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Managed Care Cautiously Embraces Complementary Medicine

From acupressure to acupuncture, consumers are leading managed care plans to test the waters of alternative health practices.

Harvard University professor David Eisenberg, in an often-quoted study, “Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use” in The New England Journal of Medicine, estimates that as many as one third of Americans use unconventional therapies.

Alternative therapies include a full range of practices—from acupuncture, herbal medicine, homeopathy, massage therapy, naturopathy, to nutritional counseling and tai chi—to name a few. Many therapies are called unconventional because they consider illness in the body as a whole rather than limited to a specific disease or symptom, says Edward H. Chapman, M.D., D.Ht., FAAFP, a homeopathic physician and president of the American Institute on Homeopathy, based in Denver, Colorado.

Continued on page 631 ▲
Today, in part because of Eisenberg's study and increased demand among health plan members, managed care organizations (MCOs), and other insurers are exploring the use of alternative therapies, and are seeking protocols to ensure their quality and cost-effectiveness for including them as a member benefit. Health plans often refer to such therapies as complementary medicine, as they generally view such practices as complementing traditional medicine.

**CONSUMER INTEREST SPURS EFFECTIVENESS EFFORTS**

Allina Health Systems, an integrated health care system based in Minneapolis, is exploring and using various complementary therapies among its 19 hospitals, seven nursing homes, 65 clinics, 9,000 staff and contract physicians, and at Medica Health Plans, its HMO serving 950,000 members.

Physicians in some of Allina’s tertiary care hospitals already use or perform acupuncture for chronic pain, says Foster North, division vice president of the company’s Diversified Services. The system's mental health centers use dance and music therapy; acupuncture is performed at one of the pain centers, and Medica Health Plans offer interested employers a network of credentialed chiropractors in benefit options. Medica members can either self-refer to providers in the chiropractic network or, if they are in the plan's point-of-service plan, they can pay extra to self-refer to a chiropractor not in the plan's network.

Soon, Allina Medical Group clinics will offer acupuncture, says North. Acupuncture has already been performed by some of the clinicians in the pain center, but these services have not been reimbursed.

By the end of this year, North and colleagues in Allina’s other operating units will have developed a long-term strategy for assessing these and other complementary therapies. The first step is to conduct a literature search to help determine what therapies are appropriate for given populations. Another effort is aimed at assessing how to organize alternative therapies under one roof, so that, certain functions, for example, provider credentialing, is centralized. The strategy will also help the health system tailor services to meet the needs of an increasingly ethnically diverse membership. The health plan has a growing number of individuals from Hispanic, Asian, and African-American communities, many of whom turn to alternative therapies periodically.

The strategic effort began as more Allina customers were demanding access to or coverage of alternative therapies. "[Consumers] told us they would like complementary medicine to be integrated into the medical delivery system," says North. Some approaches hold promise, he adds, citing chiropractic for low back pain as an example. Not only have people found relief through chiropractic services, but the medical literature supports the efficacy of chiropractic for low back pain and other kinds of conditions, he says.

**SEEKING THE QUALITY FIT**

Like Allina, Group Health Cooperative, a 500,000-member HMO in Seattle, is responding to consumer interest in alternative therapies, and is exploring how to include such therapies, where appropriate, into existing disease management or clinical pathways.

The health plan offers coverage for a number of services under certain conditions, including acupuncture, chiropractic, homeopathy, home births, manipulative therapy, soft-tissue therapy (massage), naturopathy, and podiatry (see sidebar). Of these, acupuncture, massage, and naturopathy are new therapies for Group Health Cooperative, because of a new state law enacted the first of this year that requires health plans to offer these and other benefits to all new and renewing enrollees in 1996.

Before the law, Group Health Cooperative already offered chiropractic and podiatry, and was studying the effectiveness of home birth as a benefit, says Barb Wolters-Johnson, R.N., alternative care coordinator at Group Health. The new law allows health plans to create standards to manage the cost and quality of care. Group Health has responded in several ways:

- By attempting to include such therapies in its current guidelines for assessing clinical effectiveness
- By contracting with Alternare, a Seattle-based network management firm that contracts with alternative providers.

**Group Health Cooperative Coverage of New State Mandated Therapies**

- **Manipulative therapy**: Members can self-refer for up to 10 spinal manipulation visits with chiropractors or other specialists in the HMO's network.
- **Soft-tissue therapy (massage)**: Is only covered for medically necessary cases. Palliative or sedative massage is not covered. Physician and/or physical therapist evaluation and referral required.
- **Acupuncture**: Efficacy still difficult to confirm. Provided through Group Health's sponsored clinical trials, with coverage in accordance with each patient's coverage agreement.
- **Naturopathy**: Efficacy is difficult to confirm. Group Health has asked a panel of naturopaths to join its clinical-planning efforts to identify services that demonstrate value and may be offered as covered benefits.
- **Podiatry**: Physician referral required after March 1, 1996. All patients must meet Medicare Eligibility Protocol for coverage. Special conditions apply for diabetic patients.
- **Home births**: Members can choose from a network of licensed midwives.

---Source: Group Health Cooperative, 1996---
and provides credentialing services. By requiring that all alternative providers submit treatment plans and progress summaries on patients, the plan's clinical director works with alternative providers, translating for the primary care physicians what the alternative approach means in the managed care setting.

In terms of clinical assessment, Group Health has a list of 13 clinical conditions and diagnoses by which it assesses all therapies. Working with its in-house dually skilled providers (some of the plan's physician assistants are also licensed naturopathic physicians and some physicians are trained in acupuncture) and expert out-of-house alternative providers, the plan established a list of conditions that alternative providers would treat and for which there would be measurable outcomes, such as asthma and diabetes. However, this is not always a clear cut effort. "What we found is that in the world of alternative medicine there aren't standards like clinical pathways and outcome efforts that exist for western medicine," says Wolters-Johnson.

In light of these challenges, Group Health carries out this process. The member's primary care provider verifies a diagnosis, the plan checks the diagnosis against the list of clinical conditions and diagnoses, and refers the patient to a network provider with whom Group Health has a contract. For example, pregnant members who want to give birth at home must have a low-risk pregnancy and the required laboratory tests must be routine. The plan contracts with nurse midwives who work with the HMO's obstetrics and gynecology physicians and staff, and contracts with an ambulance service.

In 1994, Blue Cross of Washington and Alaska created a one-year pilot program in the Seattle area called Alternapath, designed to offer a range of alternative therapies to assess the market among members in Health Plus, its HMO, Blue Choice, its point-of-service (POS) product, and indemnity plans. Enrollees had access to naturopaths, homeopaths (some of whom were practicing physicians), and acupuncture, the availability of which was promoted in part by health plan providers. Blue Cross covered 80% of eligible charges in the benefit plan up to a $1,000 cap, or until a person had been in the plan for 12 months.

According to Richard Winner, Blue Cross vice president of marketing, health care services, the plan exceeded the company's expectations. The 1,000-person enrollment limit was reached within three or four months and most people stayed in the plan for the full 12 months. Moreover, the plan spent three and a half times its usual amount in health care claims.

Winner notes, however, that the findings are skewed in part because many people who were already seeing an alternative provider used this benefit. "The alternative providers tell us that most of their business involves self-referrals of people who have exhausted their resources among conventional health care services. They seek services such as acupuncture or naturopathic medicine to help them with problems such as allergies or low back pain or to deal with their children's chronic ear infections," says Winner. "They're the ones strongly advocating the use of these services and will use them most often."

Now, mostly because of Washington state's new mandate, beginning with renewal dates after January 1, 1996, a range of alternative therapies will be added to renewing employee benefit plans each month.

Under the Blue Cross traditional indemnity plan, enrollees can self-refer to an alternative provider. Under the company's HMO, Health Plus, just as with a medical model, enrollees must go through their primary care physician to be referred to a provider from the contracted alternative network. "The decision was made to treat alternative care providers as if they were medical specialists," Winner adds.

Like Group Health, Blue Cross uses Alternapath to set up a statewide network of alternative providers. Alternare establishes the criteria for including alternative providers, such as appropriate licensing or board certification according to their practice. In many cases, Alternare also helps the providers create-in many cases for the first time-a claims-billing process so that these providers can then bill the payers. Enrollees in the Health Plus point-of-service plan can self-refer, but must pay a higher out-of-pocket fee—typically 30-40% more than in the main HMO plan.

REGULATING AND PRICING THERAPIES

Still, including alternative therapies as part of a medical delivery system has some plans confounded, especially in Washington state, where the law mandates coverage for all alternative therapies. In fact, Blue Cross, Group Health Cooperative, and Kaiser Permanente are three of 11 insurers that have filed a lawsuit against the state to seek clarity about the law. Plan officials expect the complaint to be resolved by year's end, but very little information is currently available on how to interpret the law and to fit alternative providers into a managed care model.

In the meantime, consulting actuaries are studying how to price alternative therapies. Lee Nauera, a partner in the New York office of Coopers & Lybrand, an actuarial consulting firm, is creating a practice focused solely on alternative therapies. One year ago Nauera created a volunteer committee.
of other actuaries through the Society of Actuaries—outside his Coopers practice—to collect data comparing alternative and conventional care therapies.

This summer, Laufer and colleagues began the arduous task of collecting cost, disability, and mortality rate data on alternative care therapies, much of which does not now exist—or at least does not conform to the format of conventional care data. Information on conventional care is extensive and can be reported in many formats. "My goal is to have data just like that for alternative care," he says. "That's a fairly far-reaching ideal scenario." Because challenges remain in getting this information into a comparable format, he says, this work will not be complete for a number of years.

Most insurers say current evidence of various alternative therapies is anecdotal and are hesitant to invest dollars in an alternative care program, Laufer admits. "The committee's goal will be to take alternative therapies out of this anecdotal mode and put it into a factual [framework]," he explains.

Efficacy will remain the biggest challenge add health plan officials, particularly with how to measure therapies that engage a holistic approach in systems designed for disease- or symptom-specific conditions. Clinical pathways should be the same or similar for conditions such as heart surgery, says Allina's North.

**TREND TOWARD ACCEPTANCE**

A less complicated issue will be traditional physicians' acceptance of complementary medicine. "We're seeing more and more acceptance," says North. "There's certainly a natural distribution on how this is accepted." In fact, in plans like Group Health and Allina Health systems, some of the primary physicians perform spinal manipulation.

Certainly, greater acceptance will continue to grow in the traditional medical delivery system, but efficacy and cost-effectiveness will play a greater role in the managed care setting. ■

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Group Health Cooperative

For decades, Group Health Cooperative of Puget Sound has been committed to providing quality, cost-effective care using a population-based, provider team approach. Today, many see the Cooperative as offering a model for how to best coordinate and integrate care for the future.

The concept of using health care provider “teams” to coordinate patient care has been at the heart of Group Health Cooperative of Puget Sound's philosophy for almost 30 years. “We believe that care is delivered best with the whole team,” explains Sherry Shamansky, vice president of nursing, and co-chair of Group Health's Practice Improvement Committee. “Every member of the team becomes an advocate for the patient.”

Group Health’s team philosophy of care and commitment to quality have not gone unnoticed. The Seattle-based not-for-profit HMO is often mentioned in discussions regarding the future direction of health care delivery in the United States. Many prominent policy makers and health care analysts—including Stanford University Economist
Abin Enthoven, who coined the term health-maintenance organization—have cited Group Health as a model for other health care delivery systems to emulate as they move toward integration.

As a consumer-owned cooperative, Group Health has always been dedicated to meeting the needs of its members. The HMO is governed by an elected, 11-member, volunteer, consumer board of trustees who—in conjunction with plan physicians—advise the cooperative on major policy decisions. Perhaps this partnership approach is one reason why Group Health consistently posts one of the highest HMO consumer satisfaction ratings in the country.

In this article, I will discuss some of the ways Group Health is working to build upon and refine further its team approach to delivering quality, cost-effective care—and how it is preparing to continue to meet these challenges as the twenty-first century approaches.

ROAD MAP TO CLINICAL QUALITY

Group Health combines its philosophy of team care with the notion of population-based medicine. Population medicine allows health care provider teams to examine and treat patients not simply as individuals, but in the context of other patients with the same condition—allowing for a more systematic and methodological approach to managing chronic care. If plan data show, for example, that a group of providers has a higher-than-average number of diabetic patients, the team can find ways to create more coordinated and cost-effective ways to address the special needs of that group of patients.

In the early 1990s, Group Health Cooperative began developing a new, system-wide care process called the roadmap for clinical quality. The clinical roadmap outlines care priorities based on which medical conditions among plan enrollees have a substantial cost impact on the plan and adverse effects on patient health. The underlying premise of the program is this: By improving clinical care processes and decreasing unnecessary practice variation, providers can improve patient health outcomes, and overall satisfaction with care. Currently, Group Health uses clinical roadmaps for the following conditions: heart care, diabetes, pregnancy care, tobacco use cessation, depression, asthma, immunizations, breast care, HIV/AIDS, and infusion therapy.

PHARMACISTS: KEY PLAYERS ON THE HEALTH CARE TEAM

Group Health has long recognized that pharmacists have a critical role to play in making sure patients' care is coordinated and enhanced during each step of the care-giving process. Pharmacists regularly work closely with the medical staff to map out the best care options for patients, explains Cindy Adkins, Acting Director of Pharmacy Administration. This approach "allows pharmacists to get in on the front line of the process," she says. Typically, after a patient sees a physician at a Group Health facility and is prescribed medication, the patient is directed to the pharmacist, who counsels the patient right on the spot. Physicians have on-site access to patient pharmacy, medical, and laboratory data. Likewise, pharmacists can retrieve data from physicians to determine which patient populations they are dealing with, and provide physicians with information on the best pharmacy care options for those patients. As pharmacy-dispensing operations at the HMO become more automated, pharmacists are increasingly involved in such care-giving tasks, Adkins observes.

Pharmacist involvement in the patient-care process has long been considered the norm at Group Health, says William Balch, Director of Medication Use Management, who has been involved with the HMO's pharmacy operations for the past 15 years. He recalls one example from a few years ago. When a widely publicized medical study determined that women on high-dose estrogens were at higher risk of developing cardiovascular illness, pharmacists involved themselves in an intervention...
PHARMACY: BALANCING QUALITY AND COSTS

Group Health has always prided itself on the quality of its pharmacy services. The HMO has long had a well-established and well-organized pharmacy and therapeutics committee that makes recommendations on which drugs to include on the formulary. It also issues prescribing guidelines for physicians to promote good patient outcomes, says Baluch.

The HMO also has had to rein in rising drug costs. About nine years ago, Group Health implemented a plan to promote rapid conversion to generic alternative therapies when appropriate. The HMO created a drug product committee, separate from the P & T committee, to work with manufacturers to get generics on the shelves as early as possible. Pharmacists helped draft memos and other educational materials for physicians and patients—encouraging physicians to use generics when appropriate, and telling patients what to expect when they switch to generic alternatives (such as whether their tablets would be a different shape or color). “Whenever we switched to a generic drug, we typically would save 50% the first year on that product,” Baluch says.

Group Health has always had exception processes in place so patients and physicians who request brand-name drugs instead of preferred generic products would have access to those medications. However, as more drugs became available, the prior-authorization process that had once worked well became more cumbersome.

In response, the HMO recently introduced a prior-authorization “help desk.” Prescribers can get regularly updated lists of which drugs on the formulary require prior authorization. This eliminates confusion and speeds the drug-approval process. Patients for whom approval is granted pay no additional charge for their medications. About 3% of all prescription drugs dispensed at Group Health require prior authorization, Baluch says.

One class of drugs requiring prior authorization are interferons, he says. These are sometimes prescribed for a variety of serious ailments, including hepatitis, cancer, and multiple sclerosis. In some situations, the benefit of using the drug are clearly documented; in others, they are not. For example, beta interferons have been shown to help MS patients in the relapse phase of the disease, but not patients in the progressive stages of MS.

campaign. The pharmacists and P & T committee members used pharmacy data to determine which patients were at high-risk, took the information to physicians, and worked with them to lower doses of estrogen for high-risk patients. “These kinds of early interventions laid the framework for what we would do later,” Baluch says.

CLINICAL ROADMAPS AND DISEASE MANAGEMENT: PHARMACY IN ACTION

Today, Group Health’s roadmap for clinical quality program gives pharmacists more opportunities than ever to become directly involved in fostering improved patient outcomes. Pharmacists help plan and implement department policy changes so the interests and goals of pharmacy are aligned with those of physicians, nurses, and other caregiver staff. Aligning these goals and approaches increases the likelihood that all providers in the system will be able to follow best practice guidelines: “If we can align our procedures and processes, we can achieve some predictable outcomes,” says Baluch.

Take heart care as an example. In the past, physicians treated patients on a case-by-case basis, but they did not know over the long term whether their interventions were making a real difference as measured by outcomes reported within that population of patients, Baluch says. There was—and still is—much variation in how physicians treat heart patients. So how does one determine which treatment course is best?

Research among heart patients has shown that myocardial infarction patients are much less likely to suffer a second heart attack or other cardiac-related death if they (1) quit smoking, (2) use lipid-lowering drugs, (3) take beta blockers, and (4) take aspirin each day. Research also showed that many physicians treating heart patients were not recommending all of these things to patients. But the problem did not rest with the physicians alone; there might be impediments elsewhere in the system, Baluch explains. For example, were smoking-cessation products covered under the plan? Were the drugs most likely to benefit this group of patients on the formulary? “These kinds of situations present an organizational problem,” Baluch says.

Under the roadmap program, pharmacists augment the work of physicians by monitoring and reviewing heart patients’ drug-use patterns and going over their findings with physicians. A pharmacist might discover, for example, that a patient who had a heart attack several years is not being prescribed a beta-blocker—perhaps because the patient had the heart attack before studies came out linking beta-blocker use with lower risk of repeat infarctions. The pharmacist can alert the physician to this situation and make recommendations so the best prescribing practices are followed. “We’re now really integrating our efforts,” Baluch says.

Group Health does not yet have

Continued on page 639
outcomes data resulting from this intervention program; however, it has documented an increase in the percentage of myocardial infarction patients who are prescribed lipid-lowering and/or beta blocker drugs.

Developing such an active outreach program could cost several million dollars in Group Health's annual pharmacy budget, according to Baluch. That's why Group Health is moving away from using the old "silo" budgeting process. A few years ago, the plan moved toward a more integrated budget plan that takes into account that increased pharmacy costs will result in lower medical costs elsewhere in the system. "By aligning your processes, you will affect your overall costs and outcomes," he notes.

Smoking cessation is another area in which pharmacists have an important role to play. Pharmacists work as part of a behavioral modification team," one that offers counseling and follow-up for patients trying to kick the habit. Pharmacists and other Group Health providers are taught and regularly reminded to ask patients whether they smoke. Pharmacists are on the lookout for patients who receive medication for asthma, bronchitis, and allergies—red flags that the patient may be a smoker. Pharmacists offer patients information about smoking-cessation programs and products, and consult with the appropriate specialists, who can then calculate the right dose if medication is chosen. Pharmacists use pharmacy data to track how long an individual stays on a nicotine patch to determine whether that patient is monitored properly and weaned off the product within a reasonable time period.

Although most of this activity occurs within Group Health's staff-model setting, some of it is starting to happen among outside providers with whom Group Health contracts. "This is something that can be done at the community [pharmacy] level," Baluch notes. "I see plans like ours doing more work with the network pharmacists to intervene on patients' behalf. Such processes are still in their infancy, he notes. But as computer and information technology improves, retail pharmacists increasingly will have instant access to information—such as whether a particular patient is a smoker or a diabetic—that can clue them in on ways to provide value-added care.

So far, the efforts at controlling tobacco use appear to be paying off. Between 1990 and 1994, the percentage of Group Health enrollees who smoked declined from 20% to 15.5%.

Immunization is another area in which Group Health pharmacists have worked with other caregivers in the system to improve plan performance. Group Health pharmacists and information specialists used pharmacy data to build a patient record system so physicians and nurses can access a patient's immunization records on their computer. By 1994, 87% of all two-year-olds enrolled in Group Health had received all their scheduled vaccinations—just shy of the U.S. Public Health's Service goal of having 90% of all two-year-olds fully inoculated by the year 2000.

Diabetes, another illness targeted under the clinical roadmap program, also offers pharmacists opportunities for direct patient care involvement. A audit at pharmacy records of diabetic patients indicated that some were receiving excessive doses of metformin. Pharmacists helped develop treatment guidelines so that diabetic patients would be placed initially on the correct dose. Guidelines for treating diabetic patients also included making sure patients are monitored every six months to determine whether renal function is impaired.

For all clinical roadmap programs, pharmacists also provide a reinforcement role. "The pharmacist is always right there at the medication pickup window with the patient," providing opportunities to check with patients to see if they are complying with their care regimen. Group Health pharmacists noticed that some diabetic patients with foot ulcers had that problem recurrently because they had difficulty finding proper supplies. In response, the Group Health pharmacists put together a foot ulcer care kit containing several weeks' supply of saline solution, bandages, instructions, and other items. Now patients can simply ask for the kit when they come into the clinic, rather than have to hunt for supplies at different locations.

INFORMATION MANAGEMENT: KEY TO HEALTH CARE DELIVERY'S FUTURE

"The computer is becoming the twenty-first century's stethoscope—an indispensable and useful tool," says Karyn Sanford, a registered nurse and Director of Clinical Systems. "It's not just the information computers provide, but that they organize enormous quantities of complex data in ways physicians find useful and practical.

In 1995, Group Health embarked on another quality improvement effort in which the computer plays a central role: clinical work stations. Under this setup,
all health care teams who work in Group Health-owned facilities have access to computer stations that give instant access to important patient clinical information, including laboratory results, pharmacy profiles, allergy and immunization status, consulting nurse calls, up-to-date research-based guidelines for caring for patients with certain medical conditions, and access to international medical reference databases. Group Health plans to continually update these stations with new information. The goal is to enable physicians to instantly compare a particular patient's profile with recommended care guidelines.

FORGING NEW PARTNERSHIPS: OPPORTUNITIES AND CHALLENGES

Having up-to-date information systems in place to promote the kinds of quality care programs at the heart of Group Health's 50-year-old mission is no easy task. Neither is the ability to compete in today's rapidly changing health care environment.

These kinds of challenges are what's prompting Group Health to consider forging closer alliances with other institutions that share a similar philosophy of care. In September, Group Health announced that it had signed a memo of understanding with Kaiser Permanente's Northwest Division to enter discussions regarding possible expanded joint marketing agreements, codevelopment of business and clinical systems, or a complete merger of the two organizations.

Although it is too early to say where the discussions will lead, Group Health would partner only with an organization sharing a similar mission and values. Group Health's track record of providing cost-effective quality care through a team of providers could only be enhanced by collaborating with Kaiser, which also brings to the table a wealth of experience and a decades-old reputation for being committed to patient care. Perhaps in the future, Kaiser and Group Health will bring together the best of both their worlds—exemplifying a new model to which health care systems can aspire.

ACKNOWLEDGMENT TO REVIEWERS 1996

The Editorial Staff of the Journal of Managed Care Pharmacy would like to thank these peer reviewers for all their efforts in making JMCP a success in its second year of publication.

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Solvay to the rescue.
COMPARATIVE RESEARCH

Retrospective Analysis of Formulary Transition at Large Metropolitan HMO: Nifedipine GITS to Felodipine ER

Steven R. Krantz, Robert S. Rase, and Robert W. Piepho

OBJECTIVE:
Evaluate the efficacy, safety, and cost-effectiveness of a formulary transition from nifedipine GITS (Procardia XL, Pfizer) to felodipine ER (Plendi, Astra Merck).

DESIGN:
Retrospective analysis of patient records for three months before and three months after formulary transition was initiated.

SETTING:
A mixed-model metropolitan health maintenance organization with 110,000 members.

PATIENTS:
Health records of 248 patients with stable hypertension were reviewed.

INTERVENTION:
The formulary long-acting calcium-channel blocker was switched from nifedipine GITS to felodipine ER.

MAIN OUTCOME MEASURES:
Patient blood pressures, frequency of adverse drug events, and cost of medications.

RESULT:
Average preconversion and postconversion blood pressure values were 144/85 mm Hg and 142/84 mm Hg, respectively. Of 380 subjects, 28% were identified as hypertensive (systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg) before conversion, while 21% were identified as hypertensive after the formulary switch. Differences between treatments were not statistically significant. Chest pain—the most commonly noted adverse effect during nifedipine GITS therapy (7.7%)—decreased after conversion to felodipine ER (4.1%). The most common adverse effect associated with felodipine ER was edema (8.9%). Felodipine ER costs represented approximately 85% of nifedipine GITS costs, resulting in a 15% savings to the health care system.

CONCLUSION:
The therapeutic equivalence and comparable safety profile of the two medications combined with the 15% cost savings realized with felodipine ER validated the successful formulary switch from nifedipine GITS to felodipine ER at this health maintenance organization.

KEY WORDS:
Formulaires, Therapeutic substitution, Calcium-channel blockers, costs, Adverse drug events, Drug efficacy, Nifedipine, Felodipine.


When similar drug therapies exhibit comparable safety and efficacy, decisions made by health care providers as to which drug to include in their formularies may depend on factors such as cost, patient response and tolerance, drug safety with concomitant disorders, and patient and physician preference. In 1992, Humana Health Care Plans, a mixed-model HMO with approximately 110,000 members, changed its formulary long-acting dihydroyprydine calcium-channel blocker from nifedipine GITS (Procardia XL, Pfizer) to felodipine ER (Plendi, Astra Merck). Felodipine and nifedipine are both members of the dihydropyridine class of calcium-channel blockers, with demonstrated safety and efficacy for the treatment of essential hypertension.

Although members of the dihydropyridine class have different pharmacodynamic effects, three comparative clinical trials conducted with hypertensive patients have shown these two agents to have similar efficacy and adverse event profiles. Felodipine is more selective for vascular smooth muscle over myocardial tissue than nifedipine; at doses producing equivalent vasodilation, felodipine lacks nifedipine’s negative inotropic effect. The probability of similar patient health outcomes combined with a potential cost savings instigated this large metropolitan HMO to undertake this formulary switch. Humana Health Care Plans’ for-
mulary transition from nifedipine GITS to felodipine ER was initiated in September 1992 and has continued to the present.

This study, a retrospective record review of 380 patients with stable hypertension who switched from nifedipine GITS to felodipine ER between January 1993 and December 1994, was conducted to determine whether health outcomes were affected by the formulary switch. This managed care organization (MCO) also sought to determine whether felodipine ER was less expensive than nifedipine GITS, and a more cost-effective treatment of essential hypertension.

METHODS

The Humana Health Care Plans formulary was modified to convert patients on nifedipine GITS to felodipine ER in September 1992. To facilitate the formulary change, information was provided to all prescribers in the Humana system, and product interchange occurred upon renewal of prescriptions at all pharmacy sites in the Humana system. Patients without angina receiving nifedipine GITS to treat hypertension were switched to felodipine ER at a dose ratio of 1 mg felodipine ER per 6 mg nifedipine GITS.

Data Collection

Records of 380 patients who were switched to felodipine between January 1993 and December 1994 were examined. A six-month period of each record was evaluated (three months before and three months after the transition from nifedipine GITS to felodipine ER) for historical, efficacy/response, and safety data. Historical data included patient characteristics (age, gender, weight, height, and race) and patient history (use of other antihypertensive drugs, use of potentially interacting drugs, and duration of therapy). Records with the following variances were excluded from consideration:

▲ Patients diagnosed with chronic stable, unstable, or rest angina (for whom felodipine was not indicated)
▲ Patients who did not receive a 6-fold nifedipine GITS/felodipine ER dosage substitution during the transition period
▲ Pregnant patients (felodipine is not approved for use in this population)

Efficacy/response data included preconversion and postconversion systolic and diastolic blood pressures, calcium-channel blocker doses, dosage adjustments, number of office visits, changes in therapy, treatment failures (i.e., lack of blood pressure control or discontinuation of felodipine ER treatment for medical reasons), and any new diagnoses during the three months following the change in therapy.

Safety data included all reported adverse effects.

The relative effectiveness of nifedipine GITS and felodipine ER was determined by comparing steady-state preconversion and postconversion blood pressure readings. Steady state was defined as the blood pressure reading on the conversion date for the preconversion measure and the last blood pressure value recorded during the study period for the postconversion measure. The interval between these measurements varied from one to three months, depending upon scheduling of visits. Hypertension was defined as a systolic blood pressure reading of ≥140 mm Hg and/or a diastolic reading of ≥90 mm Hg, consistent with the recommendation of the Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure.

Compliance and costs were also monitored. Compliance was based on patient prescription refills. Patients were considered to be compliant if their prescription refill included sufficient doses to cover the number of days in each patient’s preconversion and postconversion period. Costs to the system were estimated based upon costs per unit dose and the frequency with which the medication was administered.

Statistical Analysis

Data were coded and entered in standard format on a VAX-1 mainframe computer at the University of Missouri at Kansas City. The database was validated using standard procedures, and an error rate of less than 1% was determined. A random selection of every fifth record was verified manually.

The effects of nominal data (gender, race, and use of other antihypertensive drugs) on the outcome of the formulary transition were assessed using chi-square analysis. Interval and ra-

Vol. 2, No. 6 Nov/Dec 1996 JNCP Journal of Managed Care Pharmacy 643
Table 2. Drug Effectiveness: Blood Pressures and Hypertension Prevalence before and after Formulary Transition (n = 246)

<table>
<thead>
<tr>
<th></th>
<th>Stable preconversion blood pressures</th>
<th>Stable postconversion blood pressures</th>
<th>Prevalence of hypertension preconversion</th>
<th>Prevalence of hypertension postconversion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (±SD) systolic value (range, mm Hg)</td>
<td>Mean (±SD) diastolic (range, mm Hg)</td>
<td>Mean (±SD) systolic value (range, mm Hg)</td>
<td>Mean (±SD) diastolic (range, mm Hg)</td>
</tr>
<tr>
<td></td>
<td>144 ± 20.1 (102–200)</td>
<td>84 ± 13.5 (50–140)</td>
<td>141 ± 21.1 (90–210)</td>
<td>83.5 ± 17.0 (56–125)</td>
</tr>
<tr>
<td></td>
<td>68 (27.6)</td>
<td>69 (28.0)</td>
<td>32 (21.1)</td>
<td>69 (28.0)</td>
</tr>
<tr>
<td></td>
<td>No patients with systole &gt; 140 and diastole &gt; 90 mm Hg (%)</td>
<td>No patients with diastole &gt; 90 mm Hg (%)</td>
<td>No patients with systole &gt; 140 and diastole &gt; 90 mm Hg (%)</td>
<td>No patients with diastole &gt; 90 mm Hg (%)</td>
</tr>
</tbody>
</table>

Data were examined using analysis of variance (ANOVA) and multiple regression procedures. Multiple regression was used to identify the potential impact of factors or clusters of characteristics on clinical outcomes and adverse drug events during the transition process. The accumulated data on safety were analyzed as net data, since it is possible that some adverse effects may be ascribed to other medications initiated following the discontinuation of nifedipine GITS.

Conclusions based upon these analyses employed traditional levels of significance (p < 0.05). The study was powered on the variable of blood pressure and the analysis indicated the ability to detect very small effects (0.2 for difference analyses and r = 0.19 for correlational analyses), with 90–95% confidence intervals.

RESULTS

Of 380 patients converted from nifedipine to felodipine during the course of the study, 246 efficacy-evaluable patient records remained after removal of excluded patients or incomplete files. The majority of patients were Caucasian (53.3%), while 37.0% were African-American. Average patient age was 59 years, and average weight and height were 167.3 kg (192 pounds) and 167.6 cm (66 inches), respectively (Table 1).

Of the 246 patients, 175 (71%) received at least one adjunct medication for hypertension during the study period, with the most frequently prescribed medications being losartan (27.6%) and hydrochlorothiazide (17.9%). Approximately one third of these patients also concurrently used either an angiotensin-converting enzyme (ACE) inhibitor or diuretic (or, in some cases, both) at some point during the assessment period. Approximately 70% of patients received concurrent therapy with other calcium-channel blockers. A total of 16 patients (6%) received medications that would potentially interact with calcium-channel blockers, the most common being cimetidine (n = 12).

Statistical analyses, including ANOVA, chi-square analy-

sis, and multiple regression, yielded no statistically significant correlations or differences in preconversion and postconversion measures. Thus, no statistically significant differences were found for any safety or efficacy parameter measured.

Record review indicated 98.5% of patients were compliant with their medication regimens. Mean preconversion blood pressure values were 144/85 mm Hg, while mean postconversion values were 142/84 mm Hg. Some 28% of subjects were identified as hypertensive (systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg) during nifedipine GITS treatment, while 21% were identified as hypertensive using this definition during felodipine ER therapy. The differences in these values were not statistically significant. Mean blood pressure values and hypertension prevalence before and after the formulary transition are shown in Table 2.

Adverse effects were identified from patient-reported complaints in the medical record. Chest pain was the most common preconversion adverse effect (7.7%); prevalence decreased after the formulary conversion (4.1%). The most common adverse effect after conversion was edema (8.5%). Complete data regarding adverse effects before and after transition are in Table 3. A total of 14 new diagnoses, representing a range of medical conditions and distributed across nine patients, were recorded after transition to felodipine ER (Table 4). Only two of these (vertigo and supraventricular tachycardia) were considered to be potentially related to the new regimen.

During the study period, 27 patients (11%) stopped taking felodipine ER. Some 11 patients had no reason for the discontinuation listed in the medical record. The remainder cited these reasons for drug discontinuation: headache (n = 4), dizziness (n = 2), fixed drug eruption (n = 2), suspected congestive heart failure (n = 2), peripheral edema (n = 2), drug discontinued upon hospitalization (n = 1), "too expensive" (n = 1), hives (n = 1), and tachycardia (n = 1).

A one-time administrative "switching cost" was estimated to be approximately 2–4% of the medication cost. The mean dosage of nifedipine GITS across subjects was 9.6 mg/day, while the mean dosage of felodipine ER was 8.6 mg/day; both doses were within their recommended dosage ranges. The mean cost of nifedipine GITS was $1.26/day, or $37.77/month. The mean cost of felodipine ER was $1.04/day, or $31.12/month. Felodipine ER charges represented approximately 85% of nifedipine GITS charges, resulting in a 15% savings to the health care system.

DISCUSSION

A recent prospective study, involving a similar formulary switch at a VA hospital showed felodipine ER treatment to be therapeutically equivalent to nifedipine GITS therapy in a group of 87 elderly patients, most of whom were Caucasian men. Likewise, this retrospective analysis of a formulary transition affecting members of a large metropolitan HMO demonstrated no significant changes in blood pressures or increases.
Table 3. Prevalence of Adverse Effects before and after Formulary Transition

<table>
<thead>
<tr>
<th>Adverse Effect</th>
<th>Preconversion</th>
<th>Postconversion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Chest pain</td>
<td>19</td>
<td>7%</td>
</tr>
<tr>
<td>Edema</td>
<td>13</td>
<td>5%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>10</td>
<td>4%</td>
</tr>
<tr>
<td>Headache</td>
<td>8</td>
<td>3%</td>
</tr>
<tr>
<td>Gastrointestinal effects</td>
<td>5</td>
<td>2%</td>
</tr>
<tr>
<td>Heart rate changes</td>
<td>5</td>
<td>2%</td>
</tr>
<tr>
<td>Nocturia</td>
<td>3</td>
<td>1%</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>3</td>
<td>1%</td>
</tr>
<tr>
<td>Rash</td>
<td>2</td>
<td>0%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>2</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>flushing</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Sleep disturbances</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Impotence</td>
<td>1</td>
<td>0%</td>
</tr>
</tbody>
</table>

a Where cell frequencies were 5 or less, Fisher's Exact Test was used.

Table 4. Additional Diagnoses First Detected in the Three Months after Transition to Felodipine ER

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose intolerance</td>
<td>2</td>
</tr>
<tr>
<td>Degenerative changes/stroke</td>
<td>2</td>
</tr>
<tr>
<td>Seborrhea of scalp</td>
<td>1</td>
</tr>
<tr>
<td>Sternal osteomyelitis</td>
<td>1</td>
</tr>
<tr>
<td>Possible deep-vein thrombosis</td>
<td>1</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>1</td>
</tr>
<tr>
<td>Verigo</td>
<td>1</td>
</tr>
<tr>
<td>Nonsulin-dependent diabetes mellitus</td>
<td>1</td>
</tr>
<tr>
<td>Supraventricular tachycardia</td>
<td>1</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disorder</td>
<td>1</td>
</tr>
<tr>
<td>Left ventricular hypertrophy</td>
<td>1</td>
</tr>
</tbody>
</table>

in adverse effects when felodipine GITS was replaced with felodipine ER. The 246 patients in this analysis are typical of patients receiving treatment for hypertension. African-American individuals are disproportionately represented in both this research sample (37%) and the population of patients suffering from hypertension. The height and weight data suggest that our group was more overweight than the population in general, which is also typical of the hypertensive population. The gender distribution is fairly balanced for a cross section of hypertensive patients in this age group, since the male-to-female ratio was 4:5:36 (107 men; 139 women).

Data on before and after blood pressure values and frequencies with which hypertension continues to be a primary diagnosis suggest that felodipine ER is at least as effective in controlling blood pressure as nifedipine GITS. Indeed, of the 28% of all patients identified as hypertensive preconversion, approximately one fourth of these patients experienced better blood pressure control with felodipine ER.

One of the primary justifications for choosing felodipine ER as a formulary alternative to nifedipine GITS was its strong safety profile. For the large, heterogeneous patient population of a metropolitan HMO, medications with the least probability of exacerbating concomitant conditions are preferred. Clinical trials have established the safety of felodipine in patients with hypercholesterolemia, diabetes mellitus, arthritis, impaired renal function, asthma, and chronic obstructive pulmonary disorders. Moreover, its lack of a negative inotropic effect on myocardial tissue may make felodipine ER a better choice than nifedipine GITS for patients with impaired cardiac function.

As seen in previous clinical trials, the most common adverse effects likely to be associated with felodipine in this trial were edema and headache. Overall, adverse effect data from this trial confirm that the formulary transition introduced no additional safety risks to patients. The frequency of adverse effects potentially related to medication use were similar after formulary transition to those reported before the formulary transition, as confirmed by chi-square analysis (Table 3). No statistically significant differences were found between before and after values.

Finally, the data indicate that the formulary transition provided cost-minimization support for the formulary decision. The cost to the system, per patient per month, for this class of medication was reduced by approximately 15% as a result of the conversion to felodipine ER. Although an administrative "switching cost" was estimated to be 2-4% of medication cost, as a one-time expense, it was offset by the prospect of substantial long-term savings. Thus, this one formulary change, with no additional safety risks or reduction in effectiveness of treatment, resulted in a medication cost savings of more than $150,000 per year to Humana Health Care Plans of Kansas City.

CONCLUSION

The therapeutic equivalence and comparable safety profile of the two medications combined with a 15% cost savings realized with felodipine ER validated the successful switch from nifedipine GITS to felodipine ER at this health-maintenance organization.
References


14. Scherri MR. Unchanged glucose homeostasis in hypertensive patients with type II diabetes mellitus during one year of treatment with felodipine and nifedipine compared with placebo [abstract]. Am Heart J 1994; 64(2) part 2: 73A.


Assessment of Medicaid Prior-Approval Policies on Prescription Expenditures: Market-Share Analysis of Medicaid and Cash Prescriptions

Jeffrey A. Kotzan, Matthew Perri III, and Bradley C. Martin

OBJECTIVE: To compare market share changes produced by prior-approval (PA) policies of a state Medicaid agency and calculate costs avered by the PA system.

DESIGN: Cross-sectional, equivalent control group.

SETTING: State of Georgia.


INTERVENTIONS: Comparison of two groups.

MEASUREMENTS: Market share of PA products in the Medicaid and private-pay datasets, and odds ratios analyzed with chi square and logistic regression.

RESULTS: The cash market share for PA drugs was 5.63% of the prescription volume and 10.93% of the dollars. This compares with 2.41% and 7.93% for the respective Medicaid markets. The odds ratio of 2.26 for cash patients indicates that the private-pay patient was 2.26 times more likely to receive a PA prescription than a Medicaid patient.

CONCLUSION: The Georgia Department of Medical Assistance PA program, when viewed from the perspective of market shares for multiple drug products, appears to reduce the cost of the drug program.

KEY WORDS: Prior approval, Medicaid, Costs, Economics, Formularies, Prescribing restrictions.


State and federal Medicaid expenditures increased from $12 billion in 1975 to $126 billion in 1993. During this period, Medicaid prescription expenditures increased from $815 million to $9.7 billion, about 7.8% of the total Medicaid budget in 1993. Prior authorization (PA) for prescription drugs is one method by which state Medicaid agencies attempt to control prescription consumption and thereby reduce system costs. PA policy places selected drugs in a formulary that can only be reimbursed after the prescriber and pharmacist submit a request indicating that the drug is necessary. In Georgia, an agency of the Medicaid administration is charged with the responsibility for approving the request. This agency specifies that the drug is medically necessary.

The Omnibus Budget Reconciliation Act of 1990 supported the continuation of PA programs. However, regulations based on the law required states with PA programs to respond to prescribers' requests within 24 hours. Some 24 state Medicaid agencies reported use of PA programs during 1994. During the same year, 43 states reported physician-administered drug programs with some type of PA requirements.

The impact of PA programs on Medicaid system costs has been investigated. Studies conclude that PA programs, given specific drug categories, can save overall program costs and avoid shifting of services from prescription costs to more expensive modalities of medical treatment. For example, the nonsteroidal anti-inflammatory (NSAID) drug category includes both more expensive patented and less expensive generic alternatives with marginal therapeutic differences. Two studies indicated that PA programs for single-source NSAIDs produced state-wide Medicaid savings without shifting costs to other treatment cost centers.

A variation of a drug-specific PA process is one implemented to serve as gate keeper for defined dosage regimens. One example is a PA program for maintenance dosage programs for H₂ antagonist drug therapy. One study reported that a statewide Medicaid PA program was effective in reducing overall system drug costs by restraining prescribers to use FDA-approved dosage guidelines for H₂ antagonist therapy.
Prior-authorization drug programs have demonstrated marginal cost savings in non-Medicaid managed care institutions. Prior-authorization procedures for drug products were used by 44% of 570 health-maintenance organizations (HMOs) responding to a mail questionnaire from Kreling and Mucha. One specific example was reported for a PA program for lovastatin within an HMO setting. This PA drug program appeared responsible for a reduction in new lovastatin prescriptions and was reported to be most effective with family physicians.

Given the studies indicating that specific PA drug programs are both popular and a likely effective means of cost containment, we decided to calculate the overall impact of the state-wide Georgia Medicaid PA drug program by means of a market share analysis, that is, an analysis of the sum total of prescriptions and costs for the Medicaid and the cash markets.

We could not use a quasi-experimental or experimental research design. The Georgia PA drug program included a multitude of products for several therapeutic categories. Further, the PA programs were instituted at various times and adjusted to accommodate patent expirations, new products, and other changes in drug treatments and costs. The market approach appeared reasonable since far too many PA policy changes precluded isolation and analysis of each therapeutic category and its products before and after implementation of specific PA policies. Further, projection of product cost and therapeutic results to a single time would be tenuous given the dynamic nature of the pharmaceutical industry.

The goal of the research was to compare the market shares for PA Medicaid and cash prescriptions for the Georgia Medicaid program and to impute the effect of the PA program on total Medicaid drug expenditures. The availability of data on cash prescriptions offered a comparison market not bound by formulary and PA restrictions. Results from a market share analysis can provide meaningful insight into the impact of this program. Should the results indicate that the market share and cost for the cash market exceeded those for the Medicaid market, then the program was likely effective in limiting drug expenses for the State. Also, the magnitude of potential differences offered some indication of the acceptable limits for administrative costs required to maintain the policy.

METHODS

The first three months of 1994 were defined as the study period. This time period allowed for adjudication to be completed before undertaking the analysis. A list of all prior-authorized trade-name products was obtained from the administrative body responsible for the Georgia PA program. An algorithm of PA product names—accounting for differences in hyphenation, spelling, and punctuation—was constructed and tested on existing Medicaid prescription files. The algorithm was refined, and the first three months of Medicaid prescription data from 1994 were abstracted. A set of PA drugs and a second set of nonprior-approved (other) drugs were constructed. The sets were merged with Medicaid recipient files to determine age, sex, and race for both the users and nonusers of PA drugs. Demographic analysis and overall market share descriptions were conducted for the Medicaid prescriptions.

The next task was to create similar datasets for private payment (cash) prescriptions for the same time period. Walsh America, a national vendor, was selected, and all available prescription data for Georgia was procured. The vendor provided three months of data from approximately 1,300 Georgia pharmacies over the same time period. The dataset was examined to isolate private-payment prescriptions including trade-name, price received by the pharmacy, age, and sex (when available). Race was not included in the cash dataset. Using the same algorithm developed for the Medicaid dataset, each prescription was classified as either a PA drug or other drug. A summary of the PA and other market shares and available demographics was prepared.

The next phase of the research constructed a single examination dataset containing both the private payment and Medicaid prescription groups. The files were merged, retaining the origin of the payment. A logistic regression model was specified to determine the odds ratio of PA private to PA Medicaid prescriptions. The model was stated in such a manner to include independent covariates to control both age and gender differences in the consumption patterns for the two prescription groups.

The last stage of the analysis created comparable market shares for private payment and Medicaid PA drugs. A few PA drugs appeared in the Medicaid list but were not present in the private payment list and vice versa. These drugs were deleted from the analysis. Estimates of the total impact of the PA program were calculated from the differences between the market shares for similar Medicaid and private payment prescriptions.

RESULTS

A total of 2,957,850 Medicaid and 6,347,617 cash prescriptions were included in the market share analysis. Table 1 displays the PA drugs and summary statistics for those products that were represented in both the Medicaid and private payment markets. The initial summation of duplicated and nonduplicated PA prescriptions was 71,609 prescriptions for the Medicaid market and 370,999 for the cash market. These numbers were reduced slightly after eliminating those products that did not appear on both markets (nonduplicated). The Medicaid prescriptions were reduced from 71,609 to 71,187. Private payment prescriptions were reduced from 370,999 to 357,546. The decrease in sample size was 0.59% and 3.63%, respectively. By eliminating the nonduplicated drugs, the results reflect only those products that appear in both the cash and Medicaid markets.

Both expensive and inexpensive drugs were included in the analysis. The expensive drugs include Gammaiphene-N, Leukine, Procrin, and Neupogen, which all exceeded $1,000 per prescription in the Medicaid, cash, or both markets. The least expensive prescriptions included erax and Nephrocaps,
Table 1. Prior-Authorization Prescription Statistics for January–March 1994

<table>
<thead>
<tr>
<th>Drug Trade Name</th>
<th>No. Prescriptions</th>
<th>Cash (S)</th>
<th>Cost/Prescription ($)</th>
<th>Medicaid</th>
<th>Cost ($)</th>
<th>Cost/Prescription ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tagamet</td>
<td>26,132</td>
<td>1,149,229.38</td>
<td>43.95</td>
<td>13,954.98</td>
<td>421,436.98</td>
<td>30.94</td>
</tr>
<tr>
<td>Tegrim</td>
<td>208</td>
<td>16,622.43</td>
<td>79.92</td>
<td>39,625.81</td>
<td>118,611</td>
<td>33.38</td>
</tr>
<tr>
<td>Tomadex</td>
<td>21,890</td>
<td>657,555.85</td>
<td>28.60</td>
<td>3,186</td>
<td>106,360.35</td>
<td>33.38</td>
</tr>
<tr>
<td>Velcophen</td>
<td>13,820</td>
<td>660,767.63</td>
<td>43.47</td>
<td>1,247</td>
<td>65,160.44</td>
<td>32.25</td>
</tr>
<tr>
<td>Wimstrol</td>
<td>74</td>
<td>2,014.46</td>
<td>27.22</td>
<td>12</td>
<td>376.05</td>
<td>31.39</td>
</tr>
<tr>
<td>Xamouth</td>
<td>48,617</td>
<td>1,583,613.77</td>
<td>28.46</td>
<td>839</td>
<td>56,828.04</td>
<td>68.54</td>
</tr>
<tr>
<td>Zantac</td>
<td>74,870</td>
<td>4,143,903.10</td>
<td>55.49</td>
<td>2,362</td>
<td>1,894,508.24</td>
<td>78.09</td>
</tr>
<tr>
<td>All agents</td>
<td>537,596</td>
<td>15,678,137.37</td>
<td>71.87</td>
<td>5,320,121.71</td>
<td>80.09</td>
<td>78.09</td>
</tr>
</tbody>
</table>

among others.

Almost 3 million PA and other Medicaid prescriptions were dispensed in the first three months of 1994. Table 2 displays the totals for the prior approved and other Medicaid prescriptions. The average cost of $74.74 for the PA drugs was 3.49 times more expensive than $21.39, the cost of the other Medicaid prescriptions. The prescription volume market share for the PA prescriptions was 2.41% of the total prescription volume. Therefore, the dollar share was 3.29 times greater than the market share for prescription volume (7.93/2.41).

The results from the analysis of the private payment prescriptions are presented in Table 3. The results of the breakdown for the PA and other prescriptions for the (cash) market were distinctly different than those for the Medicaid system. The cash market share for the PA drugs was 5.63% of the prescription volume and 10.93% of the dollars. This compares with 2.41% and 7.93% for the respective Medicaid markets. The average cost for the cash market PA drugs was $43.85, only 59% of the $74.74 of the Medicaid PA drugs. The $43.85 average price for PA cash drugs was 2.06 times greater than
the average price of $21.33 for other cash prescriptions.

The proportion of men and women receiving Medicaid PA and other drugs were remarkably consistent. Approximately 72% of the Medicaid prescriptions were dispensed to women. The Medicaid gender differences are reported in Figure 1. The average age was 53.27 years for the PA prescription group but younger (46.06 years) for the other prescription group.

We could not completely describe the demographic characteristics for patients receiving cash prescriptions. About half of the sex fields were vacant, and missing values for the age were represented by ‘0’. This result reflects community pharmacies computer protocols for recording missing age information for cash patients. By discarding the prescriptions containing missing sex fields and age information, it was possible to perform a crude estimate of the demographic characteristics for cash patients. As anticipated, 65% of the cash prescriptions were dispensed to women patients (Figure 2). Since it was necessary to discard the ‘0’ ages, the average age may be slightly overstated at 58.13 years for the PA prescription group and 51.56 for the other prescription group. However, the direction and magnitude of the age differences of about seven years is consistent with those observations for the Medicaid prescriptions. In both the cash and Medicaid markets, the older patients received a greater proportion of PA drugs.

The resulting demographic differences between the cash and Medicaid markets are noteworthy. The Medicaid patients were both younger and more frequently women. The average age for the PA drugs was 53.27 years for Medicaid patients, compared with 58.13 years for cash patients. Also, 71.0% of the PA Medicaid prescription market was female, compared with 65.5% of the cash PA market. These results necessarily reflect the eligibility requirements for Medicaid and the high rate of prescription use among the eligible recipients.

The logistical regression analysis paralleled those results reported for the market-share analysis. The model was stated to reflect the odds of a cash patent receiving a prior-approved prescription compared with the Medicaid patient. The results are presented in Table 4. All of the reported odds ratios were significant, not surprising given the large chi-square values and number of observations. Most important, the odds ratio of 2.26 for cash patients indicates that the private payment (cash) patient was 2.26 times more likely to receive a PA prescription than a Medicaid patient. Conversely, the Medicaid patient was 0.44 times less likely to receive a PA prescription.

**DISCUSSION**

Private payment prescriptions, while declining, currently represent about 50% of the total U.S. legend drug market. This market is primarily constrained by the ability of patients to pay for their prescription medications. No administrative approvals, formularies, prescription cap limits, or other mechanisms to restrict supply are imposed on the cash patient. Therefore, the cash market appears to be a reasonable market to serve as the baseline for assessing the impact of cost-containment strategies in other markets. However, the results from comparison of a cash market to managed market must be interpreted with some caution. For example, the cash and Medicaid prescription markets differ in terms of demographics, utilization, illness, and behaviors of both the recipients and prescribers. Demographic variables were included in our logistic model, and both age and sex had marginal but significant impact on the results. Other factors—including behav-
Table 4. Logistic Regression Analysis for Receipt of PA Drug in Medicaid versus Cash Markets

<table>
<thead>
<tr>
<th>Variable</th>
<th>Chi-Square Value</th>
<th>Probability Greater than Chi-Square Value</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>3501.1331</td>
<td>0.00001</td>
<td>2.0150</td>
</tr>
<tr>
<td>Cash patients</td>
<td>2393.2892</td>
<td>0.00001</td>
<td>2.2900</td>
</tr>
<tr>
<td>Age</td>
<td>923.3503</td>
<td>0.00001</td>
<td>1.0100</td>
</tr>
<tr>
<td>Men versus others</td>
<td>15.4154</td>
<td>0.00001</td>
<td>1.0700</td>
</tr>
</tbody>
</table>

A significant difference in the average prescription price was reported for the cash and Medicaid PA prescriptions. The lower cost for the PA cash prescriptions relative to PA Medicaid prescriptions was anticipated. Previously published research within the Georgia Medicaid population concluded that Medicaid recipients generally received larger quantities of the more expensive prescriptions when compared with cash patients for identical drug products.10 Further, the mix of PA products for Medicaid and private payment patients were not identical. Table 1 lists PA drugs for both the Medicaid and cash markets. Marisol exemplifies the differences observed in price between the two markets. The average cash price was $311.18 and the Medicaid average was $322.15. This observed dissimilarity resulted from aggregate differences in both dispensed quantities and dosage strengths.

In both prescription markets (cash and Medicaid), the PA drugs were more expensive than other pharmaceuticals. The more expensive PA products for each patient likely experienced demand elasticity that does not exist in the Medicaid market. Cash-paying patients may not be willing or able to accept the higher priced prescriptions. They can adopt several strategies to limit their cash outflows. They can refuse to accept the drug or they can take less than the prescribed dosage regimen. In both cases they would be considered noncompliant. They can request a less expensive product from either physicians or pharmacists. They can request smaller quantities of drug or they can delay purchases until they have sufficient money. None of these strategies is pertinent for Medicaid patients. The primary limiting factor for Medicaid prescription consumption was a prescription limit per month that may be voided with a PA request.

The primary focus of this project was to determine the impact of the PA policy upon the drug costs to the Georgia Department of Medical Assistance. The study estimated that 2.41% of all Medicaid prescriptions are PA drugs versus 5.63% for the same drugs in the private payment market. The practical applications of this research project can be stated in a specific question: What additional costs will the Georgia Department of Medical Assistance incur if the market share for Medicaid prior authorized drugs were increased from 2.41% to 5.63% at the average Medicaid cost of $74.74 per prescription? Table 5 projects the annual Medicaid drug costs under this scenario.

Table 5. Projected Medicaid Drug Cost at Private Payment Market Share of 5.63%

<table>
<thead>
<tr>
<th>Category</th>
<th>No. Prescriptions</th>
<th>Total Costs ($)</th>
<th>Costs ($) Difference</th>
<th>Additional Costs ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA prescriptions</td>
<td>166,609</td>
<td>12,452,806</td>
<td>7,132,084</td>
<td></td>
</tr>
<tr>
<td>Other prescriptions</td>
<td>2,791,241</td>
<td>59,695,000</td>
<td>2,010,738</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2,957,850</td>
<td>72,147,806</td>
<td>5,081,346</td>
<td>20,365,386</td>
</tr>
</tbody>
</table>

Under this scenario, the total number of prior-approved prescriptions would increase to 166,609 from the observed 71,187 prescriptions for the three months. The result would be an additional 95,422 prescriptions priced at $74.74 and an equal reduction in the number of other prescriptions priced at $21.39. The three-month cost for the prior-approved drugs would increase from $5,320,722 to $12,452,806 at $74.74 per prescription. The reverse is true for the other prescription market share. It would decrease from 97.59% to 92.07% of the market at an average prescription price of $21.39. The net effect is a $5,091,346 increase in drug expense for the three months, or a total of $20,365,386 for the entire year.

The increase in the number of prior-approved drugs might be priced at the cash rate of $43.85 rather than the $74.74 rate for Medicaid prescriptions. This suggestion is uncertain given the larger quantities of drugs received by Medicaid recipients as compared with cash patients. However, if the 95,422 additional prior-approved drugs were priced at $43.85 and the existing 71,187 prescriptions remained at the $74.74, the net effect would be to reduce the average PA prescription price to $57.05. At this price level the net additional annual costs will total $8,571,240. The relationship between the average prescription price for prior-approved drugs and the additional cost is displayed in the Figure 3. The figure illustrates that additional costs to the Medicaid program at the cash market share would be positive at all prescription prices above the lower assumption of $57.05.

The results of the market share analysis confirm the impact of the PA policy cited in previous studies, but these results may be misleading, given the differences between the average cash and Medicaid prescription. Examination of the dollars rather than prescriptions is another means to assess the impact of the PA program. If the unit of measure were stated in terms of dollars rather than prescriptions, the results continue to illustrate the positive cost savings of the PA program. The dollar percentage for the Medicaid PA market was 7.93%, as reported in Table 2. The dollar percentage in the cash market was 10.93% (Table 3), for a 3.00% difference in dollar market shares. Of the total $67,056,460 Medicaid prescription market for the three months, 3% is $2,011,694, or $8,046,775 for the year. With either unit of measure, the total drug cost savings would be $8–20 million for the year.

The method did not capture the impact of probable cost reductions resulting from PA for the five-prescription limit per month. It may be anticipated that the five-prescription limit results in additional savings, but the effectiveness in terms of
inducing other medical costs is unknown. For example, some evidence suggests that a three-prescription limit is not cost effective for schizophrenia patients. However, the impact of a five-prescription limit per month has not been researched.

The outcomes observed in this study described a substantial reduction in the market share for PA Medicaid prescriptions. The PA policy likely establishes a sentinel or gatekeeper function. For a number of reasons, physicians appeared less likely to prescribe PA drugs for Medicaid patients. The administrative effort required to prescribe a PA drug may impose a “cost” that makes it more difficult for a physician to justify that product. The PA designation may indicate to the prescriber that other less expensive products are available or that the PA drug should be considered essential before the rendering a prescribing decision. The PA drug manufacturers may not be able to overcome this sentinel or gatekeeper effect. In the end, the policy appeared to function as desired.

We emphasize one point of caution in application of these findings. The methods employed for this research represent an assessment of the system savings to the drug program without regard to resulting medical outcomes. The techniques employed for this study do not represent a cost-effectiveness approach. The study represents an analysis of system drug costs without regard to possible negative outcomes.

However, the results provide a cost benchmark. Administrative costs and negative medical outcomes would have to be greater than the system savings in 1994 to prove the policy ineffective. The administrative costs for the program were approximately $1 million. Therefore, from the administrative cost viewpoint, the Georgia PA policy produced cost savings. Determination of negative medical outcomes and additional costs were not within the objectives of this study. The literature for PA NSAID and maintenance dose H₂ antagonist therapy concludes that additional medical costs are not incurred for these categories of drugs. The impact of PA policy on the remaining drug categories has not been reported in the literature.

**CONCLUSION**

The Georgia Department of Medical Assistance PA program, when viewed from the perspective of market shares for multiple drug products, appears to reduce the cost of the drug program.

**References**

2. Policy and procedures for pharmacy services. Atlanta, Georgia: Georgia Department of Medical Assistance, 1993 Oct.
OBJECTIVE: To document pharmacists’ pharmaceutical care activities in rural community pharmacies and associated outcomes.

SETTING: Five rural community pharmacies in Nebraska.

PRACTICE DESCRIPTION: Community pharmacies offering patient counseling and monitoring of adverse drug events, drug interactions, appropriate dosages, and indications.

PRACTICE INNOVATION: The Nebraska Drug Information Network was implemented to facilitate pharmaceutical care activities in 30 community pharmacies serving as clerkship sites for University of Nebraska pharmacy students. The five pharmacies reported here are part of this network.

INTERVENTION: Each network site was equipped with a multimedia computer, which was connected to the University of Nebraska Medical Center resources via the Synapse telecommunications program.

MAIN OUTCOME MEASURE: Number and type of pharmacists’ interventions and resulting impact on direct and indirect health care costs. Data collected included who initiated the intervention and any triage services provided by the pharmacist.

RESULT: Over a two-month period, 878 interventions were performed by five rural Nebraska community pharmacists. About 71% (n = 625) were prescription-based interventions, while 28% (n = 254) were nonprescription-based interventions. Pharmacists were the most frequent initiators of the interventions, accounting for 57% of the prescription-based interventions. Patients requested 71% of nonprescription-based pharmacist interventions. Interventions were well received, with recommendations followed in full in 96% of cases. An approximation of associated cost savings from avoided hospitalizations (secondary to adverse drug effects and toxicities), avoided office visits, and other intervention outcomes totaled $752,391.

CONCLUSION: Pharmaceutical care as rendered in this study illustrates the magnitude and breadth of pharmacist interventions. As outcomes and the associated value of these interventions are recognized, pharmaceutical care will be acknowledged as necessary in decreasing health care cost and will prove of value in managed care settings.

KEY WORDS: Pharmaceutical care, Rural community pharmacies, Pharmacists, Interventions, Adverse drug events, Outcomes, Primary care.


As managed care penetrates the ambulatory setting in communities across the United States, care is shifting to more outpatient arenas. With fewer inpatient admissions, medications are a crucial and efficient medical intervention that can minimize or avert hospitalizations e.g., well-monitored insulin treatment can prevent a diabetic coma; and well-monitored antihypertensive therapy can avert a stroke. However, with this increased use of medications comes greater accountability for drug expenditures. Hence, the role of the pharmacist in managing drug therapy (e.g., compliance monitoring, patient counseling), documenting outcomes, and providing pharmaceutical care is increasingly important.

In a study of 267 pharmacy owners in rural West Virginia, 63% (n = 162) indicated these activities were common in their pharmacies, yet lack of reimbursement was seen as a barrier to further extension of these activities:

▲ Drug-related problem identification and solving activities
▲ Patient counseling for prescription and nonprescription drug therapies
Health-related advising activities

Pharmacists, however, have proven deficient in their documentation of their daily interventions and how these interventions are affecting drug therapy; as a result, managed care organizations have been reticent to provide reimbursement.

Pharmacists, especially those practicing in rural areas, are well-poised to assume the role of primary caregiver in the area of postmarketing drug surveillance and in rendering pharmaceutical care to decrease drug-related morbidity and mortality. Pharmaceutical care has been successfully implemented in rural communities through such services as monitoring drug therapy, attending patient rounds, monitoring pharmacokinetic variables, and providing critical care clinical services, drug-use reviews, and drug information. Additionally, pharmacist-based anticoagulant clinics, first-aid training sessions, and inhaler patient education activities have been established in rural communities. In these settings, the elderly (aged 65 years and older) constitute a relatively large percentage of the patients. In Nebraska, the elderly make up 17% of the rural population. Elderly patients living in rural areas have greater communication expectations from their pharmacists. Hence, the pharmacist practicing in a rural locale has great opportunities to provide well-received and effective pharmaceutical care.

To validate this role, pharmacists must document their activities and the associated outcomes. In this project, two months of data were obtained from five established sites of the Nebraska Drug Information Network. Pharmacists interventions were documented by focusing on these activities:

- Provision of drug information
- Monitoring for adverse drug reactions
- Prevention of drug interactions
- Avoidance of duplicious prescriptions
- Observing outcomes

Through this project, the range of pharmacy professional services were identified. The financial ramifications of these interventions were documented, and patient outcomes focusing on how pharmacist interventions improved drug therapy were assessed. These activities can be incorporated into a cost-effective managed care practice.

DESCRIPTION OF PROJECT

The Nebraska Drug Information Network was formed in December 1992 with a $300,000 grant funded in the VA-HUD Independent Agencies Appropriations Bill. The project was initiated in conjunction with the Nebraska Rural Development Commission. The project resulted in the development of 30 drug information and health information centers located in rural independent community pharmacies that serve as preceptor sites for University of Nebraska Medical Center (UNMC) pharmacy students. The project is a key component of UNMC's Rural Health Education Network (RHEN).

Each of these community independent pharmacies incorporates pharmaceutical care into their daily practice. Patient counseling and monitoring for adverse events, drug interactions, appropriate dosages, and indications are conducted daily. These activities are interspersed within the traditional pharmacy construct of dispensing functions. The Nebraska Drug Information Network was implemented to facilitate the transformation from traditional pharmacy functions to integrated pharmaceutical care in rural communities. Each network site was provided with a multimedia IBM-compatible desktop 486 personal computer for use by the pharmacist, the pharmacy student, and the patient. Each site computer is connected to UNMC through the Synapse telecommunications program. This program allows the practitioner to access various professional databases such as Medline. With these resources, pharmacists are able to answer technical questions with up-to-date resources.

Additional patient education materials are provided at each site. DynaPulse allows for computerized measurement of blood pressure and heart rate with an attendant tracking system. With this system, the pharmacist records outcomes of antihypertensive medication in conjunction with compliance and adverse effects between physician visits. Home Medical Advisor Pro allows for a review of diseases and symptoms in lay language. Bodyworks provides an anatomical journey through the human body, which facilitates the pharmacist's explanation of various drug effects. Wellness Checkpoint assumes a role of promoting health awareness and maintenance and allows the patient to assess their own health status through a series of questions. Womb With a View provides a descriptive and pictorial progression of pregnancy that the pharmacist uses to describe potential drug effects at various stages of gestation. Each preceptor who receives this system is allowed access to an electronic bulletin board alerting the practitioner to drug news (e.g., drug recalls, system updates, and drug information).

The tools provided by the Network assist the pharmacist in performing interventions and patient education. This infrastructure for coordinated pharmaceutical care helps community pharmacists manage various disease states such as diabetes mellitus, hypertension, and asthma. These patients are provided drug information, disease state information, and monitoring as appropriate (e.g., application of DynaPulse technology in patients receiving antihypertensive medications). The patient whose questions have been adequately addressed is more likely to be compliant with his therapy, hence drug therapy will have been optimized for these patients serviced by the network.

Network pharmacists had previously demonstrated their ability to provide patient counseling, patient-care interven-
Figure 1. Initiators of interventions concerning prescription drugs.

- Pharmacist 57.3%
- Nurse 1.6%
- Physician Assistant 6.2%
- Patient 16.9%
- Physician 18.1%

Figure 2. Initiators of interventions concerning nonprescription drugs.

- Patient 70.8%
- Nurse 0.5%
- Physician Assistant 2.6%
- Physician 4.7%
- Pharmacist 21.4%

interventions, and participate in pharmacy student education. Intervention documentation was a prerequisite for becoming a network site. Embedded within this documentation were outcome assessments and associated cost savings as determined by the pharmacist.

For this study, five of the 30 network community pharmacists documented involvement and associated interventions with the prescriptions filled each day for a two-month period. These pharmacists also entered into the computer interventions documented manually by other pharmacists. The interventions were documented on a user-friendly computer software program developed by the network director within the Paradox program using push-button applications. The program is located on a computer not used for dispensing functions. Pharmacists were instructed on program use by a computer analyst upon installation and in consultation with the network director. Specifically, types of data to be captured, use of key fields (i.e., connecting data which bridge screens), and examples were provided.

The community pharmacists, through use of the computer software program, captured the following categories of data:

- Patient demographics (age, gender, diagnoses if known, pregnancy, and HIV status; patient names were not included to maintain confidentiality)
- Pharmacist demographics (age, gender, years in practice)
- Drug use (drug name, dosage, generic use)
- Pharmacist interventions (who initiated intervention, type of intervention, appropriateness of dose, dosing frequency, route of administration, and indication if determined)

Pharmacist interventions were categorized as:

- Adverse effect identified
- Drug–drug interaction identified
- Drug–food interaction identified
- Drug–lab interaction identified
- Avoidance of duplicative prescriptions

For adverse drug effects, the situation was described and the effect was categorized using FDA guidelines (e.g., insignificant, permanent harm). Any needed treatment was recorded.

The importance and outcome of pharmacists' interventions were also recorded. Time needed for the intervention was noted. Other information—such as provision of patient counseling, assessment of patient compliance, and contact with the prescriber—was documented.

PC Anywhere technology was used to assist in data transfer. This was accomplished by requesting the pharmacy to leave their computer on overnight. After business hours, the network director or her designee downloaded the data via telephone transmission. During the day, data were entered into the documentation program. At study completion, the network director performed descriptive statistical analyses. Types of interventions, self-assessed significance, and outcomes (when known) were evaluated.

RESULTS

Over the two-month period, 624 (71%) interventions for prescription-based products and 254 (29%) entries docu-
menting nonprescription-based interventions were recorded, for a total of 878 interventions. The average number of interventions per pharmacy was 176, with a range of 16 to 353. The site logging only 16 interventions was implementing a new satellite pharmacy during this two-month period and therefore did not devote as much time to the study. Two sites logged 353 and 355 interventions, accounting for 78% of the study total. These two sites fully embraced the study intent, documenting all interventions during the two-month study period. Two of the sites documented 48 and 126 interventions each, recording only those interventions they categorized as out of the ordinary (e.g., screening for drug interactions may not have been documented). When evaluated as a function of prescription load, the site performing the most interventions (n = 353) filled 3,138 prescriptions (one intervention for every nine prescriptions filled). This is quite a contrast to the site with the fewest interventions (n = 16), where 4.501 prescriptions were filled during the month (one intervention for every 281 prescriptions filled).

The pharmacist was the most frequent initiator of prescription-based interventions, representing 326 (57%) interventions. Patients constituted the most frequent initiator of nonprescription-based interventions (136; 71%) (Figures 1 and 2). Overall, interventions were requested by 112 physicians and 10 nurses. Patients requested pharmacist interventions in 232 (30%) cases.

Pharmacists were asked to document the time spent on each of their interventions. This was not routinely done. When time expended was documented, prescription-based interventions averaged 16 minutes (range: 1 minute to 2 hours), while nonprescription-based interventions averaged 63 minutes (range: 5 minutes to 2 hours).

PERCEIVED IMPORTANCE OF INTERVENTIONS

The pharmacists characterized their perceptions of the importance on patient care of the interventions. Fourteen (1.6%) interventions were characterized as “extremely significant,” 33 (3.7%) as “very significant,” 236 (26.9%) as “significant,” 121 (13.8%) as “mildly significant,” and 9 (1.0%) as “not significant.” The remaining 465 (53%) interventions were not characterized.

One interaction characterized as extremely significant involved a trimethoprim-sulfamethoxazole prescription presented for a patient with sulfonamide allergy; the pharmacist contacted the physician resulting in a change to amoxicillin, averting a probable emergency room visit and hospitalization for the patient. Interventions characterized as very significant included rendering care for a patient presenting at a pharmacy with an evolving myocardial infarction, avoidance of erythromycin-terfenadine interaction, and counseling against use of ciprofloxacin in a pediatric patient.

ACCEPTANCE OF INTERVENTIONS

Interventions that resulted in personal interaction with other health care providers were generally well received. When the outcome was known, recommendations were followed in full in 418 cases (96%). In 14 (3%) cases, the recommendations were partially followed, with one case in which a recommendation was not followed because the patient’s condition changed. In only five (1%) of 418 cases were the recommendations known to be ignored. Figures 3 and 4 summarize recommendation acceptance outcomes as characterized within the prescription- and nonprescription-based domains.
Figure 5. Results of pharmacist triage services.

<table>
<thead>
<tr>
<th></th>
<th>MD referral 21.2%</th>
<th>OTC use 47%</th>
<th>Other 31.8%</th>
</tr>
</thead>
</table>

PROVISION OF TRIAGE SERVICES

As primary health practitioners in these rural settings, pharmacists frequently performed health care triage functions. In 42 (21%) cases, the pharmacists recommended seeking care from a physician, while in 93 (47%) cases a nonprescription remedy was suggested. In 57 cases, the pharmacist recognized symptoms requiring further evaluation by a physician; in 32 cases the symptoms reflected noncompliance, requiring pharmacist intervention (Figure 5).

COST IMPLICATIONS

In assessing cost ramifications of interventions, the following assumptions were made:

- Subtherapeutic or toxic dosing would at some point in the patient’s course result in hospitalization, depending on the severity of the original condition under treatment.
- Duplicative therapies would result in toxic dosing, which at some point in the patient’s course would result in hospitalization depending on the severity of the original condition under treatment.
- Adverse drug reactions would lead to noncompliance or toxic reactions, which would eventually lead to hospitalization.
- Drug interactions would lead to noncompliance or toxic reactions, which would eventually lead to hospitalization.
- Pharmacists providing triage and recommending nonprescription therapies would translate into avoided office visits if physician referral was not required.
- Patient assessment performed by a pharmacist to determine need for refills with prior authorization from physician would result in an avoided physician office visit.

\[ \text{Pharmacists in this study were capable of determining if their interventions translated into cost savings achieved over the course of a year.} \]

\[ \text{While some may contest the assumptions, their intent was to provide a framework for analyses in the absence of supporting research literature and in the absence of an expert panel. Admittedly, with budget restraints, it was not possible to review daily activities onsite and provide follow-up of every encounter for outcomes to determine if these assumptions were valid for every intervention. Perhaps it would be more appropriate to assume, for example, a certain percentage of drug–drug interactions would result in hospitalization, but this percentage is unknown at this time.} \]

\[ \text{We emphasize, however, that this theoretical framework provides a starting point for analyses and should not be misconstrued as a definitive economic statement.} \]

\[ \text{Based on the above assumptions, the cost savings associated with these interventions totaled $752,391 (Table 1).} \]

\[ \text{Drug adverse effects and toxicities were avoided in 38 cases. Five DRG classifications (447–451) addressing drug allergic and toxic reactions estimated resulting hospital costs at $4,568/episode.} \]

\[ \text{Hence $173,584 in cost avoidance was realized for this intervention related to adverse drug reactions. A total of 16 drug–drug interactions were interrupted, and one drug–laboratory (blood glucose) interaction was avoided. Four drug–food interactions were avoided as well. Duplicative prescriptions were avoided in 43 cases. Hospitalization costs avoided with these interventions total $292,342. Dosing misadventures were avoided in 30 cases, with four cases representing insufficient doses and 26 medications prescribed in excessive. Too-frequent dosing was avoided in 28 cases because of pharmacist interventions. Extrapolating each of these interventions to avoidance of hospitalizations (underdosing} \]
resulting in re-emergence of the original condition and overdosing resulting in toxicity), associated cost savings were $264,944.

Physician office visits could also be avoided with pharmacist interventions. At one site, the pharmacist had established a physician relationship in which the pharmacist assessed patient need for refills (i.e., the physician provided preauthorized refills on the prescription). For several patients, the need for upward dosage titration of amitriptyline was assessed by the pharmacist. Prescriptions were refilled and dosing was adjusted based on pharmacists' evaluation. Pharmacists contacted the physician as needed, but office visits (beyond the initial session) were generally avoided. During this two-month period, 70 refill-need assessments were performed by the pharmacist, avoiding physician office visits for these patients.

Estimated cost for physician visit for this geographic area was $45 per visit; hence, this activity alone accounted for $3,150.

In an additional 224 cases, pharmacists performed triage (e.g., determining whether nonprescription drugs or physician office visits were needed); 167 possible office visits were avoided, a cost savings of $7,315.

Interventions were associated with an estimated cost savings of less than $100/year in 157 cases and greater than $200/year in 10 cases. Using estimates of $50 and $300 each, respectively, associated cost savings were $7,850 and $3,000.

While these category estimates are imprecise, they most probably underestimate the cost magnitude of the interventions. Desired pharmacologic effects were enhanced as a result of the interventions in 73 cases, permanent disability was prevented in two cases, and death was prevented in three cases. In these latter three categories, it is not possible to assign cost avoidance values.

Costs associated with inappropriate interventions were not addressed in this study and hence are unknown. Intervention types are presented in Figures 6 and 7 with a cost presentation in Table 1. (Note: When a pharmacist made a patient
intervention, several layers of activity may have followed. For example, when intervening on a prescription, dosing appropriateness, frequency, and administration route may have all been subject to question. The same phenomenon may also occur when the pharmacist intervenes in nonprescription product use to determine if the patient is using the product correctly. Hence, the number of total interventions in Figures 6 and 7 exceeds 254 and 624, respectively.

**DISCUSSION**

**Study Findings**

The major findings of this study are three fold. First, pharmacists initiated the majority of the interventions. Other health care practitioners are not in a position and may not have the prerequisite knowledge (e.g., information about both prescription and nonprescription drug use by the patient) to make these types of interventions. Hence, pharmaceutical care as rendered by a pharmacist is necessary to protect the public and to meet the needs of the MCOs. More dispensing of a drug does not constitute pharmaceutical care; in fact, it may be dangerous when drug interactions and adverse drug reactions are not prevented.

Second, pharmacist interventions were well-received. Recommendations were followed completely in 96% of cases in the study. The public sought pharmacist interventions in 136 instances of nonprescription topics and in 224 triage situations.

Third, even in approximate terms, pharmacist interventions had a sizable financial impact. Cost avoidance totaled $752,391 for all five pharmacies, with each pharmacy averaging $75,239 per month. This compares favorably with the Fincham study, in which each pharmacy averaged $62,011 cost savings per month. This four-week study of 19 community pharmacies, 712 interventions were performed. Total indirect costs of $1.2 million were averred through pharmacist interventions, based on avoidance of hospitalization, emergency room visits, and physician office visits. With the magnitude of this response from both the study herein and the Fincham report, the value of pharmaceutical care becomes apparent.

In the rural setting, many of the pharmacists are the only health care providers consistently available to members of the community. The physician, physician assistant, and nurse practitioner may be available only one or two days a week. We were therefore not surprised to find 198 cases in which these pharmacist provided triage services. In 42 (21%) cases, the pharmacist recommended physician consultation, but nonprescription remedies were sufficient in 93 (47%) cases. This personal contact had a direct impact on drug therapy in 89 cases in which pharmacists observed symptoms reflecting poor compliance and other related pharmacotherapy issues. This provides further evidence of the pharmacist's enhancement of drug therapy through personalized pharmaceutical care.

MCOs serving rural communities can use these data in designing pharmacy functions for that locale. MCOs, however, may wish to know the intervention-to-prescription volume value for a pharmacy with which it contracts. This will serve as an indicator of pharmacist involvement with the patient in nondispensing activities. Our data demonstrated a wide range of level of involvement in such activities. Certainly more study of rural pharmacy services in the managed care era are needed.

**Implications of the Study**

Approximately $77 billion in direct health care costs result each year from drug-related morbidity and mortality in the ambulatory setting in the United States. MCOs realize that this represents ill-monitored and inefficient drug use. Pharmaceutical care could reduce the costs of this drug-related mortality and morbidity in primary care settings by more than 50%. As a profession, pharmacy is well-poised to address this need and to avert such drug misadventures. As our study illustrates, pharmacists expend considerable efforts in patient counseling and interventions.

Unfortunately, our study strength was also our study weakness: the study was completed in an actual applied pharmacy setting documenting activities as encountered in its naturalistic environment. The orientation of this setting is, properly, the rendering of pharmaceutical care in conjunction with dispensing activities. Such a setting does not allow independent verification of the validity of pharmacist judgments in assessing their documentation. Nor does this setting consistently allow for complete follow-up of patient outcomes. Nor is it known whether the pharmacist documented every intervention correctly. A contrived, well-monitored setting with independent investigators verifying every detail of pharmacists activity would provide a more controlled study atmosphere. But it would also introduce observational bias for both the pharmacist and the patients, as well as proving to be an expensive study. An ideal setting for this study seems elusive, but several suggestions based on our experience can be made for future studies.

**Future Studies**

Development of a computerized database designed to document interventions and capture cost ramifications based on literature evaluation is needed. Such an unbiased, literature-based assessment of known ranges for cost savings based on pharmacist interventions would relieve the practicing pharmacist of self-analyses that others may view as biased. Such a program allows for variances based on actual patient experiences, but it could provide the needed template for
pharmacists, recording. This template may also serve a dual role in providing a standard for purposes of documenting the value of pharmaceutical care. Hence, comparative analyses of pharmaceutical care value—regardless of practice or geographic setting—can be performed using this standard.

Future studies should recognize that documentation is not incorporated into the daily activities of most practicing pharmacists; hence, pharmacist cooperation in such a study may be limited under present conditions. Such studies should include an educational component providing participants with evidence of the need for documentation as a vehicle for future professional viability. This component should also include practice with clinical cases in properly documenting an intervention. This component will allow standardization and hopefully reduce variability in pharmacist documentation as was encountered in this study.

CONCLUSION

As the Pew Foundation notes, the primary goal of drug therapy management is to improve patient outcomes in a cost-effective manner. Pharmacists are one of several health care providers likely to participate as key players in this endeavor as managed care maximizes drug therapy to reduce costs and improve outcomes. This study demonstrates this value from pharmaceutical care services administered over the relatively short time period of two months. This study also outlines that, even with a small number of similar pharmacy practitioners, the level of documentation varies widely even in study conditions. Pharmacy must develop a standardized instrument with which to document their interventions. This documentation will allow managed care entities to better understand the value of pharmaceutical care in rendering health care.

One final compelling observation arises from this study. The study pharmacists completed their pharmaceutical care activities while integrating dispensing functions as well. If pharmacists could divest themselves of dispensing functions and devote themselves entirely to pharmaceutical care activities, the favorable impact on patient care and associated financial parameters would be tremendous. Efficient use of pharmacy technicians, automation, and robotics may allow this to occur.

References

Pharmacoeconomic Evaluations: Guidelines for Drug Purchasers

Paul C. Langlely
and Sean D. Sullivan

OBJECTIVE:
To propose a set of guidelines for use by health care organizations in the United States that seek useful, comparative clinical information and economic analysis on pharmaceutical products to make sound drug purchasing decisions.

PRACTICE INNOVATION:
Based on a therapy intervention approach, the guidelines provide a structured framework to help managed care purchasers become more consistent in how they evaluate drug products for inclusion in the formulary. The guidelines factor in the need to examine the impact of new drug products on overall costs within the entire health system.

PRACTICE SETTING:
Intended for use by managed care organizations in the U.S. that purchase prescription drugs.

INTERVENTION:
Not applicable.

MAIN OUTCOME MEASURE:
Not applicable.

RESULTS:
The guidelines provide MCOs with a new systematic approach for identifying the overall cost and clinical outcomes impact of drug therapies. The guidelines are designed to take into account the characteristics of the patient population being treated and the fact that patients generally are redistributed among different treatment categories once a new drug product is introduced, thus offering MCOs an analysis model that extends beyond the traditional partial cost-outcomes approach. Emphasis is placed on looking at the cost-outcomes impact of a new drug or therapy within a system of disease area framework in which the redistribution of patients between therapy options is explicitly modeled. The guidelines specify that the following information elements be used in pharmacoeconomic analysis: product description, place in therapy, comparator products, therapy intervention framework, supporting clinical data, supporting pharmacoeconomic data, system impact assessments—costs, outcomes, overall assessment, and bibliography and supporting materials.

KEY WORDS:
Pharmacoeconomics, Managed care organizations, Pharmaceutical industry, New drugs, Formularies, Costs, Outcomes, Guidelines.


Growing awareness of the need to evaluate pharmaceutical and other health care interventions in economic as well as clinical terms has led a number of drug purchasing agencies to recommend or, indeed, mandate that pharmaceutical manufacturers and other suppliers of health care products undertake pharmacoeconomic analyses to support the assessment and subsequent formulary listing or adoption of their products by health care systems.

For example, the Commonwealth Government of Australia, through the Department of Health, has mandated since January 1993 that all submissions to the Commonwealth for national formulary listing be supported by a pharmacoeconomic evaluation of the drug. The Australian Guidelines list a series of questions to which applicants should respond and provides a framework for identifying and formatting the minimum necessary information to support an application for formulary listing and its subsequent assessment by a formulary review committee. These information requirements are spelled out in even greater detail in the November 1995 revision of these Guidelines. Needless to say, the Australian guidelines have received considerable publicity and have proven to be a catalyst in the development of both guidelines and standards-related documents in countries such as Canada, New Zealand, and the United Kingdom. However, none of the subsequent documents provides the same level of detail in specifying evidentiary requirements as the Australian Guidelines.

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DEVELOPING GUIDELINES FOR THE UNITED STATES

Our purpose in this article is to propose a set of guidelines that U.S. health systems, as drug purchasers, can use to evaluate drug products for inclusion on the formulary.

While the terms “standards” and “guidelines” are often used interchangeably, there is an important distinction between them. The term “guidelines” is used typically to describe or proscribe evidentiary standards. Specifically, guidelines set the requirements or parameters for determining the type of pharmacoeconomic analysis that is needed or will be accepted in support of a formulary application. The information—driven in large part by the analytical requirements—that should accompany the analysis is usually also identified.

In the Australian Guidelines, for example, formulary submissions must meet strict evidentiary standards. These establish a clear hierarchy of data acceptability using evidence drawn from randomized clinical trials as the gold standard. Even though the modeling of drug interventions is recognized as legitimate by the Australian Guidelines, the data used and evidence presented must meet minimum standards to be considered.

Hence, the term “guidelines” can be interpreted in essentially evidentiary terms. The term “standards” refers to the techniques of analysis used to describe and assess cost-outcomes relations and the ways in which data can be assembled and presented for analysis. While there have been attempts to define “standards” of analysis, these are more appropriately seen as techniques accepted by practitioners in the area and used routinely in peer-reviewed and published papers.

Persons or organizations making submissions should be aware of the basic techniques of pharmacoeconomic and decision analysis and the extent to which there is a consensus in the use of these techniques. For example, the analyst should be aware of the need to separately identify units of resources from the application of the appropriate unit costs, use the appropriate surrogate of final outcome measure of therapy, consider alternative outcome measurement techniques, and use techniques such as discounting long-term therapy interventions and marginal or incremental assessments. A number of texts in this field provide a basic grounding in techniques of cost assessment and outcomes measurement.

Ideally, guidelines should allow considerable latitude in the perspective to be adopted in the pharmacoeconomic analysis, the choice or type of economic analysis, data sources used, and the selection of alternative products in making comparative assessments. The standards to be applied in the analysis should be left to the discretion of the applicant. The issue of standards—and the extent to which there is agreement as to the appropriateness of particular methodologies or analytical techniques in pharmacoeconomic research—is important in what is seen as a rapidly evolving discipline. For example, awareness is growing that, from a purchaser’s perspective, a health plan or system-wide frame of reference is essential. In adopting a system perspective—inevitable if a purchaser is to take full account of the impact of adding or deleting a drug from the formulary—analysts are moving away from what can be described as the traditional approach to pharmacoeconomic assessments (i.e., simplistic drug A versus drug B comparisons) to an assessment of the overall costs and outcomes of a new therapy intervention. The proposed guidelines must permit this latitude as the field of pharmacoeconomics evolves.

Although considerable attention in the United States is being paid to the need for pharmacoeconomic analyses to support submissions to health care purchasers, guidelines to support formulary submissions are conspicuously absent. This position may seem paradoxical, given the release of the Pharmaceutical Research and Manufacturers of America (PhRMA) principles and the draft statement by the Food and Drug Administration’s Division of Drug Marketing, Advertising and Promotion (DDMAQ) on substantiation of pharmacoeconomic claims. However, these documents are only a first step toward the formulation of more prescriptive statements of the informational and analytical needs of prospective drug purchasers—statements that need to be put in place if they are to support both the activities of pharmaceutical manufacturers and health care purchasers in assessing pharmaceutical and health care technology products.

While the guidelines presented in this article draw, inevitably, on those presently in place (or being developed) in other countries, principally Australia, Canada, and the United Kingdom, they differ in one important respect: the perspective taken is that of the individual health care system as a purchasing agency. In this context, the community- and economy-wide impacts of selecting and using alternative therapy options take second place. The focus is on the costs and outcomes of accepting or rejecting therapy options for the individual health care system. It is this system-perspective that dictates the form in which the data should be presented, questions posed, and analytical techniques employed.

This is the first time guidelines for information assembly have been proposed for the U.S. market. However, these are not meant to be unduly prescriptive or static. Rather, they are intended to define what may be considered the current set of minimum information requirements necessary to support comprehensive assessments of both new and existing drugs within disease intervention or therapy areas. This is only the first version of these guidelines; no doubt, they will need regular updating as the informational and regulatory environment changes and new techniques for pharmacoeconomic assessment emerge.

PhRMA PRINCIPLES

The PhRMA principles (or industry code of practice) are not intended to be guidelines, but as a statement of principles to be followed in pharmacoeconomic studies. This industry initiative is used for both internal evaluation as part of strategic decisions on product development as well as applications...
for reimbursement and formulary listing.

The PhRMA principles focus on five areas of pharma-
economic analysis: research design, reporting, report con-
tents, data sources, and extrapolation of results. In the case of
research design, the only principle proposed is that there be
no restrictions placed on data sources. In the case of reporting
results, the key principles are for a clear statement of study
objectives and rationale for the outcome measure selected,
together with a final report that describes assumptions, meth-
ods, and data sources. A total of 34 principles are identified
for the content of pharmacoeconomic reports, all reflecting
the traditional forms of pharmacoeconomic analysis: specification
of study population, identification of alternative treat-
ments, choice of relevant time horizons, statement of rationale
for the analysis, and adopting standard approaches to the
treatment of uncertainty.

For costs and resources to support therapy, authors need
to identify the study perspective, recognize both average and
marginal analyses, employ discounting when relevant, separate
out resource units used from prices, and show how cost
estimates are derived. The same principles apply in the case of
outcomes. Data sources must be documented and their quality
assessed. Finally, if necessary, extrapolation from one treat-
ment environment to another, in terms of resource use and ef-
fectiveness, should be allowed.

Nothing in the PhRMA principles is inconsistent with the
reporting structure proposed here. However, two key points
should be made. First, the PhRMA principles are concerned
with standards for analysis and reporting, not with the way in
which assessments should be reported to prospective health
care purchasers. Second—and more importantly—the PhRMA
principles allow a range of analyses to be considered. These
can range from the traditional drug A versus drug B to a sys-
tems approach based on a therapy intervention model frame-
work. As explained below, it is this latter approach (or per-
spective) that underpins the guidelines we propose here.

ECONOMIC ANALYSIS OF PHARMACEUTICALS

The ultimate objective of economic evaluations performed
using our guidelines is to determine how introducing a particu-
lar drug product (or deleting it) from the formulary impacts
the delivery of health care for a particular disease or therapy area.
These effects can be considered both in terms of the impact of a
particular therapy or treatment option on the costs to the entire
health care system as well as the outcomes for the population
being treated. These can be expressed in terms of clinical out-
comes, measured health status, quality of life, and dollars saved.

Identifying the Proper Perspective

In taking a therapy or disease intervention approach,
evaluations of formulary alternatives focus on the anticipated
net or overall cost impacts for the health care system and the
impact on the outcomes profile for patients treated within that
disease or therapy area. Indirect cost impacts—while of po-
tential relevance—are generally secondary considerations for
health care systems as drug purchasers.

In assessing the impact of introducing a new product to a
formulary, a systems or global approach—described here as a
therapy intervention or therapy modeling approach—is much
needed. Once a therapy framework has been determined that
identifies the relevant or principal treatment pathways, data are
drawn from a variety of sources together with assumptions and
interpolations to describe costs and outcomes (typically in
probabilistic terms). While such an approach requires extensive
and reliable data, it provides the framework within which exist-
ing formulary products and those proposed can be assessed. A
therapy intervention approach identifies the following:

- Principal therapy interventions or options within disease or
treatment areas
- Process of treatment within each intervention pathway
- Resources used to support each intervention pathway
- Outcomes of therapy in effectiveness—not efficacy—terms

For each pathway, these variables can be quantified: num-
ber and characteristics of patients, probabilities of achieving
particular endpoints of therapy, patterns of drug therapy, and
costs of treatment. By expressing outcomes in probabilistic
terms for each therapy pathway, the expected costs or treat-
ment within disease areas can be estimated and related—in
cost-effectiveness, cost-utility, or cost-benefit terms—to agreed
end-points of interest to the health system.

Estimating Outcomes of Therapy

Once such a disease or therapy intervention framework
for that health care system has been developed, system cost-
outcomes relations can be specified. That is, it is possible—
from retrospective medical and pharmaceutical claims
data—to estimate therapy intervention costs using both the
treatment pathway and the disease or intervention area as a
whole, as well as the average cost and distribution of costs for
patients who have been treated. These costs can be broken
down by medical resource unit (drug costs, physician costs,
laboratory costs, emergency room, and hospital costs) and the
principal cost drivers identified.

While claims databases typically do not record outcomes
of therapy (e.g., number of patients achieving a successful res-
solution of symptoms or stabilized within a given treatment
timeframe), costs can be defined for predetermined treatment
timeliness and supplementary patient surveys could be under-
taken to identify the profile of therapy outcomes. In many cas-
es, surveys are either too costly or not practical. What should
be considered are attempts—as part of standard data-collec-
tion procedures—to develop outcome proxies. These might
include, for particular interventions or disease states, report-
ing blood pressure level (in hypertension therapy), intracra-
neral pressure (for glaucoma), cholesterol levels (for hyperchole-
systerolemia), blood glucose levels (for diabetes), and peak flow
rates (for asthma).
Defining an Equilibrium Change

The importance of prior identification of a disease or therapy intervention framework is that it forms the basis for evaluating the expected impact of either adding a new product or deleting an existing product from the formulary. Given estimates of the costs and outcomes associated with an existing or proposed therapy intervention, the impact of modifying a formulary listing can then be estimated. Such an impact assessment depends largely on projected patterns of drug substitution and the numbers of patients expected to switch therapy options. As patient-switching patterns take time to work themselves out, a plausible projection is needed for expected patterns of therapy switching and the resultant distribution of patients between therapy intervention areas. This impact assessment can be described in the language of the economist, as a comparative static or equilibrium framework, in which a new equilibrium is achieved reflecting the new (or projected) distribution of patients between therapy or drug options in the disease area. The assessment of a new product—in cost and outcomes terms—is an exercise in constructing an initial equilibrium in the distribution of patients by drug category with a projected equilibrium once patients have been reallocated between therapy options.

The assumption, all too often found in pharmacoeconomic analysis, that constant costs and outcomes obtain irrespective of the number or proportion of patients treated in a given population may not be appropriate in evaluating the impact of changing patterns of drug use. When a new drug is introduced to therapy, the patients not responsive to existing therapies are switched to the new therapy, affecting both average cost and outcomes relations. Average costs per outcome achieved may decline for existing therapies, which means that the new distribution of patients between drugs may result in quite different cost and outcomes profiles for each drug intervention within that therapy or disease area.

To summarize this section, an overall assessment of the impact of adding a new product to existing therapy must, therefore, take a health plan or system perspective. The assessment should generate estimates of the overall impact of introducing the new product on the overall costs of therapy and the outcomes profile for patients treated in a disease area. Partial analyses (i.e., drug A versus drug B) that focus on comparing a new product with one presently on the formulary are unlikely to generate the necessary data for an overall assessment—unless it can be argued that product substitution is only expected to occur against a limited number, possibly only one, of the drugs presently on the formulary for that disease or treatment area and that constant costs and outcomes per patient treated obtain. Similarly, cost-outcomes assessments drawn from clinical or other small sample data sets are also likely to be misleading as a guide to overall system benefits. Again, it is up to the pharmaceutical company to make the submission to create a case for using local or small sample (e.g., randomized clinical trial based) based cost-effectiveness, cost-utility, or cost-benefit ratios as predictors of overall system impacts and the benefits from introducing new products, at the price sought, to the formulary.

TYPES AND USES OF AVAILABLE DATA

A final point concerns the role of clinical data in modeling therapy interventions and the relationship between resources used, costs, and therapy outcomes. Clinical data, while designed to generate estimates of therapeutic impact, are of limited use in assessing the real world, intention-to-treat impact of a drug in effectiveness terms. If clinical data are used to support a formulary application, the applicant must link clinical efficacy with therapeutic effectiveness. That is, factors such as comorbidities in the prospective treating population and potential lack of compliance in assessing cost–outcomes relationships should be considered.

This emphasis on effectiveness in modeling drug interventions does not mean that clinical data obtained from drug trials are not important in supporting a formulary application. Indeed, a key element in the proposed guidelines is the identification and summary of relevant clinical data with an overview of the therapeutic impact of the drug. Clearly, if a drug does not have an acceptable therapeutic impact (or one which is not statistically significant or clinically relevant at conventional decision levels), then any evaluation should question the basis of the submission unless a cost-minimization argument is being proposed. Clinical data may be describing the therapeutic impacts or outcomes of a drug against a placebo or other drugs presently on formulary. It is unlikely that clinical trial data will be available comparing most existing and prospective formulary alternatives, making necessary an assessment of likely impacts on outcomes profiles and modeling of the therapy interventions accordingly.

PREPARATION OF THE SUBMISSION

As in any marketing or promotional endeavor, the onus is on the supplier to convince the purchaser of the benefits of accepting a drug into a formulary. In the present case the prescription is that the proposal would be undertaken by the pharmaceutical company and that, while the prospective purchaser may provide data extracts from pharmacy and medical claim databases, the use of such data and the development of intervention models would be the responsibility of that company. This does not mean that the company should not, in the process of preparing the submission, confirm its choice (for example) or competitor products. But overall, the company is responsible for the form of the submission and the justification for formulary admission at the price sought.

PHARMACOECONOMIC SUBMISSION FORMAT

The following format and information requirements are proposed for pharmacoeconomic submissions to health plans as part of the formulary-approval process.
Part I: Product Description
A pharmacologic profile is needed of the product to be considered for formulary listing. This profile should include the following:
- Name, chemical composition, and therapeutic class
- Approved indications
- Principal pharmacologic action
- Course of treatment/Regimen
- Any needed concomitant drugs
- Contraindications
- Adverse effects

Part II: Place in Therapy
The place of this product in therapy should be described as follows:
- Principal treatment options and practice patterns in the disease or therapy area
- Place of the proposed product in those treatment options
- Concomitantly prescribed drugs
- Brief pharmacological profile of principal drugs in disease or therapy area

Part III: Comparator Products
Principal comparator products (including those for which the proposed product is expected to be substituted) are then listed. In identifying the principal comparator products, information should be supplied about the following:
- Description and pharmacological profile of comparator products
- Place of comparator products in therapy
- Concomitant drugs—if any
- Criteria for selecting comparator products
- Present distribution of comparator products (in unit and cost terms) within disease or therapy area
- Anticipated patterns of drug substitution of the new product for other comparator products

Part IV: Therapy Intervention Framework
Once the place of the proposed product in therapy has been identified, together with the principal comparator products, the framework for impact assessment—in terms of a therapy intervention model—should be detailed. Such a framework should define the following elements for the prospective health system as purchaser:
- Principal treatment options in that health system
- Processes of treatment
- Principal drug and medical resources consumed in therapy, by treatment pathway (retrospective analysis)
- Costs of resources consumed by treatment pathway
- Principal outcomes of therapy in clinical and health status terms (including utility measures and quality-adjusted life years)

Part V: Supporting Clinical Data
The anticipated clinical impact of the proposed product must be detailed. Clinical trial data are summarized, including both pivotal clinical trials (to support safety and efficacy) and other trials considered important in identifying the place of the product in therapy (e.g., vis-a-vis comparator products). Key information requirements are the following:
- Justification of choice and applicability of clinical studies
- Summaries of clinical data (on a trial-by-trial basis)—location of trial, treating population, trial design and sample characteristics, comparators (including placebo), and outcomes

A clear statement of the statistical significance should be attached to the outcomes, particularly when a comparison involves the proposed therapy and those principal therapies for which it is expected to substitute in practice. If appropriate, a meta-analysis can be presented. The choice of study is to be justified by its relevance to the prospective population under treatment.

Part VI: Pharmacoeconomic Supporting Data
Any studies supporting or analyzing the impact of the proposed product in pharmacoeconomic terms should then be listed, described, and evaluated for the disease or therapy intervention area under consideration. The following should be included for each of the pharmacoeconomic studies cited:
- Justification for including the pharmacoeconomic study
- Description of the study and assessment framework
- Patient population to which the assessment relates
- Timeframe for the analysis
- Estimation of cost-outcomes relationships
- Relevance of the pharmacoeconomic study to the population under treatment

Part VII: System Impact Assessment—Costs
For the prospective purchasing organization, system impact costs for the proposed product should be assessed for the first three years of formulary listing or until the time at which a new equilibrium in the distribution of products has been established. To assess the cost impact, proposers must estimate and justify the rate of uptake of the new therapy, characteristics of the treating population (including comorbidities), patterns of substitution for other products, and resources used to support therapy. Cost estimates should include the cost of treating adverse events of therapy. The following are key information requirements (for agreed outcomes or endpoints of therapy):
- Resources used to support therapy intervention before new product is introduced (by therapy intervention pathway, an agreed classification of drug and other direct medical inputs, and unit cost)
- Resources used to support therapy intervention after new product is introduced by therapy intervention pathway (by years 1 through 3 following product introduction)
- Net impact of new product on system resource use and costs (by comparator product—given assumptions as to patterns of drug substitution—for new product)
Table 1. Checklist for Formulary Submission

- Has a comprehensive pharmacologic profile of the product been supplied?
- Has the place of the product in therapy been described and justified for the managed care setting?
- Has the proposal identified and justified the principal comparator product or products against which the proposed product is compared in the relevant managed care setting?
- Has the proposal provided a pharmacologic profile and described the principal comparator products for the managed care setting?
- Has the proposal identified, for the comparator products, those for which substitution is likely to occur and the timeframe and pattern of substitution in that managed care environment?
- Has the proposal provided a comprehensive review of clinical data to support (1) the place of the proposed drug in therapy and (2) the clinical efficacy of the proposed product against the principal comparators identified?
- Has the proposal described the outcomes of therapy considered relevant for the therapy intervention setting?
- Has the proposal considered any constraints in an intention-to-treat environment that might modify, for the managed care setting, clinical outcome measures, and the assessment of the clinical impact of the proposed and comparator products in effectiveness terms?
- Has the proposal opted for a particular type of pharmacoeconomic assessment?
- Has the proposal justified the choice of type of pharmacoeconomic assessment?
- Has the proposal detailed the structure of the pharmacoeconomic assessment, the characteristics of the treating population, and the time frame for the analysis in the managed care environment?
- Has the proposal identified the clinical and cost-effectiveness options, the resources used to support these interventions for the managed care environment?
- Has the proposal assessed resources used and generated (1) estimates of the cost of therapy interventions by treatment and drug options; (2) an estimate of the impact of introducing the new product on the costs of treatment for the managed care environment; and (3) an assessment of the impact of introducing the new product on the outcomes of treatment for the managed care environment?
- How has the proposal related the overall net cost of therapy interventions in that disease area to the therapy outcomes profile for that managed care setting?
- Has the proposal reviewed all possible outcome measures for this treatment area?
- Has the proposal provided summary measures of cost-outcome ratios?
- Has the proposal undertaken a sensitivity analysis of these cost-outcome ratios?

Part VIII: System Impact Assessment-Outcomes

The proposer must identify what are considered to be the appropriate outcomes of therapy for this intervention. These can be expressed as either intermediate or final outcomes. The outcomes must be expressed in effectiveness rather than efficacy terms and related to the anticipated treating population. Key informational requirements are the following:
- Choice and justification of outcomes
- Validity of measures used to generate outcomes
- Anticipated impact of new product (in net terms) on outcomes profile
- Justification of the assessment of impact of new product on outcomes profile
- Extent to which clinical trial results are expected to differ because of the treating environment and the characteristics of the prospective treating population (e.g., impact of comorbidities, compliance profiles)

Part IX: Costs and Outcomes—Overall Assessment

Finally, a statement is required of the estimated overall benefit for the treating population in the health care organization from bringing the product onto formulary. A number of techniques can be used in analyzing and summarizing cost-outcomes relationships, together with estimates of the robustness of these relationships. Key requirements are as follows:
- Concise description of application and analysis using the chosen therapy impact model
- Estimate of the overall costs of therapy interventions for the patient population treated
- Estimate of the overall impact of the new product on the final outcomes profile

- An evaluation of the robustness of the estimates to include the treatment of uncertainty (e.g., through a sensitivity analysis)

Part X: Bibliography and Supporting Materials
- Bibliography
- Modeling spreadsheets
- Copies of principal clinical and pharmacoeconomic papers

PHARMACOECONOMIC PROPOSAL CHECKLIST

Table 1 describes a brief checklist that can be used for both companies submitting proposals to prospective drug purchasers as well as for those evaluating proposals. This is not the only checklist that can be developed, but it provides one basis for evaluating a proposal.

CONCLUSION

In this paper, we propose guidelines for U.S. health systems to use in evaluating drug products for inclusion on the formulary. We have proposed a therapy intervention or systems approach under which drug manufacturers and suppliers are required to evaluate the net cost-outcomes impact on the disease or therapy area resulting from the introduction of that drug or health care product.

From a pharmacoeconomics perspective, these guidelines take a general, rather than partial approach to comparative evaluation. Rather than suggest the use of a narrow, clinically focused approach for evaluating cost-outcomes ratios, we propose using a system or equilibrium-to-equilibrium approach for evaluating drug impact. Such an approach—by taking into
account the shifting distribution of patients between different therapy options—assures that an appropriate cost-outcomes assessment is performed.

While this is more demanding in terms of both data and technical expertise than the traditional, partial approach, it is more appropriate. Unless account is taken of the range of comparator products, anticipated patterns of drug substitution for the treating population, and their impact on the structure of costs and outcomes, any assessment of the impact of introducing a new drug remains incomplete.

References
While Health Care Evolves, Antitrust Law Endures

Richard S. Rhodes

OBJECTIVE:
To present an overview of the federal and state antitrust laws, the methods by which they are enforced, and pertinent cases involving health care systems and providers.

DATA SOURCES:
Pertinent case law, administrative rulings, and statutes.

STUDY SELECTION:
Not applicable.

DATA EXTRACTION:
Not applicable.

DATA SYNTHESIS:
U.S. antitrust law is based on the Sherman Act, which prohibits unreasonable conspiracy in restraint of trade and monopolization. Certain activities are considered per se violations, while case law and administrative rulings have shed light on the legality of other activities. Countering the Sherman Act is the Robinson–Patman Act, which seeks to protect competitors from overly vigorous price competition. The Clayton Act and state laws further complicate the antitrust picture. Certain situations that can occur in health care systems or among health care practitioners are discussed: price-fixing, exchanging price-related data, using “most favored nation” clauses, joint purchasing, group boycotts, mergers, discriminatory pricing, and self-referrals. Special exemptions for nonprofit institutions and the insurance industry are discussed.

CONCLUSION:
A reasonable level of understanding of basic antitrust concepts can help managed care practitioners avoid spending an unreasonable amount of time and money defending or explaining commercial actions.

KEY WORDS:


For more than 100 years in the United States, the antitrust laws—federal and state—have been based on the basic economic philosophy that consumers are best served in the marketplace by free market competition among business. Until the 1970s, however, persons practicing the “learned professions,” such as law, engineering, and medicine (and, to some degree, pharmacy) were considered exempt from the antitrust laws because they were not engaged in “trade or commerce.”

That notion changed precipitously in 1975 when the Supreme Court held that a State Bar Association could not restrict advertising by lawyers because the Bar’s action restrained competition in violation of the Sherman Act, the basic federal antitrust statute.1 A few years later the Supreme Court applied the antitrust laws to an engineering society that had prohibited competitive bidding by engineers on the rationale that such activity was unprofessional and would lead to inferior work.2 Finally, in 1982, the Court clearly eliminated any notion that physicians were still professionally immune from the antitrust laws by holding that a fee schedule promulgated by a county medical society constituted price-fixing that was illegal under the Sherman Act.1

As one court has recently noted: “Health care providers are exposed to the same liability and entitled to the same defenses as businesses in other industries.”

In the 1990s, an avalanche of antitrust litigation has struck the health care field. As changes have taken place in the delivery and management of health care services and products, the antitrust enforcement agencies have

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created special task forces to keep up with these developments and related them to traditional antitrust concepts. Recent cases involved not only price-fixing, but also allegations of such indiscriminations as boycotts, anticompetitive mergers, tying the sale of discrete products together, and monopolization. Indeed, most of the charges have been against physicians and hospitals, both individually and in organizations, but without doubt the same laws apply to managed care organizations and pharmaceutical benefit managers.

In addition to precedent established by judicial decisions in lawsuits that have gone to court, antitrust law has grown through settlements reached between the government and defendants and policy statements promulgated by the government enforcement agencies. For example, the idea that physicians in a network may engage in certain otherwise questionably joint venture activities only if they are economically integrated or share substantial financial risk (e.g., by capitation or financial incentives to achieve cost-containment goals) is found in antitrust/health care guidelines published by the Department of Justice and Federal Trade Commission a few years ago.

The most effective way to explain how the antitrust laws have dealt with health care issues is through description of specific enforcement actions, from which analogies can be drawn. To the maximum extent possible, my emphasis in this article will be upon matters that directly involve the distribution of pharmaceuticals; other health care cases will be used as examples from which deductions can be drawn.

To establish an appropriate foundation, I will present an overview of the antitrust laws and the methods by which they are enforced before delving into specific health care cases.

**ANTITRUST LAWS—A VERY SHORT COURSE**

**Senator Sherman's Legacy**

The Sherman Act is intentionally broad and ambiguous. Its interpretation was left to the federal courts, as the judges crafted their opinions to apply the law to specific fact situations. It basically comprises Sections 1 and 2, which, respectively, prohibit unreasonable restraints upon and monopolization of trade.

Section 1 provides, in part, that "every contract, combination . . . or conspiracy, in restraint of trade or commerce . . . is declared to be illegal." Taken literally, every business transaction would fit this description since persons outside the transaction are excluded from it, or "restrained," from participating in it. Therefore, the courts quickly injected the requirement that only "unreasonable" restraints are illegal (the "rule of reason"). However, some combinations or conspiracies, such as a naked agreement between two competitors upon the prices they charge for goods or services, are deemed to be automatically unreasonable and indefensible, and designated as per se illegal.

The keystone of Section 1 is the requirement of joint, concerted, or collusive activity among two or more parties. An unlawful agreement need not be formal or in writing; an informal understanding or a "gentlemen's agreement" may be enough to support a conviction under Section 1. A chain of circumstantial evidence may give rise to an inference of an agreement; for example, the exchange of a "knowing wink" between two persons involved in what appears to be an innocent discussion of rates, followed by the two beginning to charge identical rates shortly thereafter, may be sufficient to lead to a complaint of unlawful price-fixing.

Bid-rigging is probably the most common form of price-fixing, but Section 1 also encompasses other collusive activities. For example, an agreement to divide customers or markets, or a trade boycott (an agreement not to buy from or sell to certain parties) or a tie-in (a requirement that a customer take a product she does not particularly want to obtain one that she does) all create risks under Section 1, with some risks more serious than others.

Section 2 of the Sherman Act prohibits monopolization, as well as attempts and conspiracies to monopolize. The offense is not just being large, or even having a large share of a market, but achieving or maintaining a dominant position in a market by the use of predatory tactics. No established market share is automatically monopolistic; it may be 60% in one market and 85% in another; the test is sufficient market power to control prices in the market or foreclose access to the market by a competitor.

Attaining even a 95% market share is not per se monopolistic, assuming the position was obtained by lawful means, such as a valid patent, superior skills or products, or greater efficiency than competitors. "Monopoly power" becomes "monopolization" when it is obtained by use of predatory acts such as price-fixing, tie-in sales; exclusionary practices, such as selling at unreasonably low prices that competitors cannot match (with the intent that the price will rapidly escalate when the competitors are eliminated); or use of unfair and unethical practices.

While these concepts may be hazy, their consequences are clear—and severe. The Sherman Act is enforceable not only by injunctive action by the Department of Justice or the Federal Trade Commission, but it may also subject offenders to criminal penalties. Convicted individuals may spend up to three years in jail, and their companies may be assessed millions of dollars in fines. In addition, a private party whose business is injured by a violation of federal antitrust law may sue for damages (such as overpayments by customers or lost profits by competitors) and recover three times the actual amount of damages suffered.

**Risk of Selling at Different Prices**

In contrast to the "hard competition" fostered by the Sherman Act is the "soft competition" engendered by the Robinson-Patman Price Discrimination Act. While the Sher-
Clayton Act Supplements the Sherman Act

The Clayton Act proscribes activities that "may" have an adverse effect on competition. One of the two most prominent sections of the Act is Section 3, which prohibits acts that may foreclose a competitor's access to a market; for example, an exclusive arrangement that requires a customer to refrain from dealing with a competitor, or a tying arrangement that conditions the sale of one (desired) product on the purchase of another (not so desirable) product.

The second principal part of the Clayton Act is Section 7, sometimes referred to as the antimerger law. It prohibits a merger, acquisition, or joint venture that will probably have the effect of substantially lessening competition or tending to create a monopoly. This section is actively enforced by both the Department of Justice and the Federal Trade Commission, which divide investigations between them. In the health care field, a plethora of hospital mergers has been reviewed by these agencies, and many have led to lawsuits for injunction or to consent decrees limiting the scope of the mergers.

State Antitrust Laws

So much of the antitrust law has been developed by the federal courts, applying federal statutes, that it is easy to overlook state antitrust laws. However, many states have legislation that parallels the Sherman and Clayton Acts, and some have their own version of the Robinson–Patman Act. Most of these statutes are enforced by the state attorneys general, and in recent years the National Association of Attorneys General has been very active in encouraging its members to engage in antitrust enforcement.

Activities Exempt from Antitrust Laws

A number of exemptions have emerged from application of the antitrust laws, generally through statutory initiatives but sometimes by court decree. Examples of these exemptions include: (1) if an act is mandated by the government, the actor is not subject to antitrust prosecution; (2) labor negotiations, even when conducted by an organization composed of competitors and obviously affecting costs and prices, are not subject to the antitrust laws; (3) solicitation of government action, even if the results may be anticompetitive, is protected by the Constitution; and (4) in some industries, such as insurance, consumers' interests are protected by regulation, rather than by competition.

The exemption for insurance was created by the McCarran–Ferguson Act. Congress declared that the "business of insurance" should be regulated by the states, and, to the extent that such regulation exists—excepting acts of boycott, coercion, and intimidation—the antitrust laws do not apply to the insurance business. This exemption has been considered by the courts in relation to health insurance, as will be addressed below.

Government Agency Edicts

An important part of the antitrust law is not in the statute books or judicial decisions but rather is found in the pronouncements of the enforcement agencies. To provide guidance on specific proposed conduct involving the changing health care industry, in 1993 (revised in 1994 and on August 28, 1996) the Department of Justice and the Federal Trade Commission jointly issued Statements of Antitrust Enforcement Policy in Health Care. The nine statements, with examples, cover such issues as mergers, joint ventures, exchange of information, and joint purchasing; they definitely provide insight to the thinking of the agencies as they review suspected anticompetitive actions.

In addition, as invited in the Statements, both agencies welcome formal requests for informal advice from parties or groups contemplating some activity that makes their antitrust
attorney uncomfortable. The Department of Justice has long had a Business Review Procedure, under which parties may fully describe in writing a course of conduct, and within a few months the Department will respond as to whether it would consider such conduct illegal. The Federal Trade Commission has a similar procedure for Advisory Opinions. With increasing frequency, antitrust specialists are recommending that clients use these methods and are also reviewing the published responses to others to ascertain current prosecutorial policy before advising clients.

Congress has considered legislation that would provide a degree of immunity to health care networks, requiring, for example, a “rule of reason” approach to enforcement actions against provider networks. In objecting to such legislation, the chairman of the Federal Trade Commission stated that health care markets are changing too quickly to lock in statutory immunities, rather than allowing the law to develop in the gradual manner it has in the past. One of the chairman’s reasons for asking Congress to be patient was a promise that the enforcement agencies were revisiting their Statements of Enforcement Policy. In revisions issued on August 28, 1996, new guidelines soften the current restrictions on joint venture activities by physician networks and multiprovider networks. The new statements describe a wider range of provider networks that will be analyzed under the “rule of reason” because their structure and activities are more likely to result in procompetitive efficiencies than in anticompetitive effects.

SITUATIONS IN WHICH ANTIMUTRUST LAW AND HEALTH CARE INTERSECT

Steer Clear of Price-Fixing

Because of the potentially harsh consequences, per se violations of Sherman Act § 1, such as price-fixing, have always been among the most feared antitrust offenses. It is surprising, then, to see how often this section is breached: over a recent 10-year period, the Department of Justice filed an average of 75 criminal antitrust cases a year. Knowledge and vigilance are the means to avoiding this pitfall.

For the most part, health care professionals have managed to steer clear of price-fixing problems. However, caution is necessary because of the complex relationships between, for example, third-party payers and groups of providers who may perceive the need for joint negotiations. The 1982 case against a medical society in Arizona actually involved an agreement among physicians to establish a maximum price ceiling, rather than an attempt to raise rates, but it was nevertheless held to be per se unlawful. The Supreme Court decided many years ago that “any tampering” with the natural economic forces that determine market prices is illegal, whether the agreement results in higher, lower, or stabilized prices. Some commentators believe that the 1982 Arizona case is still the basis for the strict approach toward joint activities by provider networks in the government's Statements of Enforcement Policy.

The same principle prevailed in 1993 when an association of pharmaceutical companies sought an agreement among its members to limit price increases on prescription drugs until the conclusion of the then-active debate on a federal health reform bill. Even though consumers would presumably benefit from such a price-limiting agreement, a Department of Justice Business Review Letter stated that the proposal would violate antitrust law.

Several years ago the Department of Justice indicted three dentists who organized meetings and provided 30 dentists with form letters to send to local prepaid dental plans requesting increased fee schedules; the plans did raise their fees, and the three organizations were charged with conspiracy to fix prices. A jury convicted the defendants, but the reviewing courts remanded for a new trial at which the judge would give more specific instructions to the jury. The difficulty the courts had in wrestling with the issues in this case is demonstrated in the following ambivalent statement by the federal court of appeals:

[The relationship between individual health care providers and medical plans is not without subtlety and complexity.]

[Health care providers who must deal with consumers indirectly through plans such as the one in this case face an unusual situation that may legitimate certain collective actions. Medical plans serve, effectively, as the bargaining agents for large groups of consumers; they use the clout of their consumer base to drive down health care service fees. Uniform fee schedules—anathema in a normal, competitive market—are standard operating procedure when medical plans are involved. In light of these departures from a normal competitive market, individual health care providers are entitled to take some joint action (short of price fixing or a group boycott) to level the bargaining imbalance created by the plans and provide meaningful input into the setting of the fee schedules. Thus, health care providers might pool cost data in justifying a request for an increased fee schedule... Providers might also band together to negotiate various other [non-price] aspects of their relationship with the plans... Such concerted actions, which would not implicate the per se rule, must be carefully distinguished from efforts to dictate terms by explicit or implicit threats of mass withdrawals from the plans.]

After the case was sent back to the trial court, the Justice Department settled with the defendants, dismissing the case against the individual dentists and agreeing that the professional corporation of the "ringleader" would pay a small fine and engage in 350 hours of community service. Given the enforcement agencies' current philosophy, as expressed in the Statements of Enforcement Policy, a serious question can be raised whether the Department of Justice today would settle such a case, rather than retrying it. At the same time, the embryonic contemplation by the court in the above statement is
Price-Related Data May Be Exchanged—Within Limits

From the dental case discussed above, the court's suggestion of the pooling of cost data is covered in the government agencies' Statements of Enforcement Policy. Consistent with current antitrust law, exchange of cost and price information among providers will not be challenged if: (1) the survey is managed by a third-party, such as a health-care consultant or a trade association; (2) the data are at least three months old; and (3) enough providers are included that the information is aggregated and anonymous. Under these conditions the exchange of data will not have the potential for being step in a collusive scheme to fix prices.

A Justice Department Business Review Letter has approved the exchange of transportation costs among the members of a trade association who were engaged in the distribution at wholesale and retail of drugs, medicines, toilet preparations, and related products. Not only did the proposed meet all of the above safeguards, but also the members purchased only a small percentage of the transportation capacity available, and the members' transportation costs were a very small percentage of their selling prices; under these circumstances, the exchange had a negligible effect on either the transportation market or the market for the sale of the members' products.

"Most Favored Nation" Clauses Are Not Favored

The Federal Trade Commission recently issued a complaint against a pharmacy network that included more than 95% of a state's pharmacies and managed the provision of pharmacy services to more than half the people of the state with third-party pharmacy benefits. The offense charged was the enforcement of price maintenance by the use of "most favored nation" clauses in the networks' contracts with member pharmacies; members agreed to give the network prices that were as low as any prices given to any other network or payer.

According to the Commission, the networks' aggressive enforcement of these most favored nation clauses eliminated any incentive members had to discount rates or engage in price competition with one another. The parties entered a consent order under which the network agreed to eliminate the clauses from its agreements with member pharmacies and to refrain from including any such clauses in the future.

Joint Purchasing May Be Acceptable

Although § 1 of the Sherman Act can be violated by a conspiracy among buyers as well as by the more typical collusion among sellers, joint buying groups regularly operate lawfully in numerous industries. The possibility of legitimate joint purchasing agreements among health care providers for items such as prescription drugs and other pharmaceutical products is recognized in the Statements of Enforcement Policy.

In fact, the agencies identify two conditions that create a "safe harbor" for joint purchasing arrangements. First, the combined purchases must account for less than 5% of the total sales of the purchased product in the market; and second, the cost of the products purchased must account for less than 20% of the total revenues from all products sold by each competing participant in the joint purchasing arrangement.

Group Boycotts Are Anticompetitive

In addition to price-fixing, § 1 of the Sherman Act condemns group boycotts and refusal to deal that may exclude competitors from a market. Numerous lawsuits have been filed against hospitals and physician organizations by individual providers or groups (such as anesthesiologists, radiologists, and osteopaths) alleging that they have been excluded from practicing in a particular venue because their competitors engineered a boycott against them. These cases have not had a consistent outcome because they have turned on their facts; for example, the issue in many cases has related to the application of a lawful policy based upon peer review. The fundamental issue is whether there is a professional or business justification for the exclusion, or whether the only reason is a mercenary, anticompetitive agreement.

At least two consent decrees have been accepted by associations of community pharmacists charged with agreeing to boycott prepaid prescription programs. In each case, the Federal Trade Commission accused an association of reacting unlawfully to a health plan for local government employees that lowered its reimbursement rate to pharmacies for prescription drugs. The associations allegedly organized their members to agree to refuse to participate in the plans if the reductions in reimbursement were not rescinded. They were not; the members apparently did refuse to participate; and the Commission investigated and prepared a Complaint.

To settle the matters without extended litigation, the associations agreed to enter consent decrees that prohibited them from fostering or entering into any agreement among pharmacies to withdraw from any proposed or existing participation agreement with a prescription drug plan. In addition, among other things, the associations agreed that for five years they would not do anything that might interfere with independent decision-making by their members, including providing them with advice, suggestions, or information about what decisions other members were making.

Merger Mania Comes to The Health Care Industry

As managed care organizations, hospital groups, and other providers consolidate for reasons of economy and efficiency, they may be subject to investigation for monopolization or violation of the antimerger law. In the past few years a substantial number of hospital mergers have been challenged by both the Department of Justice and the Federal Trade Commission.
As with all Clayton Act Section 7 cases, each matter has been decided on its own facts, so no general rule can be deduced.

The principal issue has usually been the identification of the "relevant product and relevant market," which is the starting point for analysis of all merger cases. To determine whether an acquisition may adversely affect competition, government officials must ascertain the extent to which the merged entity may dominate or control its market; this prediction is based largely upon the new entity's share of the market. To answer these questions, it is first necessary to define the market.

This factual inquiry seeks to determine the areas (both product and geographic) in which the merger partners and their competitors operate. If the government fails to prove that the defendants function in a market in which their consolidation will result in their achieving so much combined market power that competition will probably be injured, a court will not enjoin the merger. Thus, for example, the merger of the first and third largest hospitals in a county may not create an antitrust problem if the market dynamics are such that regional hospitals in 10 surrounding counties will compete in that county, and HMOs will send their members greater distances to obtain lower rates. 21

One recent case of particular interest involved Eli Lilly's acquisition of McKesson, and its PCS Health Systems subsidiary, which provides pharmacy benefit management services. The Federal Trade Commission claimed that the acquisition may lessen competition because PCS/Lilly might decline to place competitive pharmaceuticals on its formulary and would be eliminated as an independent negotiator of discounts for pharmaceutical products. The parties entered a consent order, which requires PCS to maintain an "open" formulary controlled by a committee of independent professionals. In addition, PCS/Lilly must accept and accurately reflect all discounts and other concessions offered by competitive manufacturers for inclusion in the formulary. Finally, PCS and Lilly must not share nonprofit pricing and other information obtained from competitors of Lilly. 22

Many, if not most, merger challenges are resolved nowadays by such settlements; frequently, if a number of entities are involved, the remedy is spin-off of those locations or activities that cause antitrust problems, while the balance of the merger proceeds.

Robinson–Patman Discriminatory-Pricing Litigation

A most pertinent charge of discriminatory pricing is presently pending in the federal district court in Chicago. In 1994, a number of class actions were filed on behalf of tens of thousands of independent walk-in community independent and chain pharmacies against some 20 major pharmaceutical companies, alleging that the companies gave illegal favorable discounts to community and mail-order pharmacies owned by or directly affiliated with managed care plans, such as health-maintenance organizations (HMOs). 23 The complaints alleged that this "two-tiered pricing plan" for brand-name prescription drugs was established by collusion among the sellers, and violated both the Robinson–Patman and the Sherman Acts.

The federal cases were consolidated before a single judge, Charles Kocoras, and the plaintiffs' attorneys proceeded to collect millions of pages of documents from the defendant companies and to take more than 1,000 depositions of witnesses.

In February 1996, following an earlier $1.4 million settlement with a single, small pharmaceutical company, the representatives of the plaintiffs' class sought court approval for a settlement agreement with about a dozen out of 19 remaining defendant companies, which would pay approximately $400 million into a fund. The money, plus accumulated interest, would eventually be distributed to the members of the pharmacy class, used to pay the plaintiffs' attorneys, and used (5%) to create a Foundation "to advance the position of retail pharmacy in the brand-name prescription drug marketplace in the United States." Some 14,000 stores—Independent pharmacies and affiliates of chains—had "opted out" of the class and would not be included in the proposed settlement; their claims would proceed to trial.

After giving preliminary approval to the settlement and receiving more than 3,000 objections, many on forms supplied by NARD, Judge Kocoras, acting on behalf of the members of the plaintiff class, rejected the settlement. The court refused to approve the settlement because it did not contain any "injunction or other provision eliminating the two-tiered system of pricing pharmaceutical drugs." 24

A few months later the class plaintiffs and a slightly different line-up of defendants presented an amended settlement agreement to the court, which dropped some $30 million because of the different defendants, and which purported to resolve the judge's earlier objection. The court approved this settlement, indicating that in essence it required that the settling manufacturers could no longer deny discounts to community pharmacists on the basis of their class of trade status as retailers, and that community pharmacies and buying groups that could demonstrate an ability to affect market share would be entitled to share in the same type of discounts enjoyed by managed care organizations. 25

The case is still before the courts, partly on appeal on an issue not relevant to the Robinson–Patman act, and partly because there are thousands of plaintiffs and a number of defendants who did not participate in the settlement. 26

Exemption Relevant to Many Health Care Providers

In the Nonprofit Institutions Act, Congress created a specific exemption from the Robinson–Patman Act to allow government agencies and not-for-profit institutions to purchase supplies at better discounts than those granted to for-profit businesses. In the pending Chicago case discussed above, the court has granted a summary judgment to certain pharmaceutical companies for sales at discriminatory prices to nonprofit
from vendors of their choice. The defendants also agreed to pay $300,000 in fines.  

CONCLUSION

The antitrust laws clearly apply to health care providers and organizations. With regard to antitrust laws, whether familiarity breeds contempt, they surely provide protection. A reasonable level of understanding of basic antitrust concepts can help managed care practitioners avoid unreasonable amounts of time and money unproductively spent defending or explaining commercial actions. Moreover, as the government agencies develop and express their views on changing forms of health care delivery, a knowledge of the underlying antitrust statutes and principles will enable the targets of the government’s enforcement policies to better understand those policies.

NOTATIONS

15. Id. at 1214.
18. Before leaving price-related issues, we note that the Statements of Policy discuss a considerable length the issues of provider networks that become involved in fees and rates. We are not pursuing this complex issue because we do not believe the subject bears immediate relevance to the audience for this article.
19. See, for example, Summit Health, Ltd. v. Pinhas, 500 U.S. 322 (1991); Maric v. St. Agnes Hospital Corp., 65 F.3d 310 (2d Cir. 1995); Brader v. Allegheny General Hospital, 64 F.3d 869 (3d Cir. 1995); BCR Anesthesia Care, Ltd. v. Passavant Memorial Area Hospital Association, 56 F.3d 664 (7th Cir. 1994) see list of decisions dismissing Sherman Act claims against staffing decisions at a single hospital, at pp. 667-68.
21. Sec. e.g., FTC v. Freeman Hospital, 69 F.3d 260 (8th Cir. 1995); United States v. Mercy Health Services, 902 F. Supp. 968 (N.D. Iowa 1995).
23. In re: Brand Name Prescription Drugs Antitrust Litigation, 94 C 897, MDL 997 (N.D. Ill.); see Antitrust & Trade Registration Report (BNA) No. 66, at 291 (Mar. 17, 1994).
26. It should be noted that one pharmaceutical company was dismissed as a defendant because it observed a one-price policy. In addition, wholesalers named as defendants were dismissed from the action by the court because they had opposed the two-tier price policy, their profit level contradicted the possibility that they had been members of a conspiracy; and the pricing to retailers was controlled by the manufacturers, not by the wholesalers.
28. Advisory Opinions to Presentation Health System (Dec. 21, 1993), and to Elkhart General Hospital (June 13, 1994); 8 ABA Antitrust Section, Antitrust Health Care Chronicle 7.
31. See, e.g., Ocean State Physicians Health Plan, Inc. v. Blue Cross & Blue Shield of Rhode Island, 883 F.2d 1101 (1st Cir. 1989); Klamath-Lake Pharmaceutical Association v. Klamath Medical Service Bureau, 701 F.2d 1276 (9th Cir. 1983).
32. 42 U.S.C. § 1395m.