Today, nearly every industry, from hotel management to auto manufacturing, is focused on improvement of quality. Healthcare is no exception. Health regulators, as well as consumers, employers, and third-party payers are seeking increased levels of accountability in healthcare delivery, and standards of performance are becoming commonplace. Why this interest in quality assurance and accountability? First, deficiencies in our healthcare system have become increasingly apparent, and have stimulated reform efforts at the national, state, and local levels. Second, rapidly escalating healthcare costs over the past decade have fostered the belief that consumers and payers are not getting their money's worth. Third, pressures to contain costs carry with them concomitant pressures to ensure that existing levels of quality are not eroded.

Brook has noted these problems and challenges for the profession of medicine. Pharmacy is very much affected. While pharmacy has always had performance standards, over the past decade or so these have become increasingly specific and detailed. It is possible now to delineate quite precisely the concept of quality, the process of quality assurance, and methods of quality assessment as they relate to the delivery of pharmaceutical services.

**WHAT IS MEANT BY QUALITY?**

Difficult to define but universally understood, quality implies value, worth, and degree of excellence. In general, healthcare quality has been defined in these terms:

▼ What a system of care should deliver
▼ What a healthcare professional or service unit should provide
▼ What patients expect from providers of care
▼ What patient outcomes should be expected

Consider the quality of care received by Americans, often characterized as the best in the world. To an individual receiving care this may well be true, but, to those denied ac-
cess to healthcare services because of inadequacies in health insurance, it certainly is not. This brings us to our second point. There are many "stakeholders" in the quality of care delivered by health professionals or a healthcare system. Each has priorities and different criteria for what is judged to be acceptable. With respect to pharmacy, primary stakeholder groups include the following groups and organizations.

**Regulatory agencies** Regulatory agencies, both governmental and quasi-legal, oversee, on behalf of the public, the quality of service provided by a health professional or institution. They are primarily of two types: boards of pharmacy and regulatory commissions such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). These groups set the minimum standards to which pharmacists and pharmacy systems must adhere. Their tasks are ultimately defined in terms of protecting public health and safety.

**Consumers** As ultimate users of pharmacy services, consumers have a right to expect accurate and timely delivery of prescription products and information. Consumer satisfaction is the final determinant of success in the marketplace.

**Third-party administrators and pharmacy benefits managers** As representatives of groups of consumers, these persons seek to arrange and manage networks of pharmacy services to meet most efficiently the needs of specific enrolled populations. They develop quality standards in two main areas: as part of conditions for participation in provider networks and as part of drug-use review criteria applied to drug-claims databases.

**Drug-service provider networks** Increasingly, pharmacists are becoming linked into networks, preferred-provider organizations, health-maintenance organizations, chains, or franchises. Managers of networks seek to ensure the same levels of quality from each participating pharmacy and pharmacist.

**MEASURING THE QUALITY OF SERVICES**

The structure-process-outcome paradigm of Donabedian2,3 is perhaps the best known and most often applied measure of quality.

*Structure* refers to material resources (buildings, equipment, reference materials), human resources (numbers, types, and qualifications of healthcare personnel), and the manner in which resources (particularly personnel) are organized to deliver services. As applied to pharmacy, a structural measure would be the amount of training possessed by the pharmacist and whether he or she is licensed to practice pharmaceutical care.

*Process* refers to the nature of services provided by healthcare professionals; that is, those procedures and activities undertaken in providing clinical services. Within pharmacy, a process measure might be whether the pharmacist reviewed the patient drug profile before dispensing a prescription.

*Outcome* refers to the end result of the service provided, usually measured in terms of impact on the patient or community. To continue the pharmacy example, we might measure quality in terms of improvement in the health status of the patient who consumed the prescription.

Note the implicit order of the three elements:

**STRUCTURE —> PROCESS —> OUTCOME**

A bird analogy is often used to describe this relationship. Measures of structure for a bird are feathers per square inch of skin as well as the surface area of each feather. A process measure is wing flaps per minute, and, finally, outcome is whether the bird can fly. For a pharmacist, a structural measure is whether he or she has a degree from an accredited university, the nature of the degree (B.S. or Pharm.D.), and his or her licensure status. A process measure is whether the pharmacist can appropriately review a patient drug profile, dispense prescriptions, and counsel patients. An outcome measure is whether patients received intended drug therapy. Another is whether the patient appropriately consumed the prescribed drug and was cured of the condition being treated.

Each of these examples illustrates two points. First, structure, process, and outcome measures are (or should be) linked. The only important structure and process measures are those reasonably related to, and likely to affect, defined outcomes. In the above example, the inherent assumption is that both structural and process measures are linked to outcomes. Training and licensure as a pharmacist are assumed to contribute to overall quality of pharmaceutical care services. So, too, is a pharmacist’s dispensing of a prescription, including drug consultation and review of the patient’s profile. On the other hand, it could be argued that since the type of pharmacy degree has not been related to appropriate dispensing or appropriate patient outcomes, it should not be considered as a key structural indicator.

**STRUCTURAL MEASURES**

In general, structural characteristics are the easiest to measure, while outcomes are the most difficult. For this reason, the first measures applied as indicators of quality have, historically, been those based on structural characteristics. Since the time the first pharmacy licenses were issued, pharmacy licensure boards have engaged in an inspection process that contains many structural elements such as the following:

- All practicing pharmacists licensed. All licenses on display and current.
- Pharmacy dispensing area secured from public access.
- Pharmacy dispensing area clean and sufficiently stocked with balance, spatulas, mortar and pestle, and refrigerator.
- Pharmacy inventory comprehensive for the population served and devoid of outdated drugs
- Pharmacy computer system present.
- On-line prospective DUR/DUE system present.

In a more contemporary example, conditions for participation in pharmacy provider networks often contain structural elements: Does the pharmacy have a separate counseling area?
Does it have a specialty care center (e.g., for diabetes care)? Does it have on-line computer system capabilities? Is it located in a target service area? Does it appear to have the capacity to serve a targeted number of patients in a designated geographic area?

Today, many well-accepted and time-honored structural attributes and standards are being questioned for the first time. For example, with respect to the proper processing of prescriptions, questions such as these are being asked:

- Who may dispense?
- Should physicians be allowed to dispense?
- If so, what standards should apply?
- How about nurse practitioners, physicians' assistants, and pharmacy technicians?
- Is it necessary for the pharmacist to be engaged in all dispensing activities?
- For dispensing, might it be possible for a technician rather than the pharmacist to check the unit-dose preparation of another technician?
- Must all dispensing occur in a licensed pharmacy located in a traditional setting, or could it be done elsewhere (e.g., in a mobile pharmacy, physician's office, emergency room, or health clinic)?

From the perspective of a board of pharmacy, the criterion is whether the health and safety of the public is jeopardized as structural requirements are relaxed.

**Process Measures** Today, measurement of processes receives considerably more attention than structural measures. This is, in part, because the link between structure and outcome is relatively remote and necessarily mediated by some process. Intuitively, it seems more appropriate to focus on the more direct connection between what a pharmacist does and outcomes. Consumers generally assume that there is a sound structure supporting the practice of pharmacy.

In the past few years, attention has been directed to determining how well medical care processes or practices conform to pre-established standards. Standards development continues to be a very important method of quality assessment, and the methods used in the development and application of process criteria are of great interest to healthcare providers. Explicit criteria for process of medical care appear in disease-specific treatment guidelines and in standards for pharmacy practice.

**Output and Outcome Measures** Today, a strong emphasis is on using outcomes as quality-of-care indicators. Some have interpreted this as a shift away from process assessment. In truth, however, the focus on outcomes directs attention to process measures even more, because they are usually so closely linked. Emphasis on outcomes is reflected in the definition of healthcare quality developed by the Office of Technology Assessment (OTA):

> The degree to which the process of care increases the probability of outcomes desired by patients and reduces the probability of undesired outcome given the current state of knowledge.

Angaran notes that while structure and process measures indicated a pharmacy system's capability to deliver quality care, outcome assessments measure performance. Performance may be judged by the end result or "output" of the pharmacy system. It is important to distinguish between "outputs" and "outcomes." For example, outputs of the pharmacy system may include a dispensed prescription, a patient counseling session, a problem identified and resolved, or a physician-generated consultation on drug therapy. Such an output is properly considered as an input, or a contribution, to a patient's ultimate health outcome. During the course of seeking care, the patient may receive services from several providers, each making a contribution to an ultimate health outcome. This is illustrated in Figure 1.

Figure 1 also illustrates the interlinked steps critical to disease cure. The cephalosporin prescribed may not have been the most appropriate drug, given the results of the throat culture. Also, despite the best efforts of the pharmacy system, the patient might not have been compliant.

The link to patient outcomes is often difficult to establish empirically, since appropriateness of pharmaceutical service is but one of many diverse factors that can affect health. This is illustrated in Figure 2. Note that there are several places along the continuum where pharmacists' contributions could have an impact.
Cure of infection is but one of the larger set of outcomes a health system should deliver. There is considerable discussion about which ones should be considered most important and about how to measure the contributions of a service provider (e.g., a pharmacist delivering pharmaceutical care) to patient outcomes. Figure 3 is one illustration of how pharmaceutical care services might be logically linked to outcomes measured in terms of medical care utilization (a perspective particularly important to health insurers). This model suggests that pharmaceutical care exerts its influence on outcomes either through rendering drug therapy that is most appropriate to a specific disease state, or by producing more appropriate patient behavior (e.g., increased compliance), or both.

Increased attention is being paid to qualitatively oriented health provider performance standards. For example, the American Medical Association Council on Medical Services has delineated the elements of quality care that should be part of the outcomes of a health-care system: 7:

- Optimal improvement in a patient’s health
- Incorporating health promotion and disease prevention
- Timely care
- Informed patient cooperation and participation in the care process and decisions
- The practice of accepted scientific principles

We have made the point that quality of care is defined in terms of patient-based outcomes and that there are different views about which outcome measures are most important. Providers focus on clinical outcomes, such as disease control or cure. Payers may focus on utilization-based outcomes and patient satisfaction, particularly as they relate to re-enrollment decisions. Patients view outcomes more in terms of how well they feel and how well they are able to function. Consider, for example, the following measures, known as the Five Ds of outcomes: 6:

- Sensitivity and concern for the patient’s welfare
- Efficient use of technology
- Sufficient documentation to allow continuity of care and peer evaluation

Note the inherent order in this list. The first two are the most tangible and measurable, and have been the focus of intervention. Success in managing disease and averting death is the standard way healthcare systems have been judged. As one proceeds down the list to dissatisfaction, the measures are “softer” and have been historically of less concern to the sys-

\[ \text{Figure 2. Relationship Between Pharmaceutical Services and Patient Health Outcomes} \]

\[ \begin{array}{c|c|c|c|c}
\text{Drug Prescribed and Dispensed} & \text{Disease Severity} & \text{Concomitant Drugs} & \text{Appropriateness of Prescribed Drug/Dose} & \text{Other Treatment} \\
\hline
\text{Health Status} & \text{Age} & \text{Comorbidities} & \text{Health-Related Behavior} & \text{Compliance Behavior} \\
\hline
\text{Functional Status} & \text{Drug Taking} & \text{Compliance With Other Medical Advice} & \text{Patient Health Outcomes} \\
\end{array} \]

\[ \text{Figure 3. Relationship of Pharmaceutical Care Interventions, Disease State Change, and Utilization-Based Patient Outcomes} \]
tem but of most concern to patients. In today's competitive healthcare marketplace, patient dissatisfaction is increasingly recognized as particularly important, because dissatisfied patients "vote with their feet" by transferring to a different healthcare system. The middle measures, disability and discomfort, are related to quality of life and the patient's functional status. In recent years, the entire healthcare industry, including drug manufacturers, health insurers, provider networks, and individual providers, has begun to recognize the importance of patient-based quality-of-life measures as a basis for justifying use of their products and services.

Quality-of-life terminology can be confusing, and common phrases are often used interchangeably. MacKeigan and Pathak differentiate between commonly accepted terms as follows:

- **Functional status**: Physical, mental, and social functioning
- **Health status**: Functional status, physiologic status, well-being
- **Health-related quality of life**: Functional status, physiologic status, well-being, life satisfaction

Earlier efforts to assess quality of life focused on functional status, but newer measures incorporate other dimensions. General instruments to assess quality of life include the Sickness Impact Profile and the newer Medical Outcomes Study Short Form 36 (SF-36). These standardized instruments are based on a brief set of questions asked of patients (the SF-36 contains 36 questions). In addition, instruments have been developed and used for specific target diseases. The interested reader is referred to one of several informative articles that review these and other currently used patient quality-of-life measures.

With respect to drug therapy, one study demonstrating the importance of quality-of-life indicators was that of Croog et al., who compared three equally efficacious treatments for hypertension (propranolol, captopril, and methyldopa) and documented their significantly different effects on quality of life. The occurrence of side effects, leading to decisions to withdraw from treatment, varied significantly between drugs, with methyldopa being the most troublesome, followed by propranolol. The findings of this and similar studies have direct ramifications for patient drug-taking compliance and, consequently, health outcomes.

Quality-of-life studies are now commonly performed, particularly on new drugs, and the results are used as a basis for promoting the use of one drug over another. The challenge to managed care pharmacy is to decide which results are meaningful and appropriate for making formulary decisions.

**PROCESS OF QUALITY ASSURANCE**

To this point, we have defined some attributes of quality that are applicable to assessment. The next task is to determine how—and how often—we go about measuring it. Quality assurance is the process by which we ensure that services are appropriate, effective, and efficient. Current quality-assurance approaches emphasize that assessment is not just occasional, but ongoing. Continuous quality improvement (CQI) has, in fact, evolved as a call to arms for American industry.

In its simplest form, CQI is a structured, systematic process for creating organization-wide participation in planning and implementing continuous improvements in quality. The focus of CQI efforts is to prevent quality lapses rather than to fix problems after they occur. Total quality management and continuous quality improvement have two attributes: (1) continual reassessment, done with the goal of (2) continued improvement.

Generally speaking, qualitative indicators, as applied to the healthcare industry, may be grouped as follows:

1. Those affecting a healthcare system or managed care entity (for example, a specific HMO or provider network). Typically, these involve structure and process measures.
2. Those affecting a profession or a professional service unit within it (for example, the drug-service system). These, too, usually involve structure and process measures.
3. Those affecting patients (for example, an HMO enrollee who has asthma). Typically, these involve process and outcome measures.

Efforts to ensure quality should be comprehensive and incorporate all activities within the process being assessed. From this perspective, measures of quality applicable to the drug-distribution system should not be focused specifically on the pharmacist but rather on the process by which drugs are prescribed and used, that is to say, on something we would describe as the drug-use process. Knapp described the following steps as part of that process:

1. Determine the need for the drug.
2. Select the specific drug.
3. Select the drug regimen.
4. Prepare and dispense the drug to the patient.
5. Administer/consume the drug.
6. Monitor usage by an individual or group.
7. Monitor drug effects.

To this list we would add "Educate the patient." Each step should be subject to quality-assurance criteria and assessment. For example, steps 1 through 3 imply standards for establishing a diagnosis and for selecting an appropriate drug for a given disease state. Steps 4 and 5 imply specific procedures to be followed in preparing and distributing drugs. Steps 6 and 7 imply the existence of a record-review process and reevaluation schedule for the patient.

**Measuring and Monitoring Quality** Selecting appropriate indicators is critical to quality assurance; they provide important benchmarks in the assurance process. With respect to pharmaceutical care, there are numerous indicators of quality, and often there is disagreement as to which are most appropriate. There is, however, general agreement on a process for assessing quality and developing yardsticks. This involves application of criteria, indicators, and standards. These have been employed specifically in drug use review programs and systems, but they are also more broadly applicable to pharma-
Criteria These are predetermined elements against which aspects of the quality of a medical service may be compared. They may take several forms: First, they may be either explicit (i.e., exact, objectively determined) or implicit (subjectively determined). Explicit criteria are preferred over implicit, because they are exact, can be easily communicated to all affected parties, and can be agreed upon in advance. Second, they may be used as screening criteria or in-depth criteria. Third, they may be either objective and explicit or normative.

The use of criteria as a screening mechanism is now commonplace. Large automated databases permit the screening of thousands of prescription records and other patient data to identify a subset of cases worthy of further investigation. In-depth criteria are generally applied to patient cases that fail initial screens. Records that are identified as exceptions are examined in more detail, again using explicit measures. In these cases, presumably more information about the exceptional circumstance is considered in rendering a determination that the case represents a legitimate problem or episode of inappropriate care.

Finally, criteria may be either objective and explicit or normative. Objective and explicit criteria for drug use (usually based on standard compendia or literature references) are preferred; however, they must be agreed to by healthcare practitioners whose activities are being reviewed. Normative criteria, on the other hand, compare practices or the use of drugs relative to one's peers. They identify exceptional patterns, regardless of any other explicit criteria. A normative basis for a retrospective prescriber review would, for example, identify the top 10% of most costly prescribers, the top 10% of drug users, or the most frequent dispensers of controlled substances. The idea behind norms is "safety in numbers." It is safest not to be an outlier on any qualitative or economic dimension, for to be an exception invites scrutiny, and it is presumed that the majority practices are sound. Normative measures have the attribute of recognizing "local custom" in any type of qualitative review. Reviews of drug usage by explicit criteria have historically been done in the inpatient setting, whereas normative-based reviews have been done by large third-party programs as a part of a drug surveillance or drug-use review focusing on reducing excess use and costs or detecting fraud.

Indicators Explicit criteria are often stated as indicators, specific measures of some aspect of quality of care. Medication use indicators are quantitative measures of an aspect of patient care related to medication use; they can be employed to monitor, evaluate, and improve the quality and appropriateness of healthcare delivery. Standards These are measures of acceptable deviation from a criterion. It is common to see them expressed as thresholds, or predetermined levels of performance defined for each indicator. A threshold of 0% implies that the indicator represents an undesirable or unacceptable level of care such that no cases should meet it; while 100% indicates that all cases should demonstrate the characteristic. For example, an indicator for the use of lovastatin in hypercholesterolemia might be that it be used as a second- or third-line drug, after treatment attempts and failures with more traditional and less expensive agents. A threshold might be that not more than 10% of patients are initially treated with lovastatin.

EXAMPLES OF QUALITY-ASSURANCE PROGRAMS IN PHARMACY

JCAHO and Use of Performance Indicators The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the standard-setting body of America's hospitals and is trying to become the same for related healthcare organizations. Over the years, its standards have evolved from an initial focus on assessment of structure and process to an emphasis on continual quality assurance. This was first applied to DUEs in the 1980s and gradually expanded to other aspects of pharmaceutical care delivery. The importance of the JCAHO process is that it provides a framework for the evaluation of pharmacy services in any healthcare setting. The DUE model advocated by JCAHO, for example, includes 10 steps:

1. Assign responsibility. Assignment is usually made to a committee composed of physicians, pharmacists, nurses, and administrators.

2. Delineate scope of drug use. Identify the particular aspects of drug therapy, or the particular group of recipients of a drug, for review (e.g., sedative–hypnotic use in the elderly).

3. Identify drugs to monitor and important aspects of drug use. Common criteria for identifying potential problem areas are high use, high cost, and high risk. High risk means the drug is likely to result in interactions or adverse effects or has a narrow therapeutic window of effectiveness.

4. Identify clinical indicators. These are developed for selected drugs; for example, with sedative–hypnotics, important indicators would be dosage and duration of use.

5. Establish thresholds for evaluation. For example, with sedative–hypnotics, a threshold might be use for no more than 10 consecutive days.

6. Collect and organize data. The sources of data (e.g., prescription files, medical records, laboratory records) must be identified and a sampling plan developed, including the time frame for the study of drug usage.

7. Evaluate care when thresholds are reached. This involves identifying specific cases in which usage met or exceeded thresholds; for example, all patients receiving and using sedative–hypnotics for more than 10 days.

8. Take action to solve the problem and improve care. In-depth review may reveal a particular clinical need for a patient to remain a continuous user, or may identify the need for a systematic approach to wean patients from long-term sedative–hypnotic use.

9. Ensure that actions are effective and that improvement is maintained. Reassess prescribing and usage patterns at some future date.
10. **Communicate results to affected individuals and groups.** It is important to communicate the findings, conclusions, recommendations, and intervention results to all affected groups and individuals.

Application of these steps involves the use of **performance indicators**. These, as used in institutional pharmacy settings, are tools to monitor and evaluate the quality of important governance, management, clinical, and support functions that affect patient outcomes.\(^{22}\) They serve as screens to detect potential, but not necessarily actual, problems in quality. They can provide a clue that some aspect of service or care needs attention in the form of further review and evaluation. That aspect of care or service may be (1) administrative, such as drug costs exceeding budgetary forecasts; (2) service-specific, such as a pharmacist’s failing to perform a specific service; or (3) clinical, such as a bleeding episode among patients on anticoagulation therapy.

**Evaluation and Selection of Indicators** Angharan has provided an excellent discussion of the processes involved in evaluating and selecting pharmacy-related medication-use indicators particularly applicable to the hospital environment.\(^{23}\) He notes that indicators must be selected with the missions of the hospital and pharmacy department in mind, and that the prioritization of indicators is similar to the DUE process, which focuses on the most problematic areas of drug therapy.

Indicators may be established as measures of structures, processes, or outcomes of care. If process indicators are used, they must be reasonably linked to outcomes that are of interest (e.g., prothrombin taken at frequent, regular intervals). If a utilization-based outcome measure is selected, such as rehospitalization for a bleeding incident after discharge, it must be logically and temporally linked to service activities being evaluated. The longer the elapsed time between discharge and rehospitalization, the less likely it is that a process of care rendered initially in the hospital can reasonably be expected to influence the outcome. A more appropriate process indicator would examine posthospitalization services provided at the pharmacy or clinic.

There are other "rules" for the use of indicators: they must be pertinent, specific, and measurable. The indicator must be pertinent to the mission and stated service objectives of the pharmacy department or hospital. In the above example, if the mission of the hospital is to provide optimal, cost-effective care to its patients, a short time window for examining rehospitalization rates is important. It is only over the short run that the rehospitalization event may be reasonably expected to be causally linked to services provided during the hospital stay. If, on the other hand, the hospital is part of an extensive care network (e.g., HMO) with a more long-term view of optimal patient recovery and functioning, then follow-up services after hospital discharge become a focus of concern, and other indicators such as any bleeding episode or thrombotic event should be added.

Indicators must be stated specifically, so that they can be measured easily and systematically. A bleeding event, for example, might be operationally defined as a clinic visit, an emergency room visit, or a hospital admission or discharge for specific ICD-9 codes associated with bleeding.

The next step is to establish a mechanism for gathering information about indicator events. In our example, numerator data (medical care encounters for bleeding events) can be obtained from pre-existing record sources that may very well be computerized. Virtually all hospitals maintain standard databases that identify, for each hospitalization, the dates hospitalized, admitting and discharge diagnoses, and patient name. Similar databases for recording emergency room visits exist, and databases for outpatient visits are becoming more common.

Data regarding visits represent only numerator data. It is interesting, but relatively uninformative, to learn that during the past year 20 patients were readmitted for bleeding disorders. To render the measure more interpretable and therefore more usable, we need denominator data to establish a rate. An appropriate denominator measure in this case is the number of patients discharged with specific conditions for which anticoagulant therapy was initiated and continued at time of discharge. If 100 such patients were treated during the past year, the readmission rate (20%) may appear alarming. However, if 1,000 patients were treated, the 2% rate may be quite acceptable.

Earlier, we suggested indicators of quality may be grouped at the patient level, at the health professional or professional service unit level (e.g., pharmacist, pharmacy, pharmacy service network), or at the healthcare system level. The remainder of this discussion will focus on indicators of quality at the health professional or healthcare system level.

**EXAMPLES OF PERFORMANCE APPRAISAL METHODS**

**Standards for Performance of Dispensing Services**

State boards of pharmacy regulations address the appropriate dispensing of pharmaceuticals, involving preparation of the right drug for the right patient at the right time. Structure and process criteria typically address the information content of the prescription label, the type of container to be used, and the manner in which prescription records are to be maintained in the pharmacy. Over time, these criteria have been re-focused on the patient. Federal legislation, in particular the Omnibus Budget Reconciliation Act of 1990 (OBRA ’90), established new patient-based standards for pharmacists. While they apply to federal (i.e., Medicaid) programs, they were quickly adopted by state boards of pharmacy as applying to all patients. These new performance standards address the responsibilities of pharmacists for prospective DUR and include screening prescriptions for potential problems, offering to counsel patients about medications, maintaining patient drug profiles, and documenting pertinent information related to patient drug therapy.\(^{24}\)

Adoption of these new standards simultaneously established new monitoring responsibilities for state boards of
pharmacy. Board inspectors in some states are now using techniques such as employment of actors posing as patients presenting prescriptions to be filled to assess how well pharmacists identify potential drug–drug or drug–disease interactions or conflicts and how thoroughly they provide drug use instruction to patients. Criteria elements for assessing the completeness of patient counseling are contained in federal legislation, which indicates the specific information to be conveyed to patients.

OBRA '90 legislation clearly conveys a broader set of responsibilities to identify and resolve potential or actual drug therapy problems. It has been suggested that pharmacists should be not only performing but documenting cognitive or value-added service contributions occurring in the normal course of dispensing. Documentation serves legal, administrative, political, and economic purposes. A problem–intervention–result format is often used; example documentation forms are shown in Figures 4 and 5. In addition, electronic data format standards have been developed for documenting pharmacists’ responses to identified problems. The National Council on Prescription Drug Programs (NCPDP) first included provisions for recording pharmacists’ responses to computer-generated problem alerts in its version 3.2 software. Future versions will include enhanced documentation capabilities. There is also interest at the federal level in expanded roles for pharmacists related to the performance of cognitive services.

The Health Care Financing Administration and the Agency for Health Care Policy and Research currently have several demonstration projects underway toward this end.

**Provider Profiling**
The basic idea behind profiling is that particular health plans, physicians, pharmacies, or patients may be "profiled" to reveal practice or service-utilization patterns indicative of high or low levels of quality. Further, such profiling offers the potential to analyze a particular practice or use pattern, as well as to identify "best" practices.

Patient drug profiles have been a common element of pharmacy practice for at least two decades. Not only have they been used by pharmacists to ensure the quality of pharmaceutical care received at the individual pharmacy, they have been used by large third-party programs, such as Medicaid, to detect incidents of excessive use or fraud. For example, as a first step, prescription records may be organized by patient, then screened using indicators such as six or more prescriptions received for controlled substances or receipt of controlled substances from two or more prescribers and/or dispensed in two or more pharmacies.

The notion of preparing individual practice profiles for providers is relatively new. One of the first applications of provider profiling was in retrospective DUR programs using prescription-claims data. The emphasis, consistent with a drug-use management regimen, was on identifying the most costly prescribers and pharmacies. Primary care providers...
### Figure 5. Pharmacist Care Claim Form

**PHARMACIST CARE CLAIM FORM**

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone</th>
<th><strong>SUBMIT TO</strong></th>
<th>REFERENCE NUMBER</th>
</tr>
</thead>
</table>

**CERTIFICATION STATEMENT**

I certify that the patient information entered on this form is correct, the patient named is eligible for the benefits, and the patient has received the pharmacist care/services rendered. I authorize release of information in this record to health care providers, institutions, and/or payers as may be necessary to facilitate care and/or process payment for pharmacist care rendered.

Signature: [Signature]
Date: [Date]

### PROBLEMS AND NEEDS

- **Drug Product Selection**
- **Drug Needed But Not Prescribed**
- **Prescribed Drug Not Available**
- **Duplicate**
- **Ease-of-Use**
- **Safety**
- **Cost**
- **Drug Form**
- **Dispense Form**
- **Contraindication Interaction**
- **Age**
- **Disease or Condition**
- **Weight**
- **Lifestyle**
- **Preexisting Disease**
- **Adverse Effect**
- **Addictive Effects**
- **Allergy**
- **Toxicity**
- **Other**

### ACTIONS AND INTERVENTIONS

- **Contact Health Care Provider**
- **Contact Third-Party Payor**
- **Counsel Patient**
- **Counsel Patient's Caregiver**
- **Demonstration**
- **Develop Compliance Aid**
- **Education**
- **Monitor Drug Therapy**
- **Refer**
- **Consult on Self-Care**
- **Other (Specify)**

### RECOMMENDATIONS

- **Add Drug**
- **Discontinue Drug**
- **Do Not Dispense Drug**
- **Change Drug**
- **Change Dose**
- **Change Dosage Form**
- **Change Route**
- **Change Schedule/Duration**
- **Schedule/Duration Change**
- **Route Change**
- **Referral**
- **Self-Care**
- **Other (Specify)**

### RESULTS OR OUTCOMES

- **Opinion**
- **Recommendation NOT Accepted**
- **Other**

### DISCUSSION AND SPECIFIC DRUGS INVOLVED

**PHARMACIST CARE PROVIDER**

**Patient's Caregiver**

**Third-Party Payor**

**Patient's Product/Device/Systems**

**Underuse**

**Oversuse**

**Abuse**

**Not Filled or Refilled**

**Stored Inappropriately**

**Prescription Clarification**

**Other (Specify)**

### PROFESSIONAL FEES

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<th>Code</th>
<th>Fee</th>
<th>Code</th>
<th>Fee</th>
<th>Code</th>
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</tr>
</tbody>
</table>

**TOTAL FEE**

**NAME**

**ADDRESS**

**PHONE**

**NABP NO.**

**SSN/TIN**

**SIGNATURE OF PHARMACIST**

I hereby certify that the pharmacist care rendered as indicated has been completed and the fees submitted are the actual fees I have charged and intend to collect for those services.

Signature of Pharmacist: [Signature]
Date: [Date]
License No.: [License No.]

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Table 1. Health Benefit Plan XYZ Summary Prescriber Profile Showing Patient Panel Characteristics (January 1–June 30, 1995)

<table>
<thead>
<tr>
<th>Physician Identifier</th>
<th>Panel Sizea</th>
<th>Average Age of Panel</th>
<th>% Panel Over 65 Years</th>
<th>% Panel With 1+ Office Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>32443</td>
<td>545</td>
<td>34</td>
<td>10</td>
<td>60</td>
</tr>
<tr>
<td>34234</td>
<td>365</td>
<td>38</td>
<td>15</td>
<td>85</td>
</tr>
<tr>
<td>54353</td>
<td>225</td>
<td>49</td>
<td>12</td>
<td>90</td>
</tr>
<tr>
<td>65345</td>
<td>93</td>
<td>48</td>
<td>19</td>
<td>87</td>
</tr>
</tbody>
</table>

a Panel Size = number of eligible members assigned to each primary care physician.

were the initial targets, because they tended to write the highest number of prescriptions. Individual provider profiles were not necessarily sent to providers, but instead were used as a performance-monitoring tool.

Any type of individual profile (prescriber, pharmacy, patient) may exist in summary or in detailed form. A summary profile aggregates data for a particular provider according to predefined indicators or common descriptors, such that all providers can be quickly scanned to determine outliers. A detailed profile lists, for each selected prescriber, specific services ordered and provided. These are arranged in some type of order, usually chronologically. In this way, the profile describes in detail the utilization pattern that generated the indicator on the summary report. Examples of drug-use management summary provider profiles are shown in Tables 1 and 2.

Pharmacy profiles may be similarly generated. Typical indicators are number of prescriptions dispensed, average cost per prescription, percentage of prescriptions written and dispensed DAW, percentage of prescriptions dispensed for controlled substances, and average quantity per prescription.

Disease Management Provider Profiling More recently, HMOs and pharmacy benefit programs have been focusing on disease management and have begun to develop disease-specific profiles. The difficulty with using such profiles is that a physician-visit or hospitalization database is either not available or is not linked with a dispensed prescription database. A prescription database can be used by itself to profile disease treatment, but only for a few disease in which the therapeutic class of the drug dispensed is a reasonable indicator of the patient's disease (e.g., diabetes mellitus).

Most major third-party programs and HMOs are now working to link systematically all utilization databases to permit profiling not only by patient and provider, but also by disease. Using ICD-9 codes recorded by providers and indicating the reason for the visit, linked databases permit the tracking of diseases being treated. One difficulty with using ICD-9 codes for this purpose is that they are sometimes not accurate or complete. For example, a patient with hypertension visits the physician for an acute infectious condition and receives follow-up care for his blood pressure as well as treatment for a sore throat. The prescriber may or may not record both conditions as being treated at that visit. In time, it is likely that util-

Table 2. Health Benefit Plan XYZ Summary Prescriber Profile Showing Prescribing Patterns for Specific Chronic Disease (January 1–June 30, 1995)

<table>
<thead>
<tr>
<th>Physician Identifier</th>
<th>Cost of Rx/Eligible Patient ($)a</th>
<th>No. Rx/Visit</th>
<th>Cost/Rx ($)b</th>
<th>% DAWc</th>
</tr>
</thead>
<tbody>
<tr>
<td>32443</td>
<td>101</td>
<td>1.1</td>
<td>39.60</td>
<td>13</td>
</tr>
<tr>
<td>34234</td>
<td>225</td>
<td>0.9</td>
<td>46.49</td>
<td>30</td>
</tr>
<tr>
<td>54353</td>
<td>90</td>
<td>1.2</td>
<td>38.50</td>
<td>22</td>
</tr>
<tr>
<td>65345</td>
<td>76</td>
<td>1.4</td>
<td>36.60</td>
<td>11</td>
</tr>
</tbody>
</table>

a Cost of Rx/Eligible Patient = total prescription charges per eligible member.
b Cost/Rx = average cost per prescription (ingredient cost + dispensing fee).
c % DAW = % prescriptions written "dispense as written."

Table 3. Health Benefit Plan XYZ Summary Prescriber Profile Showing Prescribing Patterns for Specific Chronic Disease (January 1–June 30, 1995)

<table>
<thead>
<tr>
<th>Patients by Chronic Diseasea</th>
<th>Your Practice (% Patients)</th>
<th>Peer Group (% Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>30</td>
<td>14</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Asthma, COPD</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Depression</td>
<td>20</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Target Disease: Hypertension</th>
<th>Your Practice (Average)</th>
<th>Your Practice Last Period</th>
<th>Peer Group (Average)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>55</td>
<td>58</td>
<td>40</td>
</tr>
<tr>
<td>Visits/year/patient</td>
<td>2.5</td>
<td>2.9</td>
<td>3.6</td>
</tr>
<tr>
<td>Total treatment costs ($)</td>
<td>960</td>
<td>945</td>
<td>1,250</td>
</tr>
<tr>
<td>Drug costs ($)</td>
<td>285</td>
<td>294</td>
<td>210</td>
</tr>
<tr>
<td>% patients in therapeutic control (diastolic: 80 to 90; systolic: &lt; 160)</td>
<td>75</td>
<td>75</td>
<td>85</td>
</tr>
<tr>
<td>% patients on diuretics</td>
<td>32</td>
<td>32</td>
<td>40</td>
</tr>
<tr>
<td>% patients of β-blockers</td>
<td>10</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>% patients on calcium channel blockers</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>% patients on ACE inhibitors</td>
<td>23</td>
<td>23</td>
<td>18</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Among Patients Not in Control</th>
<th>Your Practice (Average)</th>
<th>Your Practice Last Period</th>
<th>Peer Group (Average)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of clinic visits</td>
<td>1.2</td>
<td>0.9</td>
<td>1.3</td>
</tr>
<tr>
<td>% Rx refill compliance</td>
<td>60</td>
<td>58</td>
<td>50</td>
</tr>
</tbody>
</table>

a As determined by major therapeutic category of drug dispensed.
lization databases will be improved in completeness and accuracy as data-validity edits become more sophisticated, as providers better understand the need for accurate data, and as the patient chart becomes computerized.

Table 3 is another example of a summary profile for a provider of care, this time illustrating disease-management indicators. It is noteworthy that this type of profile can be generated using only prescription records and using the therapeutic class of drug dispensed to infer chronic disease states. Note as well that the profile focuses on specific provider-performance indicators. Such a profile can be used to describe the practice of a particular prescriber or a particular pharmacy.

Similar performance indicators for a target disease such as asthma might include the number of patients with asthma or chronic obstructive pulmonary disease, the percentage of patients using more than one β-agonist inhaler per month, the total average drug cost per patient, and average total healthcare costs for asthma.

The profiles illustrate two types of comparisons, one a comparison with peers (e.g., members of the same specialty, other pharmacies), the other a comparison to performance during a prior period. It is critically important that indicators of performance be agreed upon a priori by the provider (physician, pharmacist) whose profile is being generated. In general, profiles can serve as valuable sources of feedback to providers who are asked to manage their practices for particular target disease states. Providers generally want to know how they are doing and may seek assistance in identifying areas for further improvement of efficiency, particularly if reimbursed on a capitated basis.

To be effective as a tool for change, the profile optimally would provide some clear indication of ways to improve undesirable performance levels. One method is to provide the prescriber or pharmacy with a detailed profile of records used in deriving an aggregate statistic. For example, in the above illustration, the summary report might be accompanied by a listing of patients such as the one shown in Table 4.

**Provider Care System Profiling** For quite some time, healthcare purchasers have been frustrated in their attempts to evaluate comparatively the overall quality of care provided by competing healthcare plans. Each plan tended to have its own standard for assessing dimensions of patient access, patient satisfaction, and per-member costs of care. In response to an industry-wide need, healthcare plans have developed, under the auspices of the National Committee for Quality Assurance (NCQA), a standardized core set of performance measures that allows employers to make valid comparisons among managed-care plans on the basis of quality as well as cost. The Health Plan Employer Data and Information Set (HEDIS 2.0) became the first instrument to define performance measures and systematize the process by recommending standard definitions and specific methods for arriving at comparable data. It incorporates more than 60 different measures organized into five major areas of performance: (1) quality, (2) member access and patient satisfaction, (3) membership and utilization, (4) finance, and (5) descriptive information on health plan management.

In 1994, a pilot report card project was underway with the intent of informing consumers about healthcare plans so they could make more informed choices based on some measures of quality in addition to price. Sample benchmark quality of care measures are shown below:

- **Cholesterol:** percentage of high-risk patients screened per year.
- **Low birthweight:** percentage of infants weighing 2.5 kg or less at birth.
- **Waiting time:** time in minutes for routine office visits and urgent mental health problems.
- **Asthma:** frequency of emergency room visits and hospitalizations.
- **Member satisfaction:** percentage of members surveyed who said they were satisfied with care.

The HEDIS instrument does have some limitations; for example, the 2.0 version addresses process measures more than outcomes, and there is no risk and case mix adjustment. These deficiencies will likely be addressed in forthcoming versions.

**QUALITY OF DRUG-RELATED SERVICES: THE ROAD AHEAD**

Healthcare reform has ushered in an era in which health insurers and health service providers are integrated vertically and horizontally. The highly competitive healthcare marketplace demands attention to the bottom line without compromising quality.

This is a time when the roles and responsibilities of healthcare professionals are being redefined, often along disease state management lines. The need for quality-assurance processes is imperative, yet these are still in their infancy. Further efforts are needed in developing and eliciting agreement on criteria and standards and in integrating, organizing, and validating databases for monitoring performance levels. As
part of a comprehensive assessment of the quality of pharmaceutical care using the structure–process–outcome paradigm, Farris and Kirkling²⁸ have reported that the number of published quality assessments must first be effective at providing pharmaceutical care before its quality can be assessed. Pharmacists will need further training or retraining in drug therapy related to disease state management objectives. There is also a need to modify pharmacists’ performance expectations and performance incentives. The JCAHO 10-step process for DUEs provides a useful model for CQI applicable not just to DUEs in hospital settings, but to other dimensions of pharmaceutical care delivery in all settings. The next few years will witness much experimentation in quality-assurance processes and exciting new opportunities for pharmacists as more active participants in patient care.

▼ References

26. Bell NN. HEDIS: are we finally comparing apples to apples? Med Interface 1994(Apr);74–82.
27. Fredenheim M. Making health plans prove their worth. NY Times 1993(Aug 8).