Managing Pharmacy Benefits

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SECOND EDITION
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he success of direct-to-consumer advertising along with the widespread use of the Internet sent a wake-up call to the managed health care industry. Today’s consumers want to be involved in and even take charge of some aspects of their health care. The challenge for health care providers, and the larger industry as a whole, is how best to respond to provide all the care patients need, not necessarily all the care they could have under all circumstances.¹ As the restructuring efforts evolve, the health care system is moving from the traditional component-based model, which treats each episode of illness separately, to an integrated systems model, which views health care on a continuum from prevention (through screening, diagnosis, treatment compliance and postcare) to outcome.

Today’s health care system is facing ever-growing challenges:

- Cost concerns resulting from the managed care backlash
- Rapid medical advances
- Major breakthroughs in technology and pharmaceuticals
- The consumer’s addiction to quick fixes
- Longer life expectancies
- Increasing prevalence of chronic disease
- Recognition of racial and ethnic differences in approach and response to medical and pharmaceutical care
- The supply of physicians, nurses and pharmacists
- The lack of an information technology infrastructure to support delivery of quality care.

These issues lead to gaps in care and underuse of evidence-based medicine. According to a recent report published in the New England Journal of
Medicine, people with chronic conditions such as diabetes, high blood pressure, asthma, etc. receive only 56.1% of recommended care.\(^2\) To close these significant gaps and to support control of escalating costs associated with chronic disease, the health care industry began to focus on ways to help each individual achieve optimal health.

As reported to Congress in 2002 by the Centers for Medicare and Medicaid Services, businesses spend the equivalent of one-half to two-thirds of their after-tax profits on health care. Excess risk factors account for 25% of medical costs and lead to higher absenteeism and lower productivity. Labor relations have been harmed by cost-shifting strategies. Consequently, employers, multiemployer groups and health and welfare funds are seeking alternative solutions to provide broad-based cost management.

**Disease State Management and Wellness**

Disease state management (DSM) programs are the result of the industry’s initial efforts to move beyond medical and prescription drug claims management toward overall cost and health care management. Disease state management targets chronic diseases and conditions that require long-term treatment, where most health care dollars are spent, and where prevention strategies can have the greatest impact.\(^3\) Using a combination of screening and stratification, these programs often employ the “80/20” rule, focusing their efforts on the 20% of the patient population who generate 80% of health care costs. The challenge is that the 20% targeted today may not be the same 20% tomorrow, so quantifying the savings achieved from these targeted interventions sometimes seems elusive.

Asthma is one example of this. Often patients, as well as their personal physicians, do not even know they have asthma until they present in the emergency room with an acute attack. Also, asthma programs frequently result in increased prescription drug costs as patients receive all the drugs and devices necessary to prevent or reduce the number of acute episodes. Overall, however, published studies have shown that asthma programs do achieve savings by promoting appropriate treatment and enhancing patient compliance that result in decreased emergency department visits and hospitalizations.

Although widely used, the term disease state management is really not an accurate description of the process. Health management is a more appropriate term, because the focus of these programs is to maintain, manage and improve the health status of a carefully defined targeted population. Therefore, health management will be used throughout the rest of this chapter.
Successful health management programs are partnerships among patients, physicians, pharmacists, nurses and other health care professionals, as well as administrators and payers who understand the value of these programs. In contrast to the traditional focus on treating and/or curing disease once it has occurred, health management focuses on disease prevention and lifestyle issues.

Yet, while many talk about health management, concerns about patient confidentiality, reluctance or lack of physician buy-in, lengthy return-on-investment times and the lack of published savings from health management programs have been deterrents to widespread implementation—until recently, that is. Why the sudden interest? Today’s health plan community is looking for longer term solutions—beyond increased copays and deductibles—to lower the total cost of health care, because nearly half of the American population suffers from at least one chronic disease and one-fifth of the population from two or more chronic diseases. As the population ages and the nation’s chronic disease burden rises, health care becomes more complicated and more expensive.

The biggest challenge thus far has been channeling patients into these programs. Typically, health management programs take one of two forms: opt-in, where letters describing the program are sent asking people to sign up for the program; and opt-out, where letters are sent telling everyone they are automatically enrolled and, if they do not want to participate, they must call the telephone number listed. Opt-in programs typically reach about 25% of the population. Most likely, these are the ones who are already taking charge of their condition and probably need less help than the 75% who did not respond. On the other hand, opt-out programs generally have enrollment rates of 95%. Why? Because most people will not make the initial effort to join opt-in programs even if they believe they should be doing something, but will participate if enrolled automatically.

Wellness programs, on the other hand, focus on health promotion and disease prevention rather than health improvement and disease management. By changing behavior, the potential to prevent disease is increased, which ultimately results in lowered overall health care costs. Smoking cessation and weight management are two programs that are favored equally by health plans, employees and members. Because these programs encourage patients to adopt healthy lifestyles, are voluntary and self-directed, concerns of patient confidentiality are less than with disease management programs. They work because the interventions are tailored and promote medical self-care. Employees/members are often offered incentives to participate. Some examples of incentives include lower health care contributions for completion of a health risk assess-
ment or participation in health coaching, cash or gift certificates for reaching a predetermined goal, etc.

**Practice Guidelines**

Health management programs use treatment algorithms such as practice policies, evidence-based guidelines and standards of care that providers, case managers, patients and payers are encouraged or required to follow. This approach empowers patients, providers and specialists through education and targeted incentives to understand and work toward positive clinical and economic outcomes for a particular disease. Comparisons can be made to model treatment protocols and peer groups to assess performance. Outcomes can be tracked and data collected in an organized, standardized format that can be used to continuously improve quality and effectiveness of the program.

One important aspect of how physician-prescribing practices are influenced is the standardization of treatment guidelines that are enforced through managed care strategies. **Practice guidelines**, also known as practice policies, treatment protocols and critical pathways, are defined as recommendations issued in advance of the delivery of health care services to influence decisions about treatment interventions. According to the Institute of Medicine (IOM), clinical practice guidelines are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” Because guidelines summarize prevailing medical knowledge and base recommendations on currently accepted diagnostic, therapeutic and medical management protocols for specific conditions, practice guidelines are like a road map, or even a step-by-step set of directions, that help doctors make more informed decisions about treatment.7

Practice guidelines are developed by numerous groups, including health care associations, medical specialty societies, managed care organizations (MCOs), research centers and hospitals. Practice protocols for various medical conditions have also been developed by committees of experts (for example, the National Cholesterol Education Project) and by the federal government’s Agency for Health Care Policy and Research (AHCPR). These “official” guidelines often serve as prototypes for the practice policies developed by “front-line” organizations such as PBMs, hospitals and HMOs.

Practice guidelines relative to pharmaceuticals are intended to influence the cost and quality of medical care and drug therapy. The guidelines are often established by a health plan’s pharmacy and therapeutics (P&T) committee or similar evaluative group. (The P&T commit-
Three factors underlie the increasing prevalence and importance of practice guidelines in pharmacy benefits management. The first is the realization that practice policies are necessary to achieve the greatest improvement in health status at a given expense level. Cost-efficiency cannot be achieved simply through price discounts from drug manufacturers. Pharmacy expenditures are a function of which products are used, their frequency of use and their per unit price. Practice guidelines go beyond price guidelines and specifically address which products should be used and when and how they should be used in order to maximize clinical as well as economic efficiency.

The second is that the quality of patient care can be directly and positively affected by practice policies. Medical decision making is more complex today than ever before. Making rational treatment decisions involves accurately defining the problem, identifying alternate courses of action, assessing the risks and benefits of each alternative, determining the probability of the desired outcome and selecting the best alternative to achieve the best possible outcome. Because of the vast array of options available in modern medicine, totally rational decision making is extremely difficult, if not impossible. Medical decision making is subjective to some extent, often based on and limited to the practitioner’s own experience, because there is so little published research about what is and isn’t effective. Practice guidelines are increasingly important because so many treatment decisions are simply too complicated to be made on a one-by-one basis.

The third reason practice guidelines are becoming so important and prevalent in pharmacy benefits management is the recognition that all medical services, including drug therapy, are a means to an end: improved health status for patients. Medical services can be used in a variety of combinations, and using one service can sometimes diminish the need for another kind of service. In other cases, a service may be more effective if used in combination with another: For example, the collaborative development and implementation of pharmaceutical care plans to evaluate and monitor drug therapy, to individualize dosing regimens that encourage adherence to therapy, minimize the potential for complications and maximize the potential for positive therapeutic outcomes.

**The Process of Developing Practice Policies**

Practice policies fall into two general categories: *implicit* and *ex-
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Implicit policies are qualitative guidelines whose development is based on the opinions of experts. Explicit policies are essentially quantitative and involve systemic analysis and hard data. While explicit policies are more difficult to develop, they also tend to be more influential in changing physicians’ practice patterns. In general, pharmacy practice policies are evolving from being largely implicit, or subjective, to being explicit, that is, based on fact and research data.

There are four steps involved in developing an explicit practice policy. These incorporate quantitative evidence, preferences and clinical judgment. The first step involves estimating the positive and negative outcomes of an intervention, whether that is a drug, service or medical procedure. This analytical process calls for an evaluation and synthesis of the available research evidence and data. It also involves clinical judgment or expertise, because quantitative evidence can never be considered a finite entity. This scrutiny provides a summary of benefits and risks.

The second step is to compare these benefits and risks. Deciding whether the benefits outweigh the risks is largely a matter of the personal judgment of a skilled clinician or group of practitioners.

The third step may also involve personal judgment. If the benefits have been determined to exceed the risks, the costs of the intervention are estimated, and these costs are compared to the net benefit (benefit minus risk). This step results in the net value to patients (net value is the difference between net benefit and cost).

If resources are unlimited (which rarely, if ever, is the case), any drug, service or medical procedural intervention with a positive net value can be provided. However, when resources are limited, a fourth step is necessary. With limited resources, the net benefit and cost of the intervention must be compared to the net benefit and cost of other interventions. This allows priorities to be set that yield the greatest benefit possible based on the available resources. When resources are very limited, the use of a given intervention may not be justifiable at all, even when its benefit exceeds its cost. (See the section on pharmacoeconomics later in this chapter for more detailed information on measuring long-term benefit and cost.)

Developing practice guidelines, especially explicit ones, is not a simple, straightforward process. The credibility of a particular practice policy is affected not only by its scientific merit, but also by the reputation of its developers and the rationale behind their recommendations.

**Types of Practice Policies**

There are three types of practice policies. The first is prescribing criteria, which focus on the appropriate use of a particular drug or drug
class. The specific criteria involved indicate for whom and how that drug or drug class should be prescribed. Generally, prescribing criteria are most beneficial when used with drugs that are (1) unusually potent or high risk, (2) expensive and/or (3) effective in well-defined but limited cases.

Prescribing criteria play a central role in prospective drug utilization review (DUR) because the PBM can potentially learn more about a particular drug therapy situation through claims forms than with a medical diagnosis alone. Prior authorization (described in Chapter 4) is also used in conjunction with prescribing criteria, because the system may require approval from the PBM before a prescription is dispensed as a covered service.

The second type of practice policies is treatment guidelines, which, in contrast to prescribing criteria, focus on a disease or a set of patients instead of a drug or drug class. Treatment guidelines indicate drugs of first choice (first-line therapies) for a disease and can also include steps to be taken if the first choice fails.

The third type of practice policies involves health management, a comprehensive approach to treating chronic or high-cost illnesses.

**Health Management Programs**

Health management programs are regaining momentum and proliferating rapidly through sponsorship by pharmaceutical companies, pharmacy benefits management (PBM) companies, health plans and other health care proprietary interests. Currently, there are at least 150 health management vendors in the market. A few are linked to the product line of a particular manufacturer (although these are now rare), while most others are therapeutically based. The concept is exciting to different participants in health care for different reasons that potentially offer a winning opportunity for multiple stakeholders. Employers are hoping to keep employees healthier, reducing absenteeism, increasing employee satisfaction with their benefits and reducing total health care costs. Drug companies view it as a potentially powerful way to enhance their image while increasing product sales and market share. Managed health care organizations see it as a way to standardize treatment protocols for common disorders, thus assuring appropriate utilization and quality care for patients. But as the health management phenomenon gathers steam, it is not without its obstacles.

**Obstacles to Implementing Health Management Programs**

Despite the proliferation of health management vendors, there is a
profound lack of documented savings. Further complicating this is the delayed return on investment (ROI) of some programs, perhaps as long as ten years. Deficiencies in information systems, the absence of good medical claims data and the lack of useful and credible outcomes data contribute to the difficulty in developing and sustaining a successful program. However, as providers become more experienced in outcomes measurement and quality improvement, they will gain insight into the effectiveness of treatment alternatives, contributing to standardization of care. Experts caution that health management is a process, not an objective or an endpoint. And it’s likely that some will be unwilling to wait to realize the full potential of these programs.

**Medication Therapy Management Services (MTMS)**

Not surprisingly, pharmacy is taking a leadership role in health management as pharmacy claims data provide perhaps the most complete and accurate record of treatment interventions. But it is important to remember that pharmacy claims represent just one piece of the health management puzzle and should not be viewed in a vacuum. Drug utilization data is a snapshot of all sorts of treatments.

Practitioners of MTMS, formerly known as pharmaceutical care, are dedicated to achieving optimal patient outcomes, improving patient quality of life and containing health care costs. Along with recognition of MTMS in the Medicare Modernization Act of 2003, there is a growing awareness of the pharmacist’s ability to provide a comprehensive range of services including:

- Assessing therapeutic needs to achieve optimal outcomes
- Preventing/minimizing adverse drug reactions
- Developing patient-specific therapy such as dosing regimens to enhance quality of life
- Managing chronic disease to minimize future complications such as hospitalizations and emergency room visits
- Ensuring continuous followup to achieve the desired therapeutic outcomes
- Promoting patient empowerment to take responsibility for their own care
- Utilizing health care resources effectively to monitor, assess and evaluate practice patterns
- Providing and coordinating continuity of care to facilitate provision of therapy throughout various care settings.

The optimal use of drugs produces therapeutic benefits to patients and financial benefits to payers. The advantageous consequences of all
these activities have improved patient outcomes, reduced the cost of therapy and improved physicians’ prescribing practices.

**Pharmacoeconomics**

*Pharmacoeconomics* is the benchmark in applying health economics to disease management outcomes and optimal drug therapy. In other words, pharmacoeconomics studies how the most efficacious treatment can be applied with focus on minimizing costs. The ever-increasing costs of pharmaceuticals and overall health care has sparked an expanding interest in applying economic principles to manage clinical outcomes. Between 1990 and 1997, pharmacoeconomic research studies more than tripled in number, with the resultant data being used to make hospital formulary decisions, develop clinical practice guidelines for drug use and identify overall cost impact of new pharmaceuticals.

Pharmacoeconomics falls under the heading of economic outcomes and uses five major mathematical models:

1. **Cost-benefit analysis** weighs a drug’s benefits (efficacy, safety, convenience) against its direct costs (purchasing, stocking, dispensing) and indirect costs (quality of life, lost workdays).
2. **Cost-utility analysis** measures therapeutic outcome in quantitative and qualitative terms, with analysis of quality of life outcomes. For instance, a quantitative factor might be the cost per day of therapy multiplied by the average number of days that therapy is required. A qualitative factor might be the number of “quality-adjusted” life years that a cancer or AIDS drug makes possible.
3. **Cost-effectiveness analysis** compares similar agents and determines which drug achieves its therapeutic goal with the least cost. For example, if a more expensive agent provides greater effectiveness in the treatment of depression (i.e., no risk of relapse) than a less expensive agent that works well against depression but where the risk of patient relapse is greater, the more expensive agent would provide greater long-term cost-effectiveness than the less expensive agent. If one product is 90% effective and another is 80% effective, there’s a 10% difference. Dividing this difference into the cost difference produces a cost-effectiveness ratio.
4. **Cost-minimization analysis** is a term referring to the most economical treatment among different alternatives with equal efficacy, effectiveness and safety profiles. For example, picking the least expensive medication in a given therapeutic class of drugs that has identical effectiveness, efficacy and safety for a patient.
5. **Cost-avoidance analysis** measures the costs of different drugs.
against future costs that they might prevent, such as costs for additional drugs, office visits, hospitalizations, surgery, long-term care and lost productivity.

Another similar economic measurement has been adapted to pharmacy and utilized in pharmacy benefit analysis. Cost-consequence analysis measures multiple costs and outcomes, but does not aggregate into cost-effectiveness or cost/benefit ratios. This model is considered to be more transparent and easier to understand, thus making it easier for the decision maker to select the costs and outcomes considered relevant.13

Pharmacoeconomics is especially important in comparing cost and quality issues in the treatment of chronic, costly diseases such as cancer, AIDS and infectious diseases. The economic issues in these serious long-term diseases are more intense than in other areas of health care because of opposing forces that are simultaneously driving up costs. These include the development of new, expensive drugs, the introduction of breakthrough biotechnology products and the growth in dose-intensified treatment regimens. On the other hand, forces such as reimbursement denials for off-label drug use and participation in clinical trials, as well as the rapid growth of managed care programs, are attempting to hold costs down. Pharmacoeconomics will provide a comparison of the costs and consequences of pharmaceutical products and services, even as these opposing forces battle over health care expenditures.

Outcomes Research: The Basis for Real-World Change

Pharmacoeconomics and outcomes research are terms that are frequently used interchangeably. However, they have distinctly different meanings. Where pharmacoeconomics identifies, measures and compares the costs and consequences of pharmaceutical products and services, outcomes research assesses the effects of these programs, policies and interventions on the health status of the patient.14 Put simply, outcomes can be defined as analyzing and measuring what happens to patients as a result of their treatment. At one time in the past, outcomes referred more narrowly to mortality (incidence of death), but the concept has expanded to include broader issues such as lives saved, hospitalizations averted or shortened, and patient satisfaction with care and quality of life.

Outcomes research is a major concept in health care today for good reason. It is a central element in the health management continuum, as
well as being a feature that payers are demanding with increasing frequency. Combined with cost information, outcomes data is an important decision-making tool for payers who are concerned not only with costs but also with what they’re getting for their health care dollar.

Outcomes research focuses on three major types of outcomes:

- **Clinical**, such as stroke, heart attack, epileptic seizure
- **Humanistic**, such as quality of life, patient satisfaction
- **Economic**, such as cost of adjusted life year, cost per year of life saved.

Unfortunately, the evolution of outcomes research is being hampered by a scarcity of accurate and complete medical and claims data. The need for more research and universally meaningful data is very clear. One outcomes expert estimates that between one-half and four-fifths of major medical treatments (even those that are effective) are not backed by solid scientific studies. An increasing number of alternative therapies, increasing competition and growth of managed care, and rising health care costs have created a greater need to evaluate products and services to ensure more efficient allocation of health care dollars.

**What's Ahead?**

**Medicare Part D**

Starting January 1, 2006, prescription drugs will be added to the benefits provided by Medicare through the newly created Medicare Part D plan. To sum up what the plan incorporates: Once a $250 deductible is met, Medicare pays 75% of the beneficiary’s drug costs up to $2,250 yearly, then drops to zero. Once out-of-pocket expenses reach $3,600, Medicare then pays 95% of further drug costs for the year. Insurers and pharmacy benefits managers will contract with Medicare and deliver the benefits. With the Part D plan, employers face a difficult task of incorporating Part D into benefit offerings.

There are three possible approaches for incorporating Medicare Part D with benefit packages:

1. Accept sponsor subsidy for continuing to provide employment-based prescription drug coverage to retirees.
2. Provide a wraparound coverage where Medicare pays first and the employer follows as a secondary payer.
3. Contract with a prescription drug plan or Medicare Advantage Plan to offer prescription drug benefits.

The Part D plan will most likely be a headache to many people in the first few years of its use. With drug prices continuing to rise at extraordinary rates, the issue of availability of much-needed medication...
to a population that overwhelmingly consumes prescription drugs is a problem that will continue to face policy makers for years to come.

Importation of Drugs

Another aspect of the Medicare Modernization and Improvement Act was the inclusion of a provision allowing the importation of drugs from other countries, with a stipulation that the director of the Food and Drug Administration deem the practice and the products to be safe. This was not the first time this type of provision was passed by Congress, but it was the first time it was signed by the president. The issue of importation has received considerable media attention, particularly the importing of price-controlled drugs from Canada. Unfortunately, some very important questions and issues seem to get lost in the debate surrounding this issue.

*Is it actually legal?* The FDA considers it illegal to import drugs from other countries such as Canada, but until recently, the federal government chose not to aggressively prosecute those groups or organizations who have violated the drug importation laws and facilitated importation.

*Is it safe? Is it the same drug?* According to an article in *FDA News* in September 2003, 88% of the imported drugs that the FDA had intercepted over a three-day period at four U.S. Postal Service facilities contained unapproved drugs. Benefitnews.com contained a report in January 2004 that revealed five packages intercepted and inspected by the FDA contained medication that had been the subject of a manufacturer recall due to defect, and that nearly all of the 2,000 packages searched by the FDA contained foreign versions of medication not approved in the United States. Even more recently, headlines were made when the FDA confiscated imported drugs that, on inspection, revealed they were counterfeit (that is, they did not contain the active ingredient).

*Can it lower the cost of providing a prescription drug benefit?* The reality is that imported drugs are not always cheaper. The FDA-approved generic medications tend to be much less expensive than their imported counterparts, and with increasing fines from the FDA, any chance for savings may be diminished.

Until such time as the practice of importing drugs from foreign countries becomes a legally sanctioned distribution channel and the FDA deems foreign drug products to be safe, this practice should not be considered as a cost-saving strategy.

Genomics

Outcomes studies and pharmacoeconomics research will play
a huge part in future decisions about health care quality and cost control, particularly as genetic technologies emerge. Until recently, genetic research progressed on a case-by-case basis, responding to questions about the role of genetic variation in a specific disease or treatment outcome.\textsuperscript{19} Yet despite these tremendous breakthroughs, genetic medicine is in its infancy and expected to grow exponentially as new discoveries are made in the coming years. (See Chapter 11, The Pharmacy Forecast.) While no part of health care will remain untouched by the genomics revolution, the pharmaceutical industry is expected to experience the most dramatic impact. According to Dr. David Nash of the Office of Health Policy and Clinical Outcomes, in the very near future “primary care physicians [will be] able to routinely perform genetic tests before writing prescriptions so that they can identify the possible poor responders.”\textsuperscript{20} This would change the course of pharmacy a great deal, allowing doctors to tailor drug regimens to perform most ideally given the patient’s individual genetic profile.

Genomics is the study of all the genes of an organism, including their sequences, structures, regulation, interaction and products.\textsuperscript{21} In 1990, an international endeavor was launched to map every gene in the human body. This project, known as the Human Genome Project, has completed (in rough draft form) the first phase by obtaining the DNA sequence of all human chromosomes. On April 14, 2003, it was announced that the project was successfully completed, and science now had the ability to read nature’s complete genetic blueprint for human beings. Identification of all human genes, understanding the functions of encoded proteins and mapping a majority of sequence variants is next on the agenda.\textsuperscript{22} The genetic variation mapping project, known as the International HapMap Project, will speed the discovery of genes related to more common illnesses such as asthma, cancer, diabetes and heart disease. It is also expected that the HapMap will provide the opportunity to further explore the genetic factors contributing to individual variations in response. The HapMap was expected to be completed in three years, and in February 2005, the International HapMap Consortium announced plans to create an even more powerful map of human genetic variation than originally envisioned in 2002.\textsuperscript{23}

So what does all this mean and why is it relevant? It means that we may well be on the verge of a new era in health care, one which includes genetic testing to determine the optimal therapeutic approach—even before the disease develops! But the cost of such technological advances is high—$1,000 to $2,000 for each test to identify a patient’s genes—and the cost of individualized drug therapy is likely to be high as well.\textsuperscript{24} Some speculate that genetic testing will allow pharmaceutical companies to segment people into one of four categories based on their reaction to a given drug.\textsuperscript{25}
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- **High responders**—those who respond especially well
- **Low responders**—those who respond minimally
- **Nonresponders**—those who do not respond
- **Adverse reactants**—those who experience adverse effects.

The implication is that with genetic testing, patients can be screened for their responses to a particular drug, resulting in fewer to no adverse reactions; enhanced therapeutic regimens; ultimately, lower costs (through prevention and early, targeted interventions); and improved quality of life and patient satisfaction. Genome therapy will not totally replace today’s medications, but it will improve the outcomes.

Two recent examples of how genetic information is used to individualize treatment are the genetically engineered drugs Enbrel® (etanercept) and Herceptin® (trastuzumab).

Enbrel® relieves the symptoms of rheumatoid arthritis by targeting and blocking the tumor necrosis factor (TNF) from attracting inflammatory cytokines (cell protein) to the affected joints. TNF is an immune system protein associated with rheumatoid arthritis that is involved in the normal inflammatory and immune response and plays an important role in the structural and functional changes of affected joints.

Herceptin® was engineered for the 25% to 30% of patients who carry a defective gene called HER-2/neu.26 In some primary breast cancers, the protein HER-2 is overexpressed. If HER-2 is expressed, then the breast cancer may be receptive to Herceptin®, which selectively binds to the HER-2 protein and inhibits the proliferation of tumor cells. It is the first genetically engineered treatment that attacks a cancer gene without the side effects of chemotherapy.27

There is also a new anticancer drug called Iressa® (gefitinib), which inhibits the enzyme tyrosine kinase present in lung cancer cells. Iressa® is used for nonsmall cell lung cancer that has progressed after treatment.28

Although these technological advances are incredibly exciting, many are concerned about how genetic information will be used or misused. Because some gene patterns are linked to certain ethnic groups, some fear that racial stereotyping will occur and drug products will be developed only for those who can afford expensive therapies.29 Others fear that their genetic profile information could be used to discriminate against them for employment or health insurance.30

Foreseeing the potential ethical, legal and social implications of this, the initiators of the Human Genome Project included funding to examine these issues. Clearly though, many people think solid legislation, with provisions as to who owns the information and controls its use, is needed to protect their individual privacy and the confidentiality of their genetic information.
Health Insurance Portability and Accountability Act of 1996 (HIPAA)

In 1996, President Clinton and Congress recognized the need for national standards protecting the privacy of health information and enacted the Health Insurance Portability and Accountability Act of 1996. Congress had three years, until August 21, 1999, to pass comprehensive health privacy legislation; otherwise, Health and Human Services would have the authority to craft such protection by regulation. After three years of discussion, Congress failed to pass such a law. Thus, in October of 1999, the president and Secretary Donna E. Shalala released the administration’s proposed set of rules and regulations, which generated more than 52,000 comments from the public. Then, on December 20, 2000, President Clinton signed the finalized regulations, which differed significantly from the version proposed in October 1999 including:

1. Providing coverage to personal medical records in all forms, which creates a privacy system covering virtually all health information held by hospitals, providers, health plans and health insurers
2. Requiring consent for routine disclosures of health records, special patient authorization for nonroutine disclosures and further requiring that patients must be provided detailed written information on privacy rights and how their information will be used
3. Giving providers full discretion in determining what personal health information to include when sending patients’ medical records to other providers for treatment purposes
4. Protecting against unauthorized use of medical records for employment purposes.

Psychotherapy notes are held to an even higher standard of protection. Private hospital and government agency medical units must also comply with the full range of requirements as stipulated in the provisions of the final rule.

Health plans, health care clearinghouses and those health care providers who conduct certain financial and administrative transactions electronically, such as electronic billing and funds transfers, are covered under the final regulations. Also covered are all medical records and other individually identifiable health information held or disclosed by a covered entity in any form, whether communicated electronically, on paper or orally.

The final rule gives patients significant new rights to understand and control how their health information is used, and with few exceptions,
that information can be used for health purposes only such as treatment, payment and operations. Disclosure is limited to the minimum amount of information necessary. Civil and federal criminal penalties apply to entities that misuse personal health information.

The final regulations relating to security standards became effective in spring 2005 and will be enforced by Health and Human Services’ Office for Civil Rights. A Web site is also available to provide assistance to providers, health plans and health care clearinghouses in meeting the requirements of the regulations: www.hhhs.gov/ocr.

Over the next few years, there will be additional clarification and interpretation of the components of the final regulation, including the possibility of additional changes as a new administration possibly takes office. However, one thing that seems to have remained constant throughout the various versions of this regulation is the general acknowledgment that health management programs would be considered part of “treatment” under that term’s broad definition. Although uncertain at this time, it is anticipated that the same interpretation will apply to the final regulation. The difference may be that health management companies will be required to obtain signed consents from new patients who “opt-in” to their programs.

**Population Health Management**

As health care moves away from the component-based model and toward therapy management, it embraces the systems approach to lifelong health that begins with aggressive efforts to prevent disease and encourage wellness. Thus, *population health management* is more comprehensive than disease management and, perhaps, less pervasive, as, in general, it does not go as deeply into one specific disease category.\(^{32}\) It combines utilization management, case management and disease management\(^{33}\) to impact health status, quality of life and, ultimately, health care spending. Genome therapy fits nicely into this model as it identifies what works and doesn’t work with specific disease and patient populations, as well as what documented value both payers and patients are getting for the health care dollars they spend.

Population health management is a program whose time has come. Although lost work time and satisfaction are less important to health plans, they are extremely important to employers, especially those that are self-insured. Just ask Merrill Lynch & Co., whose health benefit was detailed in the May 23, 2000 edition of the *Wall Street Journal*. Despite the apparent generosity of the health plan, their focus on improving the quality of care using wellness and preventive medicine has resulted in cost savings.
Chronic diseases place an enormous financial burden on the nation’s health care system, with annual medical bills alone expected to almost double to $1.07 trillion by 2020.\textsuperscript{34}

Preventive care can help patients to avoid many chronic diseases. At a meeting of chronic disease specialists in November 2000, Dr. Gerard Anderson of Baltimore’s Johns Hopkins University reported that the total health care costs for one person with one chronic disease are more than five times higher than for a healthy person: $6,032 versus $1,105.\textsuperscript{35} The rate of increase of average out-of-pocket payments is even more startling: $182 per year for someone with no chronic illness, compared to $369 per year for someone with one chronic illness; and $1,106 per year for someone with three or more chronic illnesses.\textsuperscript{36}

Population health management programs involve a total health care approach, managing an entire population of people with a specific disease regardless of the severity of illness. This approach combines preventive care strategies such as patient self-management information for those with a low severity and risk profile; and more aggressive management strategies such as proactive counseling, case management and specialty care centers for those who are at high risk for complications. (See the table.)

Population health management provides a level of personal support

\begin{table}
\centering
\caption{Population Health Management Strategies}
\begin{tabular}{|l|c|c|c|}
\hline
\textbf{Interventions} & \textbf{Severity and Risk Profile} & \textbf{Cost of Intervention} \\
& Low & Medium & High \\
\hline
Patient self-management information & & & Least \\
Physician education & & & \\
Drug selection and use & & & \\
Patient self-assessment & & & \\
Patient monitoring & & & \\
Proactive patient counseling & & & \\
Case management and specialty centers & & & Most \\
\hline
\end{tabular}
\end{table}
and attention that seems to be missing from today’s health care system. The current consumer demand for information about treatment alternatives and their desire to participate and even direct their care may provide the impetus needed to launch health care into the next generation that is total health care management.

Questions to Ask About Practice Policies, Prescribing Criteria, Health Management and Outcomes Research

1. Do you have a formal process to develop practice policies (criteria, guidelines and health management programs)? What is it? Who is responsible for developing and approving practice policies?
2. Are practice policies formally and periodically evaluated and revised? How and by whom?
3. What methods are used to disseminate and explain practice policies to providers?
4. What methods are used to encourage adoption of practice policies?
5. Are prescribing criteria available? For what drugs?
6. Are treatment guidelines available? For what diseases?
7. Are health management programs available? For what diseases? Do you use a population management approach? Describe the programs. What evidence do you have that they are effective?
8. What, if any, outcomes research do you conduct? How are the results used? Are any health management programs linked to outcomes research? Describe.
9. What data integration capabilities do you have?

Endnotes

4. Academy of Managed Care Pharmacy, “Disease State Management,” Concepts in Managed Care Pharmacy.
6. Ibid.


10. Academy of Managed Care Pharmacy, “Pharmaceutical Care,” *Concepts in Managed Care Pharmacy*.

11. Ibid.


14. Ibid.

15. Ibid.


18. Ibid.


21. W. Sade’e, “Pharmacogenomics—Using Genetic Information to Optimize Drug Therapy.”

22. Ibid.


25. Ibid.


30. Ibid.


33. Ibid.


35. Ibid.

36. Ibid.