
THE CLINICAL ROLE OF THE COMMUNITY PHARMACIST



OFFICE OF INSPECTOR GENERAL
OFFICE OF EVALUATION AND INSPECTIONS

NOVEMBER 1990

THE CLINICAL ROLE OF THE COMMUNITY PHARMACIST

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EXECUTIVE SUMMARY

PURPOSE

The purpose of this study is to: (1) examine the current level of clinical services available in community pharmacy settings, (2) identify barriers that limit the availability of such services, and (3) suggest actions that can be taken to reduce barriers and improve pharmaceutical care for ambulatory patients.

BACKGROUND

This study expands on an issue identified in an earlier inspection entitled, "Medicare Drug Utilization Review." As outlined in that report, the incidence of mismedication among older adults is relatively high and reflects a number of systemic weaknesses in the health care delivery process. The role of the pharmacist in managing drug therapy can be critical, particularly for older adults who may have complex drug regimens prescribed for them by more than one physician. Our focus in this report is on the community pharmacy setting and the clinical services available to elderly ambulatory patients. Clinical pharmacy refers to functions performed by the pharmacist on behalf of the patient to identify, resolve and prevent drug-related problems.

Our data were gathered from: (1) a case study of community pharmacists who provide a broad range of clinical services to ambulatory patients, (2) a review of relevant research findings related to clinical pharmacy practice, and (3) a series of interviews with researchers, academics and practitioners, as well as a focus group session with experts in the field.

FINDINGS

There is strong evidence that clinical pharmacy services add value to patient care and reduce health care utilization costs.

- Research demonstrates that clinical pharmacy services add value to patient care for both institutionalized and ambulatory patients.
- Added value includes not only improvements in clinical outcomes and enhanced patient compliance, but also reductions in health care costs associated with mismedication problems.

Clinical services are not widely provided in community pharmacy settings.

In the community pharmacy setting, significant barriers exist that limit the range of clinical services generally provided.

- Barriers that impede provision of clinical pharmacy services include the economic structure of the retail pharmacy industry, interprofessional conflicts, limitations on information available to pharmacists, gaps in pharmacy training, and uneven patient demand.
- There are some community pharmacists who provide a broad range of clinical services to their patients. Nevertheless, the methods they use to overcome barriers do not suggest simple or immediate solutions.

RECOMMENDATIONS

The Public Health Service and the Health Care Financing Administration, individually and collaboratively, should develop a strategy to reduce the barriers to clinical pharmacy services, particularly for ambulatory elderly patients.

The National Institute on Aging should take a leadership role in developing risk indicators and treatment priorities for ambulatory elderly patients.

The American Pharmaceutical Association (APhA) and the American Association of Colleges of Pharmacy should develop standards of practice that address all components of clinical pharmacy care on the basis of patient need.

State governments should revise pharmacy practice acts to allow maximum use of technicians in community settings. The APhA and State pharmacy associations should take a leadership role in encouraging more extensive and effective use of technicians in community pharmacies.

COMMENTS

Comments on the draft report were received from the Health Care Financing Administration (HCFA) and the Public Health Service (PHS) within the Department. While PHS concurred with our recommendations, HCFA did not. The HCFA believes that current State Medicaid initiatives are adequate and sees no need for a larger collaboration effort with PHS. We continue to believe that a combined approach is warranted.

Comments were also received from several professional organizations including the American Society of Consultant Pharmacists, the American Association of Colleges of Pharmacy, the American Pharmaceutical Association, and the American Society of Hospital Pharmacists. All of these organizations were supportive of the recommendations made in the report. Copies of the comments received and our response to those comments appear in appendix VI.

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INTRODUCTION

The purpose of this study is to: (1) examine the current level of clinical services available in community pharmacy settings, (2) identify barriers that limit the availability of such services, and (3) suggest actions that can be taken to reduce barriers and improve pharmaceutical care for ambulatory patients.

We undertook this study to examine more closely an issue raised in a previous report entitled, "Medicare Drug Utilization Review." Drug Utilization Review (DUR) is also referred to as Drug Use Evaluation (DUE) and defined as a "structured, ongoing, organizationally authorized quality assurance process designed to ensure that drugs are used appropriately, safely and effectively."¹

The incidence of mismedication and adverse drug reactions (ADRs) and other drug-related illness among older adults is relatively high. Beyond the incalculable human costs associated with mismedication among the elderly, there are significant financial costs borne by patients, families, and public and private health insurers. One recent study conducted by the California State Assembly's Office of Research documented annual costs in that State of \$340.1 million associated with hospitalizations of elderly patients for treatment of ADRs.²

One level of the health care delivery system that focuses specifically on drug therapy is that of clinical pharmacy care, sometimes referred to as pharmaceutical care. Its three major functions on behalf of the patient are: "(1) identifying potential and actual drug-related problems, (2) resolving actual drug-related problems, and (3) preventing potential drug-related problems."³

As the pharmacy profession has matured, the clinical care function has evolved and has gained increasing emphasis over the past decade. (For a discussion on the history of clinical pharmacy see appendix I.)

This report focuses on clinical services available to ambulatory patients in community pharmacy settings. Community pharmacy refers to walk-in pharmacies in non-institutionalized settings and includes chain drugstores, independent pharmacies and apothecaries. (Appendix II includes a detailed discussion of these and other pharmacy settings.) The role of the community pharmacist in patient care can be critical, particularly for older adults who may have complex drug regimens prescribed for them by more than one physician. In that context, policy makers and health care providers who are committed to improving the quality of care for the elderly and reducing health care utilization costs associated with drug therapy problems are turning more attention to the role clinical pharmacy can play in achieving those goals. It is our hope that this report will assist them in expanding the level of pharmaceutical care available to all patient groups, and particularly older Americans at high risk of drug-related illness.

Data were gathered for this study from three major sources:

- a case study of community pharmacists who provide a broad range of clinical services to ambulatory patients (see the companion report entitled, "The Clinical Role of the Community Pharmacist: Case Studies," for a description of each case study);
- a review of relevant research findings related to clinical pharmacy practice, including topics such as the cost/benefit of clinical pharmacy interventions; the effects of clinical pharmacy care on patient compliance; and the obstacles to clinical services for ambulatory patients; and
- a series of interviews with researchers, academics and practitioners in the field of clinical pharmacy as well as a focus group session with experts in the field.

(Appendix III includes a more detailed description of our case study methodology.)

FINDINGS

I. THERE ARE FOUR COMPONENTS OF CLINICAL PHARMACY PRACTICE: COLLECTION OF PATIENT INFORMATION, PROSPECTIVE DUR, PATIENT COUNSELING, AND PHYSICIAN CONSULTATION. EACH OF THESE COMPONENTS ENCOMPASSES A CONTINUUM OF POSSIBLE SERVICES.

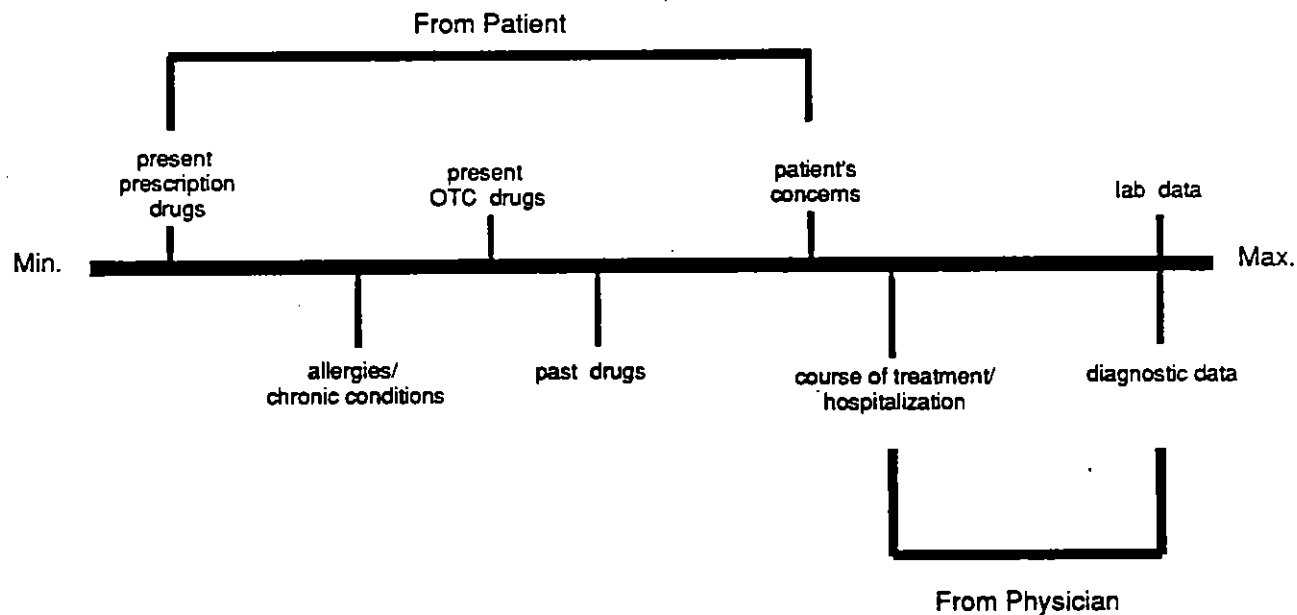
Clinical pharmacy practice is composed of four major components: collection of patient information, Drug Regimen Review (DRR), patient counseling, and physician consultation. Research on clinical pharmacy that supports this four-part analysis includes: the American Association of Colleges of Pharmacy's (AACP) Committee Report on Clinical Services in Community Pharmacy Practice,⁴ the American Pharmaceutical Association's (APhA) Standards of Practice,⁵ and Dennis Helling's study of the functions of clinical pharmacists in family practices.⁶ Our analysis is intended to be general enough to apply to many pharmacy settings, though our primary interest is in the clinical service profile of community pharmacy settings.

Within each component of clinical pharmacy, there is a range of services that define the pharmacist's activities. In that context it should be noted that none of these components is simply either practiced or not practiced, in any setting. In each of these components, i.e., areas of practice, a pharmacist may provide any combination of a wide range of possible services. The intensity of these services, in terms of the resources required to perform them, varies greatly, ranging from a minimal level of service to a maximal level. The level of services provided also varies greatly among types of pharmacy setting, among individual pharmacists, and among patients and patient groups, even within a single pharmacist's practice. The reasons for these variations in clinical practice are discussed throughout this report. It should be noted that we are not discussing only prevalent practices, or even accepted standards of practice, but all possible practices. Virtually any pharmacist in any setting can say, with some fairness, that she or he provides some level of clinical services; there is virtually no such thing as a pharmacist who provides no clinical care at all.

The continuum of services offered within each component affects but does not determine the range of services within the other three. For example, extensive data collection could enhance the pharmacist's ability to closely monitor a patient's regimen. Nevertheless, a given community pharmacist could perform a maximal level of data collection, but still provide only minimal or moderate monitoring services.

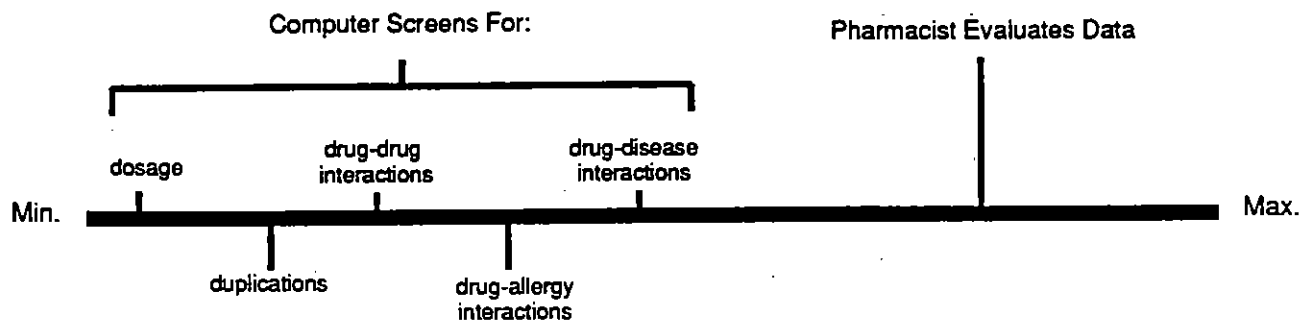
The following is a graphic display of each component. An expanded discussion of the full range of clinical pharmacy services is included in appendix IV.

Collection of Patient Information

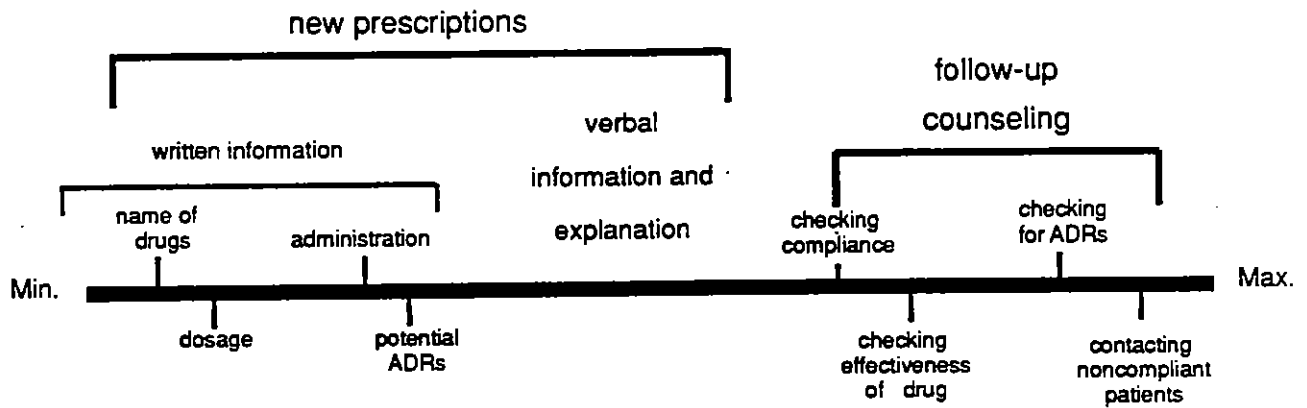


Drug Regimen Review

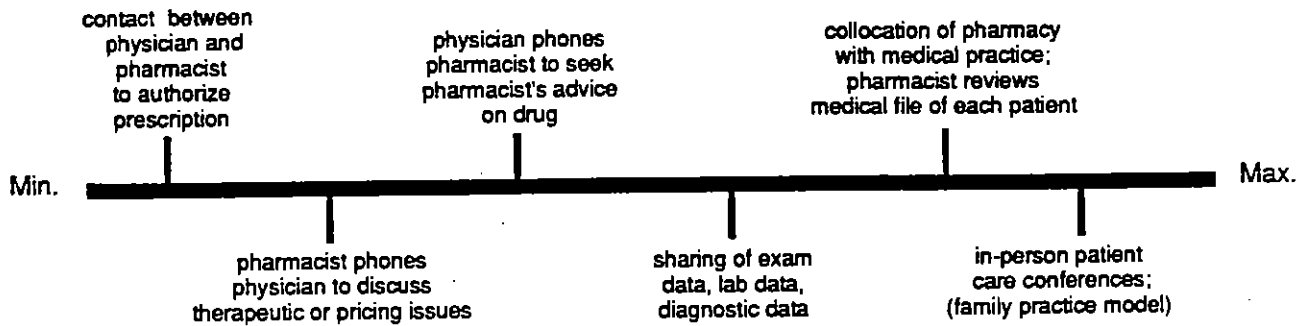
Screening and Evaluation of Data



Patient Counseling



Physician/Pharmacist Consultation



II. THERE ARE NO CLEAR STANDARDS THAT DEFINE THE OPTIMUM MIX OF CLINICAL PHARMACY SERVICES IN THE CONTEXT OF INDIVIDUAL PATIENT NEED.

In an ideal community setting, a pharmacist would have the capability to provide maximal level services in all clinical components for every patient in care. However, even in such a setting, maximal level services would not be indicated for all patients, nor would they be an efficient use of resources.

In determining the correct mix of services based on patient need, a number of questions must be addressed. For example, what constitutes counseling that patients should receive? What is the minimum amount of information that should be provided to all patients? How should that information be conveyed—orally, in written form, or both? Should pharmacists themselves counsel the patient each time a drug is dispensed? Which patients should receive close monitoring by pharmacists—that is, who are the high-risk patients in need of maximal level services? These are but a few of the issues that surface in a close examination of the functions encompassed by clinical pharmacy.

Unfortunately, there is little consensus within the profession or the industry itself about these issues. Similarly, we could find very little research in the scientific and academic communities regarding standards of clinical pharmacy care as applied to patient needs.

Two research projects that do address the issue of determining patient need, each approaching the problem from a different perspective, were identified. The first is a study conducted by Koechler et al. at the University of Minnesota on indicators for the selection of ambulatory patients who warrant close pharmacy monitoring. The researchers developed six prognostic indicators and conducted a retrospective chart review to identify adverse drug outcomes and their relationship to those indicators. The study documented evidence that adverse outcomes increased as the number of indicators present increased. Patients with a history of noncompliance (one of the indicators) appeared at highest risk of adverse outcome.⁷ A second approach that focuses specifically on standards of care is reflected in the work of Linda Strand at the University of Florida. Strand has developed an instrument that standardizes documentation of a clinical pharmacist's data base, patient care activities, and therapeutic plans. Adherence to the functions within this schema would theoretically result in an individualized treatment plan for each patient. Pharmacists would identify and treat high-risk patients not by applying generalized indicators, but by charting individualized risk profiles.⁸

These approaches to improving drug therapy for ambulatory patients clearly hold promise but require more practical application and testing to document their value. We understand that the General Accounting Office will also be conducting a study to determine categories of patients and drugs that require maximal level clinical pharmacy services. In the near term, however, the question of standardizing pharmacy services based on patient need will not be resolved easily.

III. THERE IS STRONG EVIDENCE THAT CLINICAL PHARMACY SERVICES ADD VALUE TO PATIENT CARE AND REDUCE HEALTH CARE UTILIZATION COSTS.

The value of clinical services is substantiated by the scientific literature on the subject. A number of research projects conducted in institutional and ambulatory settings have documented this added value:

- A study conducted in six pharmacies in Virginia measured the effect of pharmacists' monitoring and educational services provided to hypertensive patients. Results demonstrated better compliance in the experimental group of patients (44 of 70) than in the control group (23 of 66). Improved blood pressure was achieved in 74 percent of the experimental group and 58 percent of the control group.⁹
- A study in Memphis of non-institutionalized patients of a hospital outpatient clinic measured the relationship between the pharmacist's communication of different levels of written drug therapy information and patients' compliance rates with antibiotic drug regimens. The experimental group that received the highest level of information had a mean compliance rate of 84.7 percent while those patients receiving less information had a compliance rate of 63 percent.¹⁰
- A literature review of studies assessing costs and benefits of pharmacist-conducted drug regimen reviews in skilled nursing facilities was published by Samuel Kidder in 1987. The studies showed decreases in number of medications prescribed per patient, hospitalizations, cost of medications and other factors. Kidder's analysis projected annual savings of \$220 million in averted health care costs resulting from clinical pharmacy interventions.¹¹
- Integration of clinical pharmacy services within a private medical practice is one technique that has been used on a limited basis to involve clinical pharmacists in primary care. Under this model, the pharmacist provides a number of services to the office, including drug therapy consultation with physicians, monitoring of drug therapy for each patient, and patient education and counseling.¹² (Under this model pharmacists do not dispense drugs.) An evaluation of one such practice by the University of Iowa was able to document favorable effects of pharmacy interventions on patient care. In a retrospective review of recommendations made by pharmacists regarding specific drug therapy for patients, a peer review panel of physicians and pharmacists found that such recommendations resulted in favorable outcomes in patient care for two thirds of all cases.¹³

- In a demonstration project funded by the John A. Hartford Foundation of New York, high-risk elderly patients were enrolled in a randomized controlled trial prior to discharge from a non-teaching community hospital in northern California. The pharmacist, who had access to clinical/diagnostic data, coordinated activities with attending physicians, provided intensive discharge counseling to patients, and monitored patients' drug therapy for three months following discharge. (Monitoring included telephone consultation, home visits, and brown-bag sessions in the pharmacist's office.) Preliminary results from the study indicate that clinical pharmacy interventions provided to the experimental group improved both patient compliance and the quality of physician prescribing patterns.¹⁴
- A study conducted by researchers from the University of Washington provided a range of clinical pharmacy services to elderly residents of a congregate housing facility. Following an initial assessment in which problems of medication compliance, regimen comprehension, drug interactions, and drug storage were identified, clinical pharmacists provided the subjects with individualized instructions, drug therapy counseling and regimen monitoring in their homes over a two-year period. A final assessment of the project conducted one year after the intervention found a significant 11 percent decrease in the number of prescriptions taken and a 39 percent decrease in the number of medications taken.¹⁵

The research projects described above demonstrate that clinical pharmacy services add value to care for both institutionalized and ambulatory patients. Such value includes not only improvements in clinical outcomes and enhanced patient compliance, but also reductions in health care utilization costs associated with adverse drug reactions.

IV. CLINICAL SERVICES ARE NOT WIDELY PROVIDED IN COMMUNITY PHARMACY SETTINGS.

As mentioned previously, the concept of clinical pharmacy was first put into practice in a teaching hospital setting, and despite decades of evidence that such interventions improve clinical outcomes and reduce overall health costs, clinical pharmacy practice has remained largely within the purview of institutional settings. A large body of scientific evidence indicates that provision of clinical services outside of institutional settings is uneven and often inadequate. In terms of the typical pharmacy practice at the community level, a number of studies have found that pharmacists counsel only a small percentage of their patients, that consultations when they do occur are too brief, and that pharmacists' decisions in regard to patient care are often inadequate and inappropriate.¹⁶ An example of this research is a study

conducted by the Food and Drug Administration on patient receipt of drug information. Fewer than 60 percent of the patients studied received new (non-refill) prescriptions from the pharmacist; the remainder received theirs from a clerk or cashier. "One in three subjects who received the prescription from a pharmacist said that they were told directions for use, while only one in ten subjects receiving the prescription from a clerk or cashier said they received verbal directions for use. Precautionary and side-effect information was rarely provided, even [by] the pharmacist."¹⁷

Even when patient counseling is mandated by State board regulations, the amount of clinical services provided by community pharmacists may not increase. A study conducted in Kansas evaluated the effects of mandatory patient counseling regulations 2 years after they were implemented and found that the new requirement had no effect on the amount or quality of counseling provided by pharmacists¹⁸ In Washington, a State known for its progressive clinical pharmacy practices, a similar study was conducted before and 10 years after passage of a mandatory counseling regulation. The researchers' conclusions were that "it is doubtful that the amount of counseling and the incidence of maintaining and using patient profiles is significantly greater in Washington than in States that do not have mandatory regulations."¹⁹ This evidence suggests that imposing a regulatory requirement does not in itself have any positive effect on the gap in clinical services available to ambulatory patients.

Barriers that impede the transfer of routine clinical pharmacy practices to the community setting will be discussed in a subsequent finding. But here it should be noted that there is no conclusive evidence that the relatively low clinical service level in community settings is confined to a particular type of pharmacy. Although some researchers have found that chain or discount outlet pharmacists do not perform as well as those practicing in independent pharmacies, others have found no significant differences among types of community settings.²⁰

On a similar note, there has been heated debate within the pharmacy profession about the ability of mail service pharmacies (MSPs) to provide clinical pharmacy services to their patients. In the course of our study, we examined the services provided by the largest for-profit MSP and the largest nonprofit MSP. In both cases, patient package inserts that include information about the name and purpose of the drug, proper administration, side effects, and precautions are included in over 80 percent of the prescriptions filled. In addition, both companies offer a toll-free telephone service with pharmacists available to answer patients' questions about their drug regimens. As for prospective utilization review, each company uses automated screening processes to review dosage levels and interactions in the context of individual patient profiles, a practice that is also common among chain and independent pharmacists.

Our conclusion from this review is that the differences in clinical services provided by MSPs versus other retail settings may be more theoretical than actual. In theory, pharmacists who have face-to-face contact with patients on a regular basis are significantly better equipped to

elicit information, counsel patients and monitor drug regimens. But given the relatively low level of services that are actually provided in community settings, there may be little difference in the interventions received by patients, and in some cases, the information provided by MSP package inserts may be more than patients receive from their neighborhood pharmacist.

V. IN THE COMMUNITY PHARMACY SETTING, SIGNIFICANT BARRIERS EXIST THAT LIMIT THE RANGE OF CLINICAL SERVICES GENERALLY PROVIDED.

- A. *Barriers That Impede Provision Of Clinical Pharmacy Services Include The Economic Structure Of The Retail Pharmacy Industry, Interprofessional Conflicts, Limitations On Information Available To Pharmacists, Gaps In Pharmacy Training, And Uneven Patient Demand.***

I. THE ECONOMIC BARRIERS

Product-Based Reimbursement Structure

One of the most formidable barriers facing pharmacists at the community level is the transaction-based reimbursement structure of the industry. For the most part, pharmacists' reimbursements are linked to the sale of a product rather than provision of services. Though the retail level of the drug distribution system has always operated in a competitive environment, over the past decade competition has increased dramatically with the burgeoning growth of mail service pharmacies and discount chains. Consequently, the economics of practice tend to keep prices down and to compensate with higher volume. The result typically is a focus on product and price rather than provision of clinical services for which there is no economic incentive.²¹

This aspect of the economic barrier does not lend itself to an easy fix. Proposals to add a clinical service or counseling fee to third-party reimbursement schedules as a means of encouraging pharmacists to provide a wider range of clinical services (such as drug regimen review, patient counseling) ignore the economics of a retail practice. As long as the overall reimbursement scheme is directly tied to volume of transactions, there will be a strong incentive to increase number of sales rather than expand services. In order to shift that incentive, the reimbursement for providing clinical services (the clinical service fee) would need to exceed the opportunity cost (the cost of the pharmacist's time that would otherwise be spent filling additional prescriptions). Clearly, the overall program costs of providing such an incentive would be prohibitive.

Underutilization of Supportive Personnel

Another aspect of the economic barrier that effects the overall cost of pharmacy services is the uneven use of pharmacy technicians in community settings. The pharmacy technician is defined as "someone who, under the supervision of a licensed pharmacist, assists in various technical activities that do not require the immediate judgment of the pharmacist...for example, maintaining patient records; setting up, packaging and labeling medication doses; and filling routine orders for stock supplies."²² To the extent that technicians perform these routine activities, the overall cost of each pharmacy transaction is reduced (since technicians' time is less costly than pharmacists') and pharmacists are freer to perform clinical service functions for which they are uniquely qualified.

The use of technicians, which in theory would do much to expand the clinical role of pharmacists in community settings, is a highly controversial issue within the pharmacy profession. Regulations that govern the use of technicians vary enormously from State to State, and most often, State regulations that impose legal constraints on technicians focus on the pharmacists' perceived self-interest rather than the public's health and safety.²³ There is no documented evidence that technicians are less competent at performing routine pharmacy activities, and, in fact, technicians have been widely used in hospital settings for the past 20 years.²⁴ Resistance to the use of supportive personnel is a more a reflection of some pharmacists' fear that technicians will replace them rather than supplement the services they provide. As one expert in the field has said, "Fear of job loss to technicians is especially rampant in the community setting."²⁵

A close examination of State regulations governing use of technicians reflects a vivid picture of the controversy that surrounds this issue. Nine States ban the use of technicians in community pharmacies altogether. Although the remaining States officially recognize technicians or do not specifically forbid them, there is wide variance among them in terms of training and educational requirements, licensing and certification procedures, duties they are permitted to perform, and pharmacist/technician ratios. The degree of supervision required is also inconsistent among States. In at least 32 States a licensed pharmacist must be in the immediate physical presence of a technician while she or he is performing duties. In 5 States, pharmacists must be accessible but not necessarily in the technicians' immediate presence.²⁶

Beyond the legal constraints on the use of technicians, is the individual pharmacist's attitude about supportive personnel. Even in those States that permit wide use of technicians, individual pharmacists may choose to underutilize them out of fear that their own professional value will be eroded. To the extent that this attitude prevails among pharmacists and is reflected in legal constraints, a significant economic barrier to provision of clinical services will remain.

2. THE INTERPROFESSIONAL BARRIER

In order for pharmacists to improve the quality of drug therapy available for patients, they must work effectively with physicians who are responsible for prescribing. The pharmacist's ability to communicate effectively with a prescribing physician is a crucial aspect of clinical practice. But there are a number of impediments to communication and collaboration between community pharmacists and physicians. Dr. Carole Kimberlin, in her research on pharmacist-physician relationships, has identified three major categories:²⁷

1. *Environmental barriers:* The community pharmacist typically communicates with physicians by phone in situations that impose severe time constraints. This type of communication can intensify the distance that already exists between the two professions and reduce the amount of patient information that can be exchanged.
2. *Pharmacist hesitancy to communicate:* There is some evidence that pharmacists are apprehensive about interprofessional communication. In a discussion of this phenomenon, one researcher describes reasons why pharmacists are reluctant to challenge physicians: "Because they've been socialized to believe that doctor knows best....and despite voluminous literature about inappropriate prescribing by physicians, many pharmacists....face a significant attitudinal problem when attempting to deal with physicians on medical turf...They find it difficult to accept that physicians they deal with individually can be prone to prescribing errors ... [Pharmacists also] tend to constantly compare themselves with physicians and find themselves coming up short."²⁸
3. *Struggles for power and autonomy:* Traditionally, physicians have enjoyed a dominant and autonomous position within the hierarchy of health care professionals. This can lead to tension among professionals as well as a tendency for health professionals to interact primarily with members of their own group, with only limited interchange between professions. This in turn can lead to numerous misunderstandings as well as an "us versus them mindset."²⁹ In terms of how physicians perceive pharmacists in particular, one study that surveyed physicians reported that when physicians "responded to what annoys them about pharmacists, they overwhelmingly criticized the pharmacist's communication with patients, particularly in advising or recommending drugs to them."³⁰

There is some evidence that interprofessional barriers can be reduced when physicians are educated about the extent of pharmacists' knowledge regarding drug therapy. In our own case study interviews we found that physicians who work collaboratively with pharmacists in a hospital setting are likely to be more aware of the potential value of pharmacists as drug

advisors. Similarly, physicians and pharmacists who practice in rural or small communities appear to interact more effectively with one another than those in larger communities, because they are more familiar with one another and share a higher proportion of patients in their respective practices.

3. THE INFORMATIONAL BARRIER

In order for pharmacists to offer a full range of clinical services, they must have access to pertinent patient information, including both over-the-counter (OTC) and prescription medications, drug allergies, and diseases/conditions. As highlighted in a recent GAO report, "One area of complete agreement among physicians, pharmacists and experts is the need for establishing a sound clinical data base for effective drug utilization review."³¹

For the most part, pharmacists depend on patients to provide them with basic profile information, and in many cases patients may not be able to do this, either because they are not given this information by their physicians or because they do not understand or retain what their physicians tell them. For lab test data and diagnostic information, which enhance the pharmacist's ability to provide more sophisticated monitoring services, pharmacists must consult with the patient's physicians, and such information is rarely shared. Other circumstances described in this report contribute to these informational gaps. When pharmacists do not routinely consult with patients because of time constraints, patient profiles are not updated on a regular basis. Similarly, interprofessional barriers also inhibit exchange of more complex patient data.

4. THE TRAINING BARRIER

Some pharmacists lack adequate training in clinical pharmacy skills. Such training involves the development of both technical skills and knowledge concerning clinical pharmacology, as well as practical skills in communication.

In the era before the proliferation of pharmaceutical products and chain drugstores, community pharmacists often had a closer relationship with their patients than they have in recent decades. The pharmacist was a respected purveyor of specialized knowledge and services, and knew her or his patients relatively well, since there often was only one pharmacist in a given community. These "preindustrial" circumstances gave pharmacists experience in communicating with both patients and physicians. Today, only a minority of pharmacists, most of them older or practicing in rural settings where they have little competition, derive clinical training from such circumstances. One pharmacy scholar characterizes the clinical pharmacy movement as an attempt to restore "preindustrial" values to a "postindustrial" setting.³²

Since the clinical pharmacy movement began in educational institutions 20 years ago, pharmacists have been trained extensively in pharmacokinetics and pharmacodynamics. More

recently, pharmacy education has also witnessed the introduction of communications training based in behavioral psychology into pharmacy curricula. Such training encourages pharmacists to overcome the conventional barriers to communication with both patients and physicians.³³ But despite the fact that it has been shown to increase pharmacists' patient counseling activities, and to improve patient compliance, systematic teaching and evaluation of patient communication skills are not common within schools of pharmacy.³⁴

5. THE UNEVEN PATIENT DEMAND BARRIER

Even if the barriers described above could be eliminated, another impediment on the consumers' side of the transaction would remain—that of patient demand. In a 1986 study commissioned by the U.S. Food and Drug Administration (FDA), only three percent to six percent of patient respondents, all of whom had obtained a new prescription within the previous four weeks, reported that they had asked their pharmacist or physician for any information about their drug therapy.³⁵ These data indicate strongly that most patients are either unaware of the risks associated with drug therapy or are unwilling or unable to discuss them with a health care provider at the time a drug is prescribed or dispensed.

The issue of risk sensitivity and its effect on patient demand for information has been the subject of several recent studies conducted by health research and consumer advocacy groups.³⁶ In terms of consumer perception of medication-related risks, research evidence suggests that consumers do not associate pharmaceutical products with high risk. In one study, researchers asked respondents to rate 90 hazardous activities, substances, and technologies with regard to perception of risk, perception of benefits, and characteristics of risk. When compared to other types of hazards, pharmaceuticals were rated as "unknown" in terms of risk and less dreaded than other hazards.³⁷

Even when low risk assessment is not a factor, there are other impediments that may discourage patients from consulting with pharmacists in their role as drug advisors:

1. *Lack of knowledge about pharmacists' expertise:* Patients may not be aware that pharmacists are highly knowledgeable about the appropriate administration, interactions, and potential side effects of medications. In a 1984 study that surveyed 300 elderly patients to determine drug use patterns and relationships with pharmacists, only 1 in 6 patients mentioned the pharmacist as someone they would ask about prescription drugs.³⁸ Another study, conducted for Schering Laboratories, asked consumers to rank 15 statements that described their reasons for selecting the pharmacy they used. Ranked in first place by consumers was "the pharmacist fills prescriptions promptly," while the statement "the pharmacist will tell the patient all about the prescription" was ranked in sixth place.³⁹ The relative importance placed on speed versus information may suggest that patients place more value on the pharmacist's efficiency than on his ability to provide advice.

2. *Lack of availability:* Patients may not have direct contact with the pharmacist when purchasing a prescription drug or may perceive the pharmacist as unavailable for consultation. In pharmacies where the pharmacist, rather than a technician, conducts the counting and pouring activities, a patient's interaction may be with a clerk who is staffing the front counter. In other cases, patients may perceive that the pharmacist is too busy to answer questions. Consumers' perception of pharmacists' unavailability was well documented in the Schering survey previously cited. Respondents ranked the statements "feel pharmacist available to ask about medications" and "it's easy to get pharmacists to talk" in seventh and eighth place (of 15 items), respectively.⁴⁰
3. *Situational impediments:* The architectural design of some pharmacies may discourage patients from consulting with pharmacists. If the prescription filling area is small and crowded with customers, the noise level and lack of privacy will not be conducive to effective communication.⁴¹ Further, if the pharmacist operates from a floor raised above the level of where the patient stands, they may be forced to raise their voices in order to engage in conversation. Several studies have demonstrated that the quality of patient counseling is clearly effected by the environment in which pharmacist counseling is conducted.⁴²
4. *Communication skills/baseline information:* In some cases patients may be generally aware of potential risks but may not feel comfortable about asking specific questions, or may lack the necessary communications skills. Additionally, the absence of baseline information from which questions can be formulated may also serve as an impediment. There is some evidence that providing patients with basic written information will encourage them to be more aggressive in seeking consultation. Medical Strategies, Inc. of Boston has developed a public access software product to provide consumers with current information on medications using patient package insert data developed by the U.S. Pharmacopoeial Convention. Based on touch screen technology, PIC enables patients to query a data base about prescription or OTC drugs and obtain both print and screen displays. The PIC program is in use in a number of pharmacy settings including independents, HMOs, and teaching hospitals. In our interviews with a number of PIC users, pharmacists consistently reported a high level of customer satisfaction with the service; one independent pharmacist credited the PIC system with a significant increase in his customer base. In all cases, pharmacists reported that the information printouts stimulated questions from patients and increased the quality and quantity of verbal counseling provided.

On a positive note, there is some evidence that patient demand for more and better information about drug therapy is increasing. Research indicates that "in general, over the

past decade, Americans have become more interested in issues affecting personal health and some want more control over personal health decisions.⁴³ Augmenting this overall heightened interest in health care, consumer groups and nonprofit organizations such as the National Council on Patient Information and Education (NCPPIE) have conducted public education campaigns to alert consumers to drug-related risks and to encourage them to seek more and better information from health care providers.

We also identified several consumer-oriented information services designed to respond to patients who are not receiving information about their drug regimens from pharmacists or physicians. One such service is the Medication Information Service of California, a telephone hot line that has been in operation since 1979. The service is designed to respond to callers' questions on issues such as drug toxicity, side effects, drug interactions and safety of drug use during pregnancy. Over the life of the program, consumer inquiries have steadily increased each year. Of the 3,000 inquiries handled over the most recent 12-month period, 85 percent came from consumers, many of whom were referred to the service by health care professionals; the remaining 15 percent are from health care professionals themselves. In addition to providing information to callers, the service also refers patients to physicians and hospitals when a reported drug problem appears critical.⁴⁴

B. There Are Some Community Pharmacists Who Provide A Broad Range Of Clinical Services To Their Patients. Nevertheless, The Methods They Use To Overcome Barriers Do Not Suggest Simple Or Immediate Solutions.

As mentioned previously, in preparing this report we conducted a case study of community pharmacists who provide a broad range of clinical services to their patients. One objective of our study was to determine the methods they have used to overcome obstacles to clinical patient care. Our analysis indicates that their methods are typically a function of individual skills and personal commitment. (Case studies and analysis are included in a companion report entitled, "The Clinical Role of the Community Pharmacist: Case Studies.") We note that the flexibility inherent in managing one's own independent pharmacy can enhance a pharmacist's ability to apply these skills, but the independent pharmacy setting does not, in itself, guarantee that a range of clinical services will be provided.

We found no unusual environmental or market conditions that allowed our case-study pharmacists to develop clinical practices. All operate in highly competitive markets and compete for customers with chains, discount pharmacies, and MSPs. Populations served by the pharmacists are quite diverse, ranging from working-class urban patients to more affluent suburban patients. In sum, these pharmacists enjoy no external advantage over their colleagues. Instead, a combination of skills in clinical pharmacy, business management, and communications, coupled with an unusually strong professional self-image, appear to be the ingredients for a successful clinical pharmacy practice.

Our conclusion from the case study analysis is that this formula cannot be duplicated easily either through transaction-based reimbursement incentives or regulatory requirements. A vital question facing pharmacists as well as those who receive and reimburse pharmaceutical services is whether the more advanced clinical pharmacy care represented by our case-study pharmacists can become part of mainstream practice. In devising methods to improve clinical pharmacy care for older Americans, policy makers will be faced with the formidable obstacles we have described in this report, none of which will be easily remedied.

RECOMMENDATIONS

I. THE PUBLIC HEALTH SERVICE (PHS) AND THE HEALTH CARE FINANCING ADMINISTRATION (HCFA), INDIVIDUALLY AND COLLABORATIVELY, SHOULD DEVELOP A STRATEGY TO REDUCE THE BARRIERS TO CLINICAL PHARMACY SERVICES, PARTICULARLY FOR AMBULATORY ELDERLY PATIENTS.

There are a number of compelling reasons for the Department to assume a leadership role in enhancing pharmaceutical care for older Americans:

First, the problems associated with mismedication present a significant threat to the health of older Americans. Recognizing the serious nature of drug-related illness, PHS has included in its draft document, "Promoting Health/Preventing Disease—Year 2000 Objectives for the Nation," the objective of reducing the incidence of adverse drug reactions among older Americans by nearly 50 percent (from an estimated 17 per 100,000 in 1986 to 8.5 per 100,000 in 2000). The development of a strategy as called for in this recommendation could be instrumental in helping PHS achieve its stated goal.

Second, there is an ongoing cost borne by the Medicare program for the incidence of drug-related illness among beneficiaries. Based on the recent study in California that was cited earlier in this report, nationwide hospitalization costs alone account for billions of dollars each year. Additionally, the Medicaid program absorbs the costs of hospitalizations, doctor visits, and institutional care that result from drug-related injuries and illnesses for older Americans who are income eligible. The HCFA, in its role as manager of the Medicare and Medicaid programs, has a major stake in ensuring that costs of preventable illnesses are avoided.

Third, the Medicare Catastrophic Coverage Act (MCCA) of 1988, which was recently repealed, mandated a DUR system and included several provisions designed to ensure that certain clinical pharmacy services be provided to all beneficiaries. These provisions were based on a recognition by the Congress that mismedication problems are a serious threat to the health of older Americans and that clinical pharmacy services can add significant value to overall patient care. Prior to repeal of the MCCA, HCFA was at work designing a DUR program and developing regulations and standards for participating pharmacists. The scope and complexity of these tasks were such that experts both within and outside the Department were doubtful that HCFA could meet the implementation deadline.

Repeal of the MCCA presents the Department with an opportunity to formulate a strategy for improving drug therapy for the elderly in an environment free of implementation deadlines.

- Although a Medicare drug benefit may not be proposed again in the near future, the overall issue of drug-related problems among elderly patients is not likely to escape continued

attention of Congress, the media or the public. Research and policy development on this issue should begin now so that policy makers will be equipped to respond effectively to future Congressional mandates.

In that context, we recommend that HCFA and PHS develop a strategy that includes research, demonstration and education efforts to reduce each of the barriers to clinical pharmacy care described in this report. We strongly urge that demonstration efforts include interventions to address multiple barriers. For example, a project aimed at increasing patient demand could be successful in raising patients' expectations but have no effect on expanding clinical services if economic barriers are not addressed. Additionally, we recommend that all research efforts measure the effect of clinical pharmacy care on both total cost and clinical outcome.

There are a number of vehicles that can be employed by HCFA and PHS to facilitate such efforts, including the use of Medicaid waivers, Medicaid demonstration projects, and research and demonstration grants. Listed below are examples of interventions that may be tested:

- Test a capitated system of reimbursement to pharmacists, measuring the costs and benefits (financial and therapeutic) of such a system, when compared to a product-based reimbursement scheme. The capitated reimbursement system would be based on a flat fee per beneficiary with financial penalties and rewards that are tied to clinical outcomes.
- In a demonstration project model, measure the costs and benefits of providing clinical pharmacy monitoring for high risk ambulatory patients. Use the Medicaid nursing home model which separates the clinical monitoring functions from that of dispensing. Identify high-risk Medicaid patients by screening the Medicaid information system for patients who meet certain criteria. For example, patients who are over 65, take five or more medications, have three or more conditions and/or three or more physicians could be identified as candidates. Clinical monitoring by a pharmacist who is not dispensing the patient's drugs could be provided to an experimental group within that pool of subjects and clinical and cost outcomes could be measured to determine the effects of the intervention.
- Study existing settings where lab and diagnostic data on ambulatory patients are already available to clinical pharmacists and document the costs and benefits of such a system. There are a number of family practices where such systems are already in place, and evaluation of cost and effectiveness would provide a basis for determining the value of encouraging duplication on a broader scale.
- Furnish an experimental group of Medicare beneficiaries with blank medication charts and instructions for use. Charts would be completed by physicians, pharmacists and patients and would include information on the name and purpose

of both prescription and OTC drugs, instructions on administration, and descriptions of side effects and significant adverse reactions. Patients would use charts to record their own patterns of use as well as any side effects they note. Charts would be presented by the patients to both physicians and pharmacists during office visits and whenever a prescription is filled at the pharmacy. This is a relatively inexpensive way to encourage improved counseling by both pharmacists and physicians.

- Measure the outcomes among patients served by pharmacists who complete mid-career training programs in patient counseling skills. As mentioned earlier, training in this area has been less than adequate for many pharmacists; in order to expand clinical services in community pharmacy settings, mid-career training opportunities will need to be expanded.

II. THE NATIONAL INSTITUTE ON AGING (NIA) SHOULD TAKE A LEADERSHIP ROLE IN DEVELOPING RISK INDICATORS AND TREATMENT PRIORITIES FOR ELDERLY, AMBULATORY PATIENTS.

Although some general categories of indicators and patient groups who are at high risk of ADRs have been identified, additional research is needed to define more precisely those elderly patient groups who are at highest risk and in greatest need of close clinical monitoring of their drug therapy. The NIA, which has long been concerned with drug therapy for older adults and has considerable expertise in this area, should lead an effort to expand scientific knowledge regarding high risk indicators.

III. THE AMERICAN PHARMACEUTICAL ASSOCIATION (APhA) AND THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY (AACP) SHOULD DEVELOP STANDARDS OF PRACTICE THAT ADDRESS THE COMPONENTS OF CLINICAL PHARMACY CARE ON THE BASIS OF PATIENT NEED.

As mentioned previously, there is little consensus within the pharmacy profession about standards of care related to patient need. Although the APhA has developed standards of practice, those standards are limited in several ways: First, they were developed from a task-inventory approach and are not functional in nature. Second, they do not include a practical needs assessment model that can be used by the pharmacist to assess needs, indicate interventions, and identify patients who require maximal level services.

We therefore recommend that APhA and AACP work cooperatively to revise their standards of practice in a more functional context and to create a practical needs assessment model that practicing pharmacists can use to determine patient need.

IV. STATE GOVERNMENTS SHOULD REVISE PHARMACY PRACTICE ACTS TO ALLOW MAXIMUM USE OF TECHNICIANS IN COMMUNITY SETTINGS. THE APhA AND THE STATE PHARMACY ASSOCIATIONS SHOULD TAKE A LEADERSHIP ROLE IN ENCOURAGING MORE EXTENSIVE AND EFFECTIVE USE OF TECHNICIANS IN COMMUNITY PHARMACIES.

Underutilization of technicians to perform routine pharmacy activities such as packing and labeling medication doses and filling routine orders for stock supplies creates a major economic barrier to provision of a broad range of clinical services in community settings. Because laws and regulations governing the use of technicians rest within the purview of individual States, initiatives to maximize use of technicians must be taken at the State government level in cooperation with State boards of pharmacy.

If APhA assumes the task of developing functional standards of practice (Recommendation III), it will be well-positioned to lead an effort aimed at encouraging more extensive and effective use of technicians in community pharmacies. Defining the role of the pharmacist as a clinical provider and standardizing pharmaceutical care functions should dilute the fear that technicians would replace pharmacists, rather than supplement the services they provide. The APhA should enlist assistance and consultation from the State pharmacy associations as well as the National Association of Boards of Pharmacy and the individual State boards of pharmacy in such an effort.

COMMENTS

Within the Department of Health and Human Services, the Public Health Service and the Health Care Financing Administration (HCFA) provided comments. The American Pharmaceutical Association, the American Society of Hospital Pharmacists, the American Society of Consultant Pharmacists, and the American Association of Colleges of Pharmacy also commented.

With the exception of HCFA, all commenters expressed support for the findings and recommendations. Most provided some technical suggestions and comments that we have included in the final draft. With the support and leadership these organizations are committed to providing, we look forward to initiatives that will expand clinical pharmacy services and improve patient care, particularly for groups who are at high risk of drug-related illness. In appendix VI, we present, in full, each set of comments and respond to each of them.

APPENDIX I

THE HISTORY OF CLINICAL PHARMACY

The Pharmacist: Drug Dispenser or Drug Advisor?

The pharmacist has always played a dual role: that of drug dispenser and that of drug advisor. It is primarily the latter role that emphasizes the use of cognitive skills and extensive training by the pharmacist, and that serves to characterize the pharmacist as a health care professional rather than merely a health care worker. This role as drug advisor is also known as the pharmacist's clinical role. Through most of the twentieth century, the pharmacist has been characterized by many, inside and outside the profession, as a drug dispenser and businessman. At the same time, however, some of those inside the profession have sought to promote the pharmacist's clinical role, and in the last two decades, this professional role has gained ground both inside and outside the ranks of pharmacists.¹

The Pill-Counter View

During the first half of the twentieth century, various elements of the U.S. health care system increased in prestige and sophistication, serving to overshadow pharmacy. First, physicians intensified their process of professionalization and enhanced their public status, separating their functions from, and placing them above, that of drug dispensing. Abraham Flexner, the encyclopedist of medicine, wrote in 1915 that pharmacists were not professionals, because their function was simply to execute physicians' orders. The Federal Government shortly followed suit, denying pharmacists the commissions in the Armed Forces that physicians and others received.

Within the pharmaceutical community itself, attention shifted toward drugs and away from pharmacists. After World War II, corporate financing favored research in drug development, and similar financing was not available for research in the more service-oriented field of clinical pharmacy. A common view was that pharmacists served merely as the conduits through which the public gained access to an ever larger array of increasingly sophisticated pharmaceutical products. The pharmacist's capacity to manage this flow of drugs to patients was given short shrift.

The Clinical Pharmacy Movement

The countervailing forces to this way of thinking originated in pharmacy education. Educational institutions sought to enhance pharmacy's standing as a profession by enlarging their curricula. Beginning in 1932, following a study of pharmacy's functions commissioned by the American Association of Colleges of Pharmacy (AACP), the four-year Bachelor of Science degree in pharmacy was endorsed by national pharmacy associations and became standard. In the 1950s and 1960s, many colleges of pharmacy instituted five-year programs, expanding curricula to include extensive training in the medical aspects of drug therapy and in

more communications-oriented aspects of patient counseling. In the mid-1960s, many schools began extending their programs to six years, awarding Doctor of Pharmacy (PharmD) degrees, with the sixth year often devoted to a clinical clerkship with a practicing pharmacist; about 40 PharmD programs now exist.²

The clinical pharmacy movement accelerated within the subfield of hospital pharmacy in the late 1960s and 1970s. Hospital pharmacists began to work with physicians as part of a clinical team that performed diagnosis and treatment collaboratively. Pharmacists sometimes went on rounds with physicians; they performed retrospective and prospective DUR; and they oversaw drug distribution within hospitals. Hospital pharmacists worked under fewer competitive pressures to meet a daily quota of transactions than retail pharmacists, and they became freer to spend their time analyzing data and performing services unconnected to transactions.

Now, in the 1980s, the clinical functions of the pharmacist have moved to the forefront of discussion in the field. Pharmacy technicians and pharmacy robots have proved able to fulfill the simple dispensing functions that many—including many pharmacists—have long seen as the pharmacist's major tasks. Leaders in pharmacy and pharmacy organizations have increasingly promoted those clinical functions for which pharmacists receive unique training, as they have sought to portray pharmacy as a profession whose survival is vital to public health.

The view of the pharmacist as a drug therapy manager rather than merely a drug dispenser has received tentative endorsement from entities outside pharmacy. A recent court decision characterized the pharmacist's role as one of "risk management," analogous to the physician's role of "risk assessment," thus portraying the pharmacist as something more than a passive conduit for products and for the physician's instructions.

In sum, forces both inside and outside of pharmacy seem to be moving the profession toward an increasing emphasis on the pharmacist's clinical functions. But it is unclear at this time whether these forces will successfully supplant the view, still widespread, of the pharmacist as a drug dispenser, with little to offer in the way of unique services or analytic skills.

Endnotes

1. Hepler C.D., "The Third Wave in Pharmaceutical Education: The Clinical Movement," *American Journal of Pharmaceutical Education*, 51:369-85, 1987.
2. Giblin P.W., Manasse H.R., "Commitments to the Future of Pharmacy: Review and Opinion of the Pharm.D. Curricular Debate," *Drug Intelligence and Clinical Pharmacy*, 18(5): 420-27, 1984.

APPENDIX II

PHARMACY SETTINGS

Pharmacists practice in a variety of settings. Because the terms that refer to these different settings are frequently used in discussions of pharmacy, defining them will clarify the discussion in this report.

As the term "community pharmacy" is used in the literature on pharmacy, it refers to walk-in pharmacies in non-institutionalized settings. It includes chain drugstores and "independents." Independent pharmacies are the most traditional setting: here, the chief pharmacist also functions as a small businessperson. "Apothecaries" are those independent pharmacies that sell only drugs.

"Institutional pharmacy" includes both hospital and nursing home pharmacy. In hospitals, pharmacists oversee directly the distribution of drugs to patients and collaborate with physicians on the proper course of medication throughout a patient's stay in the hospital. In nursing homes, pharmacists usually do not oversee the distribution of drugs, which is left to nurses and other caregivers. In this setting, they are usually "consultant pharmacists" who arrive at the nursing home once each month to perform the chart reviews mandated by Medicaid.

"Home health care pharmacy" addresses a patient population that is less ambulatory than those who come to a walk-in pharmacy, but usually more ambulatory than those in fully institutionalized settings. Home health care covers a wide range of care settings, some more institutional than others, and some that should be considered community settings, for our purposes. Because we have not researched this large field exhaustively, our conclusions concerning "community pharmacy" are not as applicable to home health care as to other community pharmacy settings, namely chains and independent pharmacies. Speaking generally, this report focuses on the care of ambulatory patient populations and pharmacy settings that serve them.

APPENDIX III

CASE STUDY METHODOLOGY

The purpose of conducting the case study was two-fold:

- to observe and document activities that comprise clinical pharmacy practice; and
- to identify (in the case of clinical pharmacists who practice in traditional community settings) the barriers they face in providing pharmaceutical care to their patients and to determine the methods they use to overcome those barriers.

Given that objective, we made a purposive selection of pharmacists who were identified by members of professional and research organizations as practitioners who provide an unusually broad range of clinical services to their patients. A number of organizations and individuals were helpful to us in identifying a candidate pool, including the American Pharmaceutical Association, the American Association of Colleges of Pharmacy, the University of Florida College of Pharmacy, and the University of Maryland College of Pharmacy. We made selections from an initial pool of 35 candidates based on telephone interviews during which we solicited information about the nature of the pharmacist's practice, the population served, the pharmacist's therapeutic specialty, and her/his willingness to participate in the case study. Our final selection was based in part on geographical diversity; urban, rural and suburban practices are represented. Although we sought candidates who practice in chain, independent and apothecary settings, only the latter two are represented. None of the candidates nominated practice in chain pharmacies.

The pharmacists selected for our study are listed below:

Julee Alexander
Lifesource, Inc.
900 Larkspur Landing Circle, Suite 250
Larkspur, CA 94939

Nancy Culberson
Lexington Family Practice Pharmacy
P.O. Box 460
Lexington, SC 29072

Madeline Feinberg
Accredited Surgical Company
9515 Gerwig Lane, Suite 131
Columbia, MD 21046

Linda Garrelts
Jones Pharmacy
S. 906 Monroe
Spokane, WA 99204

Howard Juni
Capitol Drug Center
2007 E. County Rd. E
White Bear Lake, MN 55110

Calvin Knowlton
Amherst Pharmacy
332 Lumberton Rd.
P.O. Box 56
Lumberton, NJ 08048

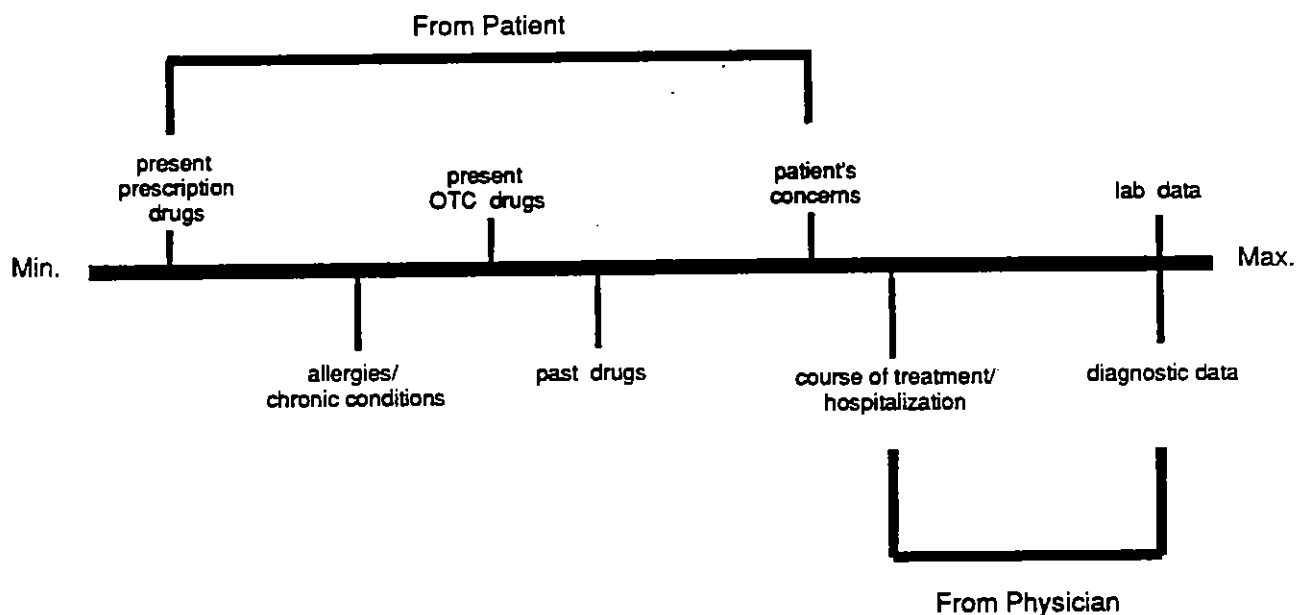
In each case, we made site visits to observe the pharmacist's practice over a 2- to 3-day period. In the case of the four pharmacists who practice in traditional community settings (Knowlton, Juni, Garrelts, and Culberson), we conducted extensive interviews with the pharmacist and other staff on site, physicians who were familiar with the pharmacist's practice, and patients served by the pharmacist. We also observed the pharmacist in practice and reviewed the information systems they use to support clinical activities.

APPENDIX IV

THE FOUR COMPONENTS OF CLINICAL PHARMACY CARE

(1) Collection of Patient Information

Collection of Patient Information



Much of our analysis of clinical pharmacy is structured around the transfer of information, which is a vital tool required by all those involved in providing clinical services to patients. The first task the pharmacist must perform in order to provide clinical care is to collect information from the patients themselves and from the physicians. Thus, data collection is in itself a major function of the clinical pharmacist.

Information from Patients

The pharmacist can collect a wide range of information from the patient. At the most basic level, she or he will inquire about what prescription drugs the patient is presently taking. The pharmacist may also ask about any allergies the patient may have and may inquire about what over-the-counter (OTC) or nonprescription drugs the patient is presently taking. Still at a fairly basic level—though not all pharmacists collect this information—are the patient's diseases and other conditions, as well as the patient's weight, height and age, which affect dosage levels. At the next level is information that a pharmacist can collect on a patient's drug use history. This includes the patient's past prescription drug use, past OTC drug use, and past

illnesses. Finally, the pharmacist may inquire about the patient's concerns about the drug regimen, such as whether previous reactions to other medications will reoccur.

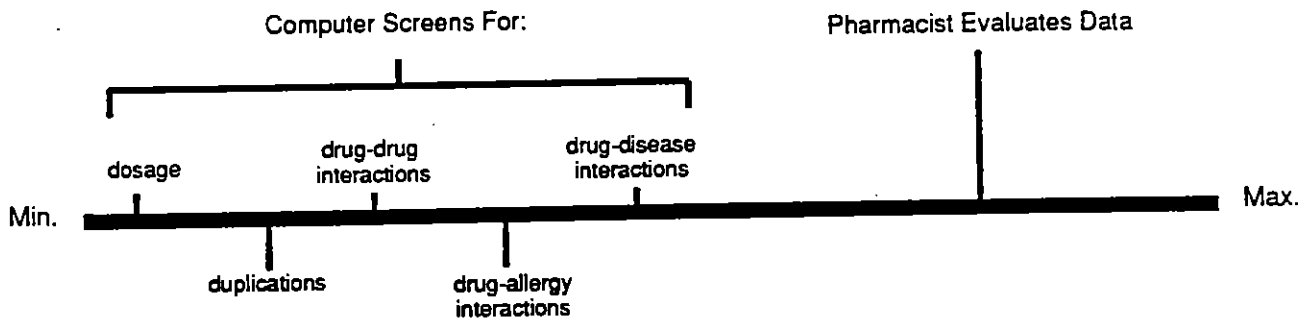
The pharmacist most likely gets all this information directly from the patient. (OTC drug information typically can be obtained *only* from the patient, since these drugs are usually purchased without the express instructions of a physician, and often are not purchased at a single pharmacy or at any pharmacy, with the result that no complete record of their purchase exists anywhere except in the patient's memory.)

Information from Physicians

In addition to collecting this information from the patient, as well as determining the patient's main concerns and questions, the pharmacist can obtain data from the patient's physician or physicians that can be useful in managing the patient's drug therapy. Most basic here are the patient's vital statistics—though the pharmacist may occasionally read the patient's blood pressure or perform cholesterol screenings, if State law allows. Next is information concerning the patient's general course of medical treatment, both present and past, including hospitalizations. Finally, the physician can share with the pharmacist data from the patient's lab tests (e.g. blood or liver function tests), and information concerning the diagnosis, which could help the pharmacist understand why the physician has prescribed a certain drug. This information is readily available to a pharmacist working in a more institutionalized setting such as a hospital, a nursing home, or a home health agency, where physicians typically cooperate closely with pharmacists. But it is not routinely available to pharmacists working in a community setting. The practicing community pharmacists we spoke with all said that among the information about a patient that they usually do not possess, lab test data and diagnostic data would be the most helpful to them if they had it.

(2) Drug Regimen Review (DRR)

Drug Regimen Review Screening and Evaluation of Data



In the community setting, the most useful type of review that pharmacists conduct is prospective utilization review, performed at the point of sale. Retrospective review usually is performed by third-party providers or nursing home pharmacists who survey large data bases in order to discern large-scale prescribing patterns. Most community pharmacists do not oversee such a large pool of prescriptions, nor do they have the sort of regulatory perspective that would make retrospective DRR an appropriate task for them. We have heard of no community pharmacist who performs retrospective DRR, and it seems to lie outside the continuum of community practice.

The first line of defense the pharmacist can employ against drug-related illness is a manual or automated review of new prescriptions for potential counter-indications. At the most basic level, the review may screen for missing or improper (for a given drug) dosage information.

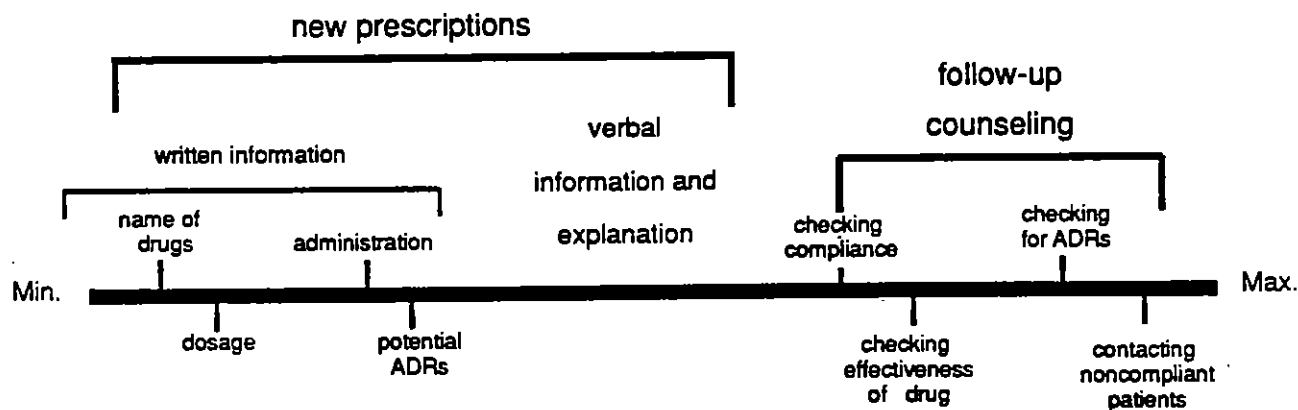
On a more sophisticated level, the review may include whatever information the pharmacist has collected on the patient's drug history. An automated review uses computer software that can be programmed to screen for therapeutic duplications in a patient's drug regimen, which can occur especially when multiple prescribers are involved in a patient's therapy. Becoming more complex still is a screening for a wide range of drug interactions, including drug-drug, drug-allergy, drug-diet and drug-disease interactions. It should be noted that if an automated system is used, the number of interactions software packages are programmed to spot can vary greatly.

The pharmacist who uses a computerized system will have to examine those prescriptions the computer identifies as potentially harmful in order to determine the appropriate course of action. The pharmacist will look for the same type of problem the computer has looked for, and will use professional judgment to decide how to proceed: whether to dispense the drug with a warning to the patient of potential hazards, to dispense it without a warning, or to contact the prescriber in order to seek a change in the prescription.

Pharmacists use computer programs primarily to save time—to speed the identification of potential drug interactions. If a pharmacist has the time, a personal examination of all new prescriptions is the highest level of professional scrutiny prescriptions could receive at the point of sale. But often, pharmacists are simply too busy, and in this case, computer programs are tremendously helpful tools.

(3) Patient Counseling

Patient Counseling



In this component, the pharmacist transfers information to the patient with the aim of ensuring that the patient understands (1) why she is taking the medication, (2) how she is to take it, and (3) what to expect (expected outcomes, side effects and what to do in each situation). Again, we find a wide variation in the level of counseling in both its form and content. In practice, information can be conveyed in written and/or oral form, and it can be given in person, through the mail, or by telephone.

Forms and Physical Settings of Counseling

Studies indicate that written information given alone is the least effective form of counseling, in terms of retention of knowledge and incidence of side effects from drugs.¹ The minimal form of written information is an auxiliary label placed directly on the container in which the drug is dispensed, and which gives the drug's name, the number of dosage units, and possibly, very brief instructions concerning administration. A recent survey of 400 community pharmacists found that all of those questioned used these labels, and that 68 percent of their patients received them.² But as indicated above, the impact of such labelling on patient knowledge is highly questionable. Containing far more information are the patient package inserts (PPIs) produced by the U.S. Pharmacopoeial Convention (USP), which include fairly complete side effect and interaction information; some community pharmacists either purchase these leaflets or receive them from pharmacy organizations. Other sources of written information include leaflets distributed to pharmacists by drug manufacturers and, occasionally, leaflets on drugs, drug classes, or conditions that pharmacists produce themselves. But research indicates that even PPIs, which are as complete as virtually any written counseling can be, are inferior to oral counseling.

Oral communication is key to effective patient counseling by most accounts. One Canadian study found that a combination of written and oral information given to patients was successful in increasing their knowledge of their medications, and in reducing and preventing mismedication, in almost any setting: in a private or nonprivate face-to-face setting or on the telephone. The same study indicated that private face-to-face counseling, conveying both oral and written information, is the most effective form of counseling, even if not the only effective form.³ This suggests that the element of privacy, whether in person or on the telephone, is crucial to effective patient counseling.

Additionally, in-person counseling provides patients with the opportunity to ask questions about the drug the pharmacist has not answered, or questions about the information the pharmacist has given them. The pharmacist can also probe for any questions, concerns, or uncertainties on the patient's part and verify that the patient understands critical information.

Information Conveyed

The specific information conveyed to patients once again covers a wide range, from minimal to maximal. The most basic information the pharmacist can give the patient is the prescribed drug's name, and number of dosage units. Fundamental as this information is, if it is simply typed on the bottle's label and not reinforced verbally, the patient may well not retain it. Moving to the next level, the pharmacist can explain the drug's proper administration to the patient, even, in the case of an unusual administration mechanism, such as an inhaler, showing the patient how to take the drug. The pharmacist can explain precisely how the patient should coordinate taking the drug with eating, and what foods to avoid, and can give instructions on how and where the drug should be stored.

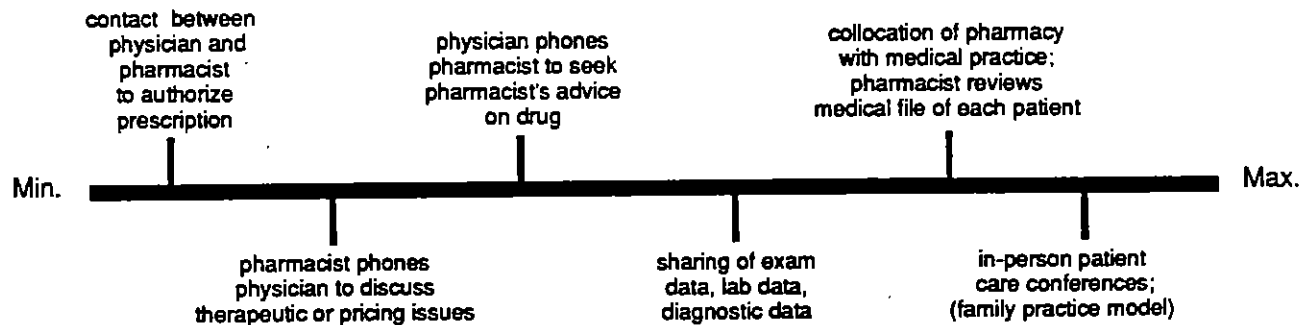
More complex is the scientific information pharmacists might give a patient. They can explain the drug's intended effect, and tell the patient when she or he can expect relief if the drug works as it should. They can also warn the patient about potential side effects and adverse interactions.

Follow-up Activities/Monitoring

All this information can be conveyed at the time of the initial prescription, which is when most pharmacists do most of their patient counseling. Occasionally, however, they raise their counseling activities to a higher level through the practice of followup counseling. They might check a patient's compliance at the first refill, and at subsequent refills, or they might monitor the effectiveness of the drug therapy at subsequent visits, and check for signs of side effects or ADRs. Pharmacists can also contact patients, either by mail or by phone, who have not come in to the pharmacy for refills at the expected time. In the case of the most personalized attention, a pharmacist will check on patients regularly, not just at refill times. Presently, in community settings, such a practice can be found in small home-health pharmacies, that have a relatively low patient-to-staff ratio. Any followup activity at all, however, should be viewed as an unusually intense patient counseling practice.

(4) Physician/Pharmacist Consultation

Physician/Pharmacist Consultation



The flow of information between the pharmacist and the physician is of key importance to clinical pharmacy. The primary contact between physicians and pharmacists occurs when a prescription is ordered either by phone or in writing.

Pharmacist-Initiated Contact

The most basic contact made by a pharmacist is for the purpose of receiving authorization to fill a prescription. In some cases, the pharmacist, after reviewing the prescription, may have concerns about the dosage level or the length of fill prescribed, or about potential side effects and interactions, and may contact the physician to discuss them. If the physician cannot satisfy the pharmacist's concerns about a potential hazard to the patient's health resulting from the use of the drug, the pharmacist may seek to have the physician change the prescription. In some States, such as Washington, individual pharmacists can arrange with individual physicians to change prescriptions, within clear limits on their own, if they think it is warranted. By and large, however, pharmacists must seek the express permission of the physician to make changes in a prescribed therapeutic regimen. Seeking such changes when appropriate is at the heart of the risk management that pharmacists are increasingly expected to perform.

Pricing Issues

A pharmacist might also contact a physician to discuss pricing issues involved with a prescription; this is more unusual, in most walk-in settings, than contacting a physician to discuss therapeutic issues. (Discussion over pricing is less unusual in an HMO setting, where payment to both pharmacists and physicians may be capitated, and where there are incentives to dispense lower-priced drugs.) A less expensive generic substitute for the prescribed drug may be available, or a less expensive non-generic substitute, and the pharmacist may wish to dispense one of these in place of an expensive prescribed drug. If a patient is paying cash for the drug the matter is most pressing, but even if a patient has third-party insurance, overall systems costs will be lowered if a less expensive drug is dispensed, so a pharmacist might contact a physician to discuss price-related substitution in any case. Again, in many States, pharmacists are free to substitute generics for prescription drugs without permission from the prescriber; there is no State, however, where community pharmacists can substitute less expensive pharmaceutical or therapeutic substitutes for more expensive drugs without the prescriber's express permission.

The issue of these pharmaceutical and therapeutic substitutes merits further discussion. Pharmaceutical alternates include drugs that are no longer on patent, but contain the same active ingredients as a much higher-priced drug that is manufactured with patent protection in a different form. The new drug is changed slightly from the old drug: it may be changed from a pill into a caplet, or the dosage may be doubled; but chemically it is the same as the old drug. Nonetheless, the manufacturer emphasizes the unique quality of the new drug in its detailing, suggesting as strongly as it can that it is somehow more effective than the old drug. As one pharmacist has observed, "Effective brand-name product positioning with prescribers, coupled with a relative lack of comparative price information for patients and prescribers,

have enabled manufacturers to establish single-source drug prices largely independent of therapeutic uniqueness or cost of comparative products. It is not unusual to find a ten-fold price differential [between a single-source drug and its pharmaceutical alternate].⁴

Therapeutic substitution is initiated when a pharmacist contacts a physician to request a change in the prescription drug, for example, from one diuretic to another that is less costly. Although therapeutic interchange is common in managed care settings and hospitals, it is rare in the community setting.⁵

Physician-Initiated Contact

More unusual, and characterizing a closer interprofessional relationship than the pharmacist contacting the physician, is the physician seeking consultation with the pharmacist. The physician, for example, might want to ask the pharmacist about the effects—and risks—of an unfamiliar drug or drug class. Clearly such contact implies a great deal of professional respect for the pharmacist on the physician's part. If the two enjoy a particularly close professional relationship, they may be aware of which patients they both care for, and the physician may contact the pharmacist to ask about a particular patient's progress, or to seek advice on prescribing for the patient. Such contact is quite unusual in most walk-in pharmacy settings. Also unusual is the sharing of a physician's examination data, lab test data, and diagnostic data on patients with a pharmacist. As noted above, pharmacists rarely possess these data when performing DUR, but they indicated they would find such information valuable.

Institutional Contact

Unusually close contact between physicians and pharmacists is facilitated in an institutionalized setting because the two professionals are located in the same building or area. This is usually not the case in a community setting, but if it is, then contact is facilitated greatly. One pharmacy we visited is collocated with several family practice physicians' offices, and all the kinds of contact described here occur there. Even in this setting, however, the discussion between physicians and pharmacists concerned individual patients, and only as particular questions or problems arose.

Still more intensive would be regular patient care conferences involving pharmacists and physicians, in which the treatment and progress of all patients could be discussed. This kind of patient care conference occurs in teaching hospitals, but almost never in the community setting. In one of the pharmacies we visited, such conferences were held weekly in which all staff pharmacists and other clinical staff participated, but not physicians, and the progress of all the pharmacy's patients was discussed. This was possible only because of the pharmacy's small patient load.

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APPENDIX V

ENDNOTES

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APPENDIX VI

DETAILED COMMENTS ON THE DRAFT REPORT AND OIG RESPONSE



Memorandum

APR 10 1990

Date

From Assistant Secretary for Health

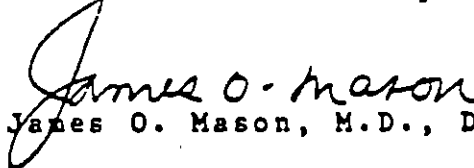
Subject OIG Draft Reports "The Clinical Role of the Community Pharmacist," and "The Clinical Role of the Community Pharmacist: Case Studies"

To Inspector General, OS

Attached are the PHS comments on the subject OIG draft reports.

We generally agree with the contents of the draft reports and concur with the recommendations directed to PHS. We will develop and implement by October 31, 1990, a strategy to reduce barriers to clinical pharmacy services, particularly for elderly patients. We are also working on increasing our knowledge in developing risk indicators and treatment priorities for elderly ambulatory patients.

Our comments on the recommendation to the American Pharmaceutical Association and American Association of Colleges of Pharmacy present alternatives for developing a uniformed review process for pharmacists in their patient encounters.


James O. Mason, M.D., Dr.P.H.

COMMENTS OF THE PUBLIC HEALTH SERVICE ON THE OFFICE OF INSPECTOR
GENERAL (OIG) DRAFT REPORTS "THE CLINICAL ROLE OF THE
COMMUNITY PHARMACIST," OAI-01-89-89160, AND
"THE CLINICAL ROLE OF THE COMMUNITY PHARMACIST: CASE STUDIES,"
OAI-01-89-89161

General Comments

The reports effectively capture the dilemma facing community pharmacists regarding the implementation of progressive patient oriented pharmacy services, i.e., clinical pharmacy services. The reports should have a positive impact on the pharmacy profession by identifying the most significant barriers to the provision of pharmaceutical care for patients, especially older persons.

A recent strategy planning conference on "Pharmacy in the 21st Century," held in October 1989, examined many of the major issues confronting pharmacy today and projected for the next 15-20 years. The consensus statements of the conference support the findings of these reports. The participants included practitioners, pharmacy leaders, selected representatives of consumer groups, and government and corporate health care decision makers. A copy of the Executive Summary (Attachment A) is attached.

We regret that the OIG inspectors did not include in their inspection and case studies the Indian Health Service (IHS) pharmacy program. IHS has nearly 30 years of experience in providing clinical pharmacy services with extensive utilization of patient consultation. The IHS practice model has eliminated most of the barriers described in the OIG report.

The PHS comments on the OIG recommendations that pertain to PHS are presented below. Additional comments regarding alternative viewpoints are also included, which we believe would strengthen the overall content of the report. The additional comments relate to (1) the concept of a needs based system, and (2) the description of clinical services, especially the graphic representation in Appendix IV of the OIG report.

OIG Recommendation I.

The Public Health Service (PHS) and the Health Care Financing Administration (HCFA), individually and collaboratively, should develop a strategy to reduce the barriers to clinical pharmacy services, particularly for ambulatory elderly patients.

PHS Comment

We concur, noting that it is essential to develop a strategy that includes research, demonstration, and education efforts to reduce each of the barriers to clinical pharmacy services as described by OIG. PHS welcomes the opportunity to develop strategies to reduce the barriers to clinical pharmacy services for ambulatory patients, with emphasis on older persons.

IHS has extensive experience in the provision of progressive pharmaceutical care and is the prototype of a functional practice model that clearly demonstrates the pharmacy services concept described in the report. IHS will develop a descriptive strategy for reducing barriers to clinical services and demonstrate its application by September 30, 1990.

The Bureau of Health Professions in the Health Resources and Services Administration, PHS, will further develop the strategy described above in collaboration with IHS and HCFA. The strategy will be developed and implemented by October 31, 1990.

OIG Recommendation II.

The National Institute on Aging (NIA) should take a leadership role in developing risk indicators and treatment priorities for elderly ambulatory patients.

PHS Comment

We concur. NIA has taken action to increase its knowledge in the area of geriatric pharmacology, including the areas of risk indicators and treatment priorities for elderly ambulatory patients. NIA has recently published a Request for Applications (RFA): "Pharmacology in Geriatric Medicine" which solicits research applications on drug utilization reviews, pharmaco-epidemiology, and other areas related to the improvement of medication prescribing and use by older persons. Two million dollars have been set aside for this RFA. Scientific review of proposals will be accomplished by a special initial review group in June 1990, with secondary review to be completed at the September 1990 meeting of the National Advisory Council on Aging. It is anticipated that approximately 8-10 high quality applications will be funded with starting dates of December 1, 1990.

However, this recommendation may be more effectively accomplished if conducted in conjunction with an expert panel from appropriate PHS agencies and professional organizations. Indicators can be developed but they will only tell you which patients may be at

high risk (not all are at high risk). What is needed is a shortened practical needs assessment process (see comments on recommendation III. below) that can be used at each encounter with each patient to determine his/her particular need for clinical intervention. In addition, the term adverse drug reactions is too limiting. The term *negative or adverse outcome* should be substituted because it includes such important items as treatment failure due to inappropriate drug use.

Technical Comments

A. Needs Based Concept

1. Page 6, Paragraph 2. The question raised in this paragraph is the key issue in the report and can be best summed up as follows: How can the community pharmacist determine what services are needed at each patient encounter and provide them in a practical and timely manner?
2. Page 6, Paragraph 3. The statement is accurate in its assessment that there is little consensus regarding standards of clinical pharmacy care as applied to patient need. There are good reasons for that, and those reasons may add difficulty to the implementation of recommendations II. and III.

First, patient needs vary with time, i.e., each evaluation of patient needs is like a snapshot of a moving or changing object. This constant change makes it very difficult to set standards based on needs that are useful. Initial encounters with patients who are on multiple drug regimens and those whose diseases are not adequately controlled, will require more comprehensive services. Once that patient is stabilized, the need for intensive monitoring will drastically decrease. To continue monitoring those patients intensively just because they are on multiple drug regimens would be an inappropriate use of pharmacists' professional time. Therefore, approaches like the one proposed by Koechler, et al., in the American Journal of Hospital Pharmacy (AJHP), which incorrectly assume a continual high level of need, will result in wasted pharmacy efforts. The authors point out these problems and others in their discussion section including the fact that a large percentage of patients that need intervention did not fall into their criteria for service.

Second, the ability to determine patient needs and the extent to which these services are provided is not consistent among pharmacists because of the following reasons and other factors:

- a. the extent of the database available to the pharmacist;
 - b. the knowledge of the pharmacist in both drug and disease information; and
 - c. the ability of the pharmacist to collect and integrate drug, disease, and patient data to identify and solve drug related problems.
3. Page 6, Paragraph 4. Two approaches were cited and listed as different perspectives. A careful review of the articles listed and other work on similar subjects by these authors revealed that these are not different perspectives, but were variations of the same concept.

Dr. Linda Strand's work was developed to teach students a skill not generally taught in pharmacy school. Primarily, pharmaceutical education has been accomplished through memorization and regurgitation. Clinical pharmacy practitioners have long recognized that students were not taught clinical problem solving skills. Dr. Strand has formalized a process that forces (teaches) students to utilize clinical problem solving skills via the collection and integration of patient and disease databases with drug databases. This is one of the end products of Dr. Strand's work on student-centered problem oriented teaching methods. The difficulty with her comprehensive approach is that it is very time consuming and, therefore, is not practical to use for all outpatients in a busy pharmacy practice setting.

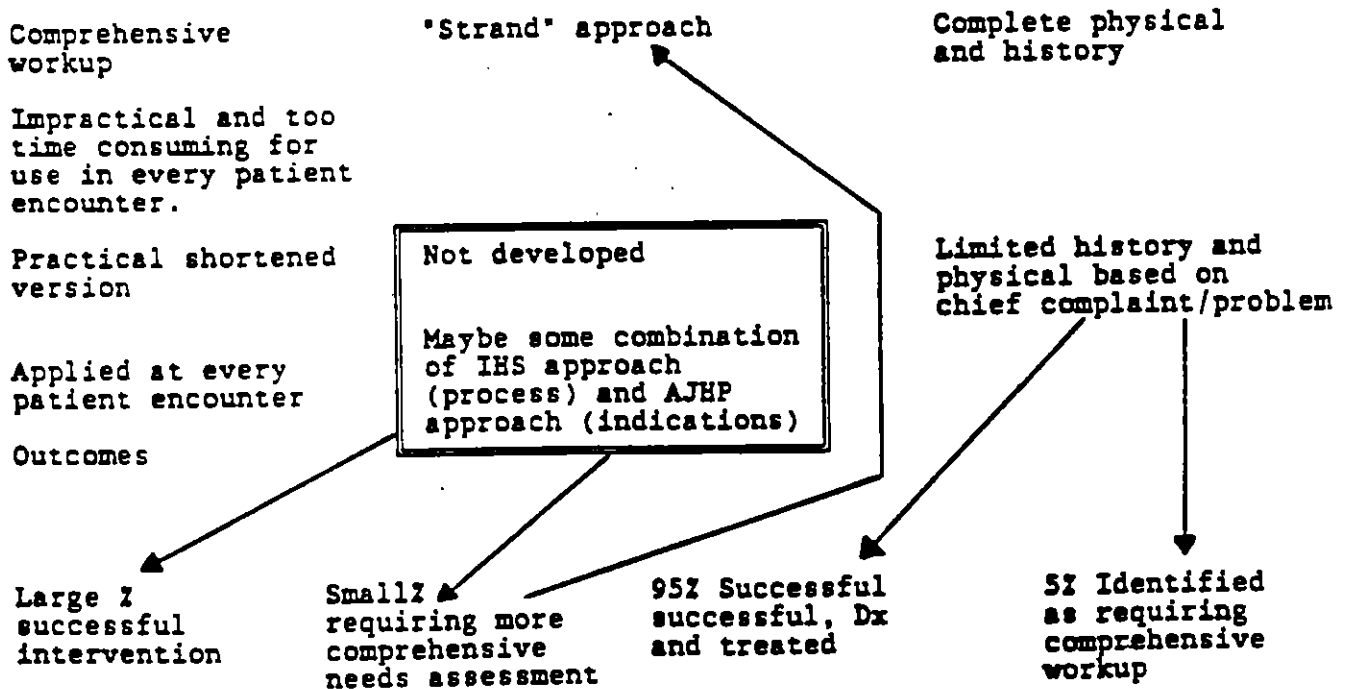
Recognizing the difficulty of providing a comprehensive approach to all patients, the authors of the AJHP article try to find a process to identify those patients that most need a comprehensive approach to clinical pharmacy services (Dr. Strand's process). Unfortunately, their criteria-based process did not address changing needs over time, plus it failed to identify a large percentage of patients who required pharmacy intervention.

What both studies ignore is the medical model of patient needs assessment which operates on the assumption that all patients at each encounter get their needs assessed via a more practical but shortened version of the comprehensive approach of the traditional complete history and physical.

4. Recommendation III., Regarding Needs Based Concept, Page 20.

Rather than focus on developing a set of needs based standards, priority should be placed on developing a practical standardized review process for pharmacists to use for each patient encounter, i.e., a shortened practical version of Dr. Strand's process. Needs based standards for every patient may be impossible due to the constantly changing nature of individual patient needs and the variability among individual pharmacists in their ability to assess patient needs. This process would be directly comparable to the medical approach of patient needs assessment (see diagram below). One approach which uses a shortened practical pharmacy needs assessment process, similar to the medical model, has been developed by IHS as presented in Attachment B.

PATIENT NEEDS ASSESSMENT PROCESS



A practical shortened version of the comprehensive approach results in (1) successful needs assessment and intervention in the vast majority of patients, and (2) identification of those requiring comprehensive evaluation. Physicians do not perform a complete history and physical on every patient they encounter. They reserve that time for those who need it most.

B. Description of Clinical Pharmacy Services (Graphic Representation), Part I., "Findings," and Appendix IV.

The breakdown of clinical pharmacy services into four groups is generally correct. However, the assumption that within each component there is a continuum and the description, especially the graphic representations, of that supposed continuum is inaccurate and/or misleading.

1. Graph "Patient Counseling," Page 5. This graph creates confusion and inaccuracy rather than clarifying concepts because it attempts to illustrate a continuum that does not exist. Instead, it describes a combination of apples and oranges, including prospective drug utilization review (DUR), pharmacist management of chronic patients, and some patient consultation activities.

2. Appendix IV, "The Four Components of Clinical Pharmacy Care," Graph "Collection of Patient Information," Page IV-1.

While most of the important items are listed, they are grouped improperly by source rather than by patient need-based continuum that this report is trying to describe and propose. The reason for the pharmacist collecting a database is to determine what type and intensity of clinical pharmacy services the patient needs. The continuum should address which type of data are most important to determine patient needs. Where the pharmacist obtains the data, e.g., from a medical record, patient profile, physician interview, or patient interview, is a totally separate issue and is a function of the practice environment and the pharmacist's professional commitment to provide clinical services.

3. Page IV-3. Paragraph 1, "(2) Prospective Drug Utilization Review (DUR)"

The report does not clearly define the DUR. Based on what is included in the report, it appears to be too narrowly defined around ADRs and drug interactions. A more appropriate definition of DUR appears on page 1, paragraph 2, of the introduction, i.e., a review of the patient, drug, and disease databases to provide those functions listed in the second half of the paragraph. IHS utilizes the term *negative patient outcomes* to encompass those three functions. The focus of clinical pharmacy practice is this review process to determine the need for pharmacy intervention at each patient encounter. Attachment C presents the IHS standards of practice. Standard I of the IHS standards is a more comprehensive version of a prospective DUR process.

In prospective DUR processes the pharmacist compares therapy against the criteria such as those listed in the IHS standards. How much, how well, and whether the DUR is done at all is determined by:

- a. the extent of the database available to the pharmacist;
- b. the knowledge of the pharmacist in both drug and disease information;
- c. the ability of the pharmacist to collect and integrate drug, disease, and patient data to identify and solve drug related problems;
- d. the pharmacist's efficiency in performing item c, and once the pharmacist has optimal data, knowledge, integration skills, and efficiency (items a-d), then workload becomes a factor; and
- e. commitment for providing these services.

4. Graphs on Page 4 and Appendix IV-4 on Prospective DUR.

Once again as in the collection of patient information, no continuum exists and the continuum presented in both graphs consist more of how it is done rather than what needs to be done.

5. Patient Counseling, Pages IV-4 and IV-5.

Page IV-4, Paragraph 3. The first statement on patient counseling about pharmacists giving information is incorrect. The ultimate outcome of patient counseling is to verify the patient's understanding of how to appropriately take the medication prescribed. That requires the patients to understand: (1) why they are taking the medication, (2) how they are to take it, and (3) what to expect (i.e. expected outcomes, side effects and what to do in each situation).

Page IV-5, Paragraph 2. IHS's 30 years of experience in patient counseling confirms the efficacy of private face-to-face consultation as the preferred mode. In addition, research and experience have identified a potentially even more important factor in determining the efficacy of patient counseling. Learning has been shown to be increased when the person receiving the information becomes actively involved in the process. By the time patients reach the pharmacy they have already received some degree of education from the physician or other provider, previous experience, and/or personal research.

IHS utilizes all three of these principles in counseling patients (private face-to-face, active involvement of the patient, and utilization of prior knowledge). Using open ended questions, the pharmacist verifies that the patient understands critical information. If incomplete understanding is detected, the pharmacist merely fills in the gaps. The consultation concludes with the patient verbalizing or the patient demonstrating his/her understanding of key elements. This is a patient needs based approach to patient consultation. Attachment C presents a summary outlining the interactive, patient needs based approach to patient consultation taught to IHS pharmacists.

Page IV-5, Paragraph 4. Since the purpose of counseling is to improve compliance, i.e., "make the patient better," information regarding expected outcomes and unexpected effects are among the most critical elements that patients need to understand. Among the major causes for noncompliance are the patient's lack of understanding of:

- a. what the medication is supposed to do (desired effect);
- b. what to do if it does not happen; and

- c. what unexpected things might happen (adverse effects), and what to do if they occur.

6. Page IV-6, Paragraph 2, Follow Up Activities and Monitoring.

This paragraph discusses prospective DURs, or what the IHS calls pharmacist managed therapy (Standard 6, IHS Standards of Practice (see Attachment D), not patient consultation, and belongs under DUR or under pharmacist managed care. It describes the patient need assessment process that occurs when patients on chronic medications come in for refills. Therefore, the statement that they (the scientific information pharmacists) raise their counseling to a higher level should be eliminated.

7. Graph "Physician Consultation," Page IV-6.

A better term for this section would be Physician/Pharmacist Interaction/Communication. There are four basic reasons for pharmacist-physician communications:

- a. Physician telephones a prescription to the pharmacist.
- b. Physician collects or verifies portions of patient/disease State/drug database.
- c. During the needs based prospective DUR, the pharmacist detects a therapeutic problem with safety, patient effectiveness, appropriateness, or cost effectiveness of the prescribed therapy and calls to resolve it prior to dispensing.
- d. The physician calls to request advice or information about a drug, what drug to prescribe in a particular situation, etc. Only this case is a classical consultation in the physician to pharmacist tradition.

8. Graph "Physician Consultation," Page 5.

There is no continuum depicted in the graph. It consists of who does the calling, where they are located, etc., rather than a continuum of functions regarding sophistication of pharmacist-physician communication.

the vast majority of patient needs, identify those who need comprehensive time consuming services, maximize limited professional pharmacy resources, and achieve improved patient outcomes and cost savings

D. Other Comments

1. A national task group should be formed to develop a shortened practical version of Dr. Strand's process modeled after the medical approach that can be used at each encounter to determine the need for intensity of intervention.
2. The APhA/AACP involve other professional organizations and redo their standards of practice based on functional rather than task inventory.
3. Broaden the definition of prospective DUR to include all adverse outcomes.
4. Appendix II, page II-1, "Pharmacy Settings." It is unclear where managed care practice and mail service fall in the definition. Certain managed care settings resemble community pharmacies while others are more like institutions.
5. Also include mail service and managed care settings in Appendix II, "Pharmacy Settings."

OIG RESPONSE TO PHS' COMMENTS

We are grateful to PHS for its very thoughtful and constructive response to the draft report. The PHS' s concurrence with the recommendations directed to it represents a significant commitment to improving pharmaceutical care, particularly for patient populations that suffer most from drug-related illness.

We agree that the Indian Health Service provides an excellent practice model for pharmaceutical care. Our reason for not including it in our case studies was that IHS more closely resembles a managed care system rather than a more typical community setting as defined for purposes of our report. This is not to say, however, that the IHS model has not influenced the practice of high quality clinical care in community pharmacy settings. In the course of conducting our study, we interviewed a number of experts in the field who consistently referred to the IHS system as exemplary. Several of the most influential leaders in the field of pharmaceutical care trained with the IHS and have devoted much of their professional careers to transferring IHS standards to other practice settings. We acknowledge the IHS's reputation for innovation and excellence in clinical pharmacy care and regret that the scope of the study did not permit a more extensive examination of managed care and institutional settings.

Our responses to PHS's technical comments are as follows:

Standard setting and needs assessment process: We agree with PHS and have made revisions in our discussion of Recommendation III.

Description of components of clinical pharmacy: We appreciate the thorough critique PHS has provided. We have made a number of the suggested changes in both graphic presentations and text. We have not made all suggested changes for several reasons: First, the description of components as presented in the report is meant to describe the spectrum of services that currently exists, and not, as PHS suggests in its comments, what *should* exist in a needs-based system. Second, the four-component description is not meant to present the best or the only construct by which the functions of pharmaceutical care can be understood. Essentially, it reflects the way in which our case-study pharmacists and other experts described their work as well as the observations we made in those practice settings we visited. Consequently, it serves only as an analytical and descriptive tool in this report, rather than as a standard. Third, because the individual components of the clinical pharmacy as we described them in the report are dynamic and related to one another in complex ways, some individual functions do not fit neatly within a single component. For example, the PHS makes a good case for including what we have called "follow-up counseling" under the DRR component, rather than the Patient Counseling

component. We submit that because the tasks involved in “follow-up” counseling include data collection, DRR and patient counseling, there is not one fit for this particular function. Our decision to classify it as we have was driven by the fact that most of our case-study pharmacists perceive it as part of their counseling role.

Again, we thank PHS for its support and for its incisive comments, which we believe have improved the quality of the report.

Date

Gail R. Wilensky, Ph.D. *GW*

From

Administrator

Subject

OIG Draft Reports: "The Clinical Role of the Community Pharmacist," OAI-01-89-89160, and "The Clinical Role of the Community Pharmacist: Case Studies," OAI-01-89-89161

To

The Inspector General
Office of the Secretary

We have reviewed the subject reports. One of the reports addresses the barriers to the provision of clinical services to ambulatory patients in community pharmacy settings. The other report presents case studies of community pharmacists who have succeeded in providing a broad range of these clinical services.

The reports recommend that HCFA develop a strategy, individually and with the Public Health Service, to reduce barriers to providing clinical pharmacy services, particularly for ambulatory elderly patients. We do not concur with this recommendation. HCFA already has a strategy to improve clinical pharmacy services through its managed care initiative. Through the managed care initiative, many State Medicaid programs have or are testing drug utilization review systems and capitation programs that encourage the kind of coordinated care called for in the OIG report. Unfortunately, the report did not address these efforts by HCFA and the States.

Medicare coverage of drugs for outpatients is extremely limited in scope and, for the most part, does not pay for drugs that ambulatory beneficiaries could obtain from community pharmacies. Thus, the recommendations cannot apply to the non-Medicaid population of Medicare beneficiaries.

Moreover, because of the limited scope of the Medicare outpatient drug benefit, we do not have sufficient data files to establish the comprehensive drug utilization review program that would be needed to monitor the effectiveness of clinical pharmacy services.

For Medicaid, however, coverage of prescription drugs is optional for the States. The level of outpatient drug coverage varies significantly across the States. Although States must meet certain broad Federal requirements, they are responsible for administering their own Medicaid programs. Thus, while no single strategy developed by HCFA to reduce barriers to clinical pharmacy services would be applicable to all States, several States (e.g., California and Kentucky) are leaders in providing clinical pharmacy services to the elderly in community pharmacy settings. It is unfortunate that the OIG report does not recognize these important efforts in this area.

HCFA is also engaged in research and demonstration projects studying methods to reduce the inappropriate use of drugs by the elderly. The University of Wisconsin has developed a set of quality care indicators that use Medicaid drug and hospital claims to monitor quality of care in Medicaid nursing homes. The University of Minnesota is studying the use of psychotropic drugs among nursing home residents. To the extent nursing homes are served by community pharmacies for their patients' drug needs, these studies will help to develop HCFA's strategy. The role of the community pharmacy in the care of nursing home patients is another area not well covered in the OIG report.

With the recent repeal of the Medicare Catastrophic Coverage Act drug benefit, we are reassessing our research and demonstration priorities in the drug area. As we develop our strategy, we will consider OIG's suggestion that we include research, demonstration and education efforts to reduce barriers to clinical pharmacy care.

Thank you for the opportunity to review and comment on these draft reports.

OIG RESPONSE TO HCFA's COMMENTS

We thank HCFA for reviewing the report and regret its nonconcurrence. We are pleased to note that HCFA already conducts several activities that partially address the spirit of our recommendations. Nevertheless, we believe that the problem of drug-related illness is sufficiently critical to warrant a more structured and comprehensive departmental response that combines the best efforts of HCFA and PHS.



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The National Professional
Society of Pharmacists

APhA

March 6, 1990

Richard P. Kusserow
Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Mr. Kusserow:

The American Pharmaceutical Association is pleased to respond to the draft report of the Office of the Inspector General entitled "The Clinical Role of the Community Pharmacist". As the national professional society of pharmacists, we are gratified by the substantial analysis that our profession has received in recent reports from your office. More importantly, we are pleased that the critical role that pharmacists play in providing quality health services to patients is finally becoming better understood at the federal level. We appreciate the department's recognition of APhA's leadership role for the profession on these issues.

Our comments include both general reflection on the report, its findings and recommendations, as well as specific responses to the recommendations addressed directly to APhA. We ask that they be carefully considered in the preparation of the final report on this subject.

We are extremely enthusiastic about both the substance and tone of this draft report. Your office, through a thoughtful process of information collection, site visits and staff analysis has developed a report which articulates many of the critical elements of progressive pharmacy practice that APhA has espoused for many years. To that end, our comments, and criticisms, are offered in the spirit of a shared mutual interest in advancing the profession of pharmacy and the services it offers to patients.

The draft report states that its focus is on the services available to elderly ambulatory patients in the community pharmacy setting. However, the concepts, principles and practices outlined in the report apply universally to all patients that pharmacists serve. In our previous comments to you on the OIG report on "Medicare Drug Utilization Review" in March of last year, we did note the particular need that elderly patients have for effective review and management of their medication regimens. The drug therapy of elderly patients is often complex as a result of multiple diseases, multiple prescribers and physiological and other changes in medication response as a result of the aging process. But complex regimens and informational needs are certainly not exclusive to the elderly.

In that same letter, we drew some distinctions, both operational and semantic, between the OIG terminology of "prospective DUR" and the profession's concepts of "drug usage evaluation" or DUE. We would

reiterate that the assessment of a patient's current drug therapy prior to the initiation of a change (new medication added, medication deleted, dosage change, etc.) is more appropriately referred to as drug regimen review (DRR). This key feature of professional practice is the sole province of pharmacists, and is the pivotal point at which the unique knowledge, skills and competence of the pharmacist can be brought to bear to improve the quality of patients' drug therapy. It is far more than "problem identification and resolution" or "risk management" as described in the draft report. Rather, it is the opportunity for pharmacists, working with patient and prescribers, to better assure high quality therapeutic outcomes.

We also suggested in that letter that because the term DUR is often associated purely with quantitative assessments of drug use, the term drug usage evaluation (DUE) better describes the type of structured quality assurance process that assures safe, effective and economical medication use. The March 1989 OIG report on this subject very effectively noted that quality of care issues are a principal reason for such programs.

RESPONSE TO FINDINGS AND THE OVERALL REPORT

As mentioned previously, APhA believes that the draft report was developed in a sound and balanced manner, and offers substantial information and insight. The observation by OIG staff of community practices around the United States where clinical services are currently being provided was a critical element of the report, and APhA applauds OIG for that effort.

APhA is in general agreement with the five findings outlined in the body of the report:

Finding I

- o There are four components of clinical pharmacy practice: collection of patient information, prospective DUR, patient counseling and physician consultation. Each of these components encompasses a continuum of possible services.

We have previously stated our concerns about the term "prospective DUR" and will not reiterate that here. We would submit that certain screening activities and physical assessment functions, e.g. blood pressure monitoring, should logically be included in the diagram depicting collection of patient information. Further, we suggest the addition of such activities as drug-food interaction screening, evaluation of laboratory data and assessment of patient compliance as part of the drug regimen review process diagram. The process begun in the patient information collection phase is dynamic, rather than static, and is integral to the effective drug regimen review function of the pharmacist. It is also critical to note that the pharmacist is not simply a screener of information but analyzes, interprets and acts upon the data presented. This should be reflected in the diagram as well.

The diagram describing patient counseling activities includes both information exchange and monitoring functions, each having a necessary feedback loop and interaction with the patient. Similar information sharing and exchange functions are depicted in the physician consultation diagram. As the continuum of these functions proceeds it becomes clear that direct, face-to-face contact between pharmacist and patient and a close, collegial relationship with the physician (or other prescriber) are essential to maximize the quality of the pharmacy services provided. Thus we would suggest that the report's statement in another section that "...differences in clinical services provided by [mail order pharmacies] versus other [community] settings may be more theoretical than actual" is not supported either by the model presented in the report, or by the experiences of the OIG staff in their site visits to the pharmacists described in the report's case studies.

Finding II

- o There are no clear standards that define the optimum mix of clinical pharmacy services in the context of individual patient need.

APhA agrees that pharmacy is still maturing as a clinical profession, and that much additional work remains to be done in identifying standards of clinically-oriented pharmacy care. We are currently working with the American Association of Colleges of Pharmacy (AACCP) in a process of examination and revalidation of the Standards of Practice for the Profession of Pharmacy that were jointly developed by the two organizations in the 1970's. That process may reveal opportunities to incorporate additional standards to address this issue.

Finding III

- o There is strong evidence that clinical pharmacy services add value to patient care and reduce health care utilization costs.

Needless to say, we are extremely gratified to have OIG reach a conclusion that the profession has been sharing with others in the health care and regulatory communities for several years. This acknowledgment should finally help set the stage for fundamental change in analyzing the costs and benefits of pharmaceutical care, and for the development of progressive payment methodologies for pharmacists' clinical and cognitive services.

Finding IV

- o Clinical services are not widely provided in community pharmacy settings.

The case studies present a very exciting and encouraging picture of several current practices and the potential for clinical practice in the community pharmacy. However, the draft report accurately notes that these services are unevenly provided in the community pharmacy setting.

While this is regrettable, the barriers to the provision of these services, outlined in Finding V, are a critical contributor to this problem. We believe that it will be necessary for the profession, government, other providers, patients and purchasers of care to work cooperatively if these barriers are to be overcome.

Finding V

- o A. Barriers that impede provision of clinical pharmacy services include the economic structure of the retail pharmacy industry, interprofessional conflicts, limitations on information available to pharmacists, gaps in pharmacy training and uneven patient demand.
- o B. There are some community pharmacists who provide a broad range of clinical services to their patients. Nevertheless, the methods they use to overcome barriers do not suggest simple or immediate solutions.

The barriers identified in Finding V-A are substantial. APhA believes that the discussion of them found in the draft report presents an excellent and accurate summary. We take particular note of two items within the economic area, primarily because of their relationship to recommendations made to APhA in the report.

We strongly concur that the focus on product-based reimbursement for pharmacy services, while excluding compensation for cognitive services, is a critical negative incentive for the development of these services. APhA's Cognitive Services Working Group, established in 1987, has focused substantial effort on identifying and promoting the value of compensation for pharmacists' cognitive services. We have appended to this letter for your review a bibliography developed by the Working Group on this subject. APhA is sincerely interested in working with government and other health policy groups to address this fundamental barrier.

APhA also supports the effective and appropriate use of pharmacy technicians in various types of pharmacy practice. The draft report is accurate in stating that the issue remains one of controversy within the profession. However, APhA believes that the training and use of qualified pharmacy technical personnel under the supervision of pharmacists will enhance pharmacists' abilities to render the professional and clinical services that pharmacists, uniquely, are able to provide.

APhA believes that these findings, along with our comments about them, can contribute substantially to a better understanding by policy makers of the potential for enhanced clinical pharmacy practice in the community setting.

RESPONSE TO RECOMMENDATIONS

The draft report's recommendations are made to the U.S. Public Health Service (USPHS), the Health Care Financing Administration (HCFA), the National Institute on Aging (NIA), APhA, AACP, state governments and state pharmacy associations. Consistent with our comments above, APhA supports:

- o the recommendation that the USPHS and HCFA, individually and collaboratively.....develop a strategy to reduce the barriers to clinical pharmacy services, particularly for ambulatory elderly patients.

The types of demonstration projects and research grants outlined in this recommendation appear to offer real opportunities to measure the effects of clinical pharmacy on patient outcomes and health care costs. APhA would encourage USPHS and HCFA to consider these recommendations to them, and would be very willing to work cooperatively with these organizations in appropriate ways to assist in the process.

- o the recommendation that the NIA ...take a leadership role in developing risk indicators and treatment priorities for elderly, ambulatory patients.

APhA generally supports this recommendation, with the understanding mentioned above that all patient categories ultimately deserve an appropriate level of clinical pharmacy services at the community level. The elderly, however, are certainly deserving of focused initial efforts in this area. APhA would strongly encourage NIA, should it accept this recommendation, to actively involve the pharmacy and medical professions in any work it undertakes in this area.

- o the recommendation that APhA and AACP ...develop standards of practice that address all components of clinical pharmacy care on the basis of patient need.

This recommendation, made directly to us, is both encouraging and daunting. APhA is currently engaged in a project with AACP to revalidate and, as appropriate, further evolve the profession's Standards of Practice. When originally conducted in 1978, this project was envisioned as the first step in a multi-step process to determine practice standards, define the necessary competencies to practice at the level of the standards, and develop programs to assure pharmacists obtained and maintained those competencies. APhA remains committed to this activity, subject of course to staff and budgetary resources. We would certainly welcome the opportunity to compete for federal grants or other resources to support this activity if they were to be made available.

We recognize the need for evolving standards to encompass the activities and services of contemporary clinical practice. Nevertheless, much work must be done to address the barriers identified in this report before a truly national standard of clinical pharmacy care can be developed. We are pleased to take the recommendation under advisement and will make every effort to keep the department informed of progress in this area.

Richard P. Kusserow

March 8, 1988

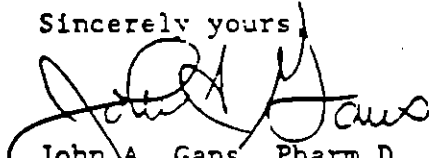
Page -6-

- o the recommendation that state governments ...revise pharmacy practice acts to allow maximum use of technicians in community settings... [and that] APhA and the state pharmacy associations ...take a leadership role in encouraging more extensive and effective use of technicians in community pharmacies.

Following the adoption of current policies on pharmacy technicians by the APhA House of Delegates in 1988, APhA has been exploring the development of new materials to assist pharmacists in the training and effective utilization of pharmacy technicians. These materials, once developed, would be made available to state associations to use as appropriate in their activities in this area. Several states have evolved rather sophisticated programs for pharmacy technician training and certification and are willing to share information and experience with other state colleagues who are interested. APhA agrees that a more thorough examination of the effective use of technicians in community pharmacy practice is warranted, and will seek opportunities to work with other national associations and state pharmacy associations on this issue.

In closing, we once again commend the OIG for its comprehensive and important draft report on the clinical role of the community pharmacist. APhA eagerly seeks the opportunity to work with you whenever possible and appropriate to advance patient-oriented pharmacy practice in all settings.

Sincerely yours,



John A. Gans, Pharm.D.
Executive Vice President

JAG:CEW/mmg

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OIG RESPONSE TO APhA's COMMENTS

We thank APhA for its careful consideration of the report and applaud the association's willingness to implement our recommendations on standard setting and expanding the use of pharmacy technicians. We acknowledge that these complex issues will require thoughtful and creative solutions and we believe that with APhA's leadership, clinical pharmacy services can be expanded to improve patient care significantly.

On a more technical note, we have made changes in terminology suggested by APhA and have added language to emphasize the pharmacist's role in analyzing and evaluating patient data.



AMERICAN SOCIETY OF HOSPITAL PHARMACISTS
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April 11, 1990

Richard P. Kusserow
Inspector General
Department of Health and Human Services
Room 5250
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: Draft OIG Report: The Clinical Role of the Community Pharmacist

Dear Mr. Kusserow:

The American Society of Hospital Pharmacists (ASHP) is the national professional organization which represents over 24,000 pharmacists who practice in organized health-care settings such as hospitals, home-care agencies, health maintenance organizations, outpatient clinics, and skilled nursing facilities. ASHP is pleased to provide comments on the draft OIG report entitled, The Clinical Role of the Community Pharmacist.

ASHP is encouraged by the Office of the Inspector General's increasing recognition of the importance of the pharmacist's role by its study and analysis of clinical services and by OIG's increased willingness to work with organizations representing the pharmacy profession. We also appreciate the willingness of the OIG's staff to study and understand issues of importance to the profession. The OIG staff has captured much of the essence of the dilemma facing the community pharmacy regarding the implementation of progressive, patient-oriented pharmacy services.

The fundamental purpose of the profession of pharmacy is to serve as a force in society for ensuring safe and appropriate use of drugs. Pharmacists should pursue this goal by promoting optimal use of drugs, including the prevention of improper or uncontrolled use of drugs, and by providing authoritative drug information to other health-care professionals, patients; and the public.

Institutional pharmacists have been engaged in the review and assessment of the drug therapy of individual patients for many years. Our members, and the profession as a whole, have the education, technical expertise, and professional responsibility and mission to perform those activities that come under the rubric of clinical pharmacy services.

The profession of pharmacy involves a good deal more than just dispensing medications. Pharmacy is a knowledge-based system, which renders a health service by concerning itself with understanding drugs and their effects upon people. ASHP believes that pharmacists should develop and provide clinical pharmacy services commensurate with the needs of each organized health-care setting and individual patients in that setting. ASHP's philosophy on the pharmacist's clinical role is stated in the "ASHP Statement on the Pharmacist's Clinical Pole in Organized Health-Care Settings", which is included in the appendix.

Pharmacists in organized health settings have provided progressive, clinical services for over a decade. The success of clinical services is based on (1) preparation and use of complete and centralized medication information for all patients; (2) prospective or concurrent routine monitoring of the drug therapy of patients; and (3) ongoing communication and education between physicians, pharmacists, and other health-care professionals.

The comments that are contained in this letter are a compilation of observations from ASHP members with expertise in providing clinical pharmaceutical services in ambulatory settings. Additionally, ASHP's comments on the draft OIG report are based on the tenets stated in the previous paragraphs and on a knowledge base of clinical services developed through years of experience in the institutional setting.

GENERAL COMMENTS

- I. It is our understanding that the original report on clinical services was requested as a study of the feasibility of these services with regard to drug use in the elderly because coverage for outpatient drugs was to expand with the passage of the Medicare Catastrophic Coverage Act. It is also our understanding that since the repeal of the Act that clinical pharmaceutical services are being studied for use with state Medicaid programs.

Although the elderly clearly represent a large, vulnerable high-risk group, we believe that the focus of the OIG report was unnecessarily narrow. Given the expanded use of the recommendations from the report, it would seem advisable to include other patient populations at high risk in the case studies and recommendations from the report. Examples of other patient populations include pediatric patients, patients with chronic renal failure, cirrhotic patients with ascites, immunosuppressed patients, patients who are on multiple medications, and patients with poorly controlled diseases like refractory seizure disorders.

- II. The draft report states that it discusses all possible pharmacy practices. The ASHP reviewers did not agree; it did not appear that the case study methodology permitted the identification of ALL types of ambulatory, community-based practices. Analyses of the following major

types of pharmacy practices were not included in the report; their inclusion would appear to strengthen the recommendations made by the report and would provide a better rounded view of the practice environment:

- * Health maintenance organizations
- * Ambulatory services offered through the Veteran's Administration
- * Primary and ambulatory care offered through the Indian Health Service

In each of these practice areas, there are outstanding examples of clinical services that are being offered to ambulatory patients. ASHP would be happy to provide you with the names of practitioners in each of these settings who could provide your office with important feedback.

- III. The interchangeable use of the terms and concepts of drug utilization review (DUR) and prospective monitoring throughout the report creates confusion. As the definition on page 1 states: "DUR is a formal program that uses comparison with explicit standards or criteria with a planned follow-up to improve care and Practice." In the community setting, the clinical pharmacist usually perform DUR, as described. The preferred term for use in the OIG report is "prospective assessment and monitoring, or "drug regimen review and monitoring" (DRRM). These terms involve clinical assessment of the patient by following a clinically appropriate intervention (changing therapy or monitoring carefully for efficacy and toxicity) in light of the risk-benefit ratio for the individual patient. In this case, the professional's judgement is based upon general knowledge (of drugs, diseases, patient behavior, ethics, and economics) and professional experience, not on explicit criteria.

SPECIFIC COMMENTS AND RECOMMENDATIONS FOR CHANGES

There are two major structural areas within the document that need to be reviewed and revised. They include the concept of a needs-based system and the description of clinical services.

I. The Needs-Based Concept

- A. Page 6, paragraph 2: The question raised in this paragraph is the key issue in the report and can best be summarized as: How can the community pharmacist determine what services are needed at each patient encounter and provide them in a practical and timely manner?
- B. Page 6, paragraph 3: This paragraph includes the statement that there is little consensus regarding standards of practice for clinical pharmacy care as it applies to patient need. There are good

reasons for this, and those reasons may negate the practicality of implementing Recommendations II and III from the report.

First, individual patient needs are highly variable. Initial encounters with patients who are on multiple drug regimens and those whose diseases are not adequately controlled, will require more comprehensive clinical services. Once the patient is stabilized, the need for intensive monitoring will decrease markedly.

Second, the ability to determine patient needs and the extent to which these clinical services are provided depends on the following factors:

1. The availability of the patient's medical and medication information to the pharmacist.
2. The extent of the pharmacist's education and training.
3. The pharmacist's ability to collect and integrate drug, disease and patient data to identify and solve drug-related problems.

Additional barriers to implementing clinical pharmacy services are outlined in the enclosed report entitled, Directions for clinical practice in pharmacy. Although this proceedings document is five years old, it still contains much germane information on the implementation of clinical services.

C. Recommendation: Needs-Based Concept

Rather than focus on developing a set of needs-based standards, priority should be given placed on developing a practical standardized review process for pharmacists to use for each patient encounter. This process would be directly comparable to the medical approach of patient needs assessment. In the medical approach, a limited history and physical is completed based on the chief complaint and problem. With this method, only a small percentage of the patients require a more comprehensive needs assessment. One approach which uses a shortened practical pharmacy needs assessment process, similar to the medical model, has been developed by the Indian Health Service and is attached as an appendix.

II. Description of Clinical Services

These comments are directed toward Appendix IV. The breakdown of clinical services into four general components is generally correct. However, the assumption that within each component there is a continuum and the description of that assumed continuum--especially the graphic representations--are inaccurate and/or misleading.

A. Collection of Patient Information

While most of the important components of the collection of patient information are included in the diagram and narrative, they are grouped improperly by the source of the information. The source from which the pharmacist obtains the data (e.g. a medical record, patient profile, physician interview, or patient interview) is a function of the practice environment. They are also affected by the pharmacist's professional commitment to provide clinical services. These components should be listed by the patient need-based continuum which is being proposed in the report. The graphic continuum should also address which type of data is most important to determine the patient's needs.

B. Prospective Drug Utilization Review

The report does not clearly define drug utilization review (DUR). Based on the information included in the report, it appears to be too narrowly focused on adverse drug reactions and drug interactions. The more appropriate definition of DUR appears in paragraph four of the introduction; this definition would be stated as follows:

DRUG UTILIZATION REVIEW is a review of the patient, drug, and disease databases to provide the following outcomes for the patient: (1) Identifying potential and actual drug related problems; (2) Resolving actual drug-related problems; and (3) Preventing potential drug-related problems.

In prospective DUR processes, the pharmacist compares the therapy against the criteria such as those included in the enclosed ASHP publication entitled, Criteria for Drug Use Evaluation. How much, how well, and whether DUR is done at all is determined by:

1. The availability of a comprehensive patient database including medical, medication, and patient data.
2. The capability of the pharmacist to collect and integrate drug, disease, and patient data to identify and solve drug-related problems.
3. The pharmacist's commitment to providing clinical services.

In the description of this component on page IV-3, the graphic does not depict a continuum. And, the information provided in both the graphic and the narrative consist more of how prospective DUR is done, rather than what needs to be done.

C. Patient Counseling

Figure 3 on page IV-4 has the same problems that have been outlined for the other graphics in the report. It creates confusion and presents inaccuracies rather than clarifying concepts because it attempts to illustrate a continuum that does not exist. It describes a combination of other clinical components including prospective DUR, pharmacist's management of chronic patients, and patient counseling activities.

The last paragraph on page IV-4 contains some incorrect information; The first sentence about pharmacists giving information back to the patient is incorrect. The ultimate outcome of patient counseling is to verify the patient's understanding of how to appropriately take the medication prescribed. This outcome requires that the patient understand: (1) why they are taking the medication; (2) how they are to take it; and (3) what to expect from the medication (i.e. expected outcomes, side effects, and what to do in all situations). Additional information on patient counseling is included in the "ASHP statement on the pharmacist's role in institutional patient education programs" and "ASHP guidelines on pharmacist-conducted patient counseling", which are attached in the appendix.

In paragraph 2 on page IV-5, pharmacists' experience confirms that the most effective mode for effective patient counseling is face-to-face counseling. Additionally, the learning curve has been shown to increase when the person receiving the information becomes actively involved in the process. A successful counseling program should use three principles in working with patients: private, face-to-face interaction; patient's active involvement in the process; and use of the patient's existing knowledge. Using open-ended questions, the pharmacist verifies that the patient understands critical information. If errors in understanding are detected in this process, then the pharmacist fills in the gaps. The consultation concludes with the patient verbalizing or demonstrating their understanding of key elements.

In paragraph 4 on page IV-5, the pharmacist should also convey additional information. Since the purpose of counseling is to improve compliance and make the patient better, information regarding the expected outcomes and unexpected effects is among the critical elements that the patient needs to understand. The major causes for noncompliance are patient lack of understanding of: what the medication is suppose to do (desired effect); what to do if it does not happen; what unexpected things might happen (adverse effects; and what to do if they occur.

The section on follow-up activities and monitoring actually discusses prospective DUR; it belongs in the section on prospective DUR because it describes the patient-need assessment process that occurs when

patients on chronic medications come in for refills. Therefore, the statement that this type of follow-up requires unusually intense patient counseling should be deleted. An additional concept which might be considered for inclusion in this section involves the pharmacist evaluating requests for refills; this involves integrated activities of monitoring, counseling, and prescribing under delegated physician authority.

D. Physician Consultation

The following term should be used to re-title and for reference in this section: "Physician-Pharmacist Interaction"; communication is also a major component in this interaction. There are four basic reasons for physician-pharmacist communications:

1. Physician calls in prescription to pharmacist.
2. Pharmacist collects or verifies portions of patient/disease-state/drug database.
3. Pharmacist detects a therapeutic problem with safety; patient effectiveness, appropriateness, or cost-effectiveness of the prescribed therapy (during needs-based prospective DUR) and calls physician to resolve issue prior to dispensing.
4. Physician calls to request advice or information about a drug or what drug to prescribe given a specific set of circumstances. This is the only one of the four reasons that is a classic consultation between physician and pharmacist.

Additionally, in this section, in Figure 4, entitled "Physician Consultation" on page IV-6, there is no continuum depicted in the graphic. It consists of who does the calling, where they are located, etc. rather than a continuum of functions addressing the sophisticated physician/pharmacist interaction.

COMMENTS ON RECOMMENDATIONS

- I. Recommendation II, page 20: Developing risk indicators and treatment priorities may be an unwise use of resources given the frequent changes in the nature of each patient's needs. Indicators could be developed, but they will only identify the patients who MAY be at high risk (not those who are at high risk). What is actually needed is a short, practical needs assessment process that can be used at each-patient encounter to determine their particular need at that time for clinical pharmacy intervention.

Additionally, in this section, the term ADR is too limiting. The term, "negative or adverse outcome" should be substituted because it includes such important items as treatment failures due to inappropriate drug use.

- II. Recommendation III, page 20: The statement that the APhA/AACP prescribe a maximal level of service in all aspects of clinical care is inaccurate. This assumption and the graphic depictions in figures 1-4 indicate a misunderstanding of the method used by national standard-setting organizations to develop professional standards of practice in general.

Generally, the standard-setting process involves establishing the range of services/activities for each function on a continuum from none to optimal. Once the range is established, the standard is selected somewhere between none and optimal, and this is defined as a minimal standard. APhA/AACP standards, which are operational standards, are minimal. Given its age, the document can be revised to a relatively small degree and still represent appropriate minimal standards for clinical pharmacy in community settings in the 1990's. Primarily, what needs to be done with these standards is to revise them so that they are functionally-based instead of task-inventory based.

ASHP has also developed numerous standards and guidelines on clinical practice for its members. The pertinent standards have been enclosed in the appendix to this letter.

III. Summary of Recommended Revisions

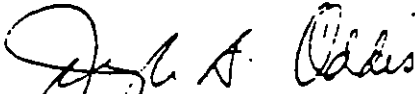
- A. Eliminate Recommendations II and III and substitute a variation of comments B and C below.
- B. Recommend that APhA/AACP revise their minimal standards of practice based on current practice and functional, rather than task-inventory, components.
- C. Recommend that a joint, national task force be formed to develop a shortened, practical process modeled after the medical approach; this process can be used at each patient encounter to measure the need for the intensity of each clinical intervention.
- D. Broaden the definition of prospective drug utilization review to include all adverse outcomes.
- E. Recommendations for Appendices III and IV
 1. Include other ambulatory settings, such as the Indian Health Service, Veterans Administration, and health maintenance organizations in the case studies.

2. Revise Appendix IV to clarify the functions under each component and eliminate or revise the graphic representations.

CONCLUSION

ASHP appreciates the opportunity to review the OIG draft report entitled, The Clinical Role of the Community Pharmacist. The growth of patient-oriented, clinical pharmacy services is crucial to the efficient, safe, cost-effective care of the drug therapy of all patients. If you have any questions about these comments or if ASHP can provide additional information on pertinent topics, please feel free to contact my office.

Sincerely,



Joseph A. Oddis, Sc.D.
Executive Vice President

lag040920w

cc: Mary Ann Chaffee; DHHS/OIG/OEI

Attachments

OIG RESPONSE TO ASHP's COMMENTS

We thank ASHP for its thoughtful comments. We note that ASHP and PHS are of one mind on a number of the issues raised. For that reason, most of responses to ASHP's comments are contained in our response to PHS. Again, we note that the scope of our study did not allow us to include managed care and institutional settings in our case studies even though there are excellent practice models to be found in those settings. Similarly, we recognize the limitations of our focus on elderly patients, but we believe that eliminating barriers to clinical pharmacy will improve patient care for all patient populations, particularly those at risk of drug-related illness.



American Society of Consultant Pharmacists

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March 28, 1990

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Dear Mr. Kusserow:

We are writing to comment on the two draft reports, "The Clinical Role of the Community Pharmacist," and "The Clinical Role of the Community Pharmacist: Case Studies." We apologize for the delay in responding to your request for comments. However, we took the time to send copies of these reports to our leadership so that we could incorporate the views of practicing consultant pharmacists into our comments.

The consistent view of those who reviewed these reports is that these are extremely well done in terms of understanding the subject and accurately assessing both the positive and negative aspects of providing clinical pharmacy services in the community setting. We are particularly pleased to see that your case studies included consultant pharmacists who provide services to long term care residents. There is no question that, with the "graying of America," this important area of pharmacy practice will become even more recognized for the valuable and necessary services that are provided to elderly residents in various home environments.

We are also pleased that your report cited consultant services provided to nursing home facilities as an example of a successful non-product related reimbursement incentive system for clinical pharmacy services. We must point out, however, that such reimbursement arrangements are made privately between long term care facility administrators and consultant pharmacists in cases where the administrator recognizes the positive impact on patient care that consultant pharmacists can make. However, that payment to consultant pharmacists is not recognized by government third party payors, specifically Medicaid and Medicare, where the only payment incentive remains product related. Your report identifies the problems inherent in a system where the payment incentive is product-based.

Mr. Richard P. Kusserow
March 26, 1990
Page Two

Your draft reports also make good initial steps toward identifying the long term health care savings that can accrue to the overall health care system when drug therapy is properly managed. We fully concur with that assessment. To further confirm that conclusion, we have enclosed a reprint of an article by Dr. Sam Kidder of HCFA that reviews several published reports indicating that clinical pharmacy services in the nursing home environment can produce significant savings to the overall health care costs of elderly Americans.

We believe that your office has made a good start toward working on these issues of great importance to pharmacy and the public we serve. To further this work, we invite your office to meet with us to discuss what we believe is the major barrier to clinical pharmacy services identified in your reports, namely the product-based reimbursement incentive system. We stand ready to work with your office to identify sites where a pilot study could be initiated and managed. We believe that such a study could produce conclusive evidence that the reimbursement incentives for clinical pharmacy must be changed to a service provided, outcome oriented system and that in doing so, patient care would improve and the overall costs to the federally reimbursed health care system would decrease.

We look forward to meeting with your staff in the near future.

Sincerely,



R. Tim Webster
Executive Director

RTW/hal

Enclosure

cc: Assistant Inspector General Michael Mangano ✓
Regional Inspector General Mark R. Yessian, PhD ✓

OIG RESPONSE TO ASCP's COMMENTS

We thank ASCP for its support of our recommendations and commend the organization for its willingness to participate in pilot projects to reduce barriers to clinical pharmacy practice.



AMERICAN ASSOCIATION
OF COLLEGES OF PHARMACY

March 8, 1990

Mr. Richard P. Kusserow
Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Mr. Kusserow:

Thank you for the opportunity to review the two draft reports, *The Clinical Role of the Community Pharmacist*, and *The Clinical Role of the Community Pharmacist: Case Studies*. Overall, the reports are very well written, comprehensive and accurately reflect the opportunities and barriers confronting pharmacists in their ability to enhance the public health in the community setting.

I am pleased to offer these comments, directed specifically at *The Clinical Role of the Community Pharmacist* with the hope that these remarks will assist you and your colleagues as you prepare the final report. My comments are directed at three areas:

- Issues related to Drug Utilization Review (DUR);
- Functions performed by community pharmacists in providing clinical services in ambulatory care settings; and
- Cost effectiveness of ambulatory clinical pharmaceutical services.

Drug Utilization Review

Page one offers a definition of DUR attributed to Rucker. AACCP prefers the definition of DUR which has been adopted by the American Society of Hospital Pharmacists:

A drug use evaluation program is a structured, ongoing, organizationally authorized, quality-assurance process designed to ensure that drugs are used appropriately, safely and efficiently.

A copy of the ASHP Guidelines on the pharmacist's role in drug use evaluation is enclosed for your information. This definition, and these principles, are applicable to the ambulatory care setting with slight modification in language only.

Functions Performed by Pharmacists

The Findings section of the Report and its Appendix contain descriptions of the activities performed by pharmacists in ambulatory settings. They are presented in a spectrum of schematic diagrams to illustrate minimum and maximum degree of clinical services. Recent events in the profession have shed considerable light on the clinical role of pharmacists practicing in all environments of care, especially the community pharmacy environment. The profession sponsored the second Pharmacy in the 21st Century Conference in October, 1989. The keynote paper presented at the Conference (Hepler and Strand) is enclosed for your information. It elaborates on the theme of *pharmaceutical care* as the philosophy of pharmacy practice, and describes functions performed by pharmacists in rendering pharmaceutical care.

Please note specifically pages 10 and 11 which offer a detailed analysis of drug-related illness. It is clear that drug-drug, drug-disease and drug-allergy interactions, as listed in the Report, comprise a relatively small portion of what may go wrong with pharmacotherapy in patients. Computer screens will not routinely and efficiently detect many of the problems listed by Hepler and Strand. The only feasible method to lower the incidence of drug-related illness is to increase the access of patients to pharmaceutical care.

Also enclosed is a Background Paper from the AACP Commission to Implement Change in Pharmaceutical Education. It describes the mission for pharmacy practice and the functions pharmacists perform in rendering pharmaceutical care.


These two documents offer new insights into the responsibilities of pharmacists in all areas of care. As your report points out, there are numerous barriers which prevent the wide availability of pharmaceutical care to ambulatory patients. None of these barriers is absolute. Our challenge is to identify and implement methods to provide incentives to pharmacists for providing pharmaceutical care.

Cost Effectiveness of Community Pharmaceutical Services

The Report concludes that there is strong evidence which supports the thesis that clinical pharmacy services add value to patient care. Three national organizations, the American Association of Colleges of Pharmacy, the American Pharmaceutical Association and the Pharmaceutical Manufacturers Association, sponsored a Task Force examining the cost effectiveness of pharmaceutical products and pharmacy services. The Report, currently undergoing final review, will be sent to you when available. One chapter in the Report discusses the cost effectiveness of pharmacy services documenting the voluminous literature verifying the observation that pharmacy services add significant value to total patient care services.

In conclusion, the Inspector General's Report outlines in succinct detail the need for clinical pharmaceutical services in the community environment and the barriers to their full implementation. AACP will consider carefully those recommendations addressed to it and will join with other organizations in pharmacy to ensure that the benefits of ambulatory clinical pharmacy are made available to as broad a population of patients as possible.

Sincerely,



Carl E. Trinca, Ph.D.
Executive Director

CET:jnc

enclosures

A drug use evaluation program is a structured, ongoing, organizationally authorized, quality-assurance process designed to ensure that drugs are used appropriately, safely, and effectively. In organized health-care settings, the pharmacist should exert leadership and work with the medical and nursing staff, administration, and others as appropriate in the design and conduct of drug use evaluations.¹⁻⁴ The basic elements of drug use evaluation are as follows:²⁻⁴

1. The use of objective, measurable criteria (standards) that describe the appropriate use of a drug.
2. The ongoing, planned, and systematic monitoring and analysis of the drug's actual use to identify problems or potential problems. Ideally, this activity should occur prospectively (planned and executed before the initiation of therapy), but it can also be conducted concurrently (with respect to treatments as they occur) or retrospectively (with respect to treatments already completed).^{1,2} As evidence of problems is revealed, the frequency of monitoring should be accelerated until (through appropriate actions) the problem is resolved. Prospective and concurrent drug use evaluation may reveal the need for immediate, patient-specific clinical interventions by the pharmacist to ensure optimal drug therapy.
3. The resolution of problems.
4. The scheduled documentation and reporting of findings, recommendations, actions taken, and results. Actions taken may be regulatory or educational as befit the circumstance and organizational policy.

Drugs whose use should be evaluated should be selected for one or more of the following reasons:^{2,4,5}

1. The drug is known or suspected to cause adverse reactions or interacts with another drug, food, or diagnostic procedure in a manner that presents a significant health risk.
2. The drug is used in the treatment of patients who may be at high risk for adverse drug reactions.
3. The drug is one of the most frequently prescribed drugs or is expensive.
4. The drug is potentially toxic or causes discomfort at normal therapeutic dosages.
5. The drug is most effective when used in a specific manner.
6. The drug is undergoing formulary evaluation for addition, deletion, or retention.
7. The drug has been selected, through organizational policy, for evaluation.

Responsibilities of the pharmacist in a drug use evaluation program include the following:

1. Providing, in cooperation with the medical staff and others, day-to-day coordination of the drug use

- evaluation program.
2. Preparing, in cooperation with the medical staff and others, drug use criteria (standards).
3. Reviewing medication orders against drug use criteria (standards) and consulting with prescribers as needed.
4. Obtaining quantitative data on drug use (e.g., the amounts and costs of specific drugs used and prescribing patterns by medical service and type of patients).
5. Interpreting and reporting evaluation findings to the pharmacy and therapeutics committee, quality-assurance staff, organization administration, and others to recommend changes in drug use control policies and procedures.
6. Participating in followup educational programs in response to evaluation findings.

Drug use evaluations should be predominantly qualitative and focus on the rationality of drug use. (Is an appropriate drug at an appropriate dose administered to the correct patient at the correct time and via an appropriate route?) Quantitative screening (e.g., determining how much of a drug is used or the total cost of a drug used) may be useful in suggesting problems of general clinical or financial importance.⁶ Quantitative data may be found in such records as purchasing records, monthly use data, drug profiles for inpatients and outpatients, patient charges, and adverse drug reaction reports.²

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3. Coe CP, Louviere ML. Preparing the pharmacy for a JCAH survey. Bethesda, MD: American Society of Hospital Pharmacists, 1986.
4. Accreditation manual for hospitals. Chicago: Joint Commission on Accreditation of Hospitals; 1987.
5. Stolar MH. Model for a formal, prospective antibiotic use review program. *Am J Hosp Pharm.* 1978; 35:809-11.
6. Stolar MH. Drug use review: operational definitions. *Am J Hosp Pharm.* 1978; 35:76-8.

Approved by the ASHP Board of Directors, November 19, 1987. Developed by the ASHP Council on Professional Affairs. Supersedes the document "ASHP Guidelines on the Pharmacist's Role in Drug-Use Review and Patient-Care Audits," approved by the ASHP Board of Directors on April 30, 1981.

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Reprinted from the *Am J Hosp Pharm.* 1988; 45:365

