

1 **Appendix B—ASHP Statement on the Pharmacy**
 2 **and Therapeutics Committee and the Formulary**
 3 **System**

4 **Position**

5 The American Society of Health-System Pharmacists (ASHP) be-
 6 lieves that health systems should develop, organize, and administer a
 7 formulary system that follows the principles set forth below in order
 8 to optimize patient care by ensuring access to clinically appropriate,
 9 safe, and cost-effective medications.

10 **Background**

11 A *formulary* is a continually updated list of medications and related
 12 information, representing the clinical judgment of pharmacists,
 13 physicians, and other experts in the diagnosis and/or treatment of
 14 disease and promotion of health.¹ A formulary includes, but is not
 15 limited to, a list of medications and medication-associated products
 16 or devices, medication use policies, important ancillary drug infor-
 17 mation, decision support tools, and organizational guidelines. The
 18 multiplicity of medications available, the complexities surrounding
 19 their safe and effective use, and differences in their relative value
 20 make it necessary for health systems to have medication-use poli-
 21 cies that promote rational, evidence-based, clinically appropriate,
 22 safe, and cost-effective medication therapy. The *formulary system*
 23 is the ongoing process through which a health care organization
 24 establishes policies on the use of drugs, therapies, and drug-related
 25 products and identifies those that are most medically appropriate
 26 and cost-effective to best serve the health interests of a given patient
 27 population.

28 **Pharmacy and Therapeutics Committee**

29 To be effective, medication-use policies must have the concurrence
 30 of those involved in the medication-use process. Such consensus is
 31 achieved by developing those policies through a properly organized
 32 and representative pharmacy and therapeutics (P&T) committee or
 33 equivalent body (hereinafter, “the P&T committee”) and ensuring
 34 the approval of those policies by the organized medical staff.

35 The P&T committee is composed of actively participating physi-
 36 cians, other prescribers, pharmacists, nurses, administrators, quality
 37 improvement managers, and other health care professionals and staff
 38 who participate in the medication-use process. Customarily, P&T
 39 member appointments are based on guidance from the medical staff.
 40 The P&T committee should serve in an evaluative, educational, and
 41 advisory capacity to the medical staff and organizational administra-
 42 tion in all matters pertaining to the use of medications (including
 43 investigational medications). The P&T committee is a policy-recom-
 44 mending body to the medical staff and the administration of the
 45 organization on matters related to the safe and therapeutic use of
 46 medications. The P&T committee is responsible to the medical staff
 47 as a whole, and its recommendations are subject to approval by the
 48 organized medical staff as well as the administrative approval process.
 49 The basic policies and procedures governing the P&T committee’s
 50 administration of the formulary system should be incorporated in
 51 the health system’s medical staff bylaws, medical staff rules and
 52 regulations, and other organizational policies as appropriate.

53 The overarching purposes of the P&T committee are policy
 54 development, communication and education, and formulary
 55 management.

56 **Policy Development**

57 The P&T committee formulates policies regarding evaluation,
 58 selection, diagnostic and therapeutic use, and monitoring of medi-
 59 cations and medication-associated products and devices. The P&T
 60 committee should establish and assist in programs and procedures
 61 that ensure safe and effective medication therapy (e.g., clinical care
 62 plans, treatment guidelines, critical pathways, disease management
 63 protocols). Members of the P&T committee, or their representatives
 64 from appropriate specialties (including pharmacists), should partici-
 65 pate in or direct the development and review of such programs or
 66 procedures, which should be kept current.

67 The P&T committee should participate in performance improve-
 68 ment activities related to procurement, prescribing, dispensing,

administering, monitoring, and overall use of medications. The P&T
 committee should advise the institution, including the pharmacy
 department, in the implementation of effective medication distribu-
 tion and control procedures, incorporating technological advances
 when appropriate. The P&T committee should initiate, direct, and
 review the results of medication-use evaluation programs to optimize
 medication use, and routinely monitor outcomes (economic, clinical,
 and humanistic) of formulary decisions. Medication-use evaluation
 should result in performance improvement initiatives to improve
 the medication-use process.

The P&T committee should take actions to prevent, monitor, and
 evaluate adverse drug reactions and medication errors in the health
 care setting, including those occurring with biologics and vaccines.
 Information from these activities should be disseminated to the ap-
 propriate health care personnel for informational and educational
 purposes (e.g., in newsletters, memoranda) and, when appropriate,
 to the Food and Drug Administration (FDA).

The P&T committee should establish clearly defined policies and
 procedures related to manufacturer sales representatives’ activities
 within the organization.

Communication and Education

The P&T committee ensures that mechanisms are in place to
 communicate with health care professionals, patients, and payers
 about all aspects of the formulary system, including changes made
 to the formulary or to policies and how formulary system decisions
 are made. The P&T committee also recommends or assists in the
 formulation of educational programs designed to meet the needs
 of professional staff, patients, families, and caregivers on matters
 related to medications and medication use. The P&T committee
 should establish or plan suitable educational programs on matters
 related to medication use for staff involved in the care of patients
 and the use of medications.

Formulary Management

Health systems should develop, organize, and administer a for-
 mulary system that follows the principles set forth below in order
 to optimize patient care by ensuring access to clinically appropriate,
 safe, and cost-effective medications.

Formulary system. The P&T committee is responsible for ad-
 ministering the formulary system. Although the basic organization
 of each health care setting and its medical staff may influence the
 specific functions and scope of its P&T committee, key elements
 of a formulary system that should be included are evaluation of
 the clinical use of medications (including outcomes), development
 of policies and quality assurance activities for medication use and
 administration, and evaluation and monitoring of adverse drug
 reactions and medication errors. The formulary system shall be
 endorsed by the medical staff based on the recommendations of
 the P&T committee. The medical staff should adapt the principles
 of the system to the needs of the particular organization and affil-
 iated institutions and ambulatory care settings. The organization,
 often through the pharmacy department, should make certain
 that all personnel involved in the care of patients and the use
 of medications in all health-system components are informed
 about the existence of the formulary system, how to access the
 formulary, the procedures governing its operation, any changes in
 those procedures, and other necessary information (e.g., changes
 in drug product availability). This information may be further
 disseminated to other interested entities (e.g., affiliated managed
 care organizations).

Formulary. The P&T committee develops an evidence-based
 formulary of medications and medication-associated products ac-
 cepted for use in the organization, provides for its timely revision
 and maintenance, and promotes the rational, clinically appropriate,
 safe, and cost-effective use of medications via guidelines, protocols,
 and other mechanisms. The P&T committee, on an ongoing basis,
 objectively appraises, evaluates, and selects medications for addi-
 tion to or deletion from the formulary. The formulary is based on
 the best clinical evidence available and reflects the current clinical
 judgment of the medical staff, pharmacists, and other health care
 experts. The selection of items to be included in the formulary

1 should be based on objective evaluation of their relative economic,
 2 clinical, and humanistic outcomes. The decisions should not be
 3 based solely on economic factors. The committee should identify
 4 potential safety concerns for each medication considered for inclu-
 5 sion in the formulary and should ensure those safety concerns are
 6 addressed if the medication is added to the formulary or used in
 7 the health system.

8 The committee should minimize unnecessary duplication of the
 9 same basic drug type, drug entity, or drug product. Optimizing the
 10 number of drug entities and products available from the pharmacy
 11 can produce substantial patient-care and financial benefits. These
 12 benefits are greatly increased through the use of generic equivalents
 13 (drug products considered identical/equivalent by the FDA²) and
 14 therapeutic equivalents (drug products differing in composition or
 15 in their basic drug entity that are considered to have very similar
 16 pharmacologic and therapeutic activities). The P&T committee must
 17 set forth policies and procedures governing the dispensing of generics
 18 and therapeutic equivalents.

19 The P&T committee, when considering formulary options, should
 20 evaluate coordination issues with local health care plans and other
 21 organizations' formularies. At a minimum, appropriateness of thera-
 22 peutic interchange should be evaluated for any formulary decisions
 23 that may conflict with known managed care or other health plan
 24 formularies.

25 The formulary should be published and updated regularly. The
 26 formulary should be readily available and accessible at all times
 27 either manually or electronically to all personnel involved in the
 28 care of patients and the use of medications. Medications should be
 29 identified in the formulary by generic name. Prescribers should be
 30 strongly encouraged to order medications by their generic names.
 31 The P&T committee must set forth policies and procedures governing
 32 the dispensing of generics and therapeutic equivalents.

33 The P&T committee should clearly define terminology related
 34 to formulary status of medications (e.g., formulary, nonformulary,
 35 not stocked at a given site, restricted by criteria specific to a given
 36 site), especially in multihospital organizations, and disseminate this
 37 information to health care professionals involved in the medication-
 38 use process. The P&T committee should establish a procedure for

appraisal and use by the medical staff of medications not included 39
 in the formulary (i.e., nonformulary medication use). 40

The pharmacist shall be responsible for specifications for the 41
 quality, quantity, and source of supply of all medications, chemicals, 42
 biologicals, and pharmaceutical preparations used in the diagnosis 43
 and treatment of patients. 44

Conclusion 45

ASHP believes that medication-use policies should be developed and 46
 implemented in organized health care systems to promote the rational, 47
 evidence-based, clinically appropriate, safe, and cost-effective use of 48
 medications. The P&T committee of health systems should develop, 49
 organize, and administer a formulary system that follows the prin- 50
 ciples set forth in this statement in order to optimize patient care. 51

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 Committee dated November 20, 1991, and the ASHP Statement on 70
 the Formulary System dated November 18, 1982. 71

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