

Governmental Affairs & Public Policy

Statement of the ACP-ASIM to the Subcommittee on Health Committee on Ways and Means, U.S. House of Representatives

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Summary

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 the majority of medical care to adults in America, including Medicare beneficiaries, and are therefore 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. Such legislation must include key consumer protections, particularly if the benefit is to be restricted by a formulary administered by pharmacy benefit managers (PBMs). Patients' access to beneficial drugs must not be hindered by restrictive formularies--or other managed care controls--that are imposed by PBMs solely to reduce costs, without regard to safety, effectiveness, or ease of administration. 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.

Background

Prescription drugs are an essential tool for treating and preventing many acute and chronic conditions. In 1965, when Medicare was first established, pharmaceutical therapies were not as commonly available as they are now, and outpatient prescription drugs were not nearly as important a component of health care. Today, however, they are a primary form of medical care and often substitute for more costly therapies, such as hospitalization and surgery.

Pharmaceuticals are the fastest-growing component of national health expenditures. In 2000, national drug spending increased by an estimated 11% compared with 7% for physician services

and 6% for hospital care. Since 1990, national spending for prescription drugs has tripled. By 2008, that figure is expected to more than double from an estimated \$112 billion today to \$243 billion. (Source: HCFA, Office of the Actuary).

The growing importance and increased use of prescription drugs have had a disproportionate impact on the elderly, who use prescription drugs more extensively than the general population because of high rates of chronic illness. Although the elderly represent only about 12 percent of the population, they account for over a third of spending on prescription drugs. It is estimated that 80 percent of Medicare beneficiaries use pharmaceuticals on a regular basis. Having drug coverage is a significant factor affecting whether Medicare beneficiaries fill their prescriptions. Lack of or limited drug coverage can expose beneficiaries to high out-of-pocket costs that may result in under-utilization of prescribed medications and adverse health outcomes.

In response to the increase in utilization and costs of prescription drugs, managed care organizations have turned to cost-control techniques, such as the use of formularies and PBMs. In fact, PBMs currently manage an estimated 71% of the volume of prescription drugs dispensed through retail pharmacies that are covered by private third-party payers. Several bills pending in Congress, including the Administration's proposal, would use PBMs to administer a Medicare drug benefit and give PBMs the authority to determine which drugs would be available to patients under such a benefit. PBMs are private companies that contract with health plans to limit the costs of prescription drugs by managing drug utilization and obtaining discounts from retail pharmacies and manufacturers. Formularies--lists of approved drugs that physicians are permitted to prescribe--are typically used by PBMs to limit access to expensive drugs.

ACP-ASIM Concerns with PBMs

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 copayments 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, patients with serious illnesses requiring more costly medications may be particularly at risk if PBMs are allowed to restrict coverage to only the cheapest drugs. If drugs are prescribed that are not listed in the formulary, patients may be penalized with higher out-of-pocket costs (increased copayments or deductibles). PBMs also monitor the number and types of drugs that physicians prescribe to their patients. Physicians who prescribe more costly drugs may

be pressured to give their patients less expensive--but potentially less effective--alternatives. All of these circumstances may result in adverse health outcomes.

PBMs need to consult with physicians on the drugs that are included in a formulary. They need to educate patients about how their prescription drug benefit works, what the impact will be on their out-of-pocket costs if they need a drug that is not on the formulary, and how to obtain approval for a drug that is not on the formulary list. Physicians should be able to prescribe beneficial "off-formulary" drugs to their patients, when supported by clinical evidence on effectiveness, without cumbersome prior authorization requirements. Beneficiaries and their physicians need to be promptly notified when formularies are changed or discontinued.

ACP-ASIM believes it is critical that any authorizing legislation on a Medicare prescription drug benefit includes sufficient oversight of how PBMs operate. As private companies, PBMs can exert a great deal of influence over which drugs will be available to Medicare beneficiaries, without any accountability to the public for their decisions. The PBM industry makes their pricing decisions without public scrutiny, oversight or regulation. The PBM industry is highly concentrated, with the top three PBMs—Merck-Medco Managed Care, PCS Health Systems, and Express Scripts - together managing approximately 45 percent of prescriptions dispensed through retail pharmacies that are covered by private third-party payers. A Medicare drug benefit administered by PBMs needs to protect against potential conflicts of interest that can arise when a PBM is owned by a drug manufacturer, or has close ties to a drug manufacturer. ACP-ASIM supports the disclosure of any financial relationships between PBM companies, pharmacists and pharmaceutical manufacturers to patients and physicians.

PBMs are coming under increasing scrutiny. The National Association of Insurance Commissioners is currently considering whether to recommend legislation to regulate the industry. Pending lawsuits contend that some pharmacy benefit managers have violated their duty to act in the best interest of patients. The U.S. Department of Justice is investigating possible illegal kickbacks at the two largest PBMs. ACP-ASIM believes that Congress should proceed cautiously in placing too much control of a Medicare prescription drug benefit program in the hands of pharmacy benefit managers. 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. **A prescription drug benefit will be a hollow promise to beneficiaries if it allows PBMs to deny them access to beneficial drugs principally on the basis of cost.**

(A list of ACP-ASIM's recommended consumer protection principles is [attached](#).)

ACP-ASIM 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.