

**Congress of the United States**  
**House of Representatives**  
**Washington, DC 20515**

April 16, 2013

Ms. Marilyn B. Tavenner  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Ave., SW  
Washington, DC 20201

**Re: Request for Examination of Regulations Based Upon Recent Court Decisions**

Dear Acting Administrator Tavenner:

I write to urge you to examine the regulations in Part 42 of the Code of Federal Regulations (“CFR”) that relate to conditions of enrollment<sup>1</sup> to determine whether some of the conditions of enrollment should be more appropriately deemed “conditions of payment” and relocated to the appropriate sections of the CFR. I am concerned that the Medicare trust fund has lost hundreds of millions of dollars when several False Claims Act (“FCA”) decisions won by federal prosecutors have been overturned on this basis. Such decisions include the following: *U.S. ex rel. Williams v. Renal Care Group, Inc.*, *U.S. ex rel. Jamison v. McKesson Corp.*, *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, *United States ex rel. Wilkins v. United Health Group, Inc.*, *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, and *United States ex rel. Mikes v. Straus*. Several of these specifically involve noncompliance with the supplier standards.

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<sup>1</sup> Though this letter will use the term “conditions of enrollment,” several courts have used other terminology as well to differentiate conduct from “conditions of payment,” including “conditions of participation.” The use of “conditions of enrollment” in this letter is intended to capture all of these conditions and also is specifically intended to include reference to the DMEPOS supplier standards at 424.57(c).

These recent decisions have, in essence, allowed some providers and suppliers with questionable conduct to escape scrutiny under the FCA. Several courts have held that while providers and suppliers may not have been in compliance with regulations outlined in the conditions of enrollment section of the CFR, such non-compliance could not form the basis of sanctions under the FCA. Such courts have reasoned that the FCA requires that the provider/supplier be in non-compliance with regulations that are outlined as conditions of payment. In one recent case, the court stated the following: “[w]e have little sympathy for [provider’s name redacted], which sometimes skirted and appears to have often ignored applicable regulations in the conduct of its centers.”

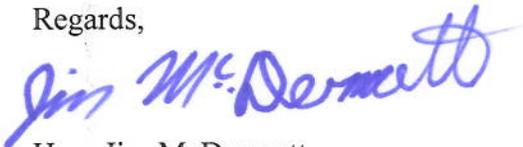
Of course, non-compliance with conditions of enrollment should not always lead to the imposition of the harsh penalties available under the FCA, particularly, given the complex web of regulations that providers and suppliers are charged with knowing. However, some of the regulations that address conditions of enrollment seem to rise to a higher level. I am particularly concerned that some of the regulations that address beneficiary protections are not conditions of payment. Thus, it seems that you may wish to consider relocating such regulations that rise to this higher level to the sections of the CFR that address conditions of payment.

That being said, I have two specific suggestions. First, I strongly urge you to examine whether some of the supplier standards need to be reclassified as conditions of payment. Second, as a related issue, I am asking that you review your claim forms and provider/supplier enrollment forms to determine whether federal prosecutors have the tools that they need to sustain a False Claims Act cause of action under a theory of express certification. Perhaps such review should be coordinated among CMS staff, the Office of General Counsel for the Department of Health and Human Services, the Office of Inspector General, and the Department of Justice. As a result of this review, if language needs to be changed in order for providers and suppliers to be held accountable where appropriate, I suggest that these changes be made to ensure that the FCA retains its potency as a tool to prosecute serious health care fraud offenses.

Should you have any questions, please do not hesitate to contact Tiana Korley in my office at [tiana.korley@mail.house.gov](mailto:tiana.korley@mail.house.gov) or at (202) 225-3106.

Thank you for your attention to this matter.

Regards,



Hon. Jim McDermott  
Member of Congress