March 6, 2018

VIA WWW.REGULATIONS.GOV

Jeanne Klinefelter Wilson
Deputy Assistant Secretary
Employee Benefits Security Administration ("EBSA")
Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: Definition of "Employer" Under Section 3(5) of ERISA – Association Health Plans
RIN 1210-AB85

Dear Ms. Wilson:

Fresenius Medical Care North America ("FMCNA") is pleased to provide comments on the proposed regulation under Title I of the Employee Retirement Income Security Act ("ERISA") that would broaden the criteria under ERISA section 3(5) for determining when employers may join together in an employer group or association that is treated as the "employer" sponsor of a single "multiple-employer employee welfare plan" and "group health plan" ("GHP") as those terms are defined in Title I of ERISA, and thus facilitate the formation of Association Health Plans ("AHPs") that ultimately will expand employer and employee access to more affordable, high quality coverage options.

FMCNA is the nation's largest provider of products and services for individuals with chronic kidney failure. Our 2,400 outpatient dialysis centers serving 190,000 individuals in the United States provide renal replacement therapy, a vital blood-cleaning procedure that substitutes the function of the kidney in the case of kidney failure. Individuals with end stage renal disease ("ESRD") are eligible for, but not required to, enroll in Medicare, regardless of age.[1] After diagnosis, many of our patients depend on employer group health insurance to continue comprehensive employer-based coverage before enrolling in Medicare. Approximately 16,942 FMCNA patients have employer group health coverage as their primary insurance coverage today.

FMCNA supports the goals of the proposed regulation in large part, with an important caveat that, if adopted by the Department, will ensure that affordable high-quality coverage options, like that offered through an AHP, remain available to individuals with ESRD.

[1] *See* Social Security Act § 226A(a) (providing that individuals medically determined to have ESRD are "entitled to benefits" under Medicare. *See also* CMS, "Frequently Asked Questions Regarding Medicare and the Marketplace," Questions B-1, B-2 and B-3 (Aug. 1, 2014, last updated April 28, 2016) (stating that individuals with ESRD are not required to enroll in Medicare).

Individuals with Kidney Failure Retain Important Health Care Choices Under Current Law

Despite automatic eligibility for Medicare, kidney patients with group health insurance may retain that coverage for up to 30 months under the Medicare Secondary Payer ("MSP") provisions of the Social Security Act ("SSA"). Pursuant to Section 1862(b)(1)(C) of the Social Security Act, a GHP **may not take into account** that an individual is entitled to, or eligible for, benefits under Medicare during the 30-month period that begins with the first month in which the individual becomes entitled to ESRD benefits under Medicare (emphasis added).[2,3]

The MSP provisions ensure that individuals with ESRD, and their dependents, are able to remain with their group health coverage for a period of time before enrolling in public programs. There are many reasons why individuals with ESRD may wish to remain in their GHP. For example, the GHP coverage may extend to their family members while Medicare covers only the patient, the coverage may offer enhanced benefits or more generous prescription drug coverage, staying with the GHP may help ensure continuity of care particularly if the patients physician does not participate in both programs. Finally, the GHP may have lower cost sharing or lower out of pocket maximums compared to Medicare. FMCNA believes it is therefore critical and essential that the final rule make clear the AHPs, consistent with other state and federal health insurance laws affecting group health plans, recognize and adhere to the MSP provisions in the SSA by making 30 months of AHP coverage available to individuals with ESRD.

Unfortunately, in current practice, FMCNA has observed GHPs in violation of MSP both in law and in fact. For instance, we have noted some GHPs misleading enrollees by suggesting that federal law requires individuals with ESRD to enroll in Medicare immediately after having been diagnosed with ESRD. We have observed some GHPs offering to pay Medicare co-insurance amounts or other cost-sharing obligations on behalf of patients if they shift their coverage to Medicare. And we have seen some plans reduce provider payments to rates at or slightly above the Medicare rate, forcing patients to pay the

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[2] Under the MSP rules, prohibitions on "taking into account" apply differently to different types of entitlement. "A group health plan of any size […] [m]ay not take into account the ESRD-based Medicare eligibility or entitlement of any individual who is covered or seeks to be covered under the plan." 42 CFR 411.102(a). This provision applies during a specified coordination of benefits period. *See* 42 CFR 411.161. *See also* Medicare Secondary Payer Manual section 20 ("Medicare is secondary payer to GHPs for individuals eligible for, or entitled to Medicare benefits based on ESRD during a coordination period […] This provision applies regardless of the number of employees employed by the employer and regardless of whether the individual or other family member has current employment status."). Group health plans "of at least 20 employees" may not take into account the age-based Medicare entitlement if an individual or spouse age 65 or older if such individual or spouse is eligible based on current employment status. 42 C.F.R. 411.102(b). A group health plan "of at least 100 employees" may not take into account the disability-based Medicare entitlement of an individual covered under the plan based on current employment status. 42 C.F.R. 411.102(c).

[3] The MSP statute appears to rely on the Internal Revenue Code description of a GHP and not ERISA's definition. However, the ERISA and Internal Revenue Code definitions of "group health plan" are very similar. Under the Internal Revenue Code, "group health plan" means "a plan (including a self-insured plan) of, or contributed to by, an employer (including self-employed person) or employee organization to provide health care (directly or otherwise) to the employees, former employees, the employer, other associated or formerly associated with the employer in a business relationship, or their families. 26 U.S.C. 5000(b)(1). Under ERISA, "group health plan" means "an employee welfare benefit plan providing medical care." 29 U.S.C. 1191b. ERISA then defines "medical care" using the same definition found in the Internal Revenue Code. *See* 26 U.S.C. 213(d)(1). An "employee welfare plan" is "any plan, fund, or program […] established or maintained by an employer or by an employee organization […] for the purpose of providing for its beneficiaries, through the purchase of insurance or otherwise […] medical […] benefits." 29 U.S.C. 1002.

difference.

For patients with kidney failure, these kinds of discriminatory, non-conforming GHP tactics have serious consequences for patient care that can result in treatment delays or limits, increased out-of-pocket costs, and requirements for patients to travel great distances to access care three times per week.

The MSP law is designed to avoid these aberrations, and FMCNA hopes to work with the Department and EBSA to ensure that non-discrimination in health plan choice, especially in AHPs, is enforced in the same way we have worked with CMS on these issues. To that end, we are encouraged by language in the proposed regulation that specifically indicates "[A]ll of the employers and employees should benefit from prudence and loyalty requirements for those running the AHP, as well as such other protections as reporting and disclosure requirements and enforcement, in the same manner and to the same extent as participants in other ERISA pan arrangements."[4]

FMCNA thus respectfully requests that the final rule's preamble include a statement to the effect that the proposed regulation's non-discrimination provisions build on the existing non-discrimination provisions applicable to group health plans, **including the MSP law** … addressing how to apply those rules to association coverage.

EBSA could also follow the Center for Consumer Information and Insurance Oversight's ("CCIIO") approach when it established the SHOP and explicitly state in the preamble to the final rule that employers purchasing GHPs via a AHP must adhere to the Medicare's Secondary Payer law, allowing individuals with ESRD to remain in the group health coverage they have for 30 months.[5]

Precedent for MSP Application in the Group Health Plan Context

Department of Labor Advisory Opinion 1993-23A addressed an ERISA plan's fiduciary's responsibilities with respect to claims submitted pursuant to the MSP statute, albeit not with respect to the ESRD provisions specifically. The Department concluded that the ERISA plan fiduciary was responsible to administer the plan "to assure compliance with both ERISA and other applicable federal laws," including the MSP statute. The Department pointed to 29 U.S.C. 1144(d), which provides that ERISA "shall not be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States […] or any rule or regulation issued under such law." The Department then explained that "if an employee benefit plan that provides health benefits is covered by the MSP statute as well as by Title I of ERISA, non-compliance with the MSP statute and any regulations issued thereunder would not be excused on the basis that the plan is in compliance with ERISA."

Conclusion

FMCNA shares the principle objective of the proposed regulation to expand employer and employee access to more affordable, high quality coverage. We believe a statement specific to the applicability of MSP in the AHP environment is consistent with both regulation and sub-regulatory guidance from CCIIO and the conventional application of MSP to GHPs under ERISA. We agree with

[4] 83 *Fed. Reg.* 4 at 621 (Jan. 5, 2018). Case law discussing ERISA and MSP note that it is possible for an ERISA plan beneficiary to use ERISA's civil enforcement procedures in 29 U.S.C. § 1132 to recover for unpaid benefits resulting from a violation of the MSP statute, in addition to using the MSP statute's enforcement provisions. *Bio-Medical Applications of Tenn. Inc. v. Cent. States Southeast & Southwest Areas Health & Welfare Fund*, 656 F. 3d 277 (6th Cir. 2011).
[5] 77 *Fed. Reg.* 59 at 18,315 (March 27, 2012).

the proposed regulation's statement that, under the proposal, "AHPs that meet the regulation's conditions would have a ready means of offering their employer members' employees, a single group health plan subject to the same State and Federal regulatory structure as other ERISA covered employee welfare benefit plans."[6]

Sincerely,

C.M. Cameron Lynch
SVP, Government Affairs, Fresenius Medicare Care North America

[6] 83 *Fed. Reg.* 4 at 619.