

Pharmacist Scope of Practice

American College of Physicians–American Society of Internal Medicine*

This paper explores the increased scope of practice of U.S. pharmacists. It presents background information on the pharmacy profession and outlines how the medical profession can work with pharmacists to enhance patient safety and quality of care. The paper calls for further research on the effects of pharmacy automation and the move to the Doctor of Pharmacy degree on pharmacy practice. Other positions include support for patient education and hospital rounds, opposition to independent pharmacist

prescriptive privileges and initiation of drug therapy, increased use of the pharmacist as immunizer (as allowed by state law), and continued support for the American College of Physicians–American Society of Internal Medicine 1990 therapeutic substitution position.

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Pharmacists, as well as other nonphysician health care providers in the United States, are advocating for increased scope of practice. Their efforts have been successful in several cases. As of early 1999, 24 U.S. states allowed some type of collaborative practice agreement in which physicians delegate patient management responsibilities to pharmacists. The responsibilities range from refill approvals to modification or initiation of patient medication regimens (1) (Appendix).

In addition to broad collaborative agreements, pharmacists are focusing on many other individual practice issues, including prescriptive privileges, disease management, immunization, collaborative drug therapy, laboratory testing and analysis, and patient education. These issues continue to appear in our state legislatures. More than 30 states are expected to consider bills this year to grant prescriptive or independent practice rights to nonphysicians, including pharmacists (1).

THE PHARMACY PROFESSION

Pharmacists practice in various settings, including community pharmacies, hospitals, long-term care facilities, the pharmaceutical industry, mail service, managed care, and government (2). State law regulates the practice of pharmacy, including licensure. To practice pharmacy in any state, a pharmacist must become a registered pharmacist (RPh), also known as a licensed pharmacist. Although requirements vary by state, a licensed pharmacist must, generally, have graduated from

an accredited college of pharmacy, participated in a residency or internship program, and passed the National Association of Boards of Pharmacy Licensing Examination (NABPLEX) (3). In addition, most states require completion of continuing education courses to maintain licensure (3).

All registered pharmacists must hold at least a Bachelor of Science degree in pharmacy, but in 1992, a majority of the nation's pharmacy schools voted to change the only professional degree in pharmacy to the Doctor of Pharmacy (PharmD) degree (4). Programs that confer the PharmD degree require 4 years of education beyond the minimum 2 years of prepharmacy study. Professional courses required for this degree include pharmacognosy, pharmacology, pharmaceutical chemistry, pharmaceuticals, clinical pharmacy, drug information, and pharmacy administration.

In 1976, the American Pharmaceutical Association established the Board of Pharmaceutical Specialties to recognize specialty areas of pharmacy practice. Board certification is a voluntary process for currently licensed pharmacists. The four basic requirements for board certification are an entry-level pharmacy degree, an active pharmacy license, defined additional training and experience in a specialty, and passing the specialty qualifying examination. The Board of Pharmaceutical Specialties currently recognizes five specialty areas (5): 1) nuclear pharmacy (recognized since 1978)—specialists seek to improve and promote the public's health through the

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safe and effective use of radioactive drugs for diagnosis and therapy; 2) nutrition support pharmacy (recognized since 1988)—specialists promote the maintenance or restoration of optimal nutritional status, designing and modifying treatment according to the needs of the patient; 3) oncology pharmacy (recognized since 1996)—specialists address the pharmaceutical care of patients with cancer; 4) pharmacotherapy (recognized since 1988)—specialists are responsible for ensuring the safe, appropriate, and economic use of drugs in patient care and frequently serve as a primary source of drug information for other health care professionals; and 5) psychiatric pharmacy (recognized since 1992)—specialists address the pharmaceutical care of patients with psychiatric disorders.

Position 1

The American College of Physicians–American Society of Internal Medicine (ACP–ASIM) supports research into the effects of pharmacy automation and the move to the PharmD degree on pharmacy practice.

Two thirds of pharmacists work in community pharmacies (6). However, it is likely that pharmacists will further branch out into areas such as research, consulting, and hospital work because automation in pharmacy is growing, pharmacy technician responsibilities are increasing, and the PharmD will be the sole pharmacy degree offered in the 21st century.

Pharmacists will be seeking new roles, especially because store-based pharmacists in July through August 1999 spent more than 60% of their time processing and dispensing orders, according to a 1999 survey (7). Clearly, much of this time will be freed up as automated dispensing and use of pharmacy technicians increase. Long-term research is needed to evaluate the effects of automated dispensing and the move to the PharmD on the pharmacy profession. These events will affect not only pharmacy practice but physician practice as well.

PHARMACEUTICAL CARE

Pharmacists are moving from prescription provider to pharmaceutical care provider. The American Pharmaceutical Association defines pharmaceutical care as patient-centered, outcomes-oriented, pharmacy practice. Pharmaceutical care is designed to promote health; prevent disease; and assess, monitor, initiate, and modify

medication use to assure that drug therapy regimens are safe and effective (8). As part of the pharmaceutical care plan, pharmacists help assess therapeutic needs, prevent adverse drug reactions, develop patient-specific therapy, manage chronic disease, and monitor follow-up care (8).

COLLABORATIVE CARE AND THE VALUE OF PHARMACIST INVOLVEMENT

Collaborative drug therapy is one of the best examples of how pharmacists work with physicians. It is designed to maximize the patient's health-related quality of life, reduce the frequency of avoidable drug-related problems, and improve the societal benefits of pharmaceuticals (9). This process involves the pharmacist, physician, other health care professionals, and the patient. It includes basic dispensing functions, drug information services, the solving of patient-related and medication-related problems, and decision making regarding drug prescribing and monitoring and drug regimen adjustments. However, to participate in collaborative drug therapy, pharmacists need access to patients, access to medical records, knowledge and skills, and documentation and compensation for their activities (9).

Collaborative drug therapy covers a wide array of pharmacist activities and takes place in various settings. Several studies have assessed pharmacist participation in drug therapy in different settings, including pharmacy-based disease management and pharmacists on hospital rounds. Generally, pharmacist involvement in drug therapy has been successful, leading to improved patient care and safety and lowered medical costs.

Numerous studies have evaluated the value of the pharmacist in patient care, and they overwhelmingly describe successful ventures, although predominantly in hospital settings. Four clinical pharmacy services were associated with lower mortality rates in hospitals: clinical research, drug information services, medication admission histories, and participation on a cardiopulmonary resuscitation team (10). In addition, six clinical pharmacy services were associated with significantly lower total health care costs: drug use evaluation, drug information services, adverse drug report monitoring, drug protocol management, medical rounds participation, and medication admissions histories (10).

Pharmacist-initiated interventions at a large university hospital significantly decreased drug costs. A study

group randomly assigned to receive pharmacist intervention had 41% lower drug costs than those of the control group. Anti-infective agents had the greatest cost savings (11). The interventions had no effect on length of hospital stay, in-hospital mortality, 30-day readmissions, or the need to readminister the targeted medication or to restart intravenous therapy, but the interventions did provide an equivalent level of care (11). Although the results of this study and others were positive, it is not clear whether pharmacist participation is more effective than more modern interventions that have been shown to improve drug use—namely, computer-generated reminders to physicians at the point of care.

Similarly, pharmacist participation on physician rounds in the intensive care unit has been found useful in preventing medication errors (12). Pharmacists reviewed medication orders at the time of prescribing and made suggestions as necessary. The rate of preventable adverse drug events was reduced by 66%, and physicians accepted 362 of the 365 pharmacist recommendations (12).

In addition to studies of clinical pharmacy services offered in the hospital setting, researchers have also analyzed the effects of pharmacist participation in local clinics and pharmacies, primarily in disease management and immunization. Disease state management credentialing is available for pharmacists through the National Association of Boards of Pharmacy and the National Institute for Standards in Pharmacist Credentialing. Pharmacists may take one of four examinations that are designed to measure knowledge and judgment in providing disease state management services. Examinations are available for anticoagulation, asthma, diabetes mellitus, and dyslipidemia (13).

Pharmacists have been involved in demonstration projects on lipid disorders, anticoagulation clinics, diabetes, asthma, and vaccination (10). These studies indicate that patient outcomes improved and medical costs decreased as a result of pharmacist involvement. By including clinical pharmacists on a heart failure management team, one cardiology clinic significantly reduced all-cause mortality and heart failure events (14).

In addition to heart failure management programs, pharmacists have also been involved in diabetes-monitoring programs. In one study, pharmacists developed a community pharmacy-based diabetes monitoring program. Data on diabetes care were gathered at prescription refills. The average morning blood glucose values

decreased, and a medication adherence rate of 90% was maintained over a 1-year period (15). In addition, pharmacists recommended drug therapies to physicians, and physicians accepted 75% of these recommendations (15).

Position 2

To improve patient safety and reduce medical errors, ACP-ASIM supports physician-directed pharmacist-physician collaborative practice agreements limited to pharmacist involvement in patient education and hospital rounds.

1. *Expanded roles for pharmacists should not be solely based on cost savings.*

2. *The responsible physician and pharmacist should be compensated for their time spent on collaborative services.*

3. *The physician should solely determine if a relationship will be formed with a pharmacist.*

4. *The physician should solely and individually refer a patient to a pharmacist.*

5. *Only the physician shall and must diagnose the patient's condition prior to any referral (16).*

Physicians are qualified to diagnose and treat patients, while pharmacist expertise lies with pharmaceuticals. An improved, more collaborative relationship between the two disciplines could improve patient care and safety and reduce medical costs. However, it is imperative that reduced cost is not the only factor considered in pharmacist scope of practice. In addition, we need to ensure that physicians control prescriptive rights and have the final approval over all patient care decisions. Decisions about the most appropriate drug for a patient's condition are often subtle and require a level of experience and training that is not provided in obtaining a PharmD degree. This, in fact, is why physician training entails many years of practical supervised experience. This is not to say that PharmD training does not add benefit in a collaborative relationship, but rather that the benefit is incremental and not a substitute for that of the physician, whose role is primary.

Pharmacist involvement in patient care activities may improve patient outcomes, but it will also consume physicians' time. For physicians working in a hospital setting, medication advice can be obtained with relatively few diversions from other responsibilities because an in-hospital physician's involvement with pharmacists is largely restricted to the physician's limited time on service and the number of patients on rounds. However,

for physicians in community-based practices, working with pharmacists may present more serious time-management problems. Physicians will have to make decisions based on how much time, realistically, their offices are able to spend working with pharmacists.

Physicians are compensated for time spent working with physician extenders, for example, nurse practitioners and physician assistants. A similar payment system should be established for physicians' collaborative work with pharmacists. Funds should not simply be shifted from one provider to the other; instead, new sources of revenue will need to be identified.

Pharmacists continue to successfully expand their scope of practice. With the transition to the PharmD degree and automated drug dispensing, pharmacists are being trained to take on a greater patient care role. Instead of taking an adversarial position, the medical community must work together with the pharmacy profession to enhance patient care and safety while maintaining physician responsibility for continuous patient care. By combining the efforts of organized medicine and pharmacy, medication errors can be reduced and patients may live fuller, healthier lives.

Simultaneously, the pharmacy and medical professions should use their collective influence to promulgate better education of physicians in the use of drugs. Doing so will reduce medication errors and result in better patient care. Examples of efforts that might occur in this area are working with the U.S. Pharmacopeia and the Food and Drug Administration to promote better reporting mechanisms for drug errors or supporting Centers for Education and Research in Therapeutics.

Position 3

ACP-ASIM opposes independent pharmacist prescriptive privileges and initiation of drug therapy.

Although several studies describe the benefits of pharmacist and physician collaboration, little evidence supports pharmacist prescribing or initiation of drug therapy (10). Physicians have complete medical histories of patients, including awareness of other conditions and past treatments. Without that information, the appropriate training, and the reassurance of patient safety, ACP-ASIM cannot support independent prescriptive authority or drug therapy initiation for pharmacists.

Physician training is rigorous and heavily relies on patient interaction. It entails numerous years of practi-

cal, supervised "hands-on" training because of the subtleties of diagnosis and therapeutics that are the reality of patient care. The insight that this experience provides cannot be replicated in a less time-intensive and rigorous experience. This is not to criticize pharmacist education but instead to emphasize that the goals of the two educational paths are different, as are the outcomes in terms of skill set. Pharmacists do not have the exposure and experience to diagnose and prescribe medications for patients. This is clearly an area that should remain under physician authority.

Position 4

ACP-ASIM supports the use of the pharmacist as immunization information source, host of immunization sites, and immunizer, as appropriate and allowed by state law. ACP-ASIM will work with pharmacy organizations to increase immunization awareness.

Thirty states already allow pharmacists to administer immunizations (17). Because of the extensive state legislation that already exists, allowing pharmacists and nurses to administer immunizations, the potential benefit of nonphysician immunization of patients is widely recognized. Pharmacists provide increased access to immunization through extended business hours and locations. Increased access to immunization by trained pharmacy professionals will help to decrease antibiotic resistance and increase adult immunization. Pharmacists and physicians should focus on delivering vaccines to those populations most at risk, in an attempt to decrease mortality rates from preventable diseases.

Position 5

ACP-ASIM reiterates its support of its 1990 therapeutic substitution position. ACP-ASIM resolves to work with pharmacists in designing therapeutic substitution policies that ensure the highest level of patient care and safety.

Another important issue in physician-pharmacist collaboration is therapeutic substitution—the selection of a chemically different drug that is considered to be a therapeutic alternative with a comparable therapeutic effect. The current ACP-ASIM policy of therapeutic substitution states the following (18):

Position 1. Therapeutic substitution is appropriate only in hospitals with an effectively functioning formulary system and Pharmacy and Therapeutics Committee.

Position 2. Therapeutic substitution jeopardizes patient management when immediate prior consent is not obtained from the authorized prescriber and when documentation of substitutions is untimely or improper. Such practices must not be permitted.

Position 3. The practice of therapeutic substitution may be acceptable in ambulatory settings that meet standards comparable to those of institutional settings.

Position 4. Effective therapeutics require physicians to be well educated in therapeutics and to instruct patients about the proper use and effects of prescribed medication.

The American College of Clinical Pharmacy also supports therapeutic substitution when physicians and pharmacists work together to develop effective policies that maximize patient care at the best price. The American College of Clinical Pharmacy's therapeutic interchange guidelines are as follows (19):

Guideline 1. Therapeutic interchange is appropriate in institutional and ambulatory settings that have a functioning formulary system and Pharmacy and Therapeutics Committee or equivalent advisory committee.

Guideline 2. A continuous drug use evaluation process must be in place for regular review of endorsed therapeutic interchange policies and procedures.

Guideline 3. Therapeutic interchange, as defined herein, may be executed by pharmacists if the authorized prescriber is notified either verbally or in writing within a reasonable time frame, and if the pharmacists have access to medical records and appropriate laboratory or other test results as required by the therapeutic interchange policy. Exceptions to this procedure must be stated clearly in the policy.

Guideline 4. The Pharmacy and Therapeutics Committee or its equivalent should ensure that professional staff are educated regarding the rationale, policies, and procedures for therapeutic interchange.

Guideline 5. The therapeutic interchange policies should define a mechanism that enables authorized prescribers to disallow therapeutic interchange.

Ensuring safe, effective therapeutic substitution is a high priority for both pharmacists and physicians. Immediate prior consent by a physician is essential in maintaining patient management responsibilities and ensuring patient safety. The physician, as patient care manager, and pharmacist, as medication expert, are in a

unique position to work together for improved therapeutic substitution policies that provide high-quality care and cost savings.

REIMBURSEMENT AND LIABILITY

Reimbursement for pharmacists' professional services, other than dispensing, is currently receiving attention by the states. Several states have requested a waiver 11 from Medicaid to develop demonstration projects with pharmacists (20). Mississippi received the first Medicaid waiver (effective April 1998) from the Centers for Medicare and Medicaid Services to reimburse pharmacists for disease management of patients. Reimbursement is available for asthma, diabetes, hyperlipidemia, and anticoagulation services (21). The Mississippi project was an effort to evaluate whether pharmacists are better suited than physicians to cost-effectively spend time educating and monitoring patients.

New Mexico also has a demonstration project that allows pharmacists prescriptive authority according to protocol; however, unlike in Mississippi, pharmacists are not restricted to managing specific diseases (20). Only board-certified pharmacists are allowed to participate, and they must be supervised by a physician approved by the New Mexico Board of Medical Examiners. Pharmacists and physicians meet every 2 weeks, and reimbursement is arranged by physicians.

However, as pharmacists begin to receive reimbursement for their patient care services, they also become increasingly liable for their actions. In January 2000, the Alabama Supreme Court held that pharmacies and pharmacists are "health care providers," thereby governed by the Alabama Medical Liability Act. In August 2000, the Texas Court of Appeals ruled that pharmacists do not have a general duty to warn about all possible side effects or adverse effects but acknowledged that they do have a duty to warn when they are aware of information that would raise the importance or probability of such effects (22). Because reimbursement was not related to the Court's decision, however, payment and liability issues were separated.

Currently, pharmacists are not approved providers under Medicare except to perform immunizations (20). For pharmacists to be added to the list of providers, the Social Security Act would need to be amended. The Centers for Medicare and Medicaid Services implemented a regulation that provides Medicare coverage for

training programs to help beneficiaries with diabetes mellitus to control their disease. Medicare pays certified diabetes educators and dietitians to provide training to help control the disease and avoid complications, such as blindness, amputation, or kidney disease. To be certified, trainers must be employees of a program certified by the Centers for Medicare and Medicaid Services and part of a collaborative team providing services to beneficiaries. Some pharmacists qualify as certified providers if they are a Medicare supplier of durable medical equipment and if they meet quality standards (23).

The Medicare proposal would help newly diagnosed diabetic patients, those who have not received training, or those in serious danger of complications from diabetes mellitus. A physician must certify that a patient needs the service under a comprehensive plan of care. With the approval of their physician or qualified practitioner, eligible beneficiaries would initially receive up to 10 hours of group training and an annual 1-hour refresher course (23).

CONCLUSION

Clearly, pharmacist scope of practice is expanding, and the medical community must proactively respond to the pharmacy movement. The ACP-ASIM remains committed to exploring new roles for nonphysicians and helping to ensure that the practice of medicine remains with physicians. By partnering collaboratively with pharmacists, physicians will be able to avoid “turf” battles and focus on their primary mission—high-quality patient care. Pharmacists can educate physicians on drug interactions and cost savings and educate patients on drug safety, while physicians provide safe, effective care to patients.

However, there are striking differences in physician work settings—that is, hospital versus private practice. Policies must be adapted to meet individual office needs. The ACP-ASIM is committed to fostering effective and productive collaborative relationships between physicians and pharmacists, while securing the physicians’ role as the medical expert who is responsible for the diagnosis and treatment of patients. There is no substitute for medical school training. The ACP-ASIM looks forward to further research on the effect on the pharmacy profession by drug dispensing automation and the move to the PharmD degree. In addition, research evaluating the effects of pharmacist and physician collabora-

tion on physicians’ time with patients and studies examining the outcomes of a community-based PharmD system is needed.

APPENDIX: SUMMARY OF RECENT STATE LEGISLATION Collaborative Practice Agreements

Data in this appendix were obtained from reference 24.

A survey by the National Association Boards of Pharmacy showed that Idaho, Louisiana, Nebraska, Ohio, and Tennessee joined a growing number of jurisdictions permitting pharmacists to develop collaborative practice agreements with prescribers. Such agreements generally allow pharmacists to initiate or modify patient medication regimens pursuant to approved protocol. States also explored this issue in 1999, when 11 states enacted legislation allowing collaborative practice agreements with other health care providers (Arkansas, California, Georgia, Minnesota, Nevada, North Carolina, Oregon, Texas, Utah, Virginia, and Wyoming).

A Minnesota law expanded pharmacists’s scope of practice to include drug administration for first dosages and emergencies and participation in drug-therapy monitoring, selecting therapeutic devices, and drug or drug-related research. This law also permits participation in managing and modifying drug therapy on a case-by-case basis according to a written protocol between the specific pharmacist and an individual practitioner who has prescribing authority and who is responsible for the patient’s care. Virginia authorized pharmacists to enter into collaborative agreements with physicians, osteopathic physicians, or podiatrists. Another law defined “collaborative agreement” and held that such an agreement is not required for the management of patients in an in-patient facility.

Scope of Practice

2000 was an active year for legislation regarding pharmacist scope of practice. Vermont enacted legislation making licensure changes. Arizona enacted a bill changing licensure, fees, and prescription labeling. Georgia now provides qualifications for pharmacists authorized to modify drug therapy. Maryland required pharmacists to maintain a log of new and refill prescriptions. Kansas allowed pharmacists to administer vaccinations to persons 18 years of age or older. Legislation in six states (Alabama, California, Colorado, Delaware, New Hampshire, and Virginia) has passed in at least one chamber. New Hampshire’s bill would allow pharmacists to sell syringes without a prescription, and Virginia’s bill addresses radiopharmaceuticals, prescribers, and distribution.

In 1999, bills relating to scope of practice became law in 17 states (Arkansas, California, Georgia, Louisiana, Maine, Maryland, Minnesota, Missouri, Nebraska, North Dakota, Nevada, Oregon, Tennessee, Texas, Utah, Virginia, and Wyoming).

Areas of expansion of the pharmacist scope of practice included authorization to administer medications and injections, perform physical assessments, and order laboratory tests. Arkansas, California, Georgia, Minnesota, Oregon, Texas, and Utah enacted some provision allowing pharmacists to perform what otherwise have been “hands-on” practitioner activities. Wyoming authorized disease management by adding collaborative pharmaceutical care to the definition of practicing pharmacy. Arkansas codified disease management in its state pharmacy act.

Legislation enacted in Virginia created provisions focusing on the duty of a pharmacist in charge of an automated drug-dispensing system for a hospital. A law in Utah expanded the definition for the practice of pharmacy to include administering and distributing prescription drugs and devices pursuant to appropriate protocols. A law in North Dakota allowed registered pharmacy technicians to receive orally transmitted new or refill prescriptions. A law in Georgia amended several provisions related to pharmacists, including the scope of practice and licensure requirements for nuclear pharmacists.

Maine amended many provisions related to pharmacists and established a statutory review committee to review the scope of practice for pharmacists and, if necessary, to make recommendations for change. The review must address the issues of drug administration and collaborative practice and the current regulatory relationship between the Board of Pharmacy and institutional pharmacies. Effective 6 January 1999, the Alabama Board of Pharmacy adopted regulations that allow pharmacists to provide pharmaceutical care to patients by administering immunizations to eligible patients with valid prescription orders.

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