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WLF Charges That CMS Reporting Rules Violate First Amendment Rights

(In re Final Rules on Transparency Reporting)

The Washington Legal Foundation (WLF) today urged the Centers for Medicare and Medicaid Services (CMS) to exempt dissemination of medical textbooks from its reporting rules governing “payments or other transfers of value” made by pharmaceutical companies to doctors. WLF charged that applying the reporting requirements to medical textbooks constitutes a serious infringement on the First Amendment rights of pharmaceutical companies to disseminate textbooks and the First Amendment rights of doctors to receive such information.

In a letter to CMS officials, WLF urged them to delay application of reporting requirements to medical textbooks until it has had an opportunity to examine the First Amendment implications of its January 2013 decision to include textbooks within the new reporting rules. Under the new rules, all transfers of value from manufacturers to doctors made after July 31, 2013 must be reported to CMS on an annual basis. CMS adopted the rules pursuant to the Physician Payment Sunshine Act, adopted by Congress in 2010.

“Healthcare is advanced significantly when doctors receive textbooks and other educational items that can be used in treating patients, yet the evidence is overwhelming that drug companies will cease disseminating all textbooks if doing so will subject them to onerous reporting requirements,” explained WLF Chief Counsel Richard Samp. “CMS’s rule is directly contrary to Congress’s intent; the disclosure law it adopted in 2010 specifically exempts ‘educational materials that directly benefit patients’ from the reporting rules,” Samp said.

Congress adopted the Physician Payment Sunshine Act because it feared that the prescribing decisions of some doctors were being corrupted by large gifts. The federal government, which provides billions of dollars each year to reimburse the costs of drugs and medical devices, has a strong interest in ensuring that a doctor prescribes use of medical products only when their use is indicated, and not because the doctor has been bribed to write such a prescription. By requiring drug companies to report to CMS gifts they make to doctors, Congress hoped to ascertain which doctors are receiving inordinately large gifts and thus to ascertain more easily whether a doctor’s prescription-writing practices have been corrupted.

In fact, drug companies have already been policing themselves on this issue for more than a decade. PhRMA, the industry trade group, in 2002 adopted its “Code on Interactions with Healthcare Professionals,” which prohibits large gifts to doctors; the Code explicitly endorses, however, gifts of “educational items such as a medical text book,” reasoning that such gifts enhance the quality of healthcare and are not sufficiently valuable to create a danger of corruption. In adopting the Physician Payment Sunshine Act, Congress closely adhered to the Code.

In January 2013, CMS issued its final regulations under the Act. CMS determined that although most drug industry support of continuing medical education programs need not be reported, gifts of medical textbooks are reportable. CMS reasoned that while textbooks enhance patient care, the benefits to patients are merely “downstream benefits” and thus do not meet the statutory requirement that they “directly” benefit patients.

In its letter to CMS, WLF pointed to strong evidence that, in light of the high costs of complying with reporting requirements and doctors’ fears of being included on lists of those receiving payments from drug companies, the new rules will cause companies to cease disseminating medical textbooks and doctors to decline to accept any such gifts. WLF noted that dissemination of textbooks has considerable communicative value and thus is fully protected by the First Amendment. WLF charged that in light of the significant burden that CMS’s disclosure rule would impose on protected speech, the rule could not withstand First Amendment challenge. WLF pointed to numerous decisions in which the U.S. Supreme Court has struck down disclosure requirements shown to impose substantial burdens on First Amendment rights. It further charged that CMS has been unable to identify any substantial government interest that is served by applying the disclosure rules to medical textbooks.

WLF is a public interest law and policy center with supporters in all 50 states. WLF regularly litigates in support of speech rights, including the First Amendment rights of patients and doctors to receive truthful information about the uses of FDA-approved medical products. As a result of a First Amendment lawsuit filed by WLF, FDA is subject to a permanent injunction limiting FDA authority to suppress manufacturer dissemination of medical textbooks discussing off-label uses of their FDA-approved products.

For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF’s brief is posted on its web site, www.wlf.org.