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CMS ADVISES ON REIMBURSEMENT FOR OFF-LABEL USE OF DRUGS

by
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Some observers of the Centers for Medicare & Medicaid Services (CMS) — the U.S. Department of Health and Human Services agency which operates the Medicare program — have expressed concern that the agency's rules for a demonstration project are laying the groundwork for exclusions of off-label prescriptions from the forthcoming prescription drug benefit program. The agency has recently advised the Washington Legal Foundation (WLF) that its limitations on coverage of off-label uses in that demonstration project will not set a precedent for the prescription drug benefit. Although the statement is not binding on the agency, it may give some comfort to those concerned about the future of reimbursement for off-label use.

WLF filed comments with CMS on June 25, 2004, asking the agency to reconsider its decision to exclude "off-label" uses of cancer therapies from its "replacement drug" demonstration project for self-administered cancer drugs. In that demonstration project mandated by Congress in Section 641 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS is to cover certain self-administered drugs on an interim basis prior to implementation of the full drug benefit (known as "Part D") in 2006. Under current law, Medicare reimburses for drugs only if administered in a doctor's office, hospital, or clinic.

Subsequently, CMS publicly announced that it was reversing its decision to exclude all off-label prescriptions from the demonstration, and that it would cover a narrow class of off-label uses — those for which the indication "is being reviewed by the FDA" and for which the FDA has stated that "no filing issues remain."

In a separate e-mail communication to WLF, the agency has stated, "We appreciate the special nature of oncology treatment and role that off label uses of certain medications plays. . . . As the Part D drug benefit that will be implemented in 2006 is not limited to replacement drugs, we do not believe that our decision in this matter is relevant to what will occur in 2006." CMS indicated that its authority to exclude some off-label uses from the demonstration was grounded in the language of the statute authorizing the demonstration, and noted that this language does not appear in the statutory language creating the new "Part D" prescription drug benefit program.

David Price is Senior Vice President for Legal Affairs of the Washington Legal Foundation. WLF's comments can be viewed on its web site, <http://www.wlf.org>.

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