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**Medicare Prescription Drug Plans Not Fully Compliant with Federal Regulations,
According to Tufts Center for the Study of Drug Development**

BOSTON – May 6, 2008 – A new study by the Tufts Center for the Study of Drug Development has found that Medicare prescription drug plans that came into being following the landmark Medicare Modernization Act of 2003 are not fully compliant with federal regulations governing medications in six therapeutic categories.

The study determined that formularies offered by Medicare-eligible plans, on average, include only 83% of 206 drugs approved by the U.S. Food and Drug Administration across six therapeutic categories, while imposing conditions of reimbursement on 18% of them. Federal regulations require that all drugs in the six categories be covered by Medicare plans.

“These formulary restrictions could impair access to medically necessary pharmaceuticals, but achieving full compliance comes at a price. More stringent laws requiring coverage of each and every drug in the categories we looked at would mean higher costs for Medicare beneficiaries,” said Joshua Cohen, senior research fellow at Tufts CSDD and author of the study.

“The Centers for Medicare and Medicaid Services must weigh the advantages and disadvantages of regulations concerning coverage and conditions of reimbursement. The more it mandates, the less leverage plans will have to negotiate favorable prices with drug companies.”

A formulary is a list of selected pharmaceuticals and dosages recommended by health insurers.

Research results of the Tufts CSDD study, reported in the May/June *Tufts CSDD Impact Report*, released today, also found that:

- * Medicare beneficiaries receiving anticonvulsants, antidepressants, antineoplastics, antipsychotics, HIV/AIDS drugs, or immunosuppressants have some of the highest drug and medical costs among all beneficiaries.
- * Drug plans, on average, pay for 72% of the costs of the drugs they cover, which violates the CMS guidance requiring coverage of 75% of the costs of “all or substantially all” drugs in the six therapeutic categories.
- * Medicare beneficiaries spend an average of \$15-\$35 per 30-day prescription out-of-pocket on covered drugs in the six categories, a figure expected to increase as the number of specialty pharmaceuticals increases.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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