

1-30-01

BOARD

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ACY



**Improving Treatment in a Managed Care Setting**

In a large managed care group in Colorado, pharmacists with advanced patient care skills managed the drug treatment of patients with heart disease. Researchers found that patients under the care of these pharmacists showed dramatic improvements in their lipid control. Seventy percent of patients reached nationally recognized treatment goals within six months, compared to only 27% of patients who were not seen by these pharmacists. Hitchcock AM, Lousberg TK, Merenich J. *The impact of clinical pharmacy management on cardiovascular risk reduction in patients with established heart disease in a group model health maintenance organization. Pharmacotherapy* 2000;20:360-1;abstract 135.

**Improving Life, Reducing Costs, Increasing Employee Productivity by Managed Care Pharmacists**

The City of Asheville, NC, and the Mission St. Joseph Health System (MSJ), the largest employer in Western North Carolina, contracted with specially trained community pharmacists to manage the drug therapy of their employees with diabetes and asthma. Eighty-six percent of the Asheville employees enrolled in the diabetes care program were highly satisfied with their care. Patients reported a higher quality of life and greater ability to function. Interaction with diabetes educators increased while payer cost for services decreased. Initial data from Asheville suggests the city saved an estimated \$14,000 over the first six months of the program. The total cost of inpatient and outpatient services declined \$20,246 during the 12-month treatment period. In addition, the average participant worked 6.5 days more during the first project year compared to the prior year, thus saving the city an additional \$18,000 (estimated) in lost wages.

The Asheville and MSJ employees enrolled in the asthma treatment program showed significant improvement in controlling their asthma, and reported an improved ability to function normally on a day-to-day basis.

*The Asheville Project. Pharmacy Times. Romaine Pierson Publishers, Inc. Westbury, NY, October 1998. Bunting B. (excerpt) Asheville Project Continues to Produce Positive Results. America's Pharmacist. May 2000:43-4.*

**Improving Treatment, Reducing Costs in a Managed Care Setting**

Pharmacists reviewed drug therapy for a population including diabetic patients, finding problems with nearly 65% of drug regimens. Drug therapy changes based on the pharmacists' recommendations reduced unscheduled hospital visits, urgent care visits, emergency room visits, and hospital days, saving over \$640 per year in health costs per individual (\$280,000/year per pharmacist). The bulk of these savings "were in the nonpharmacy sector; fewer unscheduled physician visits and fewer hospital days."

*Borgsdorf LR, Miano JS, Knapp KK. Pharmacist-managed medication review in a managed care system. Am J Hosp Pharm* 1994;51:772-7.

**Reducing Costs in All Patient Care Settings**

In a study evaluating the effect of clinical pharmacists on the economic outcomes of patient care, an average benefit of \$16.70 of value to the health care system was realized for each \$1 invested in clinical pharmacy services. This benefit was observed in a variety of health care settings (community, government, and university hospitals; clinic settings) and included drug dosing and drug therapy management services provided by pharmacists.

*Schnock GT, Meek PD, Plotz PA, Vermeulen LC. Economic evaluations of clinical pharmacy service — 1988-1995. Pharmacotherapy* 1996;16:1188-208.

Evidence of the Value of the Pharmacist

Partners  
to  
Improve  
Health  
Outcomes



*Value added to patient care can be in terms of improved disease state and drug therapy management, economic savings, and improved patient satisfaction or quality of life. A growing body of literature has emerged that supports the value of pharmacists' patient care interventions in a wide range of patient groups, health care settings, and disease states. A few are listed here to illustrate ways in which pharmacists add value to the care of patients.*

**Saving Lives, Reducing Costs in Hospitals**

Clinical pharmacy services are associated with improved patient care outcomes in two national studies of over 1000 general medical surgical hospitals. Four clinical pharmacy services were associated with lower mortality rates, averaging 386 patient lives saved per hospital per year. Six clinical pharmacy services were associated with significantly lower total health care costs totaling over \$5 billion annually.

Pharmacy Service Type	Number of Hospitals	Lives or \$ Saved for Each Hospital Each Year	Total Lives or \$ Saved Each Year
<b>Clinical Pharmacy Services Associated with Lower Mortality Rates</b>			
Researching the effects of drugs in patients	108	196 lives saved	21,125 lives saved
Providing detailed information about how drugs should be used	237	44 lives saved	10,463 lives saved
Talking to patients to find out what medications they have been taking and writing it in the medical record	30	128 lives saved	3,843 lives saved
Helping to resuscitate patients who require CPR	282	18 lives saved	5,047 lives saved
<b>Total Lives Saved</b>		<b>386 Lives Saved for Each Hospital Each Year</b>	<b>40,478 Lives Saved Each Year</b>
<b>Clinical Pharmacy Services Associated with Lower Total Health Care Costs</b>			
Evaluating how well drugs are used within the hospital	898	\$1.1 million saved	\$1.0 billion saved
Reviewing and acting on adverse drug events when they occur	684	\$1.6 million saved	\$1.1 billion saved
Selecting doses and monitoring for response for specific medications	355	\$1.7 million saved	\$614 million saved
Providing detailed information about how drugs should be used	232	\$5.2 million saved	\$1.2 billion saved
Seeing patients side-by-side with physicians to determine medical treatment	152	\$8.0 million saved	\$1.2 billion saved
Talking to patients to find out what medications they have been taking and writing it in the medical record	30	\$232,138 saved	\$7.0 million saved
<b>Total Dollars Saved</b>		<b>\$17.8 Million Saved for Each Hospital Each Year</b>	<b>\$5.1 Billion Saved Each Year</b>



The results of these studies suggest that a broad range of hospital-based pharmacist-provided patient care activities either save lives or reduce health care costs, or both.

Bond CA, Raehl CL, Pitterle ME, Franke T. Health care professional staffing, hospital characteristics, and hospital mortality rates. *Pharmacotherapy* 1999;19:130-8. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacy staffing, and the total cost of care in U.S. hospitals. *Pharmacotherapy* 2000;20:356;abstract 108.

#### Reducing Adverse Drug Events in Hospitals

Researchers from the Harvard School of Public Health found that when a pharmacist was included on patient rounds, preventable adverse drug events decreased by 66 percent. They also concluded that a projected \$270,000, related to adverse drug events, could be saved annually when pharmacists joined doctors, residents, and other members of the patient care team on patient rounds in the intensive care unit at a large, urban teaching hospital. During a 6-month period, the pharmacists intervened about 400 times on behalf of patient safety, with 366 of those occasions relating to medication errors. Errors included incomplete orders, incorrect dosages and frequency, suboptimal drug choices, and prescription duplication. Health care professionals, including nurses, responded positively to the pharmacists' presence on rounds. Physicians accepted 99 percent of the pharmacists' recommendations for intervention.

Leape LL, Cullen DJ, Dempsey Clapp M, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999;282:267-70.

#### Improving Treatment, Reducing Costs in a Hospital Clinic

A pharmacist-directed pharmacotherapy consult clinic was established in a Veterans Affairs interdisciplinary primary care medicine continuity clinic. The pharmacist initiated or modified patient care plans in collaboration with primary care physicians and maintained care plans for 336 (32.8%) of 1023 patients enrolled in the continuity clinic. Clinical outcomes were positive in 88.3% of patient visits with 95% physician acceptance of pharmacist recommendations. Average reductions of 2.4 prescriptions/patient and 6.9 doses/day were achieved. Actual and potential cost avoidance totaled \$54,731 per year. The pharmacist-provided value-added services and contributed to decreased costs associated with care.

Galt KA. Cost avoidance, acceptance, and outcomes associated with a pharmacotherapy consult clinic in a Veterans Affairs medical center. *Pharmacotherapy* 1998;18:1103-11.

#### Improving Treatment, Reducing Side Effects, Reducing Costs in Ambulatory Clinics

In a study comparing newly anticoagulated patients treated with usual medical care versus those treated in a pharmacist-managed anticoagulation clinic, it was found that patients treated in the pharmacist-managed clinic had better anticoagulation control, fewer bleeding and thrombotic complications, fewer hospitalizations and emergency room visits, and lower health care costs. Significant bleeding was reduced from 35% to 8.1%; major to fatal bleeding from 3.9% to 1.6%; thromboembolic events from 11.8% to 3.3%; mortality from 2.9% to 0%; hospitalizations from 19% to 5%; and emergency room visits from 22% to 6%. Annual health care costs for patients managed by the pharmacist clinic in Texas were reduced by \$162,058 per 100 patients.

Chiquette E, Amato MG, Bussey III. Comparison of an anticoagulation clinic with usual medical care. Anticoagulation control, patient outcomes, and health care costs. *Arch Intern Med* 1998;158:1641-7.

#### Preventing Illness, Reducing Costs in Community Pharmacies, Ambulatory Clinics, and Nursing Homes

Pharmacists in three community pharmacies produced a 74% increase in vaccination rates, compared to a control facility, by advising high-risk patients of infection risk and describing



where to go to be vaccinated. Twelve pharmacists from a suburban health care system in Illinois, after completion of an immunization certification program, offered and administered influenza and pneumococcal vaccinations in clinics, at health fairs, and in a nursing home to patients at risk for these infections. Patient acceptance was excellent, with pharmacists administering 1060 doses of influenza vaccinations and 198 pneumococcal vaccinations to 1067 patients. According to an estimate based on an experiment in North Carolina, it is projected that if pharmacists were paid to advise enrollees to be vaccinated for influenza, net savings for Medicare of \$280,000, 139 hospitalizations, and 63 deaths per 100,000 enrollees could be realized each year.

Grabenstein JD, et al. Community pharmacists as immunization advocates: a pharmacoepidemiologic experiment. *Int J Phar Prac* 1993;2:5-10. Fox AT, Tjebio DA, Teeters JH. Implementation of a pharmacy-based immunization program within a health care system. *Pharmacotherapy* 2000;20:365;abstract 159. Grabenstein JD, et al. Community pharmacists as immunization advocates: cost-effectiveness of a cue to influenza vaccination. *Med Care* 1992;30:503-13.

#### Improving Treatment in Community Settings

Project ImPACT (Improve Persistence And Compliance with Therapy): Hyperlipidemia was a 3-year demonstration project in which the contributions pharmacists made to health and quality of life in patients with lipid disorders in Virginia were documented. Twenty-six community-based ambulatory care pharmacies (including independent, chain-professional, chain-grocery store, home health/home infusion, clinic, and health maintenance organization/managed care) participated. In 397 patients who continued in the project for an average of 24.6 months, observed rates for persistence and compliance with medication therapy were 93.6% and 90.1%, respectively; and 62.5% of patients had reached and were maintained at nationally recognized goals for treatment of high cholesterol. By working collaboratively with patients, physicians, and other health care providers, pharmacists who had ready access to objective clinical data and who had the necessary knowledge, skills, and resources, provided an advanced level of care that resulted in successful management of high cholesterol.

Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia. *J Am Pharm Assoc* 2000;40:157-65.

#### Improving Treatment, Reducing Costs in Community Pharmacies

Patient-focused pharmacist interventions in the community retail setting provided targeted patient education, systematic patient monitoring, patient feedback and behavior modification, and regular communication with patients' physicians for patients with hypertension, diabetes, asthma, and/or hypercholesterolemia. The economic impact of these interventions were evaluated by comparing claims data from 188 patients in three study pharmacies in Virginia to data from 401 control patients at five different pharmacies from the same retail chain. The average cost per prescription for asthma patients was higher in the intervention group, compared to the control group, suggesting improved adherence to treatment. Substantial savings for total monthly medical costs ranged from \$143.96 to \$293.39 per patient per month. Thus, by improving patients' adherence to their medication regimens, drug costs increased, but overall medical costs decreased.

Munroe WP, Kunz K, Dalmady-Israel C, Potter L, Schonfeld W. Economic evaluation of pharmacist involvement in disease management in a community pharmacy setting. *Clin Ther* 1997;19:113-23.

#### Improving Life, Reducing Costs in a Community Pharmacy

Pharmacy practitioners in an independent community pharmacy in Indiana developed an asthma management program for patients of a nearby health maintenance organization. For each patient, peak expiratory flow rates, quality of life, and use of health care services were used to determine the success of the program. During the first full year of the program, patients experienced significant improvements in quality of life and decreases in use of health care services, including a 77% decrease in hospitalization, a 78% decrease in emergency room visits, and a 25% decrease in urgent care visits.

Rupp MT, McCallian DJ, Sheth KK. Developing and marketing a community pharmacy-based asthma management program. *J Am Pharm Assoc* 1997;NS37:694-9.



Pharmacists are responding to the rapid evolution in health care by contributing their expertise in an ever-increasing number of patient care and medication management areas that states view as opportunities for efficient, cost-effective use of scarce health care resources.

*The Alliance for Pharmaceutical Care recognizes that our current health care system lacks efficient incentives conducive to appropriate drug therapy management. Therefore, The Alliance supports legislative and regulatory efforts that will provide these incentives and empower pharmacists to take a more direct role in extending quality health care services that improve the general public health to more patients than are currently served.*

Such quality health care services include:

### **Collaborative Drug Therapy Management (CDTM)**

New models in health care are emerging that can help address patients' unmet needs and improve patient care by involving other key members of the health care team. Drug therapy decision-making and management is evolving into an approach to care that is coordinated collaboratively by pharmacists, physicians, other health care professionals, and the patient. Thirty years of research has shown that pharmacist intervention improves patient outcomes. Thus, 29 states currently allow physicians and pharmacists to enter into voluntary written agreements to manage the drug therapy of a patient or group of patients. Many other states are currently developing or reviewing proposals to provide for pharmacist/physician collaborative practice agreements.

#### **Advantages of CDTM:**

- Saves money by reducing physician office visits.
- Reduces delays in modifying drug regimens.
- Increases patient adherence to their drug therapy plan.
- Increases the likelihood that expensive drug therapy problems will be averted through early detection.

#### **CDTM Activities Include:**

- Assisting physicians to improve medication management and continuity of care;
- Selecting, initiating, modifying, continuing, discontinuing, and monitoring a patient's drug therapy;
- Ordering, performing, and interpreting medication-related laboratory tests;
- Assessing patient response to therapy;
- Counseling and educating a patient on medications; and
- Administering medications

### **Collaborative Drug Therapy Management (CDTM) in the States**



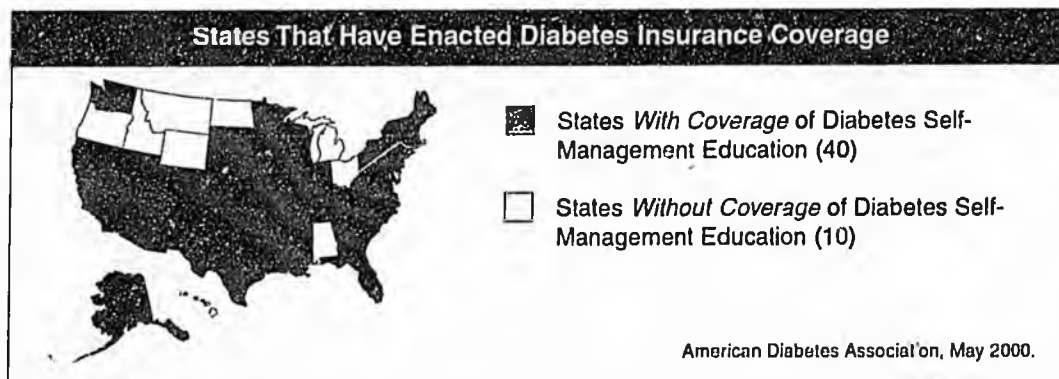
- States That *Authorize* CDTM through Legislation or Regulation (29)
- States That *Have Not Authorized* CDTM (21)

This number reflects data as of June 1, 2000. Several states are actively pursuing legislation so the number of states that authorize CDTM could rise in the next few months.



### Disease State Management ... Pharmacists Can Play a Key Role

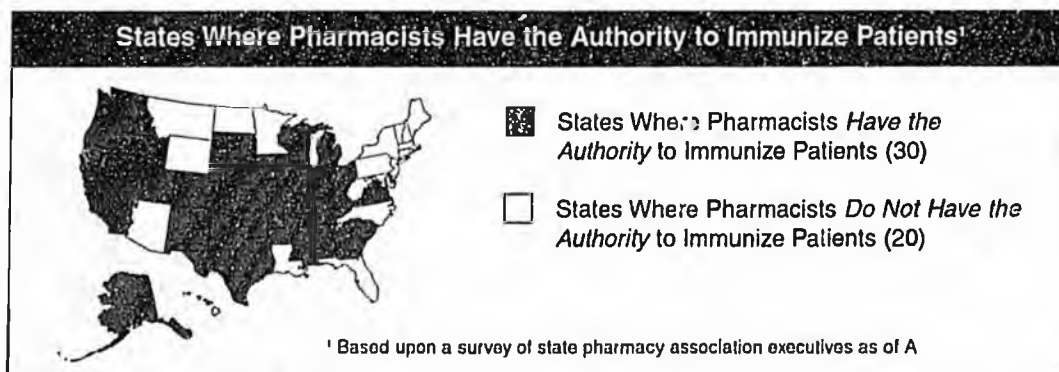
- Disease state management contains the costly progression of chronic disease and improves the patient's quality of life. It links all individual components of the health care system to offer patients with chronic diseases such as asthma, diabetes, depression, and high blood pressure, a continuous, coordinated process that seeks to manage and improve their health status over the *entire* course of the disease.
- 40 states have enacted legislation requiring insurance plans to cover self-management education for patients with diabetes. Many more states have introduced similar legislation this year.



- In Tennessee, Pennsylvania and other states, pharmacists are listed among the health professionals who may provide and receive payment for diabetes education and self management services.

### The Pharmacist and Immunization Services

- 30 states allow pharmacists to administer immunizations.
- Pharmacists can provide easy access to immunizations for patients of all ages by offering a large network of providers with extended business hours.
- Pharmacists can educate their patients and motivate them and their family members to be immunized.
- Pharmacists not trained to immunize can facilitate immunizations by hosting other health care professionals who administer immunizations.



### Pharmacists as Consultants to Physician Groups

- Increasingly, pharmacists are in demand by large physician group practices to perform highly specialized medication management services such as:
  - Develop prescribing guidelines
  - Establish speciality clinics
  - Manage and coordinate pharmaceutical care
  - Monitor and improve drug therapy for certain high-risk patients



**References**

- <sup>1</sup> ASHP *Patient Concerns National Survey*, 1999.
- <sup>2</sup> *JAMA* 1998;279:1200-5.
- <sup>3</sup> Institute of Medicine. *To Err Is Human: Building A Safer Health System*. Washington, D.C.: National Academy Press, 1999:1 (hereafter "IOM Report").
- <sup>4</sup> *Id.* at 23.
- <sup>5</sup> *Id.* at 168.
- <sup>6</sup> *Arch Intern Med* 1995;155:1949-56.
- <sup>7</sup> IOM Report at 23.
- <sup>8</sup> *Arch Intern Med* 1997;157:2089-96.
- <sup>9</sup> IOM Report at 168.
- <sup>10</sup> *JAMA* 1999;282(3):267-70.
- <sup>11</sup> IOM Report at 28.
- <sup>12</sup> *Id.* at 169.
- <sup>13</sup> *Id.* at 151.
- <sup>14</sup> *Id.* at 75 and 91.
- <sup>15</sup> *Id.* at 127.

Issues in Medication Use in the United States

Partners  
to  
Improve  
Health  
Outcomes



**The Health Care Team**

A strong health care team for you and your constituents requires the full support of all its players, including pharmacists.

*Would you be able to win a baseball game in which there was no catcher? The catcher supports the pitcher by calling pitches that get the batter out, in order for the team to win. Your pharmacist is like a catcher to your physician, the pitcher. Your pharmacist suggests drug therapies suitable to a patient's disease state. Your physician may follow such advice, and thus "strike-out" the patient's disease.*

Pharmacists, as an integral part of the health care team, play an increasingly important role in health care today. Studies show that pharmacists can save the health care system billions of dollars and improve quality of care for Americans. As one of the most accessible professionals, pharmacists are drug information specialists, highly educated and trained individuals who now spend at least 6 years in a post-secondary educational program. Pharmacists specialize in the study and understanding of medicinal chemistry; the actions and therapeutic uses of various types of medications that affect organ systems, immune systems, and infections; and the principles involved in drug dosage formulations and how drugs are absorbed by, distributed through, and eliminated from the body.

**Patient Concerns**

A recent survey<sup>1</sup> of patients checking into a hospital or other health care facility found that fears about drugs stand out among the list of possible concerns affecting patients. Patients 18-34 years of age are significantly more fearful than those patients 55 and over. The issues that cause patients concerns and their corresponding percentages are:

- Being given the wrong medicine . . . . . 61%
- Being given two or more medicines that interact in a negative way . . . . . 58%
- The cost of treatment . . . . . 58%
- Complications from the medical problems . . . . . 56%
- Having enough information about the medicines they receive . . . . . 53%
- Getting an infection during their stay . . . . . 50%
- Negative side effects from medicines . . . . . 49%
- Receiving too much medicine . . . . . 49%
- Suffering from pain . . . . . 49%
- Cost of filling prescriptions once discharged . . . . . 41%

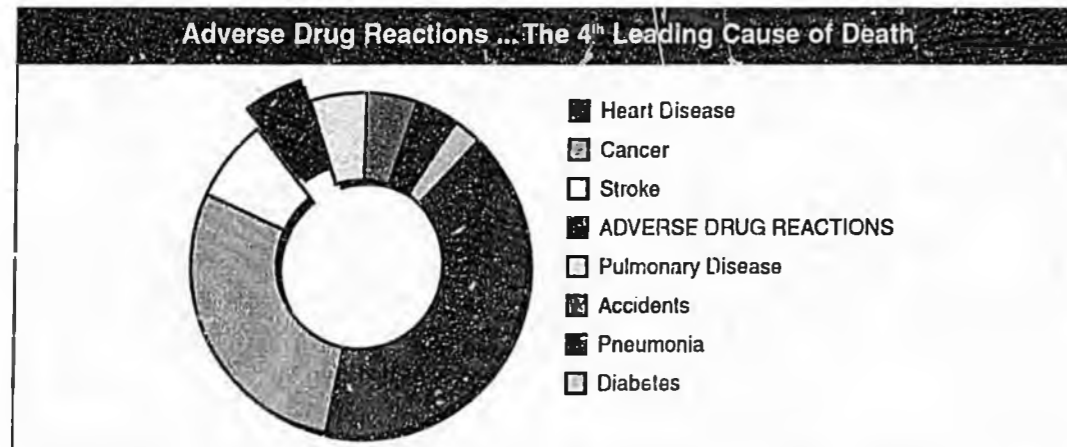
75% of those patients surveyed feel they would benefit from talking with a pharmacist. 75% of those patients — patients who are also your constituents — value the services of a pharmacist.

**Drug-Related Problems**

Pharmaceutical care services are invaluable in today's health care arena. Thirty years ago, only 650 medications were available; today the number approaches 10,000. This explosive growth of available medications has led to the advent of drug-related problems. Examples of drug-related problems include:

- Untreated medical problems;
- Too little or too much of a medication;
- Failing to take a prescribed medication;
- Adverse drug reactions or effects;
- Adverse effects from drug/drug, drug/food, or drug/laboratory interactions;
- Medication use with no indication; and
- Improper medication selection

over →



One study estimates 106,000 hospital patients died in 1994 from adverse drug reactions (ADRs) — unintended and undesired effects of drugs — which can occur even when the drugs are properly prescribed and administered.<sup>2</sup>

Pharmacist involvement makes a difference. The impact is most significant when pharmacists join forces with other members of a patient's health care team to ensure appropriate medication use to improve health status and quality of life and contain health care costs. Collaboration with physicians, nurses, and other health care professionals allows pharmacists to share their unique medication expertise for the benefit of improving public health.

#### **IOM Report Highlights Medical Errors and Associated Costs**

In late 1999, the Institute of Medicine (IOM) released "To Err is Human: Building a Safer Health System," a report which calls attention to the tens of thousands of Americans who die each year because of medical errors — of which medication errors alone are estimated to account for 7,000 of these deaths.<sup>3</sup> One recent study cited in the IOM report indicates that preventable adverse events result in increased hospital costs of \$4,700 per admission or about \$2.8 million annually for a 700-bed teaching hospital correlating to \$2 billion for the nation as a whole.<sup>4</sup>

While medication errors can occur anywhere in the health care system, from prescribing, through dispensing and administration, and finally patient error, the simple truth is that medication errors are preventable events, and pharmacists can assume active roles in reducing errors throughout the system. The IOM report specifically recognizes the value of pharmacists in increasing patient safety by speaking to the importance of pharmaceutical decision support. The report states that "[b]ecause of the immense variety and complexity of medications now available, it is impossible for nurses or doctors to keep up with all of the information required for safe medication use. The pharmacist has become an essential resource ... and thus access to his or her expertise must be possible at all times."<sup>5</sup>

A study on drug-related morbidity and mortality costs has shown the costs to be in the same range as costs of diabetes, obesity, and cardiovascular disease — leading many to suggest that drug-related problems should be considered a major category of disease.<sup>6</sup> As new medications are introduced for an ever widening number of indications, the IOM report suggests that "medication errors have the potential to increase as a major contributor to avoidable morbidity and mortality."<sup>7</sup>

Leading experts in the field, Jeffrey Johnson, M.Sc., and Lyle Bootman, Ph.D., state:

*"Medication-related problems in ambulatory facilities, hospitals, and nursing homes combined result in hundreds of thousands of deaths each year, and account for the consumption of over \$100 billion annually in scarce health care resources."*



In nursing facilities alone, a landmark initiative found that for every \$1.00 spent on drugs, \$1.33 was spent in treating drug-related problems. This same study also demonstrated the huge impact pharmacists could have on reducing these astronomical costs.

- Enhanced pharmaceutical care has increased optimal outcomes more than 40%; and
- With the current federally mandated drug regimen review (DUR), it is estimated that consultant pharmacists help to reduce health care resources attributed to drug-related problems by \$3.6 billion.<sup>8</sup>

#### **Pharmacists Decrease Medication Errors**

The IOM report also highlights the importance of including pharmacists on the health care team during rounds of patient care units. "As the major resource for drug information, pharmacists are much more valuable to the patient care team if they are physically present at the time decisions are being made and orders are being written ... Participation has been shown to significantly reduce serious medication errors."<sup>9</sup> Indeed, in a recent study conducted in one large, urban, teaching hospital, pharmacist participation in Intensive Care Unit medical rounds has demonstrated a 66% decrease in the rate of preventable adverse drug events related to prescribing.<sup>10</sup> Children are especially at risk for medication errors, primarily due to incorrect dosages.<sup>11</sup> Pharmacists' knowledge of pediatric dosing is crucial to achieve improved health outcomes in children.

Pharmacists are also key health professionals in educating patients about their medications. The IOM report specifically mentions that practitioners and staff in health care organizations should take steps to ensure that, whenever possible, patients know which medications they are receiving, the appearance of those medications, and their possible side effects.<sup>12</sup> Pharmacists, as accessible drug information experts, are natural patient educators and counselors.

Technologies are increasingly available to assist pharmacists and other health care professionals in their efforts to reduce medication errors. Order entry systems employing real-time alerts provide pharmacists with warnings that an ordered medication is out of range for age or weight, or is contraindicated. In addition, bar coding allows the pharmacist to positively identify and detect misidentified medicines, patients, and associated records. Pharmacists can also safeguard patient safety by using the "hear back" technique when accepting oral orders and instructions and phoned-in prescriptions, meaning that the pharmacists repeat the order and instructions to the individual prescribing or relaying the prescribed order. Lastly, pharmacists can provide crucial clinical oversight to patients receiving hazardous drugs by having access to patients' vital signs, blood levels and other laboratory values.<sup>13</sup>

Pharmacists, as well as all health care professionals, are able to further patient safety by contributing to medication error reporting systems. "Near misses" or errors that have already occurred provide valuable insight on how to prevent future errors in order to make improvements to systems and to ensure safer health care for patients.<sup>14</sup>

The IOM report cites professional groups as advocates for change.<sup>15</sup> The eleven organizations participating in the Alliance for Pharmaceutical Care have individually and collectively made commitments to create awareness and advocate for patient safety and to communicate such concerns to you, the nation's policy makers.

#### **What YOU Can Do**

Policy makers can have a direct and dramatic impact by recognizing the value of enhanced pharmaceutical services and working to make them more widely available through the passage of laws that recognize such services and the pharmacists' right to provide them. Studies show that increased use of pharmaceutical services will lead to significant cost savings in our health care system, a decrease in medication errors and thus increased patient safety, and improved patient health outcomes.

# Pharmacists Services Can Save Medicaid \$6.3 Billion Annually

continued



## Potential Savings to State Medicaid Programs if Comprehensive Pharmacy Services are Universally Available

State	1998 Drug Payments	Estimated Cost of Drug Morbidity and Mortality	Estimated Net Savings from Pharmaceutical Care Services
Alabama	\$236,674,147	\$203,566,885	\$120,511,596
Alaska	\$32,887,828	\$64,654,747	\$38,275,610
Arizona	\$1,442,917	\$43,539,087	\$25,775,140
Arkansas	\$150,891,615	\$212,575,424	\$125,844,651
California	\$1,553,598,462	\$1,309,474,064	\$775,208,646
Colorado	\$110,159,725	\$97,547,700	\$57,748,238
Connecticut	\$186,593,992	\$75,714,416	\$44,822,934
Delaware	\$41,350,537	\$10,012,043	\$5,927,129
District of Columbia	\$41,254,973	\$27,859,775	\$16,492,987
Florida	\$933,782,041	\$354,419,512	\$209,816,351
Georgia	\$370,562,935	\$645,976,334	\$382,417,990
Hawaii	\$39,623,380	\$57,565,379	\$34,256,305
Idaho	\$54,971,097	\$53,213,338	\$31,502,296
Illinois	\$583,239,675	\$427,207,174	\$252,906,647
Indiana	\$325,712,348	\$205,605,565	\$121,718,494
Iowa	\$147,115,884	\$119,083,040	\$70,497,160
Kansas	\$118,825,316	\$66,539,889	\$39,391,614
Kentucky	\$319,983,951	\$290,299,703	\$171,357,424
Louisiana	\$352,784,785	\$346,474,482	\$205,112,893
Maine	\$121,771,298	\$37,194,840	\$22,019,346
Maryland	\$148,532,940	\$81,898,301	\$48,483,794
Massachusetts	\$497,146,531	\$347,978,869	\$206,003,490
Michigan	\$374,145,567	\$229,814,775	\$136,050,347
Minnesota	\$173,602,492	\$149,233,629	\$88,346,308
Mississippi	\$231,735,360	\$311,738,521	\$184,549,204
Missouri	\$382,512,566	\$90,231,580	\$53,417,095
Montana	\$42,368,399	\$48,138,702	\$28,498,112
Nebraska	\$92,558,539	\$86,227,261	\$51,046,538
Nevada	\$34,518,901	\$69,419,620	\$41,096,415
New Hampshire	\$55,374,478	\$33,367,515	\$19,753,569
New Jersey	\$426,075,488	\$128,203,473	\$75,896,456
New Mexico	\$41,507,229	\$61,954,093	\$36,676,823
New York	\$1,368,451,273	\$575,488,941	\$340,689,453
North Carolina	\$466,528,812	\$589,684,191	\$349,093,041
North Dakota	\$27,619,684	\$26,008,286	\$15,396,905
Ohio	\$645,118,962	\$478,046,529	\$283,003,545
Oklahoma*			
Oregon	\$87,805,350	\$27,533,483	\$16,299,822
Pennsylvania	\$525,261,211	\$203,312,552	\$120,361,031
Rhode Island	\$61,401,958	\$12,407,808	\$7,345,422
South Carolina	\$224,962,203	\$265,547,614	\$157,204,188
South Dakota	\$31,106,511	\$36,066,239	\$21,351,213
Tennessee		\$198,683,726	\$117,620,766
Texas	\$817,591,112	\$1,163,991,919	\$689,083,216
Utah	\$68,827,853	\$35,456,566	\$20,990,287
Vermont	\$43,445,887	\$16,700,972	\$9,886,976
Virginia	\$284,578,558	\$330,174,882	\$195,463,530
Washington	\$244,478,658	\$160,993,841	\$95,308,354
West Virginia	\$148,962,081	\$195,588,108	\$115,788,160
Wisconsin	\$232,326,359	\$47,081,486	\$27,872,240
Wyoming	\$17,138,952	\$31,217,183	\$18,480,572
<b>Total</b>	<b>\$13,518,910,856</b>	<b>\$10,681,014,059</b>	<b>\$6,323,160,323</b>

\* Oklahoma did not submit detailed information for FY-1998.

Pharmaceutical Benefits Under State Medicaid Assistance Programs, National Pharmaceutical Council. Drug-related morbidity and mortality in ambulatory patients in the U.S. has been estimated to cost \$76.6 billion annually, or approximately \$114 per physician visit (*Arch Intern Med* 1995; 155:1949-56). Based on the number of outpatient physician visits, the direct cost for drug-related morbidity and mortality in ambulatory Medicaid beneficiaries is estimated for each state. Provision of comprehensive pharmacy services, as described in the accompanying materials, could reduce the total U.S. cost of drug-related morbidity and mortality in ambulatory patients by \$45.6 billion annually, or approximately \$68 per physician visit (*Am J Health Syst Pharm* 1997; 54:554-8). Based on the number of outpatient physician visits, the direct costs savings is estimated for each state.

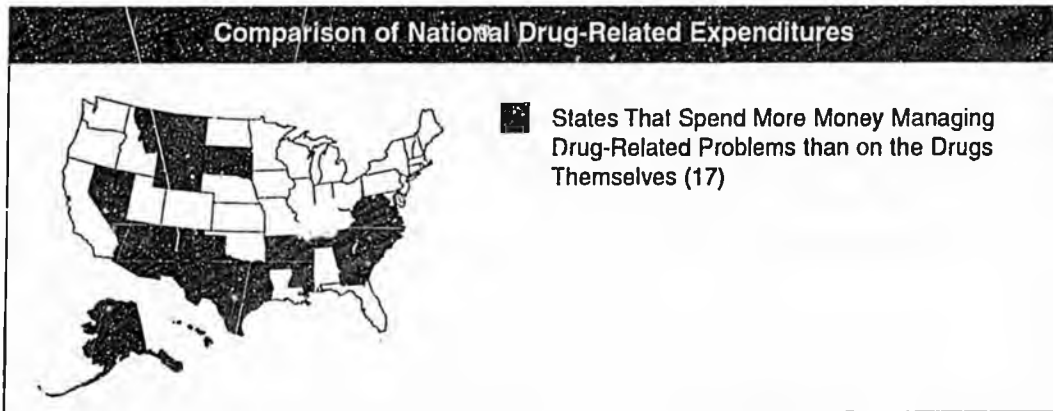


**Background**

What happens when patients receive less-than-optimal medication therapy? Often patients will then need more health care services resulting in increased physician visits, emergency or urgent care services, hospital or long-term care admission, or medications. No matter what direction is taken, more money must be spent. Studies show that drug-related morbidity and mortality among ambulatory patients cost the U.S. economy \$76.6 billion annually in direct costs alone.<sup>1</sup> Follow-up analysis suggests that \$45.6 billion could be saved annually if pharmacists are more fully enabled to provide comprehensive pharmaceutical care for these patients. Additionally, current estimates that include both long-term care and hospital care put these costs at over \$100 billion.<sup>2</sup>

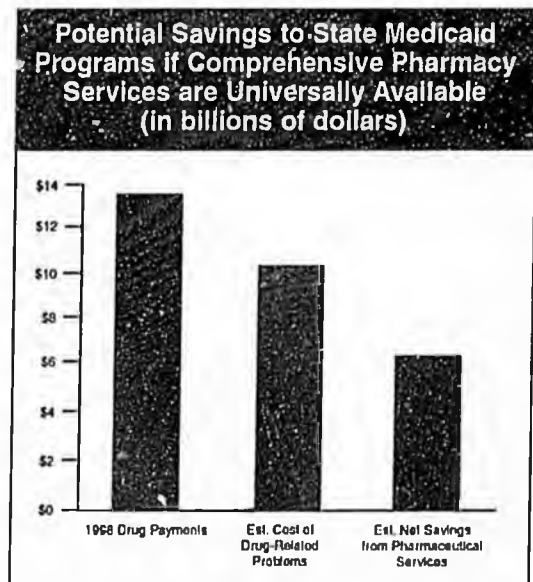
**The Issue**

The cost of drug-related illness or even death is of special interest to the nation's and individual states' Medicaid programs. Current prescription drug payments for Medicaid beneficiaries in the United States are estimated at \$13.5 billion per year. Using the \$76.6 billion spent nationwide on drug-related problems, an estimated \$10.6 billion was incurred by Medicaid in 1998. The current analysis suggests that almost 20 states may very well spend more each year on managing drug-related problems than they do on prescription medications themselves.



**The Solution**

Approximately \$6.3 billion could be saved annually within Medicaid programs through drug therapy management by pharmacists. Cost savings are achievable in nearly all 50 states. Within individual states these estimated savings range from \$5.9 million in Delaware to \$775 million in California.



<sup>1</sup> *Arch Intern Med* 1995; 155:1949-56

<sup>2</sup> *Am J Health Syst Pharm* 1997; 54:544-58; *Arch Intern Med* 1997; 157:2089-96; *JAMA* 1997; 277(4):307-11.

Sec. 08.80.005. Statement of purpose.

It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

Sec. 08.80.030. Powers and duties of the board.

- (a) The board is responsible for the control and regulation of the practice of pharmacy.
- (b) In order to fulfill its responsibilities, the board has the powers necessary for implementation and enforcement of this chapter, including the power to
  - (1) elect a president and secretary from its membership and adopt rules for the conduct of its business;
  - (2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;
  - (3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;
  - (4) adopt regulations to carry out the purposes of this chapter;
  - (5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;
  - (6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;
  - (7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy;
  - (8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;
  - (9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;
  - (10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices.

Sec. 08.80.110. Qualifications for licensure by examination.

An applicant for licensure as a pharmacist shall

- (1) be fluent in the reading, writing, and speaking of the English language;
- (2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;
- (3) be a graduate of a college in a degree program approved by the board;
- (4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;
- (5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.116. Internship and other training programs.

(a) An applicant for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with or after college attendance, or both, under terms and conditions the board shall determine.

(b) The board shall establish licensure requirements for interns and standards for internship or other training programs that are necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of preceptors used in practical experience programs.

Sec. 08.80.145. Reciprocity; license transfer.

If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person

- (1) submits a written application to the board on a form required by the board;
- (2) is at least 18 years of age;
- (3) is of good moral character;
- (4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;
- (5) has engaged in the practice of pharmacy for at least one year or has met the internship requirements of this state within the one-year period immediately before applying for a license under this section;

(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;

(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and

(8) pays all required fees.

#### Sec. 08.80.150. Temporary license.

The board shall adopt regulations regarding the issuance of a temporary license to practice pharmacy.

#### Sec. 08.80.480. Definitions.

In this chapter, unless the context otherwise requires,

(1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;

(2) "board" means the Board of Pharmacy;

(3) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device

(A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(4) "controlled substance" has the meaning given in AS 11.71.900 ;

(5) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;

(6) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";

(7) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;

(8) "distribute" means the delivery of a drug or device other than by administering or dispensing;

(9) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(10) "drug regimen review" includes evaluation of the prescription drug order and patient record for

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug, drug-food, and drug-disease interactions;

(G) adverse drug reactions; and

(H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

(11) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(12) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(13) "labeling" means the process of preparing and affixing a label to a drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packed legend drug or device;

(14) "legend drug" means a prescription drug;

(15) "manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by means of chemical or biological synthesis, and includes packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of drugs or devices; "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons;

(16) "nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

(17) "outpatient dispensing" means dispensing drugs for administration outside of the hospital pharmacy's control;

(18) "owner" means the owner of a place of business for wholesaling, retailing, compounding, or dispensing drugs, medicines, or poisons;

(19) "patient counseling" means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

(20) "person" has the meaning given in AS 01.10.060 and also includes a governmental agency;

(21) "pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in regulations of the board;

(22) "pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy  
;

(23) "pharmacist-in-charge" means a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy's personnel;

(24) "pharmacy" means a place in this state where drugs are dispensed and pharmaceutical care is provided and a place outside of this state that is subject to licensure or registration under AS 08.80.157 (b);

(25) "pharmacy located outside of the state" means a pharmacy that prepares or mixes prescription drugs outside of the state, regardless of the location at which those drugs may be shipped, mailed, or delivered to the consumer;

(26) "pharmacy technician" means a supportive staff member who works under the immediate supervision of a pharmacist;

(27) "practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; and the responsibility for: compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

(28) "practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

(29) "preceptor" means an individual who is currently licensed by the board, meets the qualifications as a preceptor under the regulations of the board, and participates in the instructional training of pharmacy interns;

(30) "prescription drug" means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) "Caution: Federal law prohibits dispensing without prescription"; (B) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only;

(31) "prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient;

(32) "prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the regulations of the board, before dispensing the drug as part of a drug regimen review;

(33) "significant adverse drug reaction" means a drug-related incident that may result in serious harm, injury, or death to the patient;

(34) "substitution" means to dispense without the prescriber's expressed authorization, an equivalent drug product in place of the prescribed drug;

(35) "wholesale" means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;

(36) "wholesale drug distributor" means anyone engaged in wholesale distribution of drugs, including but not limited to manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

Sec. 08.80.157. Licensing of facilities.

(a) A facility engaged in the practice of pharmacy or in the manufacture, production, or wholesale distribution of drugs or devices, and a pharmacy where drugs or devices are dispensed, shall be licensed by the board, and shall renew the license at intervals determined by the board. If operations are conducted at more than one location, each location shall be licensed by the board.

(b) The board may by regulation determine the licensure classifications of facilities and establish minimum standards for the facilities.

(c) The board shall establish by regulation the criteria that a facility must meet to qualify for licensure in each classification. The board may issue licenses with varying restrictions to facilities when the board considers it necessary to protect the public interest.

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(e) Licenses issued by the board are not transferable or assignable.

(f) The board shall specify by regulation the minimum standards for responsibility of a facility or pharmacy that has employees or personnel engaged in the practice of pharmacy or engaged in the manufacture, wholesale distribution, production, or use of drugs or devices in the conduct of its business.

(g) A licensed facility shall report to the board

(1) permanent closing;

(2) change of ownership; management, location, or pharmacist-in-charge of a pharmacy;

(3) theft or loss of drugs or devices as defined by regulations of the board;

(4) conviction of an employee of violation of a state or federal drug law;

(5) disasters, accidents, theft, destruction, or loss relating to records required to be maintained by state or federal law;

(6) occurrences of significant adverse drug reactions as defined by regulations of the board;

(7) other matters and occurrences the board may require by regulation.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds;

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

(3) the furnishing of false or fraudulent material in an application made in connection with drug or device manufacturing or distribution;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

(6) dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy;

(8) violation of this chapter or a regulation adopted under this chapter.

(i) The board's regulations under (b) - (d) and (f) of this section may not establish more stringent licensing requirements for the facilities governed by AS 08.80.390 than are set out in AS 08.80.390 .

(j) This section does not apply to the offices of physicians, osteopaths, podiatrists, physician assistants, advanced nurse practitioners, dentists, veterinarians, dispensing opticians, or optometrists.

**Collaborative Drug Therapy  
Management  
The Washington Experience**

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**Comparison of  
1993 - 1999  
Survey Results**

# Introduction

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Collaborative drug therapy management by pharmacists has been practiced in Washington State for 20 years. A survey of pharmacists and physicians was conducted in year 1993 to examine numerous aspects of this practice.

The survey was repeated in 1999 for follow-up and to develop additional data related to quality assurance and outcome measurements.

# Survey Methodology

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All of the prescriptive authority protocols in Washington State are on file at the Washington State Board of Pharmacy. These documents identify pharmacists and physicians who sign these agreements.

A separate survey was developed for pharmacists and physicians participating in this practice.

These surveys were mailed to the sponsoring pharmacist. The physician survey was forwarded to the physician sponsor

# 1993 & 1999 Survey Goals

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## Goals for 1993 Survey

- measure satisfaction

- determine frequency of use and participation

- identify perceived impact

- determine whether the Board should promote collaborative protocols

## Additional goal for 1999 included

- determine quality assurance measures used

- determine outcome data collected

# Survey results

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1993 survey --57 protocols

response received from participants in 44

135 prescribers / 84 pharmacists

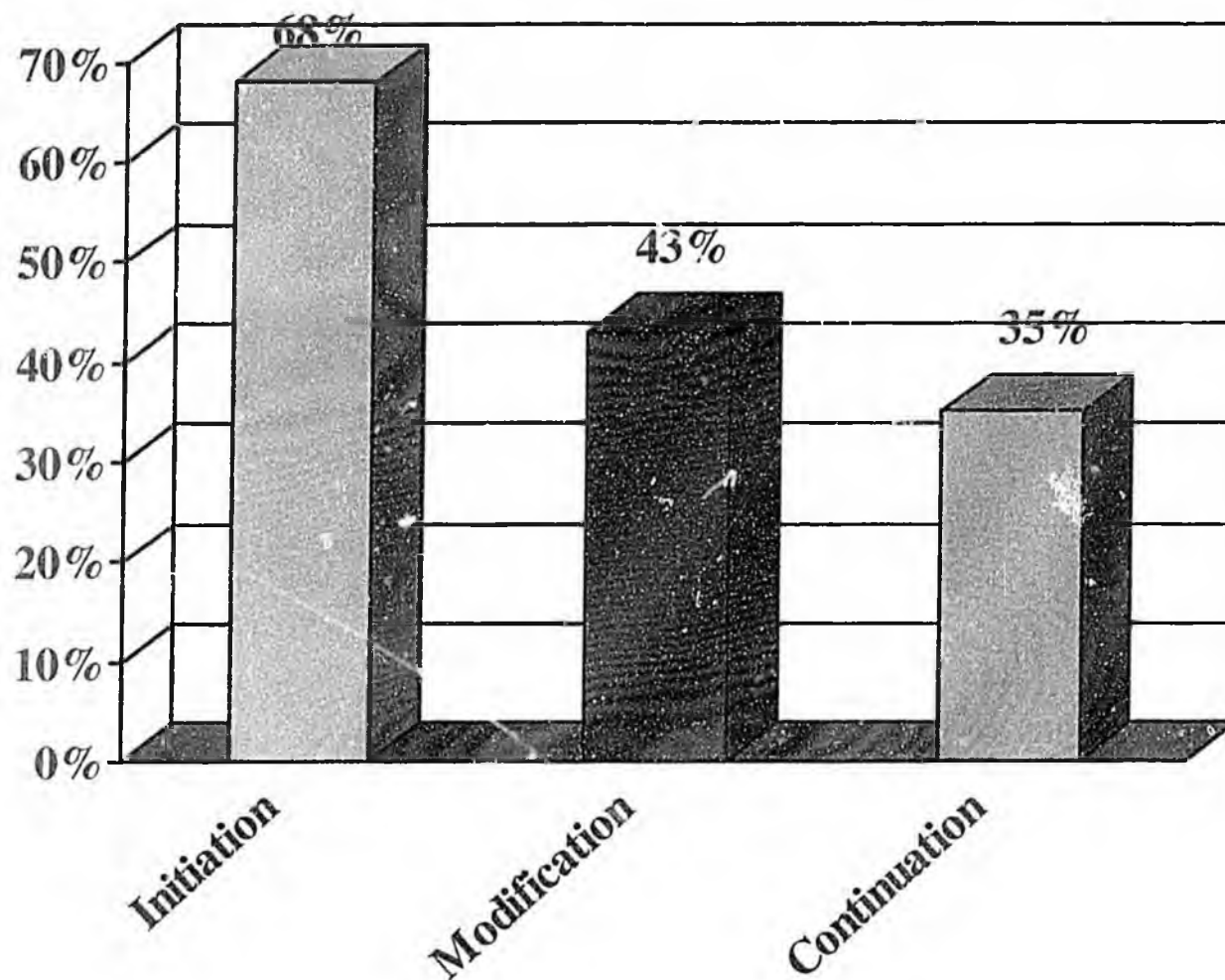
utilization was 7 RPhs & 27 prescribers  
per protocol

1999 survey-- 358 protocols

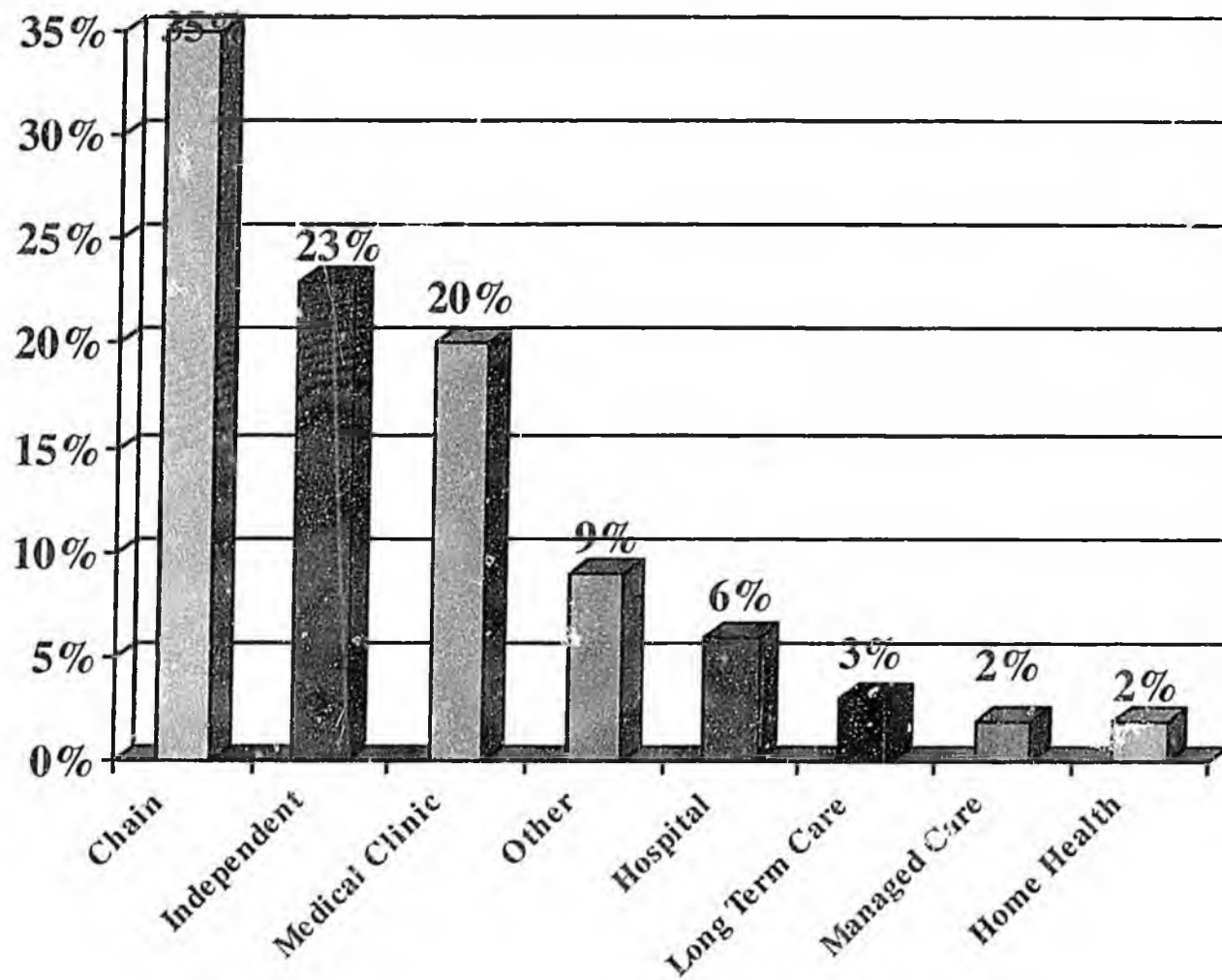
response received from participants in 88

utilization was 6 RPhs and 45 prescribers  
per protocol

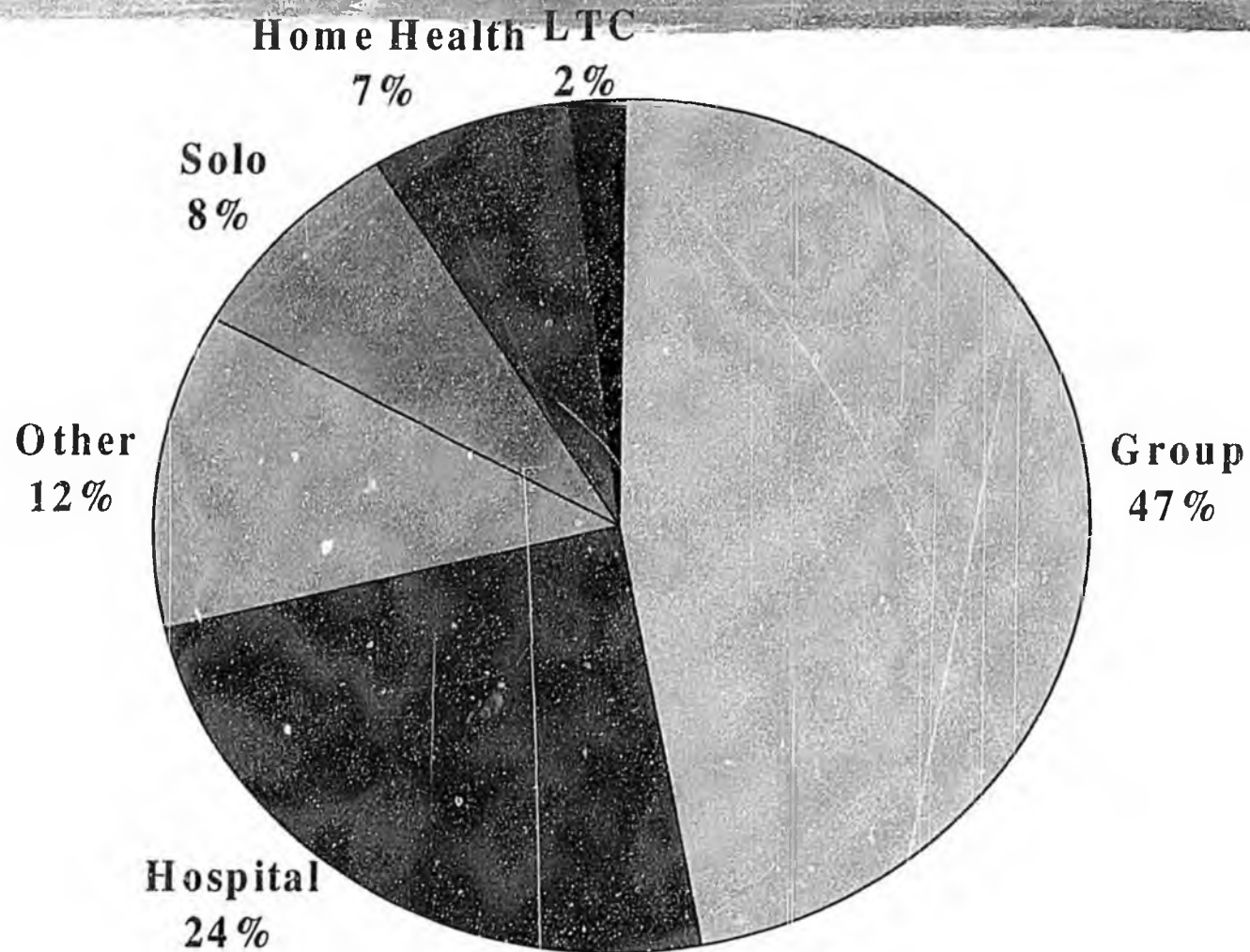
# Type of Prescriptive Authority



# Practice Setting: Pharmacists



# Practice Setting: Physicians



# Survey results: Satisfaction

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Physicians were either very satisfied or satisfied

1993 (98%)

1999 (95%) none were dissatisfied

Pharmacists were either very satisfied or satisfied

1993 (95%)

1999 (99%)

# **Survey results:**

## **Quality Assurance Measures**

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Case review	50%
Chart audit	40%
ADRs	45%
Complaints	40%
Note review	34%

# Survey results:

## Frequency of Q.A. measure

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Monthly	17%
Quarterly	54%
Yearly	9%
"Other"	12%

# Survey results:

## Outcome data collected

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Clinical measures	48%
Satisfaction	44%
Access to care	18%
Adverse events	64%
"None"	24%

# Survey results:

## Perceived impact (prescriber)

	1993	1999	**
Increased patient convenience	91%	80%	97%
Decreased cost of care	59%	49%	85%
Increased quality of care	70%	80%	95%

\*\* if the numbers for "or same" are added to the 1999 totals

# Survey results: Perceived impact (RPh)

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	1993	1999	**
Increased Patient Convenience	92%	86%	100%
Decreased Cost of Care	43%	57%	96%
Increased Quality of Care	77%	89%	100%

\*\* if the numbers for "or same" are added to the 1999 totals

# Recommendation to Board of Pharmacy re: CDTM 1999

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	prescribers	RPhs
Promote CDTM	76%	98%
Do nothing	24%	2%
Discourage	0%	0%

# **University of Washington: Additional survey**

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1998 Survey of 153 Emergency  
Contraceptive Pill (ECP) Protocols  
generated very similar responses

COPY

FEB 05 2001

2811 Iliamna Avenue  
Anchorage, Alaska  
99517

January 31, 2001

State Capitol, Room 418  
Juneau, AK 99801-1182  
907-465-2995  
fax: (907) 465-6592

Dear Representative Lecil McGuire,

I would like to thank you and the rest of the Regulation Review Committee for the opportunity to both listen and testify at the meeting of January 30, 2001.

The Rules Committee raised multiple questions that prompted thoughtful responses. The general discussion was quite stimulating. For additional clarification, I have attached information (to this e-mail) dispelling any remaining confusion related to emergency contraception. Two other related handouts will be mailed to your office:

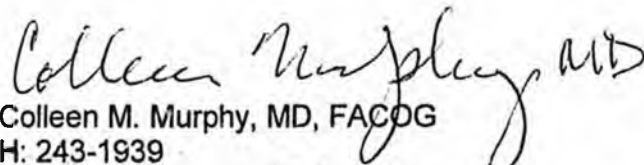
- Talking Points used for a presentation to the Medical Board on 10/27/00
- A DRAFT handout that clients would be given by a pharmacist when dispensed emergency contraception under our proposed collaborative agreement.

The Alaska State Pharmacy Board is an autonomous board. Other state licensing boards are conferred with the autonomy, responsibility, and authority to draft separate regulations for their respective licensed professionals. I feel concern about excessive interference by other regulatory boards and professional associations.

It is my belief that our shared customer, the patient, will greatly benefit from increased communication and collaboration between health care professionals. I ask that you support proposed Alaska State Pharmacy Regulations entitled, 2.12 AAC 52.240 Pharmacy Collaborative Practice Authority.

Once again, I thank you for the opportunity to both listen and testify at the meeting of January 30, 2001.

Sincerely,



Colleen M. Murphy, MD, FACOG  
H: 243-1939  
E-mail: [murphylogue@alaskalife.net](mailto:murphylogue@alaskalife.net)

**State Medical Board Meeting**  
**October 27, 2000**  
**The Alaska Emergency Contraception Project**  
**Colleen M. Murphy, MD, FACOG**

**Alaska Emergency Contraception Project is:**

- ◆ a coalition of women's health care providers from the private and public sectors, organized in 1998
- ◆ modeled after the Northwest Emergency Contraception Coalition, launched in 1997.

Our mission of the is "to educate the public and health care providers about the option of emergency contraception and to increase availability and acceptability of this contraceptive option. The Project is dedicated to reducing unintended pregnancies and maximizing reproductive health."

**What is emergency contraception?**

- ◆ contraception used after unprotected intercourse
- ◆ birth control pills given within 72 hours (75-90% effective)
- ◆ IUD inserted within 5 days of unprotected intercourse (99% effective)

**How does emergency contraception work?**

- ◆ ECPs can delay or inhibit release of the egg
- ◆ No clinical data to support theories that may involve cervical mucous, fertilization, or tubal transport of sperm, egg, or embryo
- ◆ Not clear how emergency IUD insertion prevents pregnancy- it may interfere with sperm transport or fertilization.

**Is emergency contraception safe?**

- ◆ No serious or long-term complications associated with ECPs. If ECPs are taken inadvertently during early pregnancy- no known risk of birth defects
- ◆ If ECPS taken in 1<sup>st</sup> trimester, there is no higher risk of miscarriage (In 1997, the FDA removed warnings about adverse effects of OCPs on a developing pregnancy)
- ◆ An IUD should be immediately removed if IUP diagnosed: ↑ risk of SAB, infection, & PTL

**Why is emergency contraception needed?**

- ◆ Rape- Alaska highest rate of reported sexual assault in US
- ◆ In Alaska and nationwide, 50% of pregnancies are unintended
- ◆ Unintended pregnancies are associated with later prenatal care, lower birth weights, higher substance abuse rates, and infants more likely to be victims of abuse and neglect
- ◆ Nationwide, 47% of unintended pregnancies end in voluntary abortion.
- ◆ Alaska: 14,000 pregnancies per year. 10,000 livebirths (69%) 2000 terminations (16%)
- ◆ EC, if more widely available, could prevent up to 50% unintended pregnancies and decrease the need for abortion by 50%

**Innovative Ways of Increasing Access to Emergency Contraception while Maintaining Safe Use**

- ◆ Advance Distribution
- ◆ Prescription by phone to new clients
- ◆ Prescription through Allied Health Professionals

**Results of a Washington State Pilot Project Using Collaborative Drug Therapy Agreements**

- ◆ The pilot project was conducted July 1997 thru July 1999
- ◆ 130 pharmacies participated (819 pharmacists trained)
- ◆ 11,969 ECP prescriptions were provided by pharmacists- estimated to have prevented 677 pregnancies (315 induced abortions, 272 births, 83 miscarriages, and 7 ectopic pregnancies)
- ◆ 42% of women received emergency contraception after regular business hours (in the evening, on a weekend, or on a holiday).
- ◆ 70% of women received ECP services within one day of unprotected intercourse (when the treatment is most effective)
- ◆ 92% of pharmacist respondents who had ECP prescribing experience and 92% of prescriber respondents reported being "satisfied" or "very satisfied" with the ECP program
- ◆ Obtaining ECP thru a pharmacy compared to not: a \$158 [95% confidence: \$76 to \$269] reduction in cost for private payer and a \$48 [95% confidence: \$16 to \$93] reduction in cost for public payers.

## When to Contact a Referral Provider

- ◆ If you want to get a routine method of birth control or maybe switch to one that you are less likely to forget to use
- ◆ If your period does not start within 3 weeks of taking ECPs, you may need pregnancy testing
- ◆ If you have an unusual reactions to ECPs: severe nausea & vomiting, excessive fatigue, or severe swelling
- ◆ If you need to be checked for a sexually transmitted infection

## List of Referral Providers for after Emergency Contraception

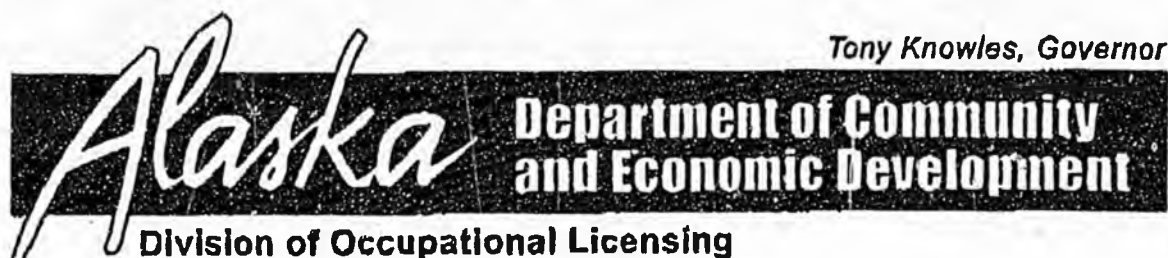
<b>Anchorage</b>	<b>Alaska Native Medical Center Women's Health Service</b> <i>(Services restricted to Indian Health Service clients)</i> 729-3100 <b>Alaska Womens Health Services</b> 563-7228 <b>Barbara Norton, CNM</b> 561-5152 <b>Bearing In Mind Birth Center</b> <b>Zeida Collett-Paule, CNM</b> 561-2822 <b>C. Jane Wiggins, MD</b> 563-5151 <b>Department of Veterans Affairs</b> <i>(Services restricted to eligible military families)</i> 257-4929 <b>Family Health &amp; Wellness</b> 336-3500	<b>Jeffrey Lawrence, MD</b> 561-7111 <b>Medical Solutions Paulette Lequizamon, CFNP</b> 522-3334 <b>OB/GYN Associates</b> <i>(Services restricted to established clients)</i> 562-2965 <b>Oops - Emergency Contraception</b> (907) 770-6677 <b>Planned Parenthood of Alaska</b> (800) 230-7526 <b>University of Alaska, Anchorage, Student Health Center</b> <i>(Services restricted to students)</i> 786-4040
<b>Eagle River</b> Aurora Medical Clinic 696-5680	<b>Fairbanks</b> Public Health Center 452-1776 Urgent Care Center 452-2178 Interior Neighborhood Health Corporation <i>(Services restricted to established clients)</i> 455-4567 Ralph Wells, MD 459-3518 University of Alaska at Fairbanks; Center for Health and Counseling <i>(Services restricted to students)</i> 474-7043	<b>Fort Wainwright</b> Bassett Army Community Hospital, Women's Health Center <i>(Services restricted to eligible military families)</i> 353-5253
<b>Mat-Su Valley</b> Mat-Su Valley Public Health 376-2437	<b>Palmer</b> Valley Women's Health Care 745-8379	<b>Talkeetna</b> Sunshine Community Health Center 733-2273

## If you have been sexually assaulted, and need help soon:

<b>Anchorage/Eagle River</b>	STAR AWAIC AK Women's Resource Center	276-7273 272-0100 276-0528
<b>Mat-Su Valley</b>	Valley Women's Resource Center	746-4080
<b>To report Sexual Abuse of a Minor</b>	Division of Family and Youth Services	269-4000

**Disclaimer: This list does not include all available services in your community. Fred Meyer Pharmacy does not have a financial interest in the above services nor can Fred Meyer guarantee their quality.**

Written 9/23/00 CMurphy



Tony Knowles, Governor

**Division of Occupational Licensing**

P.O. Box 110806, Juneau, AK 99811-0806

Telephone: (907) 465-2534 • Fax: (907) 465-2974 • Text Telephone: (907) 465-5437

Email: license@dced.state.ak.us • Website: www.dced.state.ak.us/occ/

January 19, 2001

Colleen Murphy, MD  
2811 Iliamna  
Anchorage, AK 99517

Dear Dr. Murphy:

This is in response to your letter of November 14, 2000, in which you requested a formal opinion from the board that your proposed agreement with pharmacists to provide emergency contraception conforms to the practice of medicine under Alaska statutes.

At the October 26-27, 2000 Alaska State Medical Board meeting, the Alaska Board of Pharmacy asked the medical board to consider their proposed new regulation that would provide for pharmacists to enter into collaborative relationships with physicians for specified purposes.

The medical board has opined that if the Board of Pharmacy's proposed regulations (or regulations similar to those proposed) are passed into law, physicians would have the ability to enter into collaborative relationships with pharmacists.

In the medical board's opinion, the burden to a physician entering such an agreement would be to insure that the individual to whom the physician has delegated a task is properly educated and trained to perform the task being delegated. New pharmacy regulations would define agreements such as you propose, if approved by that board, as being within the scope of practice that a pharmacist is qualified to perform. Therefore, as long as a physician licensee, participating in an agreement such as the one you propose, discharges the duty to insure appropriate education and training of collaborating pharmacists, he or she would be acting within the definition of professional practice of medicine as described under Alaska Statute 08.64.326 and regulation 12 AAC 40.967.

Sincerely,

A handwritten signature in dark ink that reads "Sarah A. Isto, MD". The signature is written in a cursive style.

Sarah A. Isto, MD  
Chair  
Alaska State Medical Board

SAI/JS/go3140  
011901a



Department of Community and Economic Development

Division of Occupational Licensing

3801 C Street, Suite 722, Anchorage, AK 99503-5934
Telephone: (907) 269-8180 • Fax: (907) 269-8156 • Text Telephone: (907) 465-5437
Email: License@dced.state.ak.us • Website: www.dced.state.ak.us/occl

December 6, 2000

RECEIVED

Kurt West, Regulations Specialist
Division of Occupational Licensing
Post Office Box 110806
Juneau AK 99811-0806

Division of Occupational Licensing
JAN 10 2001

The Alaska State Medical Board appreciates the opportunity to comment on proposed regulation 12 AAC 52.240 entitled "Pharmacist Collaborative Practice Authority."

The medical board reviewed this proposed regulation at its meeting on Friday, October 27, 2000. Mr. Mark Bohrer, member of the Board of Pharmacy, met with the board and discussed the intentions of the Board of Pharmacy in proposing this regulation.

The State Medical Board determined that, with the exception of the dispensing of emergency contraception medication, it could not support the collaborative practice authority regulation as written. Board members expressed their concerns about pharmacists possibly performing blood draws, xray tests, laboratory analyses, and making assessments and medical decisions which they are not adequately trained and experienced to perform. Examples were cited where patients might not fully inform the pharmacists about all their physical problems and fail to disclose vital information that will be affected by the pharmacists' treatment. The board voiced concerns that complete medical records would not be maintained for the patient, and that patient care would be fragmented between the physician and pharmacist.

The board believes that a complete history and physical examination are essential components in the provision of good health care. Board members noted that in the absence of a complete history and physical examination, the dispensing of medications could lead to more harm than benefit to the patient.

The board indicated it would consider supporting a more narrowly defined collaborative relationship regulation for physicians and pharmacists, for situations where the pharmacists might dispense medications that require immediate or emergent use and that could not be easily or reliably obtained otherwise.

The medical board thanks the Board of Pharmacy, most especially Mr. Bohrer, for meeting with the board and giving board members the opportunity to review the proposed regulations. The medical board looks forward to continued, cooperative, mutually beneficial work with the Board of Pharmacy to provide the safest and highest standard of care to Alaska's citizens.

FOR: Sarah A. Isto, MD.
Chair, Alaska State Medical Board

xc: Margaret D. Suden, RPh, Chair
Board of Pharmacy

Promoting a healthy economy and strong communities

*Alaska*

**Department of Community  
and Economic Development**

**Division of Occupational Licensing**

3601 C Street, Suite 722, Anchorage, AK 99503-5934

Telephone: (907) 269-8160 • Fax: (907) 269-8156 • Text Telephone: (907) 465-5437

Email: [Lir\\_ense@dced.state.ak.us](mailto:Lir_ense@dced.state.ak.us) • Website: [www.dced.state.ak.us/occ/](http://www.dced.state.ak.us/occ/)

December 13, 2000

Board of Pharmacy

Dear Members of the Board:

Thank you for your letter of October 24, 2000 regarding proposed regulations for collaborative practice authority and monitoring of drug therapy. We appreciate your desire to work together on issues that affect both our licensees.

After a review of the proposed regulations at our December 13, 2000 board meeting, the board expressed concerns in the following areas:

1. Under 52.240(b)(1) we suggest you add that the statement of agreement between prescribing practitioner and pharmacists be signed by both parties to ensure that prescribing practitioners have seen and are aware of their responsibilities under the agreement. In addition, stipulate that the prescribing practitioners be licensed in Alaska.
2. The documentation of decisions made under 52.240(b)(1) should have criteria addressing what the documentation should include, just as your requirements for documentation on prescriptions are set forth in regulation.
3. Your letter notes that you "expect that the prescribing practitioner would be required to obtain approval of the protocol by the Board of Nursing prior to implementation". Do you anticipate that requirement as being promulgated in our regulations?

Should there be any questions concerning this issue, please feel free to contact me or any of the other board members.

Sincerely,

*Barbara Berner*  
Barbara Berner, RN, ANP, Ed.D  
Chairperson  
Alaska Board of Nursing

Cc: Nursing Board Members  
Kurt West, Regulations Specialist

*Alaska*

**Department of Community  
and Economic Development**

**Division of Occupational Licensing**

P.O. Box 110806, Juneau, AK 99811-0806

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FYI

DATE: December 12, 2000

TO: Kurt West, Regulations Specialist  
Division of Occupational Licensing

FROM: James A. Clark, DMD, MS, Vice Chair  
Alaska Board of Dental Examiners

SUBJECT: Proposed Changes in Pharmacy Regulations  
12 AAC 52.240, Pharmacist Collaborative Practice  
12 AAC 52.250, Monitoring of Drug Therapy by  
Pharmacists

The Alaska Board of Dental Examiners met recently and discussed the above-referenced changes to the Board of Pharmacy regulations. The Board of Dental Examiners is unanimously opposed to the proposed changes in 12 AAC 52.240 and 12 AAC 52.250. It is obvious to us that the terms of these proposals (if enacted) would constitute the practice of medicine and the practice of dentistry. Further, we have serious doubts that the State Medical Board, the State Dental Board or individual practitioners have the statutory authority to approve the clinical practice of medicine or dentistry by persons not licensed in these fields.

JAC/JM/dgl/S210jm.doc  
121200a

cc: Catherine A. Reardon, Director, Division of Occupational Licensing  
Dr. Dave Logan, Chair, Board of Dental Examiners  
Jennifer McElwain, Licensing Examiner

• Make Copy and give original to (H) Records.



**Administrative Regulation  
Review Committee**

**SIGN-IN**

Official Business

Date: 01/30/01

PLEASE PRINT

**Subject of Meeting**  
Board of Pharmacy Regulations on Collaborative Practice Agreements

Pg \_\_\_\_\_ of \_\_\_\_\_

NAME	ADDRESS (MAILING & ZIP)	Phone	Representing	Do you want to testify?
✓ Lin Carey Bynne	P.O. Box 101185 Anchorage 99570-1185	563-8480	AK Pharmaceutical Assn	yes
✓ PROSHAFFER	1501 TAYLOR AVE SW <sup>RENTON WA</sup> <del>SEATTLE</del> 98055	425-229-7171	WA STATE PHARMACIST ASSOCIATION	yes
✓ Mark Boliver	19725 Highland Ridge Dr. Eagle River <sup>99571</sup>	694-9725	Pharmacist - AK Pharmaceutical Assn	YES
✓ Rob Miller	P.O. Box 671167, Chugiak AK	688-0545		
✓ <del>Elizabeth Courney</del>	25740 BERRYHILL RD E.R.	694-5482	PHARMACEUT - NORTH UNCLINICAL	YES
✓ GARY Givens	19638 DELPHIN Circle Eagle River 99571	729-2126	AK Pharmaceutical Association	Yes
✓ Cindy Andet	10637 Horizon Drive Juneau	586-5841	AK Pharmaceutical Assoc	YES
✓ Catherine Pearson	Box 110806 Juneau 99811	465-2550	Dept. of Community & Economic Dev Div of Occupations	yes
✓ Debra Stover	Box 110806 Juneau 99811	465-2589	DCEP Occupations	no

THE  
FOLLOWING  
DOCUMENT(S)  
ARE  
POOR  
ORIGINAL  
COPIES

# Patients get break on drugs

■ **PHARMACIES:** Prescriptions such as contraceptives could be dispensed quickly without a visit to a doctor.

By ANN POTEPA  
Anchorage Daily News

Despite concerns from the state medical and dental boards, the Board of Pharmacy unanimously agreed to allow Alaskans to pick up emergency contraceptives and other prescription drugs from pharmacies without first seeing a physician.

Pharmacists at the board meeting Friday said this regulation change will help patients keep on top of certain health concerns by seeing a pharmacist and filling prescriptions between doctor's visits.

"It's hard to get in to your doctor sometimes," said Cindy Bueler, a pharmacist on the board. "It's expensive."

The new regulation allows a physician to sign a collaborative agreement with a pharmacist to dispense certain medications without a doctor's visit. Each agreement must be approved by the Pharmacy Board.

This arrangement isn't new; other states such as Washington have it. Applications for this new approach could include dispensing flu shots, helping patients manage asthma and diabetes or obtain emergency contraceptives, the board said.

The proposal drew almost 70 public comments. The majority discussed emergency contraceptives and agreed with allowing collaborative agreements for prescribing them, Buel-

*See Back Page.* PHARMACIES

*Continued from A-1*  
er said. Dr. Colleen Murphy, an Anchorage obstetrician and gynecologist, has pushed for this regulation change to give women another option to avoid pregnancy and control the size of their families.

"And it's all about access in a timely manner," she said Friday. Emergency contraception is not the recently approved abortive tool RU-486. It is a contraceptive that usually prevents pregnancy if taken 72

hours after sexual intercourse; the pills are more effective if taken within 12 hours, local doctors said.

The Alaska State Medical Board and the Board of Dental Examiners wrote letters to the Pharmacy Board saying they were concerned about the regulation change.

"The Board of Dental Examiners is unanimously opposed to the proposed changes," the board's letter stated. The collaborative agreements

would, in effect, give pharmacists the ability to practice medicine or dentistry, the letter said, and physicians don't have the statutory authority to give that ability to anyone who lacks the proper licensing. The Alaska State Medical Association wrote a letter expressing similar concerns about inadequate authority.

In a preliminary opinion, the Department of Law has said these agreements are within the pharmacist's scope

sibly as long as a year. Stovern said.

The Medical Board expressed concern that these collaborate agreements would fragment patient care, according to written comments signed by Dr. Sarah Isto, board chairwoman. The board said it might support collaborative agreements only for emergency contraception or other drugs requiring immediate use.

Stovern said Friday that

of practice, said Debora Stovern, licensing examiner with the Division of Occupational Licensing. The Department of Law will review the regulation change again, now that the Pharmacy Board has approved it.

If state lawyers find no fault with the change, the regulation goes next to the lieutenant governor's office for signature and a 30-day waiting period. The process could take as little as two months, or pos-

other boards can consider applying their own regulations to affect how collaborative agreements are handled in the state. The topic isn't listed in the medical board's agenda for next Thursday meeting on Friday.

"I don't see this as some big conflict between the boards," Isto said. "Boards differ in their opinions."

■ Reporter Ann Potempa can be reached at apotempa@adn.com or 257-4581.

**PHARMACIES:** *Rule still must be OK'd by lawyers,  
lieutenant governor*

December 6, 2000

Kurt West, Regulations Specialist  
Division of Occupational Licensing  
Post Office Box 110806  
Juneau AK 99811-0806

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Sarah A. Isto, MD.  
Chair, Alaska State Medical Board

xc: Margaret D. Soden, RPh, Chair  
Board of Pharmacy

**AK STATE MEDICAL BOARD LETTER**



## ALASKA PHARMACEUTICAL ASSOCIATION

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January 17, 2001

Representative Lesil McGuire  
Chair,  
Joint Administration Regulation and Review Committee  
Room 418  
State Capitol  
Juneau, Alaska 99801-1182

Dear Representative McGuire:

The Alaska Pharmaceutical Association, a statewide professional society of pharmacists, supports the proposed changes in Alaska State Pharmacy regulations to authorize physician-pharmacist collaborative drug therapy management. While the proposed change was drafted and introduced by the State of Alaska Board of Pharmacy, the AKPhA supports the regulation as a tool to assist the State in providing an efficient, cost effective use of scarce health care resources.

The proposed regulations authorize the implementation of voluntary physician-pharmacist agreements, *dictate strict adherence to approved protocols* within the scope of the prescriber's practice, specialized training as defined by the protocols, and ongoing documentation and quality assurance activities. We believe there are *limited circumstances* in which such agreements would improve patient access to therapeutic medications. The fall influenza vaccine programs held at various retail pharmacies is an example of literally thousands of adult immunizations in our state which occurred due to the convenience, access and low cost to our population.

Enclosed is literature that supports collaborative drug therapy as well as a list of the 30 other states where such agreements have been successfully implemented. We believe the proposed pharmacy regulations are a clarification of the authority currently provided by the Alaska Pharmacy Statutes and fully support their implementation.

Sincerely,

Erin Carey Byrne,  
Executive Director

---

*E-mail: [akphrmcy@alaska.net](mailto:akphrmcy@alaska.net)*

P.O. Box 101185 • Anchorage, Alaska 99510 • (907) 563-8880 • Fax: (907) 563-7880

**AK PHARMACEUTICAL ASSOC  
LETTER**

Pharmacists Finding Solutions Through Collaboration

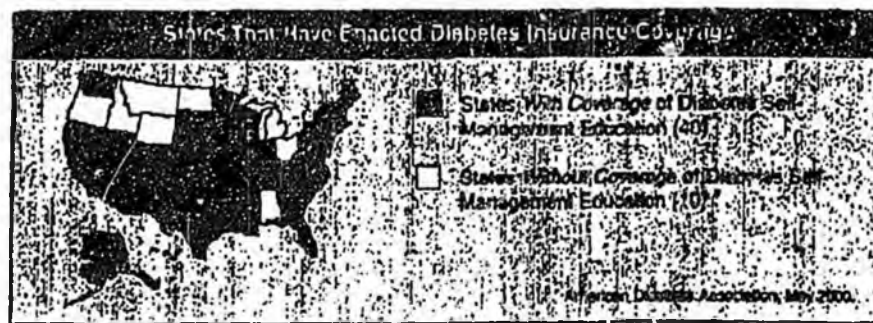
## Pharmacists Finding Solutions Through Collaboration

*continued*



### Disease State Management — Pharmacists Can Play a Key Role

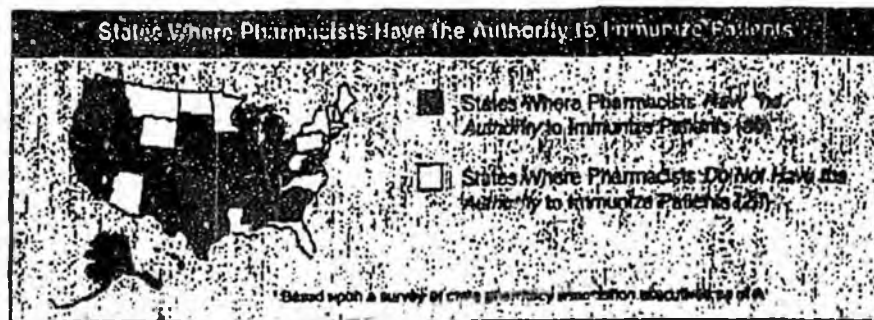
- ▶ Disease state management contains the costly progression of chronic disease and improves the patient's quality of life. It links all individual components of the health care system to offer patients with chronic diseases such as asthma, diabetes, depression, and high blood pressure, a continuous, coordinated process that seeks to manage and improve their health status over the entire course of the disease.
- ▶ 40 states have enacted legislation requiring insurance plans to cover self-management education for patients with diabetes. Many more states have introduced similar legislation this year.



- ▶ In Tennessee, Pennsylvania and other states, pharmacists are listed among the health professionals who may provide and receive payment for diabetes education and self management services.

### The Pharmacist and Immunization Services

- ▶ 30 states allow pharmacists to administer immunizations.
- ▶ Pharmacists can provide easy access to immunizations for patients of all ages by offering a large network of providers with extended business hours.
- ▶ Pharmacists can educate their patients and motivate them and their family members to be immunized.
- ▶ Pharmacists not trained to immunize can facilitate immunizations by hosting other health care professionals who administer immunizations.



### Pharmacists as Consultants to Physician Groups

- ▶ Increasingly, pharmacists are in demand by large physician group practices to perform highly specialized medication management services such as:
  - ▶ Develop prescribing guidelines
  - ▶ Manage and coordinate pharmaceutical care
  - ▶ Establish specialty clinics
  - ▶ Monitor and improve drug therapy for certain high-risk patients

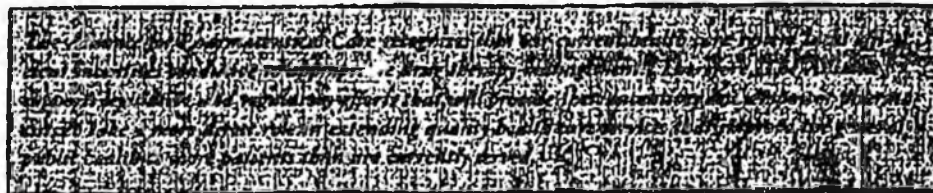
PA, JPPS  
to  
Improve  
Health  
Outcomes

Pharmacists Finding Solutions Through Collaboration

### Pharmacists Finding Solutions Through Collaboration



Pharmacists are responding to the rapid evolution in health care by contributing their expertise in an ever-increasing number of patient care and medication management areas that states view as opportunities for efficient, cost-effective use of scarce health care resources.



Such quality health care services include:

#### Collaborative Drug Therapy Management (CDTM)

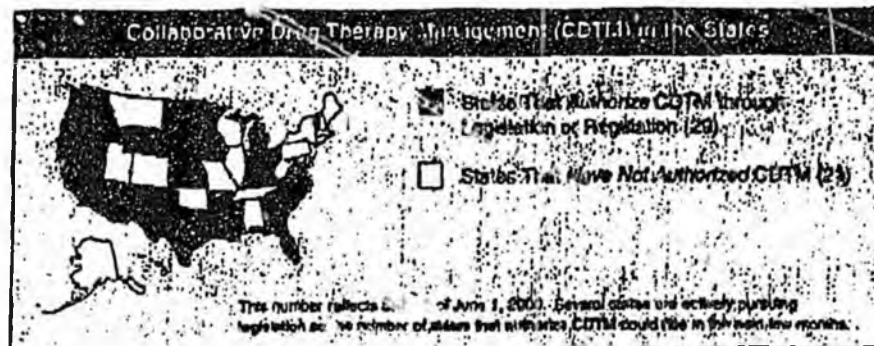
New models in health care are emerging that can help address patients' unmet needs and improve patient care by involving other key members of the health care team. Drug therapy decision-making and management is evolving into an approach to care that is coordinated collaboratively by pharmacists, physicians, other health care professionals, and the patient. Thirty years of research has shown that pharmacist intervention improves patient outcomes. Thus, 29 states currently allow physicians and pharmacists to enter into voluntary written agreements to manage the drug therapy of a patient or group of patients. Many other states are currently developing or reviewing proposals to provide for pharmacist/physician collaborative practice agreements.

#### Advantages of CDTM:

- ▶ Saves money by reducing physician office visits.
- ▶ Reduces delays in modifying drug regimens.
- ▶ Increases patient adherence to their drug therapy plan.
- ▶ Increases the likelihood that expensive drug therapy problems will be averted through early detection.

#### CDTM Activities Include:

- ▶ Assisting physicians to improve medication management and continuity of care;
- ▶ Selecting, initiating, modifying, continuing, discontinuing, and monitoring a patient's drug therapy;
- ▶ Ordering, performing, and interpreting medication-related laboratory tests;
- ▶ Assessing patient response to therapy;
- ▶ Counseling and educating a patient on medications; and
- ▶ Administering medications



Partners in Improving Health Outcomes

**American Pharmaceutical Association  
States with Some Form of Collaborative Drug Therapy Management (CDTM)  
As of September 2000**

Total number of states with some form of CDTM: 30  
Total number of states with statutes authorizing some form of CDTM: 26  
Total number of state with regulations (only) authorizing some form of CDTM: 4

**Statutory Authority (26 States):**

- Arizona (new law)
- Arkansas
- California
- Florida
- Georgia (new law)
- Hawaii
- Indiana
- Iowa (new law)
- Kansas
- Kentucky
- Michigan
- Minnesota
- Mississippi
- Nebraska
- Nevada
- New Mexico
- North Carolina (new law)
- North Dakota
- Ohio
- Oregon
- South Carolina
- South Dakota
- Texas
- Virginia
- Washington
- Wyoming (new law)

**Board of Pharmacy Regulations (4 States):**

- Idaho
- Louisiana
- Tennessee
- Vermont

**Notes:**

The definition of "collaborative drug therapy management" varies by State.

Several additional states are currently developing or reviewing proposals to recognize some form of collaborative drug therapy management arrangements.

Collaborative Drug Therapy may include, but is not limited to:

- Initiating, modifying, and monitoring a patient's drug therapy
- Ordering and performing laboratory and related tests
- Assessing patient response to therapy
- Counseling and educating a patient on medications

JAN-11-2001 11:06 FROM:APHA

2026383793

TO:907 563 7880

P.006

- **Administering medications**

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<sup>1</sup> In addition to the 26 states listed, the Territory of Guam also has statutory authority for collaborative practice.

# Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

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December 13, 2000

Honorable Deborah B. Sedwick  
State of Alaska  
Department of Community and  
Economic Development  
PO Box 110806  
Juneau, Alaska 99811-0806

Transmitted by Fax: 907-465-2974

Attention: Kurt West

RE: Written Comments on Proposed Board of Pharmacy Regulations Noticed October 16, 2000

Dear Commissioner Sedwick:

The Alaska State Medical Association (ASMA) represents Alaska's patients and the physicians who care for them. The purpose of this letter is to comment on the regulations proposed by the Board of Pharmacy noticed on 10/16/00. ASMA will limit its commentary to proposed section 12AAC 52.240 and 12AAC 52.250.

In general, it is ASMA's opinion that insufficient statutory authority exists to adopt 12AAC 52.240 and 12AAC 52.250. Additionally, these proposed sections would also change the regulation of the practice of medicine by allowing a physician to delegate a duty. The Board of Pharmacy does not have the jurisdiction to do so.

The statutory authority for both of these sections as listed in the proposed regulation is AS 08.80.030 and AS 08.80.480. AS 08.80.030 gives the general authority to the Board of Pharmacy. Presumably, the cite relied upon is the general authority to adopt regulations at AS 08.80.030(b)(4). This section does not address collaborative arrangements with any practitioner authorized under AS 08 to prescribe drugs.

AS 08.80.480 is the "Definition" section of the Pharmacy Act. There is no provision that refers to collaborative arrangements with any practitioner authorized under AS 08 to prescribe drugs. Because the statutory authority listed is for the entire section, one can only surmise as to which subsection is being relied on. Presumably, that subsection is AS 08.80.480 (27), which defines the term "practice of pharmacy." Again, nothing in this subsection pertains to collaborative arrangements with any practitioner authorized under AS 08 to prescribe drugs. One can only guess that the collaborative arrangements would fall under the general rubric of a "prescription drug order." ASMA asserts that this is an inappropriate and illegal expansion of the law's intent by regulatory fiat.

**AK STATE MEDICAL ASSOC.  
LETTER**

Honorable Deborah B. Sedwick  
December 13, 2000  
Page 2

Given this absence of direct statutory authority, ASMA asserts that such a change as proposed can only be enacted by the passing of a new law by the Legislature which specifically authorizes such collaborative arrangements. Furthermore, any such law would need to change the practice acts for all practitioners authorized to prescribe drugs under AS 08 to allow such a delegation as is proposed under 12AAC 52.240. Additionally, it would also have to be either drug specific; or provide for a determination as to which drugs would be allowed to be prescribed and dispensed in this manner be made by all of the regulatory boards for the practitioners authorized to dispense. The Pharmacy Board needs the official consultation from other boards such as the State Medical Board. The criteria for the protocols and the collaborative arrangement would also need to be developed in more detail than that found in 12AAC 52.240.

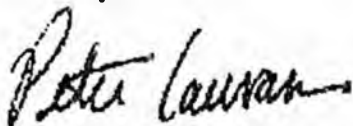
Proposed 12AAC 52.240 (b) (5) indicates that any protocol must include a list of the types of patients eligible to receive drugs under a collaborative arrangement. This criterion is broad enough to allow persons to receive drugs who are not patients of the collaborating practitioner. Two important issues are raised by this situation. First, it's possible for a person to receive a prescription without being seen by a physician. This is not good patient care. Second, such a situation would provide for problematic liability issues. Issues of vicarious liability are raised for the collaborating physician. Such issues can lead to professional liability insurance coverage issues for physicians and most likely would lead to increased professional liability premiums. The negative impact of both circumstances is obvious.

Again, ASMA recommends that the proposed regulations subject of this letter not be adopted because:

1. insufficient statutory authority exists;
2. the regulatory "reach" to other licensed professions (e.g., physicians) is beyond the authority of the Pharmacy Board; and
3. such major changes in the scope of practice for pharmacists and the delegation of practice responsibility (prescribing drugs) is more appropriately in the domain of the Legislature.

We suggest you seek legislation in order to make the major changes that you propose. Such a major change in scope of practice should not be accomplished by a regulatory fiat based on questionable, if not, non-existent statutory authority.

Sincerely,



By: Peter Lawrason, MD, President

For: Alaska State Medical Association

JJJ/