

March 3, 2010

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality
540 Gaither Road, Suite 2000
Rockville, MD 20850

Dear Director Clancy:

The national organizations listed below, representing pharmacists and pharmacies in all practice settings, respectfully request the opportunity to meet with you and your staff to discuss provisions included in both the pending House and Senate – passed health care reform bills that would establish a medication therapy management (MTM) grant program under the purview of the Agency for Healthcare Research and Quality. We intend to pursue the resources necessary to implement this grant program in this Congress, and hope you will also support its scope and purpose.

We are pleased that there are a number of provisions in the pending health care reform legislation which recognize the importance of providing patients and prescribers with the tools necessary to optimize appropriate medication use, reduce medication-related problems, and improve health outcomes through the delivery of medication therapy management services, health promotion, disease prevention and chronic care management activities. In particular, the pharmacy profession welcomes the inclusion of a stand-alone grant program (see attached) that tests pharmacist-provided MTM services as defined by the profession in its Core Elements of an MTM Program.¹ The grant program ensures testing of delivery care models, such as patient-centered self-management programs, that improve patient outcomes through team-base collaboration between prescribers and pharmacists.

Proper use of medications helps improve quality of life and health outcomes. However, under the current health care system, we incur more than \$177 billion annually in mostly avoidable health care costs to treat adverse events from inappropriate medication use.² The proper use of medication is very important in the treatment of chronic disease, which costs the health care system \$1.3 trillion annually, or about 75 cents of every health care dollar.³ A 2006 Institute of Medicine report requested by the Senate Finance Committee estimated "that there are at least 1.5 million preventable ADEs [adverse drug events] that occur in the United States each year. The true number may be much higher."⁴ Clearly, more must be done to address this crisis.

Our organizations, which have been working together throughout the health care reform debate to promote the role of pharmacists in improving patient medication use, would appreciate the opportunity to discuss the MTM grant program. To this end, please contact John Coster, Senior Vice President of Government Affairs for the National Community Pharmacists Association at (703) 888-0859 or

1 American Pharmacists Association; National Association of Chain Drug Stores Foundation. Medication therapy management in pharmacy practice: core elements of an MTM service model (version2.0). J Am Pharm Assoc. 2008;48:341-53

2 Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc. 2001;41:192-9

3 "An Unhealthy America: The Economic Burden of Chronic Disease," Milken Institute, Oct. 2, 2007

4 Preventing Medication Errors: July 2006, Institute of Medicine

john.coster@ncpanet.org or Kristina Lunner, Vice President of Government Affairs for the American Pharmacists Association at (202) 429-7507 or klunner@aphanet.org.

Sincerely,

Academy of Managed Care Pharmacy
American Association of Colleges of Pharmacy
American College of Clinical Pharmacy
American Pharmacists Association
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
College of Psychiatric & Neurologic Pharmacists
Food Marketing Institute
International Academy of Compounding Pharmacists
National Alliance of State Pharmacy Associations
National Association of Chain Drug Stores
National Community Pharmacists Association
Rite Aid Corporation
Safety Net Hospitals for Pharmaceutical Access
Walgreen Co.

Enclosure

cc: Howard Holland
Scott Smith
Boyce Ginieczki
Christine Williams

The Patient Protection and Affordable Care Act (H.R. 3590)

SEC. 3503. MEDICATION MANAGEMENT SERVICES IN TREATMENT OF CHRONIC DISEASE.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), as amended by section 3501, is further amended by inserting after section 934 the following:

“SEC. 935. GRANTS OR CONTRACTS TO IMPLEMENT MEDICATION MANAGEMENT SERVICES IN TREATMENT OF CHRONIC DISEASES.

“(a) **IN GENERAL.**—The Secretary, acting through the Patient Safety Research Center established in section 933 (referred to in this section as the ‘Center’), shall establish a program to provide grants or contracts to eligible entities to implement medication management (referred to in this section as ‘MTM’) services provided by licensed pharmacists, as a collaborative, multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.

“(b) **ELIGIBLE ENTITIES.**—To be eligible to receive a grant or contract under subsection (a), an entity shall—

“(1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);

“(2) submit to the Secretary a plan for achieving long-term financial sustainability;

“(3) where applicable, submit a plan for coordinating MTM services through local community health teams established in section 3502 of the Patient Protection and Affordable Care Act or in collaboration with primary care extension programs established in section 399W;

“(4) submit a plan for meeting the requirements under subsection (c); and

“(5) submit to the Secretary such other information as the Secretary may require.

“(c) **MTM SERVICES TO TARGETED INDIVIDUALS.**—

The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include—

“(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

“(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

“(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

“(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

“(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional followup interventions on a schedule developed collaboratively with the prescriber;

“(6) documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

“(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

“(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

“(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

“(10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.

“(d) TARGETED INDIVIDUALS.—MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who—

“(1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);

“(2) take any ‘high risk’ medications;

“(3) have 2 or more chronic diseases, as identified by the Secretary; or

“(4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.

“(e) CONSULTATION WITH EXPERTS.—In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.

“(f) REPORTING TO THE SECRETARY.—An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures endorsed by the entity with a contract under section 1890 of the Social Security Act, as determined by the Secretary.

“(g) EVALUATION AND REPORT.—The Secretary shall submit to the relevant committees of Congress a report which shall—

“(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

“(2) assess changes in overall health care resource use by targeted individuals;

“(3) assess patient and prescriber satisfaction with MTM services;

“(4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;

“(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

“(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

“(h) GRANTS OR CONTRACTS TO FUND DEVELOPMENT OF PERFORMANCE MEASURES.

The Secretary may, through the quality measure development program under section 931 of the Public Health Service Act, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.’’.