May 5, 2000

The Honorable Bill Archer
U.S House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

Dear Congressman Archer:

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM) is the largest medical specialty society in the country, representing over 115,000 physicians of internal medicine and medical students. ACP-ASIM's members provide medical care for our nation's adult population, including Medicare beneficiaries, and therefore, we are in a unique position to evaluate the need for and the appropriate structure of any proposed Medicare prescription drug benefit.

ACP-ASIM strongly supports enactment this session of legislation to provide a prescription drug benefit with sustainable financing, with the highest priority going to help low-income beneficiaries. As physicians, the members of ACP-ASIM know that the lack of prescription drug coverage can significantly reduce patient compliance with prescribed drug therapies. However, our members also recognize that the cost of prescription drugs is escalating at a rate far greater than health care spending generally and that legislation must work to create and maintain a careful balance between the need for a prescription drug benefit and the cost of such a benefit. It is critical, however, that cost not be the primary factor in structuring any prescription drug benefit program.

Physicians constantly are forced to strike a balance between ensuring that their patients receive medication that is medically necessary and minimizing their patient's out-of-pocket costs. Formularies and/or PBMs that limit beneficiaries' coverage, either in terms of increased copays or deductibles, or by restricting the availability of certain medications, increase the likelihood that patients will not be able to comply with their physicians' recommended regimens. Moreover, prescription management programs that use restricted formularies may be inappropriate for certain individuals and special subpopulations. Cost-effective rather than cost-control practices recognize the patient's well being as primary and promote quality patient care. Patients should have access to effective treatment rather than the least expensive therapy.

As Congress prepares to consider legislation on Medicare prescription drug benefits, ACP-ASIM urges you to ensure that consumer protections are included in the authorizing language, particularly if the benefit is to be restricted by a formulary or administered by pharmacy benefit managers (PBMs). If a formulary is instituted, by a PBM or otherwise, decisions on which drugs should be included should be based on effectiveness, safety, and ease of administration – not just costs. Physicians should have the option of prescribing drugs that are not on the formulary without cumbersome prior authorization requirements. Beneficiaries should be informed of the impact of the formulary on both co-payments and access to prescription drugs. Also, they should be promptly notified of changes in the formulary. PBMs or others defining a formulary should be required to consult with physicians on the drugs that are included in the formulary. A more detailed list of consumer protections is attached.

Thank you for considering our concerns and we look forward to working with you and your colleagues as prescription drug legislation moves forward this session in Congress.

Sincerely,

Sandra Adamson Fryhofer, MD, FACP

CONSUMER PROTECTION PRINCIPLES FOR MEDICARE PRESCRIPTION DRUG LEGISLATION

1. A method of pricing Medicare payments for prescription drugs should be included that will balance the need to restrain the cost of the benefit with the need to create financial incentives for manufacturers to continue to develop new products. Rigid price controls that will discourage innovation should be rejected.

2. The use of formularies should not be mandated. If a formulary is instituted, by a PBM or otherwise, decisions on which drugs should be included and evaluation of physician prescribing patterns should be based on effectiveness, safety, and ease of administration, rather than just costs.

3. Physicians should have the option of prescribing drugs that are not on the formulary (based on objective data to support a justifiable, medically indicated cause) without cumbersome prior authorization requirements.

4. Beneficiaries should have access to comprehensive, accurate and understandable educational and informational material about their prescription drug benefits; such material should include information on how the formulary functions and the impact of the formulary on co-payments and/or deductible requirements, and access to prescription drugs.

5. Beneficiaries and their physicians should be promptly notified (at least ninety days notice) when formularies are changed or discontinued.

6. PBMs or others defining a formulary should be required to consult with physicians on the drugs that are included in the formulary. Formularies should be approved on a regional basis by a professionally qualified body that includes practicing physicians using that formulary.

7. Any request by a benefit manager to alter medication regimes should occur only when such requests are based on objective data supported by peer-reviewed medical literature and which undergo review and approval of associated managed care organizations'/managed behavioral health organizations' pharmacy and therapeutic committees.

8. Physicians should continue to be able to prescribe covered drugs for accepted off-label uses.

9. The prescription drug benefit should not require an expansion of prescribing privileges for non-physician health professionals beyond what can be supported based on their level of training.

10. Issues of generic and therapeutic substitution under the Medicare program should be addressed through the development of a national system that would allow physicians who permit generic substitution to: designate substitution by only "A" rated generic drugs; require any prescription medication crossing state lines, such as those as part of a prescription filled by an out-of-state pharmacy, to use only "A" rated generic drugs if a brand name is not required by the prescribing physician; and require a national uniform policy regarding a phrase that can be used to denote the need for a brand name drug.

11. PBMs should be required, with a patient's consent, to provide treating physicians with all available information about the patient's medication history.

12. PBMs should be required to disclose to beneficiaries and their physicians any financial relationships among the benefit manager, pharmacists and pharmaceutical managers.