



SEP 21 2016

Michael Carome, M.D.  
Director  
Public Citizen's Health Research Group  
1600 20<sup>th</sup> Street NW  
Washington, DC 20009

Dear Dr. Carome:

This letter responds to Public Citizen's recent filing of a lawsuit in the United States District Court for the District of Columbia (Civil Action No. 16-1520 (JDB)). On May 29, 2014, Public Citizen submitted a letter to the Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) that requested the issuance of a notice of proposed rulemaking (NPRM) to amend the National Practitioner Data Bank (NPDB) regulations. Specifically, Public Citizen requested that HRSA address the so-called "corporate shield" loophole. By letter dated June 16, 2014, HRSA responded to this request thanking Public Citizen for its letter, acknowledging the importance of the issue, and stating that HRSA regularly considers all options available to improve NPDB reporting.

Given the lack of a response from Public Citizen to HRSA's June 16, 2014 letter, HRSA believed that Public Citizen considered that letter a sufficient answer. HRSA now understands that Public Citizen apparently did not view the response as sufficient.

HRSA has carefully reviewed your request and hereby denies Public Citizen's petition for HRSA to engage in rulemaking to address the "corporate shield." As Public Citizen is aware, HRSA issued an NPRM on December 24, 1998 (63 FR 71255), to address the "corporate shield." HRSA received a large number of thoughtful comments regarding the proposed regulatory change, with the large majority of commenters voicing opposition. Among other concerns, commenters suggested that: (i) the method chosen in the NPRM was overbroad; (ii) the current regulations are adequate to address the problem; (iii) HHS may not have the legal authority to address this issue through regulation; (iv) the NPRM's assertion that the current regulations are inconsistent with the intent and purposes of the statute may not be accurate; and (v) addressing the "corporate shield" needs to be done in a manner that is both fair to practitioners and not burdensome for medical malpractice payers.

Given the significant opposition and well-founded concerns raised in the comments, HRSA reevaluated whether rulemaking was the most appropriate and effective means to address the "corporate shield." Many of the commenters argued that the current regulations are much more aligned with the intent and purposes of the statute and that the proposed changes in the NPRM exceeded HRSA's authority.

In HRSA's view, the regulatory solution proposed in the NPRM and again suggested by Public Citizen in its May 2014 letter is not a viable answer for many of the reasons raised by commenters to the 1998 NPRM. Though HRSA remains open as to how to address the "corporate shield," HRSA is currently unaware of any regulatory mechanism that does not raise similar concerns. Accordingly, it denies Public Citizen's request to engage in rulemaking on that subject at this time.

Sincerely,

A handwritten signature in black ink, appearing to read "James Macrae". The signature is fluid and cursive, with a large initial "J" and "M".

James Macrae  
Acting Administrator