On October 30, 1991, tremendous hurricane forces converged in what the National Weather Service labeled the “perfect storm,” causing significant damage to parts of the U.S. Today we are witnessing the confluence of major factors involving U.S. senior citizens and their medications, which may represent another type of perfect storm. These factors include the increasing number and age of our older adults and the anticipated $400 billion+ Medicare pharmacy benefit. Whatever the result, one fact is sure to be true—we will see an expanding role for pharmacy and therapeutics (P&T) committees in long-term care.

We have seen P&T committees grow beyond the exclusive property of hospitals and expand upon their role of just a few decades ago. Many P&T committees and their members have moved from hospitals to health maintenance organizations (HMOs) and to other health care associations. These organizations include many in the long-term care field, such as skilled nursing facilities and some nursing-home facilities that suddenly find themselves responsible for the cost of pharmaceuticals. In addition, the movement to extend Medicare benefits to include outpatient pharmaceuticals, while making pharmacy benefit managers (PBMs) and other organizations liable for an additional $40 billion per year in pharmaceutical expenses, will have a major impact on P&T committees and their members.

THE DEMOGRAPHICS OF AGING

Between 2010 and 2030, a growth spurt in the number of senior citizens is expected because the first wave of the “baby-boomers” will reach age 65. By 2030, the total number of persons aged 65 and older will reach 70 million. Meanwhile, as the elderly population grows by 75% during this period, the under-65 population is expected to increase by only 7%. The fastest-growing segment of the elderly population is, and will continue to be, the over-85 population. By 2050, nearly 25% of all elderly people will be over age 85, and at least one in 13 Americans will be 80 years of age or older. This change will not only have major implications for the quantity of medications utilized but, because of the physiology of aging, will also require careful monitoring to prevent adverse drug reactions (ADRs) caused by polypharmacy (the regular daily consumption of multiple medications as well as the use of high-risk medications and inappropriate dosing) and other factors.

By 2030, it is expected that approximately 14 million older adults will require some type of long-term care. Of those 14 million people, just over five million will reside in nursing homes and the remaining nine million will receive alternative forms of long-term care.

“Long-term care” is not the same as “nursing-home care”; it encompasses a wide variety of care environments that can offer improved outcomes and may use fewer resources, compared with traditional nursing-home care. With an increased demand from both consumers and payers for higher quality at reduced costs, we have—and will continue to see—a stimulated growth of long-term care facilities that are alternatives to nursing homes. Long-term care is simply and most appropriately defined as care that is provided for an extended period of time. These services can be provided in a range of settings outside of the nursing-home environment.

The spectrum of long-term care can be visualized as follows:

- hospital-based nursing facilities
- subacute care
- nursing facilities
- psychiatric hospitals
- intermediate-care facilities for mentally retarded populations
- community-based care
- adult congregate living
- adult day services
- home health care
- community mental health centers
- hospice care
- “senior centers”
- retirement housing
- independent community living

Several challenges are involved in caring for the elderly. First, older adults are at an increased risk of experiencing problems with drug therapy, including ADRs and drug interactions, poor compliance, and medication errors. In fact, in 1995, Jerry H. Gurwitz, MD, made a statement that is still true today: “Any symptom in an elderly patient should be considered a drug side effect until proved otherwise.”

In addition, the physiology of older adults is such that changes in the kidneys, liver, and other organs influence the pharmacokinetic and pharmacodynamic properties of many medications and may affect the efficacy or toxicity of drug therapy.

As one might imagine, besides the obvious financial pressures to optimize medication management, the need for quality clinical outcomes places additional pressures on providers.
As a result of the landmark Institute of Medicine report in 1986 that highlighted the problem of quality and that recommended stronger federal regulations, Congress passed the Nursing Home Reform Act as part of the Omnibus Budget Reconciliation Act (OBRA) of 1987. A large portion of OBRA 1987 was related to drug therapy, including limits on chemical restraints, limits on other unnecessary or harmful drug use, efforts to discourage polypharmacy, mandated drug regimen reviews by consultant pharmacists, and initiatives to disseminate geriatric best-practice information to medical providers. The result was the most far-reaching revision to the standards, the inspection process, and the enforcement system since the passage of Medicare and Medicaid in the mid-1960s. The new standards address the process of care that is expected and the requirement that care will promote “the maximum practicable functioning” for each individual resident.

A constant theme in these reports is that polypharmacy is a known significant risk factor for ADRs, failed patient compliance, and increased health care costs. Several studies have documented the significance of the problems associated with polypharmacy as well as the tie between iatrogenic events that account for a large number of emergency-room visits, hospital admissions, and nursing-home placements. In nursing homes, two studies reported an incidence of ADRs of 0.44 to 0.71 per patient-month. Because of these issues, the need for optimizing medication management has gained much attention.

In an effort to extend regulations to optimize medication management, the U.S. Department of Health and Human Services (DHHS) incorporated the recommendations of Beers and his colleagues, who published a list of medications that are harmful to the elderly. In the 1991 paper, they used a thorough literature review to develop a survey of statements or guidelines on the inappropriate use of medications. The statements were of two general types:

- Medications or medication classes that should be avoided because they are ineffective or pose an unnecessarily high risk for frail, elderly adults.
- Special limits for the frail elderly in terms of the doses, dosing frequencies, or durations of therapy with certain medications.

In the 1997 update, Beers reported on a panel of six experts who rated the earlier criteria following a group discussion. These standards, which are widely accepted as appropriate for geriatric medication use, are referred to as the Beers Criteria. Despite these regulations, research suggests an opportunity for improvement if P&T committees and their members actively participate in the process of care planning and implementation. A study funded by the Agency for Healthcare Research and Quality (AHRQ) observed that approximately 50% of nursing-home residents had at least one potentially inappropriate medication prescription, according to the Beers criteria. P&T committees can play an active role by excluding these drugs or by forcing a structured process for prescribing to ensure the appropriate use of medications, such as those described in the Beers Criteria. Several Veterans Administration studies have reinforced these findings.

In order to demonstrate the importance of pharmacist involvement in this process, the Congress and the Senate have each passed bills establishing a Medication Therapy Management Assessment Program, which moves some of the same control utilized in managed care programs to the fee-for-service beneficiaries. This plan provides for the Secretary of DHHS to contract with qualified pharmacists for medication therapy management services for traditional fee-for-service Medicare beneficiaries. A beneficiary identifies a qualified pharmacist to whom the Secretary pays a fee under different payment methodologies to be tested. These services are intended to encourage compliance with medication regimens, to ensure that drugs are used appropriately, and to reduce adverse events. Beneficiaries may participate if they have asthma, diabetes, chronic cardiovascular disease, or other diseases specified by the Secretary. This is an example of the movement to increase the utilization of P&T committee members in expanded areas of practice.

Yet another example of the increased use of P&T committees is outlined in the Senate Medicare Pharmacy Benefit legislation that was passed in late June 2003. Included in the Senate bill are the following provisions:

- Prescription drug card sponsors must establish a P&T committee to develop and review their formulary. This committee shall include at least one academic expert, one practicing physician, and one pharmacist, all with expertise in care of the elderly or disabled. Most of the committee members shall be practicing physicians or pharmacists.
- Formulary decisions shall be based on strength of scientific evidence and standards of practice, including assessment of peer-reviewed medical literature, randomized clinical trials, pharmacoeconomic studies, outcomes research data, and “such other information as the committee determines to be appropriate.”
- P&T committees shall establish policies and procedures to educate providers about the formulary.

THE EXPANSION OF MEDICARE PHARMACY BENEFITS

In late June 2003, the House and Senate passed separate bills addressing the longstanding void that has existed since Medicare’s inception in the 1960s regarding the provision of outpatient medications. Although the bills differed, some major features are the same; only the exact amount and percentage of coverage must be worked out in committee.

The plans would pay for 50% to 80% of drug costs after enrollees pay a deductible of $250 to $275. After a total of $2,000 to $4,500 has been spent for medications, enrollees would pay for all prescription drugs until they reached the “true” out-of-pocket maximum of $3,500 to $3,700, referred to as the “donut hole”—the void in coverage at which point enrollees must pay 100% of the pharmacy costs. After this point has been reached, the plan would cover 90% to 100% of expenses.

The prescription drug cost-sharing and premiums are reduced or eliminated for certain low-income beneficiaries. Depending on the premiums and cost-sharing, the break-even...
point (the point at which the amount that enrollees pay for in
cost-sharing and premiums is equal to what they would have
paid without any drug coverage) is between $775 and $1,155
in total annual drug spending for beneficiaries who do not
meet the low-income assistance levels.

In addition to these cost-sharing and coverage levels, each
bill provides for this benefit to be managed by private PBMs
that use formularies and other utilization-management tools to
control costs and optimize outcomes. This $40 billion-a-year
program has tremendous implications not only for the bene-
ficiaries but also for those plans and professionals that choose
to manage this risk.

**SHIFTING OF RESPONSIBILITY FOR MEDICA-
TION COVERAGE TO OTHER ORGANIZATIONS**

**Prospective Payment System**

A similar paradigm shift occurred in skilled nursing facil-
ities on July 1, 1998. These facilities, delivering Medicare-
reimbursed post-acute services, began operating under a
**prospective payment system (PPS)** using the **Resource Utilization
Group** (RUG-III) to calculate payments. This was a major
change for those facilities that had previously been paid on the
basis of “average costs” and that had not been responsible for
medication costs. Under the new system, each resident falls
into one of 44 specified RUGs with a prospectively calculated
reimbursement. With this shift, one problem is that although
nursing-home operators are held accountable for pharma-
cutical costs, they are not directly responsible for prescribing
these medications; however, they can assist in the process
through their P&T committees.31

Skilled nursing facility providers have responded to the PPS
in several ways. The Office of Inspector General (OIG)32–34 has
found that skilled nursing facilities have:

1. increased scrutiny of patients’ health status related to
   admissions.
2. placed renewed emphasis on utilization management after
   patients have been admitted.
3. developed preferential admissions policies for patients
   for whom they believe the PPS rate is adequate or better.
4. improved internal utilization monitoring and documen-
tation processes.

In a study on optimizing medication use in skilled nursing
facilities, we concluded that such optimization was possible
only by establishing formulary drugs, algorithms, and elimi-
nating inappropriate drugs as effective strategies.31 This focus
is possible only with the active participation of P&T com-
mittees.

**New York State Medicaid Nursing-Home Program**

Besides the major shift in financial responsibility of the
Medicare pharmacy benefit from older adults to PBMs and
others, additional movements promise to continue this trend
and to transfer the financial burden from the government and
other payers to provider groups. For example, in all states
except New York, the financial risk for medications belongs to
the state Medicaid program. New York is the first state to shift
this risk to the nursing facility for Medicaid residents in a
manner similar to the way in which the federal government,
through Medicare, has shifted financial responsibility to skilled
nursing facilities. In New York, most drugs are lumped into the
Medicaid daily rate for the nursing facility. As a result, the nurs-
ing-facility provider is liable for the Medicaid residents’ med-
ication costs. Medicaid typically reimburses institutional phar-
armacy providers according to the average wholesale price
(AWP) plus a dispensing fee. As a result of this payment sys-
tem, all states (except New York) find that their nursing facil-
ities have no economic incentive to control drug usage; in
fact, pharmacy providers benefit when a greater number of
medications are prescribed. New York nursing facilities are
forced to rely heavily on their P&T committees to optimize
their medication management.

**PACE**

One important initiative—because of the tremendous
acceptance it is acquiring at the Centers for Medicare and
Medicaid Services (CMS)—is the **Program of All-inclusive
Care for the Elderly** (PACE). PACE is based on the belief that
it is better for the well-being of older people with chronic care
needs and their families to be cared for in the community
whenever possible. PACE serves individuals who are 55 or
older and who are certified by their state as needing nursing-
home care, as being able to live safely in the community at the
time of enrollment, and as being able to live in an area served
by PACE. When a PACE participant needs nursing-home care,
the program pays for it and continues to coordinate care. Only
7% of PACE participants reside in nursing homes annually.

PACE receives a lump payment from Medicare and Medi-
caid for delivering all needed medical and supportive services.
Outcomes from these programs have been positive in con-
sumer satisfaction, reduced institutional care, controlled use
of medical services, and cost savings to public and private
payers of care, including Medicare and Medicaid.35,36 These
positive outcomes are the direct result of the active participa-
tion of pharmacists as part of the interdisciplinary team. One
study that examined PACE concluded that consultant
pharmacists can ensure that appropriate medication changes
are made.37

**INCREASED RESPONSIBILITIES FOR P&T
COMMITTEES**

Bootman and colleagues estimated that pharmacy review
might save $3.6 billion each year for nursing-home patients
and noted the importance of active pharmacy review.38 Although
pharmacy consultants play a vital role in this process, there is
concern about the pressure to produce positive financial
results. In a position paper, the American Society of Consultant
Pharmacists stated its belief that the PPS system promotes
dramatic alterations in drug utilization and drug choice, and
because these are not currently tied to outcomes, no safe-
guards exist to prevent inappropriate medication usage.39
Despite this belief, clinical pharmacists who provide pharma-

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**P&T Committees and Long-Term Care**

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P&T Committees and Long-Term Care

cutical care for elderly primary care patients can reduce inappropriate prescribing, and possibly ADRs, without negatively affecting health-related quality of life.10 The result of the changing demographics and the expansion of pharmacy benefits can produce either the perfect storm or an opportunity to improve health outcomes for elderly adults; either way, the role of P&T committees and their members will continue to grow. Perhaps, in this expanded role, P&T committees will do what they do best—optimize the result for all parties through active team involvement.

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