



March 06, 2018

Office of Regulations and Interpretations
Employee Benefits Security Administration
Room N-5655
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Submitted via: regulations.gov

Re: [RIN 1210-AB85] Definition of Employer – Small Business Health Plans

Dear Ladies and Gentlemen:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to provide input on the *Definition of “Employer” under Section 3(5) of ERISA -- Association Health Plans (AHP)* proposed rule. Rheumatologists provide care for millions of Americans, both adults and children, and are the experts in diagnosing, managing and treating arthritis and rheumatic disease. These life-long, chronic conditions include rheumatoid arthritis, systemic lupus erythematosus, and vasculitis. Rheumatologic diseases including arthritis are the leading cause of disability in the United States, and early and appropriate treatment by a rheumatologist is vital to controlling disease activity, preventing and slowing progression, improving patient outcomes, and reducing the need for costly downstream procedures and care. Rheumatologists practice in every state, the District of Columbia, and Puerto Rico, and in communities urban and rural, providing critical care for people with diseases that can be crippling, life changing, and life threatening.

Health policy proposals should promote and protect access to adequate and affordable health insurance. In particular, the ACR recommends that all Americans should be covered by sufficient, affordable, and continuous health insurance that encourages high quality, high value health care – including treatment for arthritis and rheumatic diseases with access to a rheumatologist and other rheumatology health professionals for both consultative and maintenance care. While some proposals in this rule may lower insurance premiums for some, we are concerned that the essential health benefits that are vital to individuals living with rheumatic disease – such as rehabilitation, prescription medicines and lab testing – could be reduced or restricted. Additionally, we have concerns regarding consumer protections and discrimination from AHPs. Please find our specific comments in the subsequent paragraphs.

Employers Could Band Together for the Single Purpose of Obtaining Health Coverage.

The proposed rule would allow employers to form an AHP on the premise of geography or industry. Theoretically, a plan could serve employers in a state, city, county, or a multi-state metro area, or it could serve all the businesses in a particular industry nationwide. There is a marked lack of current data available related to the risk profiles of existing and potential associations and how those intersect with the individual and small group markets. We believe that moving forward with new polices without the

totality of evidence can be dangerous and potentially harmful to patients with chronic diseases. The ACR cautions the Department of Labor (DOL) that that needs of employees over different geographic locations can be quite different, and we especially have concerns regarding patient access to care in rural and remote areas of the United States.

We suggest that future regulation address and ensure network adequacy for specialty care such as rheumatology and physical therapy. We also urge the DOL to give consideration to reforms that are taking place with regard to prior authorizations by payers and plans, which will help reduce administrative inefficiencies, and reduce wait times to see a physician and obtain the prescribed service or therapy. These processes and forms should apply to AHPs and be standardized across regional boundaries.

In response to the Department's request for comments on geographic classifications and whether there should be a special process established to obtain a determination from the Department that all of an association's members have a principal place of business in a metropolitan area, the ACR would like to highlight concerns regarding the scarcity of resources within a given area, which applies to rheumatologic care in many areas of the country. Specifically, if there are no pediatric rheumatologists for child patients, or non-pediatric rheumatologists for adult patients within a state, metropolitan or micropolitan area, we urge the Department to clarify what the requirements would be to ensure coverage for those limited or non-existent services. We suggest that if plans cross state boundaries or boundaries of the District of Columbia or other territories in which patient protections differ, the plans should be held to the laws that offer the most protection to patients.

Health Nondiscrimination Protections – Two distinct potential issues prompt the nondiscrimination protections in the proposed rule.

The proposed regulation would ensure the group or association does not restrict membership in the association itself based on any health factor, as defined in the HIPAA/ACA health nondiscrimination rules. The HIPAA/ACA health nondiscrimination rules define a health factor as: health status, medical condition (including both physical and mental illnesses), claims experience, receipt of healthcare, medical history, genetic information, evidence of insurability, and disability. We are pleased to see that the proposed rule lays out certain nondiscrimination protections, but we do not feel these protections go far enough.

The ACR believes there are other discriminatory practices that could be used to skirt the listed non-discrimination requirements. For example, AHPs may opt to not cover prescription drugs as a way of keeping premiums low and discouraging enrollment of sicker employers or self-employed individuals. Other discriminatory practices that currently occur and would be exacerbated by the current proposals include extreme utilization management protocols, caps on coverage and services, increased co-insurance for patients, and discriminatory tiering or other formulary designs affecting access to high cost medications. The ACR supports and encourages the DOL, CMS, and HHS to develop, issue, and continue to update guidance regarding discriminatory practices. The ACR also strongly opposes excessive patient cost sharing that results in untenable patient financial burden, thereby creating a de facto situation in which the patient does not have access to a medically-necessary treatment. For patients with complex conditions like rheumatoid arthritis, biologic medications are very expensive and excessive cost sharing can reduce adherence and patient access to treatment, leading to risk for irreversible damage, excess morbidity and even mortality.

We reiterate concerns raised in response to the *HHS 2019 Benefit and Payment Parameters proposed rule*. The ACR believes it was the intent of Congress to protect American patients and consumers by establishing a set of essential health benefits (EHBs) that should be followed. We oppose allowing AHPs to select their own EHBs, warning that this could create a "race to the bottom" wherein insurance plans may seek the minimum permitted coverage at the lowest cost to the plan, thereby restricting patient access to care. Granting flexibility to this extent could lead to AHPs severely restricting or eliminating coverage for the biologic drugs that are critical for many people with rheumatic and musculoskeletal diseases. We urge the DOL to ensure clinical decisions about treatments – particularly those relating to drug therapies – remain in the hands of providers. Insurers should not be allowed to determine treatment plans, nor should they be able to mandate the use of a certain therapy over another. The treating provider has the clinical experience, knowledge of disease states, and access to relevant patient-specific data to make informed decisions about the appropriate therapies for specific patients, and safety and efficacy are not always comparable between therapies even when they are of the same class. In summary, EHBs of particular importance to rheumatology patients include office visits, laboratory tests rehabilitation, and prescription services including complex biologic therapies. If access to specialty care, and complex treatments, is reduced, then disability or costly procedures will become more likely, which could increase costs for government programs.

Transparency and Public Notices.

The DOL has requested comments on whether any notice requirements are needed to ensure that employer members of associations, and participants and beneficiaries of group health plans, are adequately informed of their rights or responsibilities with respect to AHP coverage. The ACR believes that transparency is necessary and that patients and doctors should be well informed in order to make shared treatment decisions.

We also have further system transparency concerns that we believe will still exist within the proposed AHP policies. Presently the cost of drugs is determined by pharmaceutical companies and may be negotiated—for example, between a manufacturer and a pharmacy benefit manager (PBM). Unfortunately, there is a lack of transparency in pricing, and pricing differences among companies or plans may not be based on clinical decision-making or standards of practice, and are subject to change with tremendous frequency. While rebates and price fixing with particular contracts may reduce the cost of a drug for the plan, privately-negotiated cost savings to the insurance company should not be allowed to undermine the important clinical considerations and decisions made by patients and providers when choosing a therapy. Essentially, plan savings should not override medical necessity or intrude on safe medical practice. We also believe there should be contract standards and definitional agreement for money flowing into PBMs. Definitional agreement and consistency are the foundation to most other policy solutions. Therefore, we urge the DOL to create a common definition of "rebate," "discount," "fee," and any other terms a PBM may use. The ACR looks forward to working with the Department and all stakeholders in this process.

Further, in regard to patient/consumer notification, we urge the DOL to consider providing notifications of alternative options or comparisons of the AHPs to the existing plans in the marketplace. Consideration also should be given to who will regulate these plans and who will address problems or grievances typically handled by state insurance boards. We believe patients and providers deserve a transparent, fair, meaningful and timely appeals process and we encourage the DOL to provide guidance on how this would be accomplished in AHPs. Additionally, laws related to issues such as step therapy and prior authorization currently differ from state-to-state. Especially in cases where an AHP crosses

state lines, the ACR is concerned that patients will be susceptible to adverse events resulting from changes in negotiations from year to year, inconsistencies among plans and applicable state laws, and the harmful impact of negotiations that may be driven by profit rather than by sound medical practice.

Finally, the DOL appropriately acknowledges that some AHPs have “failed to pay promised health benefits to sick and injured workers while diverting, to the pockets of fraudsters, employer and employee contributions from their intended purpose of funding benefits” and that Congress has enacted reforms to address AHP abuse in the past. We believe these policy proposals as they currently stand could potentially increase insolvency and unpaid claims, thereby endangering the care of rheumatology patients due to the high prices of the therapies their conditions require. We suggest including safeguards such as requiring that plans to regularly report adequate financial viability.

The ACR is dedicated to ensuring that patients with arthritis and rheumatic diseases have access to continuous comprehensive high-value and high-quality care. We appreciate the work that the DOL does and the opportunity to respond to the *Definition of “Employer” under Section 3(5) of ERISA -- Association Health Plans (AHP)* proposed rule. We look forward to being a resource to you and to working with the agency as this rule is finalized. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "David I. Daikh". The signature is fluid and cursive, with a prominent initial "D".

David I. Daikh, MD, PhD
President, American College of Rheumatology