & Nir Menachemi, *High-Deductible Health Plans Reduce Health Care Cost And Utilization, Including Use Of Needed Preventive Services*, 36 Health Affairs 1762 (2017).

Adoption of reference pricing will likely exacerbate patients' cost sharing burdens. For enrollees in large employer health plans, between 2006 to 2016, the average payments by enrollees deductibles rose 176% and the average payments towards coinsurance rose 67%. Meanwhile, the payments made by health plans themselves increased just 48 %.[30] Reference pricing will shift additional cost sharing onto patients by design, requiring them to pay the difference between the reference price and the price of a given product. This is likely to serve as an additional barrier to patients accessing the drugs that they need.

Premium Adjustment Percentage (§ 156.130)

PhRMA opposes HHS's proposal to incorporate individual market premium rates into the calculation of the annual premium adjustment percentage. Doing so automatically increases costs for enrollees by lowering the value of premium tax credits and establishes higher annual limitations on cost sharing. It is inappropriate to for HHS to do this, especially at a time when health insurance premiums and the out-of-pocket medical costs remain unaffordable for many. The decision to change the premium adjustment percentage's calculation is an entirely discretionary one, which will, by HHS's own analysis, result in 100,000 people losing coverage in the exchange.[31] Further, this will impact millions more people who obtain coverage through their employer and will face higher out-of-pocket spending.

As the proposed rule makes clear, HHS initially excluded individual market premium growth from the calculation of the premium adjustment percentage because the percentage was intended to be a measure of growth in health care expenditures under commercial health coverage. Including individual market premium growth would skew this figure because of the disruptions that were anticipated, and actually occurred, with the establishment of the exchanges. Specifically, most states did not have individual market community rating and guaranteed availability prior to 2014, so when those protections became applicable federal law in 2014, the risk pool of the individual market changed dramatically, with millions of previously uninsured people obtaining coverage. HHS recognized in its earlier rulemaking that it would have made no sense to include individual market premiums in the calculation as the change in premiums from 2013 to subsequent years would principally reflect the impact of regulatory changes, not health care inflation.

The proposed change in methodology directly contradicts HHS's earlier decision, and HHS does not explain its reversal. It does not matter that the market impact of the regulatory changes that occurred in 2014 may now have stabilized. Because the premium adjustment percentage is a measure of *cumulative* change since 2013, any measure that includes the individual market will inevitably be artificially higher because the ACA changed—and expanded—the composition of the individual market risk pool in 2014. HHS should not change its premium adjustment percentage methodology.

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[30] Gary Claxton et al., Peterson-Kaiser Health System Tracker, *Increases in Cost-Sharing Payments Continue To Outpace Wage Growth*, https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/ (2018).
[31] Proposed rule at 308.

Risk Adjustment Model Recalibration (§ 153.320)

PhRMA supports HHS's decision to maintain stability in the risk adjustment model, by using fundamentally the same approach for 2020 as it has in recent years, including the use of prescription drug categories (RXCs) as an element in calculating adult risk scores. RXCs are an appropriate and important element in the model since it improves the model's predictive accuracy, especially for certain condition categories in which the predicted medical expense for a patient varies dramatically depending on whether or not a patient is receiving active treatment. We recognize that as drug prices change—and in some cases, decline—it may be appropriate to recalibrate or constrain the coefficients for particular RXCs to reflect the current market environment, as HHS proposes to do with respect to the hepatitis C RXC coefficient.

While these recalibrations are appropriate if necessary to improve the model's predictive accuracy, we continue to believe that it is unlikely that insurers game the model by encouraging providers to prescribe particular treatments when they are unnecessary. The professional independence, and ethical standards, of health care providers would prevent them from prescribing drugs that they did not believe were medically necessary and appropriate. In addition, enrollee cost-sharing would likely prevent patients from filling prescriptions of dubious clinical benefit. We think the much greater concern is that the risk adjustment model could fail to adequately compensate issuers for enrollees with serious chronic conditions and this could cause issuers to discourage enrollment by these patients, or design formularies or utilization management practices to make it difficult for patients to access innovative medicines. Thus, we encourage HHS to evaluate the model continually to ensure it fully captures the cost of the current standard of care for conditions in the model.

Standards for Direct Enrollment Entities (§ 155.221(b))

To the extent that HHS is promoting the use of private-sector direct enrollment entities, include web-brokers, with the aim of making it easier for individuals to find and enroll in exchange coverage, we urge HHS take additional steps to ensure that consumers who intend to enroll in a QHP do not accidentally sign up for short-term, limited duration insurance. Recent analysis highlights the limitations of states to adequately monitor the marketing tactics of brokers selling short-term, limited duration insurance and to ensure that enrollees have the necessary information to make informed enrollment decisions[32]. Thus, it is important for HHS to adequately safeguard enrollees from the unintended consequences of inadequate information and porous consumer protections. PhRMA is concerned that the proposed regulations governing direct enrollment entities' display of QHPs and non-QHPs may not provide sufficient protection to enrollees.

The proposed rule appears to have been developed on the belief that the non-QHP coverage that would be offered by direct enrollment entities would principally be coverage that is

[32] Sabrina Corlette, et al. Urban Institute, The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses (2019), https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses

complementary to a QHP, such as adult dental or vision coverage, instead of coverage that would be a substitute for a QHP. Last year the Administration permitted insurers to sell "short-term, limited-duration" coverage that can have an initial duration of nearly 12 months but does not need to provide the EHB package or comply with the prohibition on annual or lifetime dollar limits on benefits—or any other federal requirement that ordinarily applies to individual health insurance coverage.[33] A new analysis of short-term, limited-duration plans shows that 71 percent do not cover outpatient prescription drugs at all.[34]

HHS should require that a disclaimer be provided by the direct enrollment entity that incorporates the information required in the short-term, limited duration notice regulation.[35] The existing regulation requires short-term, limited-duration notice to be provided only in an enrollment application or insurance contract. Receiving such notice when filling out an application for enrollment may be too late in the sales process for a purchaser to rationally weigh the risks of buying such a limited product. Further, HHS should state clearly that that no links or information about short-term, limited duration insurance can be provided at all on webpages related to QHPs. Even with these policies in place, we suggest that HHS monitor whether such safeguards are sufficient or whether consumers are accident inadvertently enrolling in short-term coverage when they intended to enroll in a QHP.

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PhRMA appreciates HHS's consideration of our concerns. We stand ready to assist with any of the issues raised in our letter. Please contact Karyn Schwartz at 202-835-3491 or kschwartz@phrma.org with any questions.

Sincerely,

/S/ /S/

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[33] Short-Term, Limited-Duration Insurance, 83 Fed. Reg. 38212 (Aug. 3, 2018).
[34] K. Pollitz, et al "Understanding Short-Term Limited Duration Health Insurance," Kaiser Family Foundation, April 23, 2018.
[35] 45 CFR § 144.103.