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March 6, 2018

VIA REGULATIONS.GOV

The Hon. Preston Rutledge
Assistant Secretary, Employee Benefits Security Administration
United States Department of Labor
200 Constitution Ave NW
Washington, DC 20210

Re: Definition of "Employer" Under Section 3(5) of ERISA—Association Health Plans

Dear Mr. Rutledge:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Labor Department's proposed rule, "Definition of 'Employer' Under Section 3(5) of ERISA—Association Health Plans" (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. Since 2000, PhRMA member companies have invested more than $600 billion dollars in the search for new treatments and cures, including an estimated $65.5 billion in 2016 alone.

We share the administration's concern that many consumers continue to face rising costs of coverage and a lack of quality affordable healthcare options. We appreciate that the administration is taking steps, like this proposed rule, to promote consumer choice and affordability. Most Americans under age 65 obtain health coverage today through employment-based plans.[1] It is therefore critical that any effort to expand access to coverage for small businesses, through association health plans, does not undermine the affordability of coverage or robustness of benefits available today through existing employment-based health plans. Among the policies described in the proposed rule are key protections that seek to mitigate the impact of the expansion of association coverage on existing employer-sponsored plans. As the Labor Department finalizes its regulatory approach to association health plans, PhRMA urges the Department to include the following policies in the final rule:

- Prohibit association health plans from excluding small businesses from membership in the association based on their employees' health status and monitor for discriminatory benefit designs
- Ensure that the Labor Department and state regulators have adequate resources to oversee association health plans

[1] 83 Fed. Reg. 614, 626 (Jan. 5, 2018).

- Exclude from association health plans those "working owners" that already have access to subsidized group health plan coverage through their or their spouse's job
- Verify that working owners who self-attest to their eligibility for association health plan coverage are doing so accurately

These safeguards will reduce the likelihood that the millions of Americans who receive employment-based coverage would be adversely affected by the expansion of association health plans. These policies will also help ensure meaningful coverage for small businesses, and their employees and owners, who purchase association health plans.

Prohibition on health status discrimination

PhRMA supports the proposed rule's restriction on associations engaging in health-status discrimination in setting membership criteria, benefits, and premiums, extending the long-standing prohibition on health status discrimination against health plan participants, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under HIPAA and existing law, group health plans, including association plans that constitute a single group health plan, cannot discriminate in eligibility, benefits, or premiums against particular participants based on their health status. The proposed rule reasonably extends this protection in light of the unique characteristics of association plans. Specifically, the proposed rule would prohibit associations that offer association health plans from excluding particular member-employers on the basis of their employees' health status, and would prohibit associations from charging different member-employers within an association different rates based on their employees' health status. These modest restrictions on association health plans are necessary protections to prevent the circumvention of HIPAA's health status discrimination prohibition. It would be meaningless to say an association health plan could not discriminate against plan participants based on health status, if the association could nonetheless exclude employers from participating in the plan on the basis of health status, or charge those employers more.

PhRMA cautions, however, that the modest health status nondiscrimination protection proposed may not be adequate to prevent plan participants from being denied access to necessary health coverage on the basis of their health status. We urge the Labor Department to continue to monitor the practices of association health plans to evaluate whether future amendments of these regulations should prohibit additional practices. For example, an association health plan that would be considered a large group health plan or that is self-insured would not need to comply with federal essential health benefits requirement and may not be subject to any state or federal benefit mandates, other than the federal requirement to cover certain recommended preventive services. As such, these plans could decide to offer very narrow benefit designs or eliminate benefits for certain chronic conditions to discourage employers or employees with chronic conditions from enrolling. This could have the practical effect of creating the exact health status discrimination about which the Department is concerned. Even in more regulated insurance markets, a *New England Journal of Medicine* article concluded that "many insurers may be using benefit design to dissuade sicker people from choosing their plans."[2] It is foreseeable that association plans may adopt similar practices.

[2] Douglas B. Jacobs & Benjamin D. Sommers, "Using Drugs to Discriminate: Adverse Selection in the Insurance Marketplace," 372 New Eng. J. Med. 399, 401 (2015); *see also* Avalere Health, *2016 Exchange Plans Improve*

In addition, it appears that association could still condition eligibility or set premiums for particular employer-members on the basis of factors such as age and sex that could be proxies for health status. The Labor Department should monitor these plans to evaluate whether further regulatory intervention is necessary. Unchecked health status discrimination in these plans could adversely affect both participants discriminated against and others who rely on commercial health insurance coverage, in light of the potential implications for the risk pools of non-association coverage.

Oversight of association health plans

The proposed rule acknowledges that association health plans have a history of mismanagement and even fraudulent practices. PhRMA appreciates the Labor Department's acknowledgment that oversight by federal and state regulators will be necessary if this market expands, and encourages the Labor Department to work with state insurance regulators to leverage their combined resources in protecting participants in these plans. As the proposed rule indicates, the Labor Department has authority to issue cease-and-desist orders to association plans engaging in abusive or fraudulent conduct, and state regulators have concurrent authority to enforce state insurance laws. However, because association health plans may develop in many forms, sizes, and regions of the country, it may be difficult for a state alone, or the Labor Department alone, to adequately oversee this market. Therefore, we urge the Labor Department to develop common oversight tools that could be adopted by state regulators in their review of locally operating plans. Working together, the Labor Department and state regulators should evaluate both the financial resources of association plans and whether the level of benefits they are providing is adequate to meet the needs of their participants. Further, the Labor Department and state regulators should communicate regularly and develop strategies for ensuring this important market does not become prey to the abusive practices it has been known for in the past.

Participation of "working owners"

The proposed rule would permit "working owners"—individuals who might not be considered employers at common law because they lack employees—to participate in association plans, as long as they meet certain requirements set in the proposed rule. Among these, the working owner must not be eligible for subsidized group health plan coverage through his or her own employer or that of his or her spouse, and the working owner must work a minimum number of hours per week or month in the business or trade, or earn a minimum amount of income from the business or trade. Under the proposed rule, the association would be permitted to rely on the working owner's written representation that he or she meets the criteria for being a working owner, absent indications to the contrary. PhRMA supports the proposal that a working owner not be permitted to participate if he or she has access to subsidized group health plan coverage, and urges the Labor Department to monitor the self-attestation process by working owners to ensure individuals who do not satisfy the working owner definition are not fraudulently participating in these plans.

As noted at the outset of this letter, most Americans under age 65 obtain health coverage through an employment-based plan today and permitting working owners to opt out of their existing

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Access to Medicines Used to Treat Complex Diseases (2016), *available at* http://avalere.com/expertise/managed-care/insights/2016-exchange-plans-improve-access-to-medicines-used-to-treat-complex-disea

coverage to replace it with association coverage could detrimentally impact the coverage that most Americans under age 65 rely on today. Affordable, comprehensive health coverage depends on stability and predictability, and permitting this population to opt out of existing coverage options would unnecessarily disrupt commercial health coverage. Further, the history of abusive practices in association plans necessitates that the Labor Department carefully oversee self-attestations by working owners, and take steps to require verification of those attestations, if there is evidence of fraud or misuse.

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Thank you for your consideration of these comments. With these enhancements, the final rule will help ensure that the development of association health plans will be best positioned to reduce the likelihood of adverse effects on employees covered under existing employer-sponsored health plans. PhRMA appreciates HHS's consideration of our concerns. We stand ready to assist with any of the issues raised in our letter. Please contact Rebecca Davison at 202-835-3458 or rdavison@phrma.org with any questions.

Sincerely,

/s/

Amanda Pezalla
Assistant General Counsel

/s/

Rebecca Davison
Director, Policy and Research