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An Overview

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3 A USER'S GUIDE TO THE DRUG COMPENDIA

An Overview

by David K. King, M.D., F.A.C.P.

New Year's Day 1994 marked a turning point in Medicare payment for off-label drugs used to treat cancer. Beginning January 1, 1994, citation in any one of the three compendia assures that Medicare must pay for a chemotherapy or biological agent for that indication. Passage of the law was hailed as a great victory for cancer patients, bringing much needed uniformity to the care they can receive throughout the nation.

In passing the law, Congress joined California, Georgia, Illinois, Indiana, Massachusetts, Michigan, New Jersey, New York, North Carolina, and Oklahoma, which had passed versions of the uniform model legislation on off-label use developed by the Association of Community Centers (ACCC). Recently, Alabama, Connecticut, Maryland, Ohio, Rhode Island, and Virginia were added to the list of states passing similar legislation.

Passage of this federal law, however, will not directly affect local insurers. That is why ACCC will continue to press for passage of this legislation at the state level to help eliminate unnecessary and arbitrary calls by some state regulated insurance carriers.

The passage of state and federal laws requiring the use of the three compendia has focused attention on how drugs come to be included in these publications. To better understand the three drug compendia, *Oncology Issues* asked representatives from the U.S. Pharmacopeia, the American Medical Association, and the American Society of Hospital Pharmacists to explain the history, objectives, and contents of their publications.

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A Guide to the U.S. Pharmacopeia and the USP DI

by Keith W. Johnson

The basic mission of the United States Pharmacopeia (USP) when it was founded in 1820, was to establish standards (or, at that time, recipes or formulas) for drug preparations in the United States. This standards-setting process continues today; manufacturers must meet the standards specified in the USP and the National Formulary (NF)–standards that are legally enforceable by the Food and Drug Administration (FDA) by Congressional mandate. The USP and NF are recognized by federal and state laws, as well as by many foreign countries, as the primary sources of industry standards. In meeting the needs for public standards, USP continuously reviews and revises existing standards to account for new data and technology, and develops standards for new products, including genetic and biotechnology products, such as interferons.

Eligible organizations that may appoint delegates to the quinquennial meeting of the USP Convention (the next one will be in March 1995) include the U.S. Colleges of Pharmacy and Medicine; state pharmaceutical associations and medical associations; national professional and scientific organizations, such as the American Medical Association (AMA) and the American Hospital Association; and federal agencies, such as the FDA, the Public Health Service, and the Department of Health and Human Services. In addition, there are positions for consumer and international representatives, as well as a small percentage of at-large members who are appointed because of their special knowledge and expertise. It is anticipated that delegates to the 1995 Convention will consider expanding the delegate pool to better reflect drug standards and drug information issues and needs as they exist today.

The USP, however, is a public interest group; it does not represent industry, medicine, pharmacy, or any other special interest group. It represents the public in its need for unbiased standards of drug quality and information.

The database reflecting USP's drug information activities was initiated in 1977. After three years of development, the first edition of *USP Dispensing Information (USP DI)* was published (1980). The information is under constant review. The official and most up-to-date *USP DI* information is in fact that found in the electronic database maintained at USP headquarters. New information is added to this database daily and is the basis for print and electronic applications provided by USP itself and by

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