March 2, 2018

The Honorable Alexander Acosta
Secretary of Labor
U.S. Department of Labor

The Honorable Preston Rutledge
Assistant Secretary of Labor
U.S. Department of Labor
Employee Benefits Security Administration

Submitted Electronically

RE: Definition of "Employer" under Section 3(5) of ERISA -- Association Health Plans

Dear Secretary Acosta and Assistant Secretary Rutledge:

Medela LLC (Medela) appreciates the opportunity to submit comments on the proposed Definition of "Employer" under Section 3(5) of ERISA -- Association Health Plans (AHPs) rule (RIN 1210-AB85).

Medela is one of the world's leading advocates for breast milk, focusing on babies' health and nutrition. Medela supports babies in receiving mothers' milk early in life by providing research-based products together with clinical education. Every year, over a million mothers in the U.S. rely on our technology. Medela has proudly served hospitals and American families for over 35 years and employs over 950 full-time personnel across the nation including at our U.S. headquarters in rural Illinois. Our company is fully dedicated to supporting mothers so that they can provide breast milk to their babies for as long as possible.

Each year, an estimated four million babies are born in the United States.[1] A number of the most prominent physician organizations, including the American Academy of Pediatrics (AAP), the American Congress of Obstetricians and Gynecologists (ACOG), and the American Academy of Family Physicians (AAFP), recommend that infants be exclusively breastfed for the first six months with continued breastfeeding alongside introduction of complementary foods for at least one year.[2,3] These organizations support breastfeeding in the first year of life because, as described in further detail below, human breast milk protects against a host of the most common, deadly, and costly childhood diseases.

The Patient Protection and Affordable Care Act of 2010 (ACA), recognizing the health and economic benefits of breastfeeding, requires all non-grandfathered commercial health insurance plans to offer breastfeeding support, supplies, and counseling to mothers without cost-sharing. States that have expanded their Medicaid programs under the ACA are also required to provide the no-cost breastfeeding benefit to these beneficiaries.

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This comment letter discusses several recommendations and issues in the proposed rule that Medela has identified as high-priority. In particular, our comments:

1. Encourage the Department of Labor (DOL) to clarify that the ACA's breastfeeding support, supplies, and counseling benefit continues to apply to non-grandfathered AHPs under the proposed rule;
2. Highlight the benefits of breastfeeding to employers and employees; and
3. Request that any future actions DOL takes to modify health insurance coverage preserve the breastfeeding support, supplies, and counseling benefit.

I. The ACA Breastfeeding Support, Supplies and Counseling Benefit Applies to AHPs under the Proposed Rule

The proposed rule would change certain definitions and criteria in Title I of the Employee Retirement Income Security Act (ERISA) so that more AHPs would qualify as large group health plans under ERISA. AHPs that qualify as large group coverage under the proposed rule would be exempt from most ACA rules except for those that apply specifically to large groups. As the proposed rule notes, the applicability of health insurance regulatory requirements to AHPs "depends on whether the coverage is treated as individual or group coverage and, in turn, whether the group coverage is small or large group coverage."[4]

Section 2713 of the ACA requires all non-grandfathered private health plans, including individual, small group, large group, and self-insured plans, to cover, without cost-sharing, women's health preventive services as defined in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). [5,6,7] Current HRSA guidelines require coverage for "comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment" without cost-sharing.[8] Updated guidelines, which will be effective for plan years beginning on or after December 20, 2017, recommend coverage without cost-sharing of "comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and the postpartum period to ensure the successful initiation and maintenance of breastfeeding."[9]

Thus, under the proposed rule, non-grandfathered AHPs would continue to be required to cover section 2713 preventive health services, including the breastfeeding support, supplies, and counseling benefit, regardless of whether an AHP is considered large group coverage under the proposed rule or are regulated as individual or small group coverage under the ACA. The proposed rule also notes that DOL is "interested in comments on how best to ensure compliance with the ERISA and ACA standards that would govern AHPs and on any need for additional guidance on the application of these standards or other needed consumer protections."[10] We therefore urge DOL to clarify in the final rule that insurers offering AHP coverage in accordance

with the proposed rule must also comply with section 2713 of the ACA and corresponding regulatory and subregulatory guidance.

II. Breastfeeding Saves Employers Money and Helps Moms Return to Work After Giving Birth

Breastfeeding is a cost-saver for employers and employees. For example, Cigna found in a two-year study of 343 employees that enrollment in a corporate lactation program led to annual savings of $240,000 in health care expenses, 62 percent fewer prescriptions, and $60,000 in reduced absenteeism rates.[11] Additionally, researchers found that one-day absences due to a sick child were twice as likely to occur for mothers who formula-fed versus women who breastfed their babies.[12]

Furthermore, access to comprehensive breastfeeding services assist mothers in returning to work after giving birth. Today, more mothers than ever return to the workforce after giving birth. Between 1961 and 1965, just over 16 percent of mothers returned to their jobs after having a child. In contrast, between 2005-2007, more than 60 percent of mothers returned to work after giving birth.[13] Returning to work is a risk factor for meeting duration and exclusivity guidelines. The proportion of babies receiving breast milk drops precipitously at the one to two month mark, as soon as mothers return to work.[14] Providing comprehensive access to breastfeeding support, supplies, and counseling can keep mothers from having to choose between working and breastfeeding.

III. Any DOL Actions on Health coverage should preserve the breastfeeding support, supplies and counseling benefit

We strongly support the ACA's breastfeeding benefit because as described in further detail below, the benefit: (1) has indisputable health benefits for moms and babies; (2) increases breastfeeding rates; (3) is a low-cost, high-value benefit; (4) helps mothers achieve their breastfeeding goals; (5) has strengthened the clinician's role in supporting breastfeeding; and (6) saves the healthcare system significant money. We therefore encourage DOL to preserve access to this important benefit in any future rulemaking that impacts health insurance coverage.

1. **The health benefits of breastfeeding for moms and babies are indisputable.** Breast milk in the first year of life reduces the most common and costly childhood illnesses: otitis media (i.e. ear infections), diarrhea, and respiratory infections.[15] Additionally, babies who are given breast milk are less likely to develop asthma, obesity, and sudden infant death syndrome.[16] Furthermore, the clinical community has found that young infants in critical care who receive breast milk have sharply reduced rates of necrotizing enterocolitis (NEC), a devastating gastrointestinal infection, resulting in a significant reduction in morbidities and mortality, fewer hospital readmissions, and less costly medical bills in the longer term.

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2. **Breastfeeding rates have increased as a result of the ACA's breastfeeding benefit**. In 2014, an estimated 47,000 more infants were breastfed because of the ACA breastfeeding benefit, which has disproportionately helped minority, less educated, and unmarried mothers.[17] The healthcare system has made noticeable strides in getting babies to start their lives breastfeeding, with 81.1 percent now starting their lives out receiving breast milk, up from 76.5 percent in 2012. Across all measures of duration and exclusivity, breastfeeding rates have improved compared to data collected in 2012 prior to implementation of the ACA breastfeeding provision. Fifty-one percent of all babies are given breast milk for at least six months, up two percentage points from 2012. Moreover, 30.7 percent of all babies are given any breast milk for at least a year, up over 3 percentage points from 2012.

3. **The breastfeeding support, supplies, and counseling benefit is an extremely low-cost, high-value health insurance benefit**. According to an actuarial analysis from Milliman, the total cost for breastfeeding support, supplies, and counseling for the commercial health insurance population in 2017 dollars is $1.54 per member per year (PMPY) or approximately 0.028 percent of total premium dollars. To provide context, if an individual had employer-sponsored health insurance with a $500 monthly premium, approximately $0.14 would be attributable to the breastfeeding benefit. Similarly, for the Medicaid population, the total cost for the breastfeeding support, supplies, and counseling benefit is approximately $2.21 PMPY in 2017 dollars or approximately 0.041 percent of total per-enrollee expenditures. For reference, if the total per-enrollee expenditures for a Medicaid enrollee were $500 per month, approximately $0.20 would be attributable to the breastfeeding benefit. Milliman determined that because the premium impact associated with this benefit is so low, it is not possible to use actuarially sound methods to calculate a direct offset to insurance premiums. Given the negligible impact to insurance premiums and the high return in future years of cost-savings at a population level, we believe the breastfeeding provision in section 2713 and implementing subregulatory guidance as an extremely low cost, high value health insurance benefit.

4. **The breastfeeding benefit helps mothers achieve their breastfeeding goals.** Recently, Medela conducted a survey with over 4,500 mothers across the United States in order to understand the impact the breastfeeding support, supplies, and counseling benefit has had on babies and mothers.[18] The mothers included in this survey acquired breastfeeding supplies through their health insurance plans within the last 18 months. Our review found that 79 percent of mothers surveyed said that having access to breast pumps through their health insurance plans helped to meet their expectations of feeding their child breast milk. Put another way, the existence of the breastfeeding support, supplies, and counseling benefit has changed mothers' commitment to providing their babies with breast milk for a longer amount of time.

5. **The breastfeeding benefit has strengthened the clinician's role in supporting breastfeeding**. Due to the insurance breastfeeding benefit, mothers now look to their healthcare providers for information about lactation. This benefit has elevated breastfeeding as a topic of shared decision-making between the patient and clinician. Our most recent data shows that one-third of all mothers now learn about the breastfeeding benefit directly from their health care provider, typically around the second trimester of pregnancy. Being educated sooner in pregnancy and from a trusted source allows mothers to make informed choices about how to best breastfeed their children.

6. **The breastfeeding benefit saves the healthcare system a significant amount of money**. When promoted on a population level, breastfeeding leads to lower costs and better health outcomes. Recent testimony before the U.S. House of Representatives Appropriations Committee shows that over $500 million per year could be saved in Medicaid alone if babies were given breast milk for the recommended time periods.

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Medela is committed to working with DOL to ensure that babies and moms have access to breastfeeding support, supplies, and counseling services. We look forward to working with DOL to ensure that the breastfeeding benefit continues to improve the health of babies and mothers throughout the country. Thank you for your attention to our perspectives and concerns. If you have any questions regarding these comments or the breastfeeding benefit more broadly, please contact Juli Goldstein, Medela's Director of Government Affairs Director and Channel Strategy at 815-345-9819 or juli.goldstein@medela.com.

Sincerely,

Melissa Gonzales, Managing Director, Medela LLC

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[1] Centers for Disease Control and Prevention. Birth and Natality. Last updated Mar. 31, 2017. *Available at*: https://www.cdc.gov/nchs/fastats/births.htm.
[2] American Academy of Pediatrics. Breastfeeding and the Use of Human Milk. *Pediatrics*. Mar. 12. Volume 129, Issue 3. *Available at*: http://pediatrics.aappublications.org/content/129/3/e827.full#content-block.
[3] Breastfeeding Report Card. Progressing Toward National Breastfeeding Goals. United States. 2016. CDC. Breastfeeding Report Card 2016. Healthy People 2020. http://www.cdc.gov/breastfeeding/data/reportcard.htm.
[4] 83 FR 615.
[5] §2713 applies to "group health plan" and "health insurance issuers offering group and individual coverage." "Group health plan" is defined in Health Insurance Portability and Accountability Act of 1996 requirements that are

codified in the Public Health Service Act (PHSA; *See* 42 U.S.C. §300gg-91(a)(1))) and the Employee Retirement Income Security Act of 1974 (ERISA; *See* 29 U.S.C. §1002(1)).
[6] *See* ACA §715(a)(1), which adds language to 29 U.S.C. §1185d(a)(1) to incorporate the provisions of part A of title XXVII of the PHSA into ERISA. The PHSA sections incorporated by this reference are sections 2701-2728. *See also* Department of Health and Human Services. 29 C.F.R. Part 2590. Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under Patient Protection and Affordable Care Act: Amendment. Available at: https://www.regulations.gov/document?D=EBSA-2010-0018-0002.
[7] 42 U.S.C. §300gg-13(a)(4).
[8] *See* Health Resources and Services Administration. Women's Preventive Services Guidelines. *Available at* https://www.hrsa.gov/womensguidelines/.
[9] *See* Health Resources and Services Administration. Women's Preventive Services Guidelines. *Available at* https://www.hrsa.gov/womensguidelines2016/index.html.
[10] 83 FR 625.
[11] Dickson, Hawkes, C., W., L., Cohen, R. Slusser, W. (2000). The positive impact of a corporate lactation program on breastfeeding initiation and rates: help for the working mother. Manuscript. Presented at the Annual Seminar for Physicians on Breastfeeding, Co-Sponsored by the American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and La Leche League International. Chicago, IL: July 21, 2000.
[12] Cohen R, Mrtek MB, and Mrtek RG. Comparison of maternal absenteeism and infant illness rates among breast-feeding and formula-feeding women in two corporations. *Am J Health Promot*. 1995 Nov-Dec;10(2):148-53. *Available at*: https://www.ncbi.nlm.nih.gov/pubmed/10160049.
[13] Bureau of Labor Statistics. First-time Mothers at Work. *Available at*: https://www.dol.gov/wb/First-Time_Mothers_final_508.pdf.
[14]Centers for Disease Control and Prevention. National Immunization Survey. Rates of Any and Exclusive Breastfeeding by Age among Children Born in 2013. Samples from 2014 and 2015 National Immunization Surveys. *Available at*: https://www.cdc.gov/breastfeeding/data/nis_data/.
[15] Ball, Thomas M., and Wright, Anne L. "Health care costs of formula-feeding in the first year of life." Pediatrics 103.Supplement 1 (1999): 870-876.
[16] U.S. Department of Health and Human Services. The Surgeon General's Call to Action to Support Breastfeeding. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2011.
[17] Kapinos, Bullinger, and Gurley-Calvez. Lactation Support Services and Breastfeeding Initiation: Evidence from the Affordable Care Act. *Health Services Research*. Nov. 10, 2016. Available at http://onlinelibrary.wiley.com/doi/10.1111/1475-6773.12598/abstract.
[18] Medela LLC. *Real Stories. Babies and Moms.* Survey conducted with mothers who acquired their insurance covered breast pump directly through Medela within a period of 18 months. All survey respondents opted into the Medela community for future communication and granted permission to share their story. May 2017.