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WLF URGES MEDICARE AGENCY NOT TO TIE REIMBURSEMENT TO CLINICAL TRIALS

(*In re CMS Draft Guidance on Coverage With Evidence Development*)

The Washington Legal Foundation (WLF) filed comments today with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services that operates the Medicare program, asking the agency to withdraw its proposal to tie reimbursement for selected new treatments to the patient's participation in a clinical trial or a similar evidence-gathering process.

WLF's comments are in response to an April 7, 2005, draft guidance document from CMS, *Factors CMS Considers in Making a Determination of Coverage with Evidence Development*. While CMS has previously required participation in a few cases, such as coverage of certain implantable cardio defibrillators, the new proposal appears to reflect an intention by the agency to impose such requirements on a more regular basis.

WLF argued in its comments that such requirements may restrict patients' access to needed care and that CMS has many alternative tools to spur research on therapies relevant to the Medicare population that do not involve coverage limitations. Such tools include research grants authorized by the Medicare Prescription Drug, Improvement and Modernization Act of 2003; coordination with patient groups, manufacturers, and research-oriented agencies; payments to providers for voluntary participation in data collection efforts; and implementation of the 2000 national coverage determination that would reimburse for costs of participating in clinical trials. WLF further argued that CMS has not justified such requirements under the Medicare statute's "reasonable and necessary" provision governing reimbursement.

WLF is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government, including in the area of patients' rights. For example, WLF successfully challenged the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. *Washington Legal Found. v. Friedman*, 13 F. Supp.2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF has previously submitted comments to CMS, on February 10, 2004 and June 25, 2004, concerning Medicare coverage of off-label uses of FDA-approved cancer drugs under Part B, Part D, and the Section 641 demonstration program.

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For further information, contact WLF Senior Vice President for Legal Affairs David Price, (202) 588-0302. A copy of WLF's comments is posted on its web site, www.wlf.org.