

# INVESTOR

# NEWS

CMS TRO Release January 7, 2017





### Statement of Fresenius Medical Care Regarding Lawsuit Challenging Premium Assistance Regulation

Fresenius Medical Care today issued the following statement:

Fresenius Medical Care Holdings, Inc. (FMCNA) has joined other United States dialysis providers and patient advocates in filing a lawsuit challenging the rulemaking process used by the United States Centers for Medicare and Medicaid Services (CMS) to promulgate a new regulation regarding premium assistance programs that help to fund health insurance premiums for patients with end stage renal disease (ESRD). Many financially needy Americans receive grants from nonprofit charities to help them obtain health insurance. For decades, the American Kidney Fund (AKF) has provided such premium assistance to ESRD patients, and we have supported their mission with charitable contributions made in accordance with guidelines established by the HHS Office of Inspector General.

The new regulation, which is scheduled to become effective on January 13, 2017, threatens to put an end to premium assistance for certain ESRD patients, including those who access individual market plan coverage both on and off the marketplace exchanges. The lawsuit describes how CMS promulgated this rule without providing patients, healthcare providers, issuers and the public the opportunity to review and comment, as required by law. If finalized, the rule will cause severe and immediate harm to those patients who are among the most vulnerable in society: individuals suffering from kidney failure, which is a life-threatening condition.

We joined this lawsuit to ensure that Americans with kidney failure have the same right as every other American to receive charitable assistance to pay their health insurance premiums. The issue before the Court is whether CMS engaged in a proper rulemaking process as required by the Administrative Procedures Act. While we are supportive of CMS' efforts to preserve patient independence in making decisions about healthcare coverage, it is clear that the new regulation is not a thoughtful or well-reasoned step forward. Instead, it heightens the potential for discrimination by issuers against dialysis patients and it increases the potential for disruption in access to dialysis care by the neediest Americans. We are urging the Court to stay the effectiveness of the regulation so that CMS can engage in the deliberative and informed rulemaking as required by the Administrative Procedures Act. We have asked the Court to issue an order blocking this "midnight" regulation from taking effect days before the inauguration of our new President. While we cannot predict the outcome of litigation, we believe that our claims have merit. The regulation, should it become effective, and the continuing efforts by insurers – through their discussions with CMS and otherwise – to reject premium assistance for ESRD patients, may result in a material adverse effect on our business. The factors that may impact the future use of premium assistance by FMCNA ESRD patients include (i) how the regulation is interpreted, (ii) the status of the regulation, (iii) federal regulatory, legislative and/or executive action, (iv) state regulatory, legislative and/or executive action, (v) the status of the regulation, its interpretation or application, and (vii) responses to the regulation by issuers, providers, and patients. Between 700 and 2,000 FMCNA ESRD patients who currently use premium assistance in connection with individual market plans on and off the exchanges may be impacted by the regulation and/or continuing insurer efforts to reject premium assistance, but that range could also be impacted materially by the above factors.

On January 3, 2017, FMCNA accepted service of a subpoena from the United States Attorney for the District of Massachusetts calling for the production of information related to the premium assistance program operated by the AKF. FMCNA is cooperating with this investigation.

Fresenius Medical Care is the world's largest provider of products and services for individuals with renal diseases, of which around 2.8 million patients worldwide regularly undergo dialysis treatment. Through its network of 3,579 dialysis clinics, Fresenius Medical Care provides dialysis treatments for 306,366 patients around the globe. Fresenius Medical Care is also the leading provider of dialysis products such as dialysis machines or dialyzers. Along with the core business, the company focuses on expanding the range of additional medical services in the field of care coordination.

For more information about Fresenius Medical Care, visit the Company's website at www.freseniusmedicalcare.com.

#### Disclaimer

This release contains forward-looking statements that are subject to various risks and uncertainties. Actual results could differ materially from those described in these forward-looking statements due to certain factors, including changes in business, economic and competitive conditions, regulatory reforms, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in Fresenius Medical Care AG & Co. KGaA's reports filed with the U.S. Securities and Exchange Commission. Fresenius Medical Care AG & Co. KGaA does not undertake any responsibility to update the forward-looking statements in this release.

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