FROM THE NAIC CONSUMER REPRESENTATIVES

To: Bob Wake, ERISA (B) Working Group

Date: August 24, 2017

Re: Comments on Draft ERISA Handbook

We write as Consumer Representatives to the NAIC to comment on the draft of the NAIC ERISA handbook exposed for comment at the NAIC's summer national meeting. We thank the ERISA (B) Working Group for its continued efforts to update the handbook and for incorporating many of the comments we offered on earlier drafts. It is important that state regulators understand the scope—and the limits—of federal regulation of health plans under ERISA, as well as the considerable authority that states retain to regulate ERISA plans. It is also vital that state regulators be aware of attempts by health insurers to avoid state regulation or requirements of the ACA and other consumer protection laws by claiming the protection of ERISA and that regulators oppose these attempts when they are not justified.

In response to the ERISA (B) Working Group's request for comments on the latest handbook draft, we ask you to consider a number of additional edits. Our specific comments are:

- Page 72: We believe it would be helpful to clarify that the ACA repealed the guaranteed issue exception for bona fide associations. We urge you to state this at the end of the first paragraph on page 72.

- Page 89: In previous comments, we raised concerns about the characterization of the employer mandate on page 89, which we thought was unduly negative and more opinion than fact-based. We continue to think this paragraph is inappropriate for the handbook and encourage you to delete or substantially revise this content to be more relevant for state regulators.

- Page 90: As raised in previous comments, we urge you to add a note that wellness programs are also regulated under the Americans with Disabilities Act and the Genetic Information Nondiscrimination Act. In particular, we would urge you to add the following sentence to the wellness section of the handbook on page 90: "Wellness programs are also regulated by the EEOC under the Americans with Disabilities Act and Genetic Information Nondiscrimination Act. See http://healthaffairs.org/blog/2016/05/17/eeoc-rules-allow-significant-rewards-penalties-in-connection-with-wellness-program-participation/. A recent court decision has asked the EEOC to reconsider whether the ACA and GINA permit wellness programs to impose penalties as large as those permitted under HIPAA on employees who refuse to provide wellness programs health information on themselves or their spouses.[1]"

- Page 91: We ask you to clarify the effective date of the 2017 changes to the Summary of Benefits and Coverage (SBC) by editing the last sentence of the SBC section on page 91 to read: "The summary of benefits and coverage form was changed by the federal agencies for plan years with open enrollment periods beginning after April 1, 2017."

[1] *See* AARP v. EEOC, No. 16-2113 (D.D.C. Aug. 22, 2017).

- We urge you to add two new sections to the "Significant Reforms" section of the ACA changes on 1) the annual out-of-pocket maximum; and 2) the clinical trials coverage requirement. We believe that both requirements are substantial and that state regulators should be aware of these consumer protections as they enforce federal and state law. We recommend the following language for these two new sections:

    13. Maximum Annual Limitation on Out-of-Pocket Costs (PHSA §2707(b))

    Group health plans are subject to a maximum in-network out-of-pocket limit on essential health benefits that is adjusted annually for inflation ($7,150 for self-only coverage and $14,300 for other than self-only coverage in 2017). The out-of-pocket limitation applies to deductibles, coinsurance, and copayments for essential health benefits for in-network providers. Out-of-pocket costs do not include premiums, balance billing amounts for non-network providers, or spending for non-covered services, although nothing prohibits a plan or issuer from counting such expenses toward the plan's annual maximum out-of-pocket limit.

    To determine which benefits are essential health benefits, group health plans must adopt a reasonable definition that is generally consistent with the approach applied in the individual and small group insurance markets.[2] For plan years beginning on or after January 1, 2017, a group health plan must define essential health benefits in a manner consistent with any of the 51 essential health benefits base-benchmark plans applicable in a state or the District of Columbia, or one of the three Federal Employees Health Benefits Program (FEHBP) essential health benefits base-benchmark plans, as specified under 45 CFR 156.100.[3]

    For plan or policy years beginning on or after 2016, the self-only maximum annual limitation on out-of-pocket costs under a group health plan applies to each individual, regardless of whether the individual is enrolled in self-only coverage or in coverage other than self-only, resulting in embedded deductibles for non-self-only coverage.[4] Plans are also permitted to structure a benefit design using separate out-of-pocket limits, provided that the combined amount of any separate out-of-pocket limits applicable to all essential health benefits under the plan does not exceed the annual limitation on out-of-pocket maximums for that year.

    The federal agencies have issued guidance addressing reference-based pricing for group health plans under which the plan pays a fixed amount for a particular procedure (such as a knee replacement), which certain providers will accept as payment in full.[5] This guidance notes that federal regulators will consider all the facts and circumstances of a plan's reference-based pricing design and factors such as the type of service, reasonable access, quality standards, exceptions processes, and disclosure.

    14. Coverage for Participating in Approved Clinical Trials (PHSA §2709)

[2] 29 CFR § 2590.715-2711(c); see also https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xix.pdf
[3] 29 CFR § 2590.715-2711(c)
[4] https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvii.pdf
[5] https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf

Group health plans may not deny a qualified individual's participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; deny (or limit or impose additional conditions on, such as prior authorization of services only because they are part of a trial) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; or discriminate against the individual on the basis of the individual's participation in the trial. A qualified individual is a participant or beneficiary who is eligible to participate in an approved clinical trial according to the trial protocol with respect to the treatment of cancer or another life-threatening disease or condition, and either 1) the referring health care professional is a participating provider and has concluded that the individual's participation in such trial would be appropriate or 2) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

Routine patient costs include "all items and services consistent with the coverage provided in the plan (or coverage) that are typically covered for a qualified individual who is not enrolled in a clinical trial." This also includes items and services to diagnose or treat complications or adverse events (e.g., side effects) arising from participation in an approved clinical trial. Routine patient costs do not include the investigational item, device, or service being studied in the approved clinical trial; items and services that are provided solely to satisfy the clinical trial's data collection and analysis needs and that are not used in the direct clinical management of the patient; or a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis. Plans are not required to provide benefits for routine patient care services provided outside of the plan's health care provider network unless out-of-network benefits are otherwise provided under the plan.

The federal agencies have issued subregulatory guidance[6] but not regulations regarding this requirement, and group health plans are expected to implement the requirements using a good faith, reasonable interpretation of the law.

Thank you in advance for your consideration, and we look forward to continuing to work closely with the ERISA (B) Working Group and its members to address these issues. If you have any questions about the content of this letter, please contact Tim Jost (jostt@wlu.edu).

Sincerely,

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[6] See https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resourcimposese-center/faqs/aca-part-xv.pdf; https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf

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