

August 16, 2007

Secretary Mike Leavitt
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

**RE: Newly Mandated Tamper-Resistant Prescription Pad Requirement
for Medicaid Prescriptions**

Dear Secretary Leavitt:

As organizations with an interest in the continuity of medication therapy for Medicaid patients, we are writing to urge a delay in, and further consideration regarding, the new federal statutory Medicaid mandate which requires that Medicaid prescriptions be written on tamper-resistant prescription forms beginning October 1. The provision was inserted into a recent military funding measure.¹ We are very concerned about the impact this mandate could have on the ability of Medicaid beneficiaries to obtain their prescriptions.

On-Schedule Implementation Could Impact Beneficiary Access

As you can imagine, it will be very difficult for this mandate to be implemented within the next two months. The Centers for Medicare and Medicaid Services (CMS), which will be administering and enforcing the requirement, has not yet issued direction to State Medicaid Directors. Implementation issues include whether a sufficient number of pads will be available to the tens of thousands of prescribers who write hundreds of millions of prescriptions for Medicaid beneficiaries each year, where and how prescribers will obtain the pads, the specifications for the pads, and who will pay for the cost of the pads.

We are particularly concerned about the potential for delays in Medicaid beneficiaries receiving their prescription medications caused by uncertainty over what action a pharmacist should take if a prescription is written on non-tamper-resistant paper. Prescriptions not written on the mandated forms will be ineligible for Federal matching funds, and states will not want to reimburse for noncompliant prescriptions. A pharmacy faced with the possibility of having its reimbursement denied or recouped for a noncompliant prescription could be put in the difficult position of being unable to fill that prescription, or having to delay dispensing crucial medication until the prescriber can be contacted to rewrite the prescription on the specified form. It is essential that pharmacists be permitted to dispense an emergency supply until a proper script can be executed.

Issues Demanding Clarification

We urge a 6- to 12-month delay in the implementation of this mandate. During the delay, we advocate for the Administration and/or Congress to address the following issues:

¹ § 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (P.L. 110-28).

- Need for a consistent definition of “tamper-resistant”;
- Need to avoid changes in existing state requirements and specifications for tamper-resistant prescription paper;
- Allowing adequate time to amend state laws and regulations;
- Allowing adequate time to educate providers;
- Recognition of the impact of tamper-resistant prescription forms on dispensing and storage; and
- Need to exempt prescriptions dispensed to beneficiaries with retroactive eligibility.

It is essential for patient health and for the cost-effectiveness and efficiency of the entire health care system that individuals have timely access to their prescribed medication. We will greatly appreciate your taking the steps necessary to ensure this access and to address this implementation date and related issues.

Sincerely,

American Academy of Allergy, Asthma and Immunology
 American Academy of Family Physicians
 American Academy of Hospice and Palliative Medicine
 American Academy of Neurology
 American Academy of Otolaryngology – Head and Neck Surgery
 American Academy of Pediatrics
 American Association of Clinical Endocrinologists
 American Association of Homes and Services for the Aging
 American College of Emergency Physicians
 American College of Obstetricians and Gynecologists
 American College of Osteopathic Internists
 American College of Osteopathic Surgeons
 American College of Physicians
 American College of Rheumatology
 American Diabetes Association
 American Gastroenterological Association
 American Medical Association
 American Medical Directors Association
 American Medical Group Association
 American Osteopathic Association
 American Psychiatric Association
 American Society of Addiction Medicine
 American Society of Anesthesiologists
 American Society for Reproductive Medicine
 Association of American Medical Colleges
 Medicaid Health Plans of America
 Medical Group Management Association
 National Association of Rural Health Clinics
 North American Spine Society
 The Endocrine Society

State Medical Associations and Societies:

Alaska State Medical Association
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Connecticut State Medical Society
Florida Medical Association, Inc.
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Maine Medical Association
Massachusetts Medical Society
MedChi, The Maryland State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Medical Society of the State of New York
Medical Society of Virginia
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
New Mexico Medical Society
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society