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December 30, 2020

VIA ELECTRONIC FILING — *http://www.regulations.gov*

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

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS–9914–P, Mail Stop C4–26–05
Baltimore, MD 21244-1850

David J. Kautter
Assistant Secretary (Tax Policy)
Department of the Treasury
1500 Pennsylvania Ave NW
Washington, DC 20220

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations, CMS-9914-P

Dear Secretary Azar, Administrator Verma, and Assistant Secretary Kautter:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the 2022 Notice of Benefit and Payment Parameters (NBPP) proposed rule published by the U.S. Department of Health and Human Services (HHS) and the U.S. Department of the Treasury (Treasury).[1] 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. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

America's biopharmaceutical companies are committed to developing solutions to help diagnose and treat those with COVID-19, a disease caused by a novel strain of coronavirus. Our members also recognize the unequal impact that COVID-19 is having on communities of color. The data show that in the United States, Black people account for 13 percent of the population but make

[1] 85 Fed. Reg. 78572 (Dec. 4, 2020).

up 22 percent of COVID-19 deaths where race is known.[2] In addition to applying their scientific expertise to find ways to diagnose, treat, and prevent infections from the virus, the biopharmaceutical industry is committed to finding ways to enhance the diversity of vaccine and therapeutic clinical trials for COVID-19 and help reduce health care disparities.[3] PhRMA member companies are also providing financial support and in-kind donations and collaborating with U.S. and global health authorities to combat this global public health emergency. Most PhRMA members have research and development efforts underway and are providing donations of medicines and critical medical supplies to support patients and first responders in addressing this evolving crisis.

During this public health emergency, access to comprehensive, affordable, and accessible prescription drug coverage is more important than ever. Affordable access to medicines is crucial to preventing, treating, and potentially curing acute and chronic medical conditions, as well as improving quality of life and reducing spending on other health care services. However, too many Americans today struggle to afford the out-of-pocket costs for the brand medicines they need. Recent research shows that affordability challenges are primarily driven by health plans' increased use of benefit designs utilizing high deductibles and coinsurance. Across the seven therapeutic areas included in a recent IQVIA analysis, patients with deductibles or coinsurance paid as much as 30 times more out-of-pocket annually for brand medicines than patients with copays only.[4] The increasing use of deductibles and coinsurance by health plans disproportionately burdens patients with chronic conditions who are prescribed brand medicines, who are often some of the most vulnerable in the health system. More needs to be done to ensure that patients have access to affordable medicines and to counteract current trends in benefit design that are detrimental to patients and exacerbate health disparities. For example, research from Harvard University shows that reduced cost sharing for cardiovascular medicines increased adherence, but had a disproportionate impact to reduce risk of vascular events and medical costs among nonwhite patients.[5]

PhRMA appreciates the opportunity to provide comment on this proposed rule, which will shape the health insurance coverage options for the vast majority of Americans. However, we are concerned that several proposals in the 2022 NBPP proposed rule would promote access to insurance options that do not provide adequate coverage for prescription drugs, including short-term limited duration insurance (STLDI). Additionally, we are troubled by HHS's continued misunderstanding of the role manufacturer cost-sharing assistance plays in helping patients pay for the out-of-pocket costs of their medicines. This includes the recent HHS/CMS final rule that requires manufacturers to "ensure" the full value of assistance goes to patients in order for it to be excluded from a drug's Medicaid best price – a policy we strongly oppose because cost-sharing assistance is intended to benefit patients, and manufacturers have no control over

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[2] COVID Tracking Project. The COVID racial data tracker. https://covidtracking.com/race.
[3] PhRMA. Principles on conduct of clinical trials communication of clinical trial results. October 2020. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMAPrinciples-of-Clinical-Trials-FINAL.pdf.
[4] PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost-Sharing-for-Brand-Medicines.pdf.
[5] Choudhry, NK., Bykov, K., Shrank, WH., et al. Eliminating medication copayments reduces disparities in cardiovascular care. *Health Affairs* 2014 33:5, 863-870. https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.0654.

whether plans use accumulator adjustment programs.[6] For many patients facing high out-of-pocket cost burdens, manufacturer cost-sharing assistance programs are an important source of financial support which can help to improve patient adherence and lead to improved patient outcomes.[7] Manufacturer cost-sharing assistance is provided to patients and is not a "price concession" to plans. Accordingly, we ask HHS to delete "coupon" from the definition of price concession under medical loss ratio (MLR) reporting rules and to reverse the misguided policy finalized in the 2021 NBPP that allows for the proliferation of accumulator adjustment programs to the detriment of patient access.

PhRMA has the following specific comments, which we discuss in greater detail below:

- *Medical Loss Ratio Reporting.* HHS correctly requires that health insurance issuers report manufacturer rebates retained by pharmacy benefit managers (PBMs) as reductions to the issuers' MLR. However, we note that manufacturer cost-sharing assistance (commonly referred to as coupons) is intended to benefit the enrollee, not the issuer, and therefore should not be treated as a form of manufacturer price concession – in the context of MLR reporting or otherwise.
- *Annual Limit on Cost Sharing.* The Affordable Care Act (ACA) requires group health plans and health insurance issuers to count cost sharing for essential health benefits – including manufacturer cost-sharing assistance and other third-party payments – toward the annual limitation on cost sharing.[8] HHS's recent actions have significantly undermined this important patient protection. HHS should revisit the policy finalized in the 2021 NBPP[9] and implement the ACA maximum annual limit on cost sharing provision as Congress intended. While PhRMA opposes accumulator adjustment programs, which are contrary to the requirements and goals of the ACA, at the very least, HHS should revert to its position from the 2020 NBPP final rule,[10] which limited the circumstances in which health insurance issuers and group health plans may exclude manufacturer cost-sharing assistance from the accumulator for the annual limit on cost sharing. The policy finalized in 2021 NBPP compromises enrollees' ability to adhere to prescribed medicines and is an arbitrary and capricious reversal from the policy finalized in the 2020 NBPP.
- *Direct Enrollment.* If HHS continues to promote expansion of direct enrollment options, HHS should ensure that direct enrollment entities are completely clear with applicants about the shortcomings of plans that do not meet qualified health plan (QHP) standards,

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[6] Final Rule: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-F) from the Department of Health and Human Services, Centers for Medicare & Medicaid Services will be published in the Federal Register on 12/31/2020. https://public-inspection.federalregister.gov/2020-28567.pdf.

[7] PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost-Sharing-for-Brand-Medicines.pdf.

[8] ACA § 1302(c)(3), 42 U.S.C. § 18022(c)(3).

[9] 85 Fed. Reg. 29164, 29230 (May 14, 2020).

[10] 84 Fed. Reg. 17454, 17544 (Apr. 25, 2019).

including STLDI, if they sell it, and ensure that consumers who seek an eligibility determination through a direct enrollment website do not face additional hurdles to enroll in coverage if they are eligible for Federal programs such as Medicaid.

- *State Innovation Waivers.* PhRMA continues to believe that HHS and Treasury's 2018 guidance on State Innovation Waivers is insufficiently protective of people with chronic and pre-existing conditions. PhRMA opposes codifying this guidance in regulation.
- *PBM Standards.* PhRMA generally supports the proposal that HHS collect required data directly from PBMs. We believe this is a positive first step, but we note that the extensive restrictions that section 1150A imposes on HHS's use of this data limits the impact of these provisions on reducing health care costs for patients, employers and other purchasers.
- *Premium Adjustment Percentage.* PhRMA continues to oppose HHS's decision to incorporate individual market premium rates into the premium adjustment percentage methodology, which artificially depresses the value of premium tax credits and increases the maximum annual limit on cost sharing, making health care less affordable.
- *Risk Adjustment.* PhRMA welcomes the continued inclusion of prescription drug categories (RXCs) in the risk adjustment model but continues to question HHS's concern that coefficients in the risk adjustment model could lead to inappropriate prescribing.
- *Special Enrollment Periods.* PhRMA favors the expansion of special enrollment opportunities, especially during the public health emergency, and encourages HHS to make these changes applicable in 2021. HHS should explore requiring QHPs to transfer accumulated cost-sharing payments when an individual switches plans during a special enrollment period.
- *Enrollment Process for Qualified Individuals.* PhRMA remains concerned that using employer-funded health reimbursement arrangements (HRAs) to buy individual health insurance coverage could ultimately undermine the robustness of health coverage available to working Americans.

Medical Loss Ratio Reporting: Definitions (§ 158.103)

HHS correctly requires health insurance issuers to report manufacturer rebates retained by PBMs as reductions to the issuers' MLRs, but, for this purpose, remuneration to the issuer should exclude "coupons." Manufacturer coupons, or cost-sharing assistance, are intended to benefit the enrollee, not the issuer and therefore should not be treated as a manufacturer price concession – in the context of MLR reporting or otherwise.

As we noted in our comments on the 2021 NBPP proposed rule,[11] PhRMA supports the requirement, now codified at 45 C.F.R. § 158.140(b)(1)(i), to require health insurance issuers to reduce their reported incurred claims to reflect the value of all price concessions, including manufacturer rebates retained by the issuer's PBM and not passed through to the enrollee and/or

[11] PhRMA's comments on Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans (CMS-9916-P). https://beta.regulations.gov/comment/CMS-2020-0009-0998.

the issuer. PhRMA is concerned, in general, with the practice of issuers or PBMs receiving price concessions on prescription drugs and not sharing the benefit of those concessions with enrollees in the form of lower cost sharing. Failure to pass along rebate savings directly to enrollees may create misaligned incentives for PBMs and issuers and could create significant affordability challenges for patients.[12]

PBMs and issuers generally do not directly pass through the substantial rebates they receive from manufacturers to patients at the pharmacy counter.[13] PhRMA would prefer that patients benefit directly from rebates by having them reflected at the point-of-sale, as the Administration recently took steps to do in Medicare Part D through the Office of Inspector General's final rebate rule,[14] which could significantly reduce out-of-pocket costs for patients with coinsurance and in their deductible. Barring that, enrollees should benefit from having price concessions for prescription drugs reflected in higher MLR rebates (just as is done with negotiated rates for medical benefits). While many issuers claim to use rebates to lower enrollee premiums, premiums have continued to rise despite increases in rebate amounts.[15] Prior to the application of 45 C.F.R. § 158.140(b)(1)(i)(B), for the 2022 MLR reporting year, MLR reporting rules did not ensure that the substantial discounts and rebates paid by biopharmaceutical companies to PBMs would be reflected in reported claims in the MLR calculation. Under the new rule, all price concessions, including those retained by PBMs, should be taken into account in determining MLR rebate obligations.

As HHS noted, this change appropriately aligns commercial MLR reporting with the reporting rules for Medicare and Medicaid managed care. In defining the "direct and indirect remuneration" (DIR) that would be subject to reporting, the proposed rule incorporates the DIR definition used in Medicare Part D: "discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers."[16] PhRMA is concerned that the inclusion of "coupons" in this definition could result in the mischaracterization of the assistance drug manufacturers may provide to enrollees to help them pay their health plan cost sharing. Manufacturer cost-sharing assistance is not intended to reduce plan liability, regardless of how a plan treats this assistance, and should therefore not be considered as direct or indirect remuneration to the issuer.[17] Manufacturer cost-sharing

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[12] BRG. Revisiting the pharmaceutical supply chain: 2013-2018. January 2020. https://www.thinkbrg.com/insights/publications/revisiting-the-pharmaceutical-supply-chain-2013-2018/.
[13] The Pew Charitable Trusts. The prescription drug landscape, explored: a look at retail pharmaceutical spending from 2012 to 2016. March 2019. https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.
[14] 85 Fed. Reg. 76666 (Nov. 30, 2020).
[15] *See*, Drug Channels. The gross-to-net bubble hit $175 billion in 2019: Why patients need rebate reform. August 2020. https://www.drugchannels.net/2020/08/the-gross-to-net-bubble-hit-175-billion.html, and Kaiser Family Foundation. 2020 Employer health benefits survey - section 1: cost of health insurance. October 2020. https://www.kff.org/report-section/ehbs-2020-section-1-cost-of-health-insurance/.
[16] 85 Fed. Reg. at 78681 (proposed to be codified at 45 C.F.R. § 158.103); *see* 42 C.F.R. § 423.308 (definition of "actually paid").
[17] It would be appropriate to apply different definitions to Part D and individual and group health insurance, because the federal antikickback statute will generally prohibit manufacturer cost-sharing assistance for Part D enrollees, but does not apply to group or individual health insurance coverage. *Compare* Office of Inspector General Adv. Op. No. 20-05,

assistance is simply the form by which an enrollee pays cost-sharing obligations and enrollee cost sharing is, by definition, not included in the MLR numerator.[18] Therefore, including "coupons" in the proposed definition of remuneration is unnecessary and PhRMA urges HHS to remove it.

Annual Limit on Cost Sharing (§ 156.130)

PhRMA remains deeply concerned about HHS's precipitous reversal in the 2021 NBPP final rule to permit group health plans and health insurance issuers to use accumulator adjustment programs without limitation,[19] which will likely result in higher out-of-pocket prescription drug costs for millions of patients across the Nation.[20] Specifically, this policy allows plans and issuers to exclude the value of manufacturer cost-sharing assistance from accruing towards the statutorily required annual limitation on cost sharing regardless of whether a medically appropriate generic equivalent is available. Historically, such cost-sharing assistance has counted toward the annual limitation on cost sharing under the ACA, which helps protect enrollee access to medically necessary treatment options. The latest policy undermines this important patient protection under the ACA that provides patients and families with greater predictability and certainty about their maximum out-of-pocket exposure on an annual basis.

Further, the 2021 NBPP's policy change compromises patients' ability to adhere to prescribed medicines at a moment when insurance coverage for medicines continues to erode; it puts patient health and financial security in danger; and it runs directly counter to the important policy goals of lowering patient out-of-pocket costs for prescription drugs, particularly in the middle of a global health pandemic.

The 2021 NBPP final rule represented a complete reversal of final regulatory action taken by HHS in its 2020 NBPP final rule. Further, the 2021 NBPP final rule is not consistent with the statutory or regulatory definition of cost sharing because federal law requires that amounts charged as deductibles, coinsurance, or copayments under a health plan count toward the plan's annual limitation on cost sharing, without limiting the sources of funds that may be used to pay those amounts.[21] HHS failed to explain how it can simply "interpret" cost sharing not to include manufacturer cost-sharing assistance, in light of the existing statute and regulation, as well as the fact that the interpretation would not apply to many other types of patient assistance or financing

https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-05.pdf *with* Letter from the Secretary of Health and Human Services to the Hon. Jim McDermott (Oct. 30, 2013), https://www.hlregulation.com/wp-includes/ms-files.php?file=2013/10/The-Honorable-Jim-McDermott.pdf. Therefore, the reference to "coupons" in the Part D definition of DIR does not have the same implications as it does in the definition applicable to group and individual health insurance coverage.

[18] Public Health Service Act § 2718(a), (b), 42 U.S.C. § 300gg-18(a), (b) (MLR numerator includes amounts "expended" by issuer or coverage).

[19] HHS Notice of Benefit and Payment Parameters for 2021, 85 Fed. Reg. at 29261 (codified at 45 C.F.R. § 156.130(h)).

[20] We have discussed our opposition to accumulator adjustment programs at length in both our comment letter on the 2021 NBPP proposed rule and our comment letter on the Medicaid Value-Based Purchasing proposed rule (85 Fed. Reg. 37286 (June 19, 2020)). When a health plan uses an accumulator adjustment program, it jeopardizes patients' ability to access needed medications, particularly when there may be no alternative options. This disruption can reduce adherence and increase abandonment, exacerbating underlying health conditions and leading to worse outcomes. Accumulator adjustment programs hurt enrollees, and HHS should not permit or encourage them.

[21] Patient Protection and Affordable Care Act § 1302(c)(3), 42 U.S.C. § 18022(c)(3); 45 C.F.R. § 155.20.

mechanisms that similarly eliminate, reduce, or delay patient out-of-pocket spending for covered services.

Conversely, the 2020 NBPP final rule required plans to count towards the annual limitation on cost-sharing amounts paid using manufacturer cost-sharing assistance for drugs that lack medically appropriate generic equivalents, protecting patients from facing significant, unexpected bills for drugs without alternatives as a result of plans implementing accumulator adjustment programs, while also ensuring that the availability of cost-sharing assistance does not steer patients towards higher-priced branded drugs over appropriate generic equivalents.[22] The abrupt reversal of the balance struck in the 2020 NBPP final rule was not adequately addressed by HHS in the 2021 NBPP final rule, and it directly contradicts the agency's prior determination that the potential for market distortion does not exist when manufacturers provide cost-sharing assistance for medicines without a generic equivalent.[23] Additionally, an incorrect HHS interpretation of 16-year-old Internal Revenue Service (IRS) guidance is the sole justification offered for this policy shift – a shift that could dramatically erode patient access to critical medicines.

When accumulator adjustment programs are implemented by health plans, they can substantially increase patients' out-of-pocket costs, increasing financial burden and health risk, especially for those with serious and chronic illnesses. HHS itself, in its recently finalized Medicaid rule, acknowledges "situations when a patient has been subject to significant out-of-pocket costs because the patient has not progressed through the deductible phase of the health plan [due to accumulator adjustment programs not applying the value of the manufacturer-sponsored assistance to the patient's deductible]."[24] Further, HHS notes that "when this happens, the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions."[25] Thus, accumulator adjustment programs can undermine medication adherence, which can lead to negative health outcomes for patients and increase overall health care costs.[26] Accordingly, we urge HHS to protect patients by reinstating the requirement from the 2020 NBPP final rule that plans must count manufacturer cost-sharing assistance towards the annual limitation on cost sharing for drugs that lack an appropriate generic equivalent. [27]

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[22] 84 Fed. Reg. 17454, 17544-46 (Apr. 25, 2019).
[23] In 2017, less than one percent of all commercial market medicine claims were filled with cost-sharing assistance for a branded medicine where a generic equivalent was available. *See*, 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.
[24] Final Rule: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-F) from the Department of Health and Human Services, Centers for Medicare & Medicaid Services will be published in the Federal Register on 12/31/2020. https://public-inspection.federalregister.gov/2020-28567.pdf.
[25] Ibid.
[26] 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.
[27] For a more detailed discussion, please see our comment letter on the Notice of Benefit and Payment Parameters for 2021.

We likewise encourage HHS to clarify that there continues to be a "general rule that all prescription drugs covered by . . . a plan are considered [essential health benefits]."[28] This general rule, that all covered prescription drugs are considered essential health benefits 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 Public Health Service Act § 2707(a), but also non-grandfathered group health plans – whether insured or self-insured, and whether small or large – under Public Health Service Act § 2707(b).

Standards for Direct Enrollment Entities (§ 155.221)

HHS is proposing to take several steps to promote the use of the direct enrollment pathway, where applicants use health insurance issuers' or insurance brokers' websites to apply for and enroll in Exchange coverage. Because these direct enrollment entities can sell other types of individual market insurance plans in addition to QHPs, including those that do not need to comply with the most basic patient protections under federal health insurance law, such as STLDI, PhRMA remains concerned that promotion of direct enrollment will increase the number of people who are misled and confused into enrolling in health coverage that leaves them inadequately protected from financial and health risks. We recommend that HHS study closely whether increased availability of these plans through direct enrollment entities has exposed more enrollees to ruinous health care expenses.

PhRMA is particularly concerned about the increased availability of STLDI through direct enrollment entities. STLDI is not required to provide the essential health benefits package, limit cost sharing, or comply with the prohibitions on annual or lifetime benefit limits or pre-existing condition exclusions. One analysis showed 71 percent of these plans provided no coverage for prescription drugs at all, and some plans may impose cost sharing of $20,000 a year.[29] Other research has shown that patients who develop chronic conditions while enrolled in STLDI may face significant financial hardships due to the lack of comprehensive essential health benefits and drug coverage.[30] Overall, STLDI benefit limitations can confuse and surprise enrollees who may be attracted by these plans' lower premiums, but who misunderstand how broad pre-existing condition exclusions can reach. These individuals may therefore end up buying less comprehensive health insurance coverage that they intend or that would be prudent for them.

We ask HHS to require that a disclaimer be provided by the direct enrollment entity that incorporates the information required in the STLDI notice regulation.[31] The existing regulation requires a STLDI 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,

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[28] 2020 NBPP proposed rule, 84 Fed. Reg. 227, 320 (Jan. 24, 2019) (proposed to be codified at 45 C.F.R. § 156.130(h)(1)(iii) ("Notwithstanding the general rule that all prescription drugs covered by such a plan are considered EHB . . .")).
[29] Kaiser Family Foundation. Understanding short-term limited duration health insurance. May 2018. https://aahd.us/wp-content/uploads/2018/05/ShortTermLimitedDurationHInsurancePlans_NHC_UnderstandingThem.pdf.
[30] Health Affairs. The Short-term, limited-duration coverage final rule: the background, the content, and what could come next. August 2018. https://www.healthaffairs.org/do/10.1377/hblog20180801.169759/full/.
[31] 45 C.F.R. § 144.103.

HHS should state clearly that no links or information about STLDI 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 inadvertently enrolling in STLDI when they intended to enroll in a QHP.

Furthermore, we are aware of concerns raised by stakeholders that direct enrollment entities may be setting up hurdles to enrollment for individuals who are eligible for Federal programs, like Medicaid. An important feature of the Exchanges is the "no wrong door" policy that is intended to allow uninsured people to be determined eligible for all appropriate government health programs and enrolled no matter where they begin an application for coverage. Because brokers and insurers do not have a financial interest in serving individuals enrolling in Federal programs, they may make insufficient efforts to assist these applicants with signing up for suitable coverage. This may result in individuals going uninsured or buying inappropriate coverage because they are unaware of their Medicaid eligibility.[32] HHS should investigate these claims and ensure that individuals do not face barriers to signing up for appropriate coverage through these entities. Failing to do so could result in increased numbers of uninsured individuals.

State Innovation Waivers (Part 155; 31 CFR Part 33)

PhRMA opposes the 2018 guidance that purported to relax the standards for approval of a State Innovation Waiver under section 1332 of the ACA, and therefore opposes the proposal to codify standards from that guidance in HHS and Treasury regulations.

We are concerned that this guidance, and the proposed regulations, could increase the availability of coverage that does not meet the standards included in the ACA market reforms—including the requirement to cover individuals with pre-existing conditions. For example, the 2018 guidance reversed a requirement that State Innovation Waivers may not harm certain subpopulations. Such a change is likely to make comprehensive coverage less affordable and less accessible for people with pre-existing and chronic conditions, including patients who rely on innovative medicines. We urge HHS and Treasury, when evaluating waivers under section 1332, to ensure that increased flexibilities do not come at the expense of affordable, comprehensive coverage for those most in need.

Any substantial efforts to create greater access to less comprehensive coverage (e.g., STLDI plans) will come at the expense of those who need more comprehensive coverage, because of the adverse impact such waivers will have on the insurance risk pool. This would lead to patients with chronic and pre-existing conditions being unable to afford coverage at all—or facing unaffordable cost sharing for medicines and other health care once they obtain coverage. While less comprehensive coverage might have lower premiums, it would also likely have limitations or exclusions that leave patients in greatest medical need without access to the services and coverage they require. We are particularly concerned that consumers may not have the information necessary to ensure they are choosing the best coverage for their health needs. We urge HHS and Treasury to include requirements for states to expressly differentiate plans with

[32] Center for Budget & Policy Priorities. Direct enrollment in marketplace coverage lacks protections for consumers, exposes them to harm. March 2019, https://www.cbpp.org/sites/default/files/atoms/files/3-15-19health.pdf.

less comprehensive coverage from plans with more comprehensive coverage, wherever plans are displayed, including through agents and brokers. We also note that one way to minimize the impact of increased STLDI plans on a state's risk pool would be for a state to include STLDI coverage in the same risk pool as more comprehensive individual market coverage.

Pharmacy Benefit Manager Standards Under the Affordable Care Act (Part 184)

PhRMA appreciates HHS's acknowledgment that greater transparency of PBM practices would benefit patients and employers. HHS has proposed to require that PBMs directly report the data required under section 1150A of the Social Security Act to HHS. We support this proposal as a positive first step, but we note that the extensive restrictions that section 1150A imposes on HHS's use of this data limits the impact of these provisions on reducing health care costs for patients, employers and other purchasers. We urge HHS to use the data supplied under section 1150A to analyze PBM industry practices, produce public reports, and propose policies that would require PBMs to report detailed data that could benefit patients and employers.

While the current system has helped to control overall spending, PBMs commonly negotiate arrangements with their health plan and employer clients that allow them to retain a portion of negotiated rebates and other price concessions as compensation for their services.[33] Because the portion of the rebate retained by the PBM, as well as the administrative fees they charge their clients, may be based on a percentage of a medicine's price, PBMs may have incentives to establish formularies that favor medicines with high list prices, and large rebates, over lower cost medicines.[34]

The complex set of rebates and fees can make it difficult for payers to assess whether they are fully benefiting from all price concessions that PBMs negotiate. While a share of rebates is generally passed on to plan sponsors, smaller employers and health plans may not benefit from the price concessions negotiated by the PBM, particularly if the PBM decides not to classify certain fees or other concessions as "rebates." For example, one benefits consultant has observed that PBMs are increasingly changing the contractual definition of rebates to exclude certain administrative fees, allowing the PBM to retain these payments rather than passing them back to the plan sponsor. These administrative fees can be as high as 30 percent of the total amount paid in rebates and fees by the manufacturer to the PBM and in some cases may not be reported to the plan sponsor by the PBM.[35] Many plan sponsors question the share of rebate savings being passed through, how much the PBM is retaining for administrative fees, and whether the PBM is disclosing and passing on other price concessions, such as savings from price protection rebates.[36]

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[33] Altarum. The impact of prescription drug rebates on health plans and consumers. April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf.
[34] STAT News. Rebates to pharmacy benefit managers are a hidden contributor to high drug prices. November 2016. https://www.statnews.com/2016/11/28/rebates-pharmacy-benefit-managers-contribute-high-drug-prices/.
[35] Mercer. Will point-of-sale rebates disrupt the PBM business? July 2017. https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html.
[36] Midwestern Business Group on Health. Drawing a line in the sand: employers must rethink pharmacy benefit strategies. September 2017. https://higherlogicdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27c65545cb8/UploadedImages/Specialty%20Pharmacy/DMJ_MBGH_Line_in_the_Sand_RV12_9617.pdf.

PhRMA supports policies that help patients make better health care choices and will make the health care system operate more efficiently without harming competition in the market or putting proprietary information at risk. Such policies should: (1) give meaningful information to employers or patients about how to use health care and health insurance; (2) apply prospectively so that regulated industry has time to comply accurately and completely with the reporting obligations; and (3) preserve the confidentiality of proprietary information.

Under section 1150A and the proposed regulations, PBMs are required to disclose several data elements, including the total amount of rebates and price concessions the PBM negotiates with manufacturers, and how much of that is passed through to plan sponsors, and the aggregate amount of the difference between what a plan sponsor pays for prescription drugs and the amount the PBM pays pharmacies. These data would provide meaningful information to health insurance issuers, employers, and other plan sponsors that would allow them to effectively negotiate on behalf of enrollees to ensure patients and health care purchasers are benefiting from PBM-generated savings. HHS should study the reported data, publish summary findings, and propose policy changes that would permit broader access to information about PBM practices.

Premium Adjustment Percentage (§ 156.130)

PhRMA continues to oppose HHS's decision 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 for HHS to do this, especially when health insurance premiums and out-of-pocket medical costs remain unaffordable for many. The decision to adopt this methodology for the premium adjustment percentage's calculation is an entirely discretionary one, which has, by HHS's own analysis, resulted in 100,000 people losing coverage in the exchange.[37] Further, this impacts millions more people who obtain coverage through their employers and will face higher out-of-pocket spending. HHS should revert to its prior premium adjustment percentage methodology.

When the premium adjustment percentage was first established, for the 2015 benefit year, HHS 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.[38] 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.

[37] HHS Notice of Benefit and Payment Parameters for 2021, 85 Fed. Reg. at 7151.
[38] HHS Notice of Benefit and Payment Parameters for 2015, 79 Fed. Reg. 13744, 13802 (Mar. 11, 2014).

The change in methodology that HHS implemented beginning with the 2020 benefit year directly contradicts HHS's earlier decision, and HHS has never adequately explained this reversal.[39] 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 revert to its original premium adjustment percentage methodology.
We also request that HHS not adopt its proposal to set the premium adjustment percentage through guidance in future years, without the opportunity for advance public comment. This is an important benchmark that has implications for the entire commercial health coverage marketplace. Stakeholders need an opportunity to evaluate how it is changing from year to year and to comment on the implications of those changes for HHS's consideration.

Risk Adjustment (Part 153)

PhRMA supports HHS's decision to continue including prescription drug categories (RXCs) as an element in calculating adult risk scores. RXCs are an appropriate and important element in the model since they improve 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.

While these recalibrations are appropriate if they are 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, as HHS implies with its proposal regarding the pricing adjustment for Hepatitis C drugs. 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.

Special Enrollment Periods (§ 155.430)

HHS proposes to create a new special enrollment triggering event when an employer completely ceases contributions to the individual's COBRA continuation coverage. HHS believes this proposal provides an important opportunity for individuals to maintain coverage in the commercial market, which is especially important during the COVID-19 pandemic, and related

[39] *See*, *e.g.*, HHS Notice of Benefit and Payment Parameters for 2020, 80 Fed. Reg. at 17540; HHS Notice of Benefit and Payment Parameter for 2021, 85 Fed. Reg. at 29229.

public health and economic emergencies. We support this proposal and ask HHS to consider making this new triggering event applicable earlier than January 1, 2022, so that individuals facing economic crises now can benefit from the ability to maintain health coverage.

Similarly, PhRMA supports the proposal to clarify that individuals who did not receive timely notice of triggering events may select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event, and suggests that this clarification be effective early than January 1, 2022, given the potential applicability during the current public health emergency.

HHS also solicited comment on the trade-offs involved in permitting individuals whose eligibility for advance payment of premium tax credits (APTC) has changed with the ability to switch to a lower cost plan. HHS was concerned that individuals who opt to switch plans in this circumstance would be worse off if their deductibles or other accumulators reset, increasing their overall cost sharing for the year. PhRMA supports this proposal, to the extent it allows individuals to maintain coverage when the increase in premiums they face due to the change in their APTC status might otherwise force them to drop coverage. However, HHS should consider requiring QHP issuers to transfer accumulated cost-sharing amounts when individuals switch QHPs within the benefit year. If this is operationally difficult, HHS should consider requiring this when enrollees switch from one QHP to another offered by the same issuer. Enrollees should not be forced to continue paying a higher premium amount than they can afford due to changed circumstances in order to avoid forfeiting their accumulated cost-sharing spend. If HHS does not require QHP issuers to transfer accumulated amounts, Exchanges should provide enrollees clear notice that switching QHPs under these circumstances would result in the forfeiture of accumulated spend.

Enrollment Process for Qualified Individuals (§ 156.240)

In order to promote the use of HRAs, HHS proposes to require QHP issuers to accept premium payments from qualified HRAs. PhRMA continues to oppose HHS's decision to permit employers to fund HRAs that can be used to buy individual health insurance coverage. The individual coverage HRA rule permits employers to replace a comprehensive group health plan with a fixed subsidy that may be insufficient for employees to access affordable individual market coverage. Even if employees do enroll in individual health insurance coverage, shifting substantial populations from the group to individual market at this particularly turbulent time could have financial and health effects on patients who need health care and medicines. Individual market coverage typically has higher out-of-pocket expenses and more limited benefits and provider networks than group coverage,[40] so encouraging movement to the individual market may disrupt access to care for patients with significant medical needs, including for medicines. HHS, with the Departments of Treasury and Labor, should reconsider the rules permitting the integration of HRAs with individual health insurance coverage.[41]

[40] Thorpe, KE., Allen, L., and Joski, P. Out-of-pocket prescription costs under a typical silver plan are twice as high as they are in the average employer plan. *Health Affairs* 2015 34:10, 1695-1703.
[41] For more detailed discussion of these issues, please see PhRMA's comments on Health Reimbursement Arrangements and Other Account-Based Group Health Plans Proposed Rule, REG–136724–17, 83 Fed. Reg. 54420 (Oct. 29, 2018).

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PhRMA appreciates the opportunity to provide comments regarding this proposed rule. Please feel free to contact Ashley Czin (202-835-3400) if we can provide any further information or if you have any questions about the topics discussed in our comments. We look forward to continuing to engage with the Departments on these important issues.

Sincerely,

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