



MAINE MEDICAL ASSOCIATION

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TESTIMONY OF THE MAINE MEDICAL ASSOCIATION

IN SUPPORT OF

L.D. 712, AN ACT TO EXPAND ACCESS TO CLINICAL TRIALS

Joint Standing Committee on Insurance & Financial Services
Room 220, Cross State Office Building
Wednesday, March 23, 2011, 1:00 p.m.

Good afternoon Senator Whittemore, Representative Richardson, and Members of the Joint Standing Committee on Insurance & Financial Services. My name is Andrew MacLean and I am speaking in favor of L.D. 712 on behalf of the Maine Medical Association (MMA). The MMA is a professional association of more than 3400 Maine physicians, residents, and medical students whose mission is “to support Maine physicians, advance the quality of medicine in Maine, and promote the health of all Maine citizens.”

L.D. 712 addresses issues of interpretation or gaps in coverage of the “access to clinical trials” part of the Maine Insurance Code enacted by the 119th Maine Legislature in L.D. 750, *An Act to Establish a Patient’s Bill of Rights* (P.L. 1999, Chapter 742). This legislation along with a companion administrative rule known as Bureau of Insurance Rule Chapter 850, *Health Plan Accountability* provide all of us as patients with important protections in our business relationships with health insurance carriers in Maine. The legislature enacted these protections with strong bipartisan support from this committee. The protections were necessary at that time – more than a decade ago – and they are even more important today with the substantial consolidation of market power and conversion from non-profit to for-profit status that has taken place in the health insurance industry during this period.

The MMA urges you to pass L.D. 712 to address the concerns of clinicians and patients about the “access to clinical trials” law.

The American Medical Association’s (AMA’s) policy statement on reimbursement for clinical trials in cancer treatment is House of Delegates Resolution 55.983, *Reimbursement and Coverage Implications of Clinical Trials in Treatment of Cancer*.

The AMA recommends that CMS and other third party payers not deny coverage and reimbursement for the costs of medical care to patients entered in qualifying clinical trials of therapeutic regimens at any Phase. Covered costs should include those usually covered (hospital care and physician and other health care services), as well as the costs of all FDA-approved agents utilized in the trial, regardless of whether use is for an on-label or off-label indication. Qualifying clinical trials must satisfy all of the following inclusion criteria:

- (1) Treatment is provided with a therapeutic intent (intent refers to an intention to improve patient outcome, relative to survival or quality of life);
- (2) Treatment is being provided pursuant to a clinical trial which has been approved by the National Cancer Institute (NCI) or any of its cancer centers, Regional Cooperative Oncology Groups or community clinical oncology programs, the FDA in the form of an investigational new drug exemption, the Department of Veterans Affairs, or a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants;
- (3) The proposed therapy has been reviewed and approved by a qualified institutional review board;
- (4) The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training;
- (5) There is no noninvestigational therapy that is clearly superior to the protocol treatment; and
- (6) The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as noninvestigational therapy. (Res. 502, A-93; Reaffirmed: CMS Rep. 10, A-03)

I thank the Committee for considering the MMA's views on L.D. 712. I would be happy to respond to any questions you may have.