DRUGS

Medicare Prescription Drug Coverage
(This memo presents ACP—ASIM positions on Medicare Prescription Drug Coverage. Although written and approved as a preliminary statement for further policy development, upon further review, the Health and Policy Committee found that the broad policy positions of the paper are appropriate statements of College policy.)

1. ACP-ASIM supports adding a prescription drug benefit under Medicare, provided that it is financed in such a way as to bring in sufficient revenue to support the costs of the program, both short and long-term, without further threatening the solvency of the Medicare program or requiring cuts in payments for other services or reduced benefits in other areas. Given the anticipated high cost of a prescription drug benefit, Congress must assure that revenues for financing the benefit do not depend on overly optimistic assumptions about tax revenues resulting from growth in the economy or under-estimates of the costs of the benefit. A predictable and stable source of financing, which will assure that revenues keep pace with the costs of the benefit without requiring cuts in other benefits, should be identified. If it turns out that costs in future years exceed anticipated revenues, Congress will need to consider making adjustments in the benefit and/or financing mechanism to assure that prescription drug coverage can be sustained without requiring cuts in other benefits.

2. ACP-ASIM believes that the highest priority should go toward providing prescription drug benefits for those most in need: low income beneficiaries who do not have access to drug coverage under other plans. This could be accomplished by varying cost-sharing and premium contribution requirements by income, thereby requiring that lower income beneficiaries pay less for prescription drug coverage. For instance, cost-sharing requirements (deductibles and/or co-payments) could be waived or reduced for low-income beneficiaries. Premium contributions could vary by income, or if a flat premium is charged to all beneficiaries, premium assistance could be provided to lower-income beneficiaries.

3. ACP-ASIM strongly prefers that the Government not require the use of formularies for covered prescription drugs. If a formulary is required, it should operate in a way consistent with ACP-ASIM policies on drug formularies.

4. 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.

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

6. 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.

7. Issues of generic and therapeutic substitution under the Medicare program should be addressed in a way that is consistent with existing ACP-ASIM policies on those issues. [BoR 7-99]

Methadone Regulation
The American College of Physicians - American Society of Internal Medicine (ACP-ASIM), recommends that Methadone be considered no differently than any other DEA Schedule II agent. [BoR 4-99]

Post-Marketing Surveillance and Drug Safety
ACP—ASIM adopted the Council of Medical Societies resolution, pending the Finance Committee’s review of a financial impact statement:

“Be it resolved that the American Society for Clinical Pharmacology and Therapeutics (ASCP) and the ACP—ASIM support the allocation of increased federal funding for the drug safety programs of the Food
and Drug Administration (FDA). ASCPT and ACP—ASIM further resolve to establish a joint working group on drug safety with the charge to update the recommendation of the 1980 Commission and develop a plan for their implementation.” (CMS Resolution, American Society of Clinical Pharmacology, ACP 1998)

**Recruitment for FDA Positions**

ACP—ASIM adopted the Council of Medical Societies resolution:

“As the Food and Drug Administration (FDA) fills these and all other positions of leadership, Be It Resolved that the American Society of Clinical Pharmacology and Therapeutics (ASCPT) and the ACP—ASIM encourage the FDA to utilize national search committees and include some members external to the agency. ASCPT and ACP—ASIM further resolve to encourage FDA to consider clinical pharmacologists who have expertise in drug safety as desirable candidates for one or more of the newly created positions.” (CMS Resolution, American Society of Clinical Pharmacology, ACP 1998)

**FDA Regulation of Drugs and Medical Devices**

ACP—ASIM opposes any efforts to weaken FDA authority to demand rigorous evaluations of drugs and medical devices for both safety and effectiveness based on sound scientific and medical evidence and opposes legislative attempts to curtail FDA authority to establish and maintain standards of safety and effectiveness for approval of drugs and medical devices. (ACP AMA Del A-95)

**Removal of Drugs by the Food and Drug Administration (FDA)**

ACP—ASIM recommends that the FDA inform the medical profession of the evidence for the need to withdraw drugs of long standing use prior to implementation of such an order and there shall be opportunity and time for a response by the medical profession except in instances of immediate threat to life and well being. Consideration should be given to the experiences, views and opinions of physicians in the clinical practice of medicine before condemning or removing drugs from the market. (HoD 71; revised HoD 73; reaffirmed HoD 87)

**Statement of the American Pharmaceutical Association (APA) and ASIM on Prescriptions**

**Introduction**

Historically, the pharmaceutical and medical professions have devoted considerable time and effort to the development and rational utilization of safe and effective drugs for the treatment and prevention of illness. Today, that successful effort continues, helping to achieve the highest standards of health in the world for the American people. But in order to gain maximum benefit from the use of drugs while minimizing their adverse side effects, prescribers and pharmacists must maintain effective communications not only among themselves, but with their patients as well. The directions for drug use and other information which prescribers indicate on prescription orders and which pharmacists transfer to prescription labels are critical to safe and effective drug therapy. In order to assure that this information is conveyed clearly and effectively to patients, the following guidelines have been developed by the APA and ASIM.

**Guidelines for Prescribers**

The following guidelines are recommended for prescribers when writing directions for drug use on their prescription orders: The name and strength of the drug dispensed will be recorded on the prescription label by the pharmacist unless otherwise directed by the prescriber. Whenever possible, specific times of the day for drug administration should be indicated. (For example, "Take one capsule at 8:00 am, 12:00 noon, and 8:00 pm" is preferable to "Take one capsule three times daily." Likewise, "Take one tablet two hours after meals" is preferable to "Take one tablet after meals.") The use of potentially confusing abbreviations, i.e., qid, qod, qd, etc., is discouraged. Vague instructions such as, "Take as necessary," or, "Take as directed," which may be confusing to the patient, are to be avoided. If dosing at specific intervals around-the-clock is therapeutically important, this should specifically be stated on the prescription by indicating appropriate times for drug administration. The symptom, indication or intended effect for which the drug is being used should be included in the instructions whenever possible. (For example, "Take one tablet at 8:00 am and 8:00 pm for high blood pressure," or, "Take one teaspoonful at 8:00 am, 3:00 pm and 6:00 pm for cough.") The metric system of weights and measures should be used. The prescription order should indicate whether or not the prescription should be renewed and, if so, the number
of times or the period of time such renewal is authorized. Statements such as "Refill prn" or "Refill ad lib" are discouraged. Either single or multi-drug prescription forms may be used when appropriately designed, and pursuant to the desires of local medical and pharmaceutical societies. (reaffirmed HoD 87)

When institutional prescription blanks are used, the prescriber should print his or her name, telephone number, and registration number on the prescription blank.

**Guidelines for Pharmacists**

Pharmacists should include the following information on the prescription label: name, address and telephone number of pharmacy; name of prescriber; name, strength and quantity of drug dispensed (unless otherwise directed by the prescriber); directions for use; prescription number; date on which prescription is dispensed; full name of patient; any other information required by law. Instructions to the patient regarding directions for use of medication should be concise and precise, but readily understandable to the patient. Where the pharmacist feels that the prescription order does not meet these criteria, he or she should attempt to clarify the order with the prescriber in order to prevent confusion. Verbal reinforcement and/or clarification on instructions should be given to the patient by the pharmacist when appropriate.

For those dosage forms where confusion may develop as to how the medication is to be administered (for example, oral drops which may be mistakenly instilled in the ear, or suppositories which may be mistakenly administered orally), the pharmacist should clearly indicate the intended route of administration on the prescription label. The pharmacist should include an expiration date on the prescription label when appropriate. Where special storage conditions are required, the pharmacist should indicate appropriate instructions for storage on the prescription label.

**Conclusions**

Communicating effective dosage instructions to patients clearly and succinctly is a responsibility of both the medical and pharmaceutical professions. Recent studies documenting the low order of compliance with prescription instructions indicate that inadequate communication between the medical and pharmaceutical professions and poor comprehension by the public may be causative factors. The APA and ASIM believe that the guidelines as stated above will serve as an initial step toward patients achieving a better understanding of their medication and dosage instructions. The two organizations urge state and local societies representing pharmacists and prescribers to appoint joint committees for the purpose of refining these guidelines further as local desires and conditions warrant. Cooperative efforts between the professions are essential to good patient care and significant progress can be made in other areas by initiating discussions between the two professions concerning common interests and goals. (HoD 74; reaffirmed HoD 87)

**DRUGS: ADVERTISING**

**Direct to Consumer Advertising for Prescription Drugs**

This ACP-ASIM policy statement was prepared in response to the FDA's request for comments on its current procedures regarding direct-to-consumer advertising for prescription drugs. Although the College continues to maintain that the promotion of commercial products does not constitute appropriate patient education about therapeutics, ACP-ASIM recognizes that drug advertising targeted to consumers is now here to stay, and therefore, supports strong regulations and strict guidelines to make such advertising as honest and useful as possible. This paper presents existing policies of the American College of Physicians and the American Society of Internal Medicine and current concerns regarding DTC advertising. It provides a brief history of the FDA and its regulation of prescription drug advertising. It also contains information dealing with current practices and controversies. The pros and cons of DTC advertising are summarized, and ACP-ASIM recommendations for public policy are offered. ACP-ASIM believes that the FDA must impose serious limits on the pharmaceutical industry to ensure that consumers receive complete and non-confusing information. The current retrospective regulatory process used by FDA is much too lenient. It allows drug companies to transmit advertising messages directly to the public before the FDA has had a chance to check the appropriateness of the information. ACP-ASIM supports mandatory pre-release screening of all pharmaceutical advertisements. The College also favors a forum in which physicians and pharmaceutical representatives can work together to create advertisements that inform
patients with clear information about specific medications and that will facilitate discussion of treatment options between patients and physicians. [BoR 10-98]

**DRUGS: LABELING AND PACKAGING**

**Pharmacy Labeling**
In order to reduce patient confusion and the potential for therapeutic errors, ACP—ASIM calls upon pharmacy organizations, mail-order pharmacies, national pharmacies to label prescriptions with both the generic drug name and brand name substituted for. (HoD 93)

**Quality Assurance and Labeling**
ACP—ASIM believes that appropriate action should be taken to ensure that, through federal regulations or laws, all pharmaceutical manufacturers be required to perform effective and meaningful ongoing quality assurance studies of the biologic efficacy and purity of prescription medications they are marketing. (HoD 89)

**DRUGS: PRESCRIBING AND DISPENSING**

**Drug Formularies and Pharmacy Benefit Management**

1. **Drug Formularies**
   a. ACP—ASIM opposes any formulary that may operate to the detriment of patient care, such as those developed primarily to control costs.
   b. Decisions about which drugs are chosen for formulary inclusion should be based upon the drug’s effectiveness, safety, and ease of administration rather than solely based on cost.
   c. Evaluation of physician prescribing patterns (i.e., drug utilization review) should give priority to the effectiveness, and safety and ease of administration of the drugs prescribed rather than solely based on costs.
   d. ACP—ASIM recommends that financial incentive arrangements should be linked to cost-effective practices rather than formulary compliance.
   e. ACP—ASIM opposes financial arrangements that place the physician’s financial interest in conflict with his or her patient’s well-being.
   f. ACP—ASIM recommends that formularies should be constructed so that physicians 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.
   g. ACP—ASIM recommends that a patient information program be instituted by MCOs to make patients aware of formulary utilization and any associated costs such as co-pays.
   h. Patient formulary education should include how the formulary functions, and a discussion of how co-payment and/or deductible requirements may affect their pharmacy benefit.
   i. ACP—ASIM supports prompt prior notification to patients and physicians when formularies are changed or discontinued.
   j. ACP—ASIM recommends such notification be given within a specified time period, not fewer than ninety (90) days prior to change implementation.
   k. Formularies should be approved on a regional basis by a professionally qualified body which includes practicing physicians using that formulary.
ACP—ASIM recommends that Pharmacy &Therapeutic (P&T) Committees be representative of, and have the support of, the medical staffs that will utilize the formulary.

m. ACP—ASIM supports industry moves to develop technology to make formularies more accessible and easier to utilize. ACP—ASIM recommends physician input in designing, and pre-testing of, these technologies.

n. ACP—ASIM supports continued government and industry studies of the impact of formularies on patient care. ACP—ASIM recommends that HCFA develop an annual report-card on the impact of formularies on beneficiaries enrolled in Medicare MCOs.

o. Prescribing patterns should be influenced primarily through educating physicians on safety and efficacy. Cost should be a determinant only when safety and efficacy are equal among specific drug choices.

II. Pharmacy Benefit Management

a. ACP—ASIM supports government regulation and industry self-regulation of Pharmacy Benefit Managers (PBMs). ACP—ASIM particularly supports close government oversight of mergers between PBMs and pharmaceutical manufacturers.

b. ACP—ASIM supports the disclosure to patients, physicians, and insurers of the financial relationships between PBMs, companies, pharmacists, and pharmaceutical manufacturers.

c. ACP—ASIM supports requiring that PBM organizations’ requests 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 MCOs/MBHOs’ P & T Committees.

d. ACP—ASIM supports requiring that, with a patient’s consent, PBM organizations be required to provide treating physicians with all available information about the patient’s medication history. [BoR 4-00]

Internet Prescribing

The ACP-ASIM advocates that a direct physician patient relationship remain inviolate and that the use of the Internet for prescribing should facilitate, not circumvent that relationship, and that Internet prescribing should be used only in the context of an established physician-patient relationship. [BoR 10-99]

Misuse of DEA Numbers

ACP—ASIM, in order to protect confidentiality and minimize administrative burdens on physicians, supports the AMA policy to eliminate requirements by pharmacies, prescription services and insurance plans to include physicians’ DEA numbers on prescriptions written for non-controlled drugs. (HoD 95)

Mail Order Pharmacy Confidentiality

ACP—ASIM opposes the use of confidential prescribing data by third parties to directly contact patients for any purposes. (HoD 93)

Proper Use of Accepted Drugs

ACP—ASIM believes that physicians in clinical practice are best suited to determine the proper usage of accepted drugs, and professional judgment should not be restricted by legislative or administrative fiat. Physicians should be permitted to use already approved drugs in any manner consistent with prudent medical judgment. (HoD 78; revised HoD 89)

Physician Drug Dispensing

ACP—ASIM believes that patients should be informed that they have the right to have their prescription filled at a pharmacy of their choice. However, physicians should have the option to dispense medication in their offices, especially when it is to the medical or economic advantage of their patients. Under no circumstances should physicians who dispense medication place their own financial interest above the welfare of their patients. (HoD 87)
**DRUGS: SUBSTITUTION**

**Use of "A" Rated Generic Drugs**
ACP—ASIM will petition the FDA or other appropriate agency to develop 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 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. (HoD 94)

**Drug Product Selection and/or Substitution**
ACP—ASIM opposes therapeutic substitution in an outpatient setting without the prescribing physician’s consent. ACP—ASIM physicians should prescribe generically when therapeutic equivalency, therapeutic safety and bioavailability are established. Physicians should carefully consider the advice of the pharmacist and use his or her knowledge and experience regarding selection of drug product alternatives that could result in cost savings to the patient. When therapeutic equivalency and bioavailability of alternative generic drug products are assured, then the privilege of drug product selection may be delegated to the pharmacist. Any generic drug product selected by the pharmacist must be therapeutically equivalent and bioavailable and should result in cost savings to the patient. The physician, at his or her discretion, must at all times have the authority to specify in some simple manner the source of the drug product to be dispensed. (HoD 79; HoD 88; revised HoD 93)

**Generic Drug Prescriptions**
ACP—ASIM believes that the Food and Drug Administration and other state regulatory agencies should require that generic drugs be held to the same standards as the trade name drug. (HoD 90)