American Association of Clinical Endocrinologists

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September 17, 2004

Roger L. Williams, MD
Executive Vice President and CEO
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Attention: Lynn Lang

Dear Dr. Williams,

We are writing to you on behalf of the American Association of Clinical Endocrinologists (AACE) concerning US Pharmacopeia's effort to comply with the legislative mandate of the Medicare Prescription Drug Improvement and Modernization Act 2003 (MMA). This mandate was to develop Model Guidelines for the Centers for Medicare and Medicaid Services as a framework of drug categories and classes to be used by prescription drug plan sponsors in the development of their own formularies. It was the expectation of Congress and the medical community that this pharmaceutical benefit would meet an important need of elderly Americans in obtaining their required prescription drugs. As a part of the process of developing these Model Guidelines, your organization created the Model Guidelines Expert Committee and has held hearings, at which it was our privilege to participate. Dr. Richard Dolinar, Chair of the AACE Future of Health Care Task Force, represented AACE at the public meeting held on August 27th in Baltimore and discussed our recommendations which had been previously submitted to you by letter (see attachment).

At this time, we are responding to your request for public comment and consultations prior to September 17, 2004. Upon reviewing the information in your publication of the Medicare Prescription Drug Benefit Draft Model Guidelines, we are very concerned that, if the recommendations elaborated in this document become the Guidelines for the implementation of the Prescription Drug Benefit Plan of the MMA, the beneficiaries of these programs will not have access to the medications that are needed for the management of endocrine and metabolic disorders. The lack of access to the needed drugs will certainly prevent many beneficiaries from enrolling in this program; and those low-income individuals that are required to be in this program in order to obtain drugs will find themselves unable to access appropriate medical care.

It is critical that beneficiaries of this program have access to the standard of medical care that is expected from physicians. The three areas that most directly affect patients of clinical endocrinologists are diabetes mellitus, hyperlipidemia and osteoporosis. In your Guidelines, the column "pharmacologic class," of which the plan will require that two agents be selected by any approved pharmaceutical benefit program, will severely limit the options in the management of Adult Onset (Type II) Diabetes Mellitus. The five categories that you list under "recommended subdivisions" are quite appropriate and most patients with Type II Diabetes require medications from two or more of this subdivision category. Limiting patients to only two drugs would mean that few could be controlled without insulin injections.

The same concern applies to the pharmacologic class "antilipemic agents." You list five recommended subdivisions under that class, which are again appropriate. Most patients,

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especially those with combined hyperlipidemia, require treatment with drugs from two or more of these "subdivision" groups

of medications. Restricting beneficiaries of these plans to only two agents from these five groups would severely compromise their access to the standard of quality care.

We would also take exception to your categorization of drugs used to treat and prevent osteoporosis. These are grouped under the therapeutic category hormones, stimulant/replacement. Almost none of these medications are appropriately considered hormones. The pharmacologic class which contains these medications, parathyroid/calcium regulating agents also does not adequately describe these drugs. The column "recommended subdivisions," however, does include most of the agents used to treat and prevent osteoporosis. Unfortunately, it is quite likely that, of the five principle types of medications used in this treatment, only two would be included on your list; and therefore, once again, beneficiaries of these plans would be denied access to quality care.

A combination of Vitamin D and calcium supplementation are a critical part of these treatment plans; and they do not seem to be included under any of these except, possibly, #146, Therapeutic Nutrients, Minerals and Electrolytes. I cannot imagine the number of agents that would fit under the classification of electrolytes that would be necessary. Calcium and Vitamin D may not make this list at all.

We are very concerned that beneficiaries of these plans will not have access to appropriate or satisfactory, much less quality, medical care. This will serve as a serious detriment to the acceptance of these plans by our patients and by physicians. We would urge you and your Committee to seriously reconsider the Guidelines, and to include those groups listed under "recommended subdivisions" in those that will require plans to have represented in their formularies. AACE would like to strongly recommend extreme caution, as we are concerned that the number of categories and classes are limited; and, by so doing, frontline lifesaving drugs were relegated to Column #3, which is not protected. AACE requests that the Committee make its decision regarding the number of classes and categories based on the scientific merit of the various drugs and not be limited by economic consideration.

We appreciate your favorable consideration of these comments and urge your heightened awareness of the needs of patients with endocrine and metabolic diseases in your design of the Guidelines for these formularies.

Sincerely yours,

Carlos R. Hamilton, Jr., MD, FACE
President
American Association of Clinical Endocrinologists

Richard O. Dolinar, MD, Chair
AACE Future of Health Care Task Force

CRH/ROD/bd
Attachment
cc: AACE Board of Directors

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