

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**State Pharmacy Boards' Oversight of
Patient Counseling Laws**



**JUNE GIBBS BROWN
Inspector General**

**August 1997
OEI-01-97-00040**

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

To assess State pharmacy boards' oversight of State patient counseling laws.

BACKGROUND

MISMEDICATION AS A NATIONAL PROBLEM

Adverse drug reactions associated with the misuse of prescription drugs are widespread. They reduce the quality of health care received by millions of people. They also add as much as \$100 billion a year to health care costs.

Pharmacists can help address this problem--by serving as a last line of defense to identify and correct prescription errors and by providing patients with oral and written information to improve their understanding and use of prescription drugs. This patient education role has been of longstanding interest to The Food and Drug Administration (FDA) and is central to a public-private prescription information program recently approved by the Secretary of the Department of Health and Human Services (HHS).

STATE PATIENT COUNSELING LAWS HAVE QUESTIONABLE EFFECTS

In 1990, Congress required that pharmacists offer to counsel Medicaid beneficiaries who present prescriptions and that States establish counseling standards. Nearly all States responded by passing patient counseling laws that extend to all patients, not just Medicaid beneficiaries. They look to State pharmacy boards to oversee compliance with the laws.

Recent survey results suggest that the offer to counsel often is not extended. Worse yet, investigations conducted by "shoppers" pretending to be patients reveal that pharmacists often fail to warn patients about drug interactions that could be harmful or even fatal. Our inquiry, based primarily on a survey of State pharmacy boards, focuses on the performance of the boards in ensuring compliance with patient counseling laws.

FINDINGS

State pharmacy boards have played an active role in explaining and urging pharmacist compliance with State patient counseling laws.

During the past year, 38 of 46 responding boards conducted educational efforts directed to pharmacists.

The boards have carried out three major types of educational activities. They include: (1) the distribution of newsletters, (2) the presentation of information at professional association meetings, and (3) the provision of information during inspection visits.

However, the boards' enforcement of the counseling laws has been minimal.

They have made little use of "shopping" visits, whereby board representatives pose as patients to assess compliance with counseling requirements. In the past year, only 17 of 46 responding boards made such visits. Generally, they were made only to pharmacies against which a complaint had been lodged.

They have relied on inspection visits as the major means of enforcement. Such visits are conducted with widely varying degrees of frequency. At best they offer limited opportunities for assessing the extent and adequacy of counseling.

They have taken few final, formal disciplinary actions involving violations of patient counseling laws. Of the 354 actions taken during the past year by 23 reporting boards, 208 (59 percent) were in just 3 States.

The boards identified major obstacles to the successful implementation of patient counseling laws.

ECONOMICS OF PHARMACY PRACTICE. About three-fourths of the boards noted as a major obstacle the limited reimbursement for counseling services; about one-half noted the lack of pharmacy owners' commitment to counseling. Workload pressures on pharmacists often too great to allow for routine counseling.

LIMITED PATIENT DEMAND. About 60 percent of the boards underscored the lack of patient knowledge about the patient counseling requirements. Patients often reluctant to spend the additional time counseling would require.

LACK OF RESOURCES FOR ENFORCEMENT. Cited by close to one-half of the boards as a major obstacle. Insufficient staff support, especially for labor intensive "shopping" investigations. Complaints about having responsibility for enforcing Federal Medicaid counseling requirements without additional funding.

RECOMMENDATIONS

The HHS Secretary and the FDA are committed to a public-private prescription information program that by the year 2000 will result in at least 75 percent of the individuals receiving new prescriptions being given useful patient written information. The Health Care Financing Administration (HCFA) is committed to Federal-State efforts that will result in full adherence to Medicaid patient counseling requirements.

Pharmacy boards, through their oversight efforts, have a vital role in ensuring that progress is made in providing individuals with useful written and oral information. Our review indicates that there is much room for progress in State oversight efforts and that

major obstacles impede the integration of counseling into pharmacy practice. We offer two sets of recommendations intended to address this situation--one to FDA, the other to HCFA.

The FDA should collaborate with State pharmacy boards to collect survey data on the usefulness of written information offered to patients receiving new prescriptions.

Pharmacy boards, in concert with FDA, could conduct "shopping" efforts to a sample of pharmacies to determine the extent and type of information being offered to patients. A joint effort of this kind would help FDA carry out its responsibility to measure progress being made in offering "useful" written information to patients. At the same time, it would facilitate State board oversight of counseling law provisions governing the provision of both oral and written information.

The HCFA should facilitate State efforts to enforce the Medicaid patient counseling mandate.

Working in partnership with the States and the above-noted HHS agencies, HCFA could take the following initiatives:

DEVELOP AND ASSESS STATE PROGRESS TOWARD A PATIENT COUNSELING PERFORMANCE OBJECTIVE. This objective could resemble the year 2000 objective noted above. The States' annual drug utilization review reports could reflect progress made in meeting it.

DEVELOP GUIDELINES ON STATE OVERSIGHT OF THE FEDERAL PATIENT COUNSELING MANDATE. Such guidelines, incorporating best practices currently being carried out by the States, could help State boards in developing cost-effective enforcement approaches.

COMMENTS ON THE DRAFT REPORT

Within the Department, we solicited and received comments on the draft report from FDA, HCFA, the Health Resources and Services Administration (HRSA), and the Assistant Secretary for Planning and Evaluation (ASPE). From external organizations, we requested and received comments from the National Association of Boards of Pharmacy, the Citizens' Advocacy Center, Public Citizen's Health Research Group, the American Pharmaceutical Association, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the American Society of Health-System Pharmacists. We include the complete text of comments in appendix C. Below we summarize the major thrust of the comments on our recommendations and, in italics, offer our responses. We made a number of minor edits in the report in response to comments.

FDA, HCFA, HRSA, AND ASPE COMMENTS

The FDA, HCFA, and ASPE concurred with our recommendations. *In our draft report, we suggested that one initiative that HCFA could take in facilitating State efforts to enforce the Medicaid patient counseling mandate would be to "facilitate the convening of a national symposium on oral counseling by pharmacists." In this final report, we have eliminated that suggestion because pharmacy associations have decided to sponsor such a symposium in September 1997. We still suggest, however, that HCFA pay careful attention to the issues raised in the symposium and that it exert leadership in examining and even showcasing constructive ways of addressing the major obstacles to patient counseling that we identified in this report.*

The HRSA did not comment specifically on the recommendations, but it noted that the draft report made it appear that it was the responsibility of the State pharmacy boards to enforce the Federal Medicaid patient counseling requirement. *We modified the introductory text to clarify that States typically have relied upon the boards as the enforcement arm for both Federal and State counseling laws.*

EXTERNAL ORGANIZATIONS' COMMENTS

These comments serve as an important complement to our report. They add useful perspective, especially with respect to the obstacles to patient counseling. The associations tend to emphasize the need for Federal initiatives to address these obstacles (especially with respect to the economics of pharmacy practice) while more generally expressing their concern about any broadening of the Federal role. The consumer-based organizations call for stronger Federal action in ensuring that patients are adequately informed. *We are sensitive to the scope of the obstacles inhibiting oral counseling by pharmacists and to the primary role of State government in enforcing existing counseling laws. At the same time, we must reemphasize that our survey reveals that the enforcement of Federal and State oral counseling laws has been minimal. It is vital, we believe, for both levels of government to give greater attention to the implementation of these laws and to support "shopping" and other techniques toward that end.*

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INTRODUCTION

PURPOSE

To assess State pharmacy boards' oversight of State patient counseling laws.

BACKGROUND

Mismedication as a National Problem

Mismedication is a major national problem. It contributes to adverse drug reactions that severely impact the quality of health care received by millions of persons, particularly the elderly.¹ It also adds greatly to health care costs. Costs associated with the waste in misused drugs and the results of not receiving intended therapy have been estimated to account for as much as \$100 billion a year.²

Patient failure to comply with a prescribed drug regimen is one factor responsible for this problem. Studies have shown that noncompliance rates average between 30 and 50 percent.³ But there are also other important contributing factors, such as the inadequate prescribing and dispensing of drugs.⁴

Pharmacists as Counselors

In hospitals and nursing homes, pharmacists, working collaboratively with physicians, have long played important clinical roles. In community pharmacies, the barriers to such roles have been imposing and the practice of clinical pharmacy has been less pronounced.⁵ But with the advances in computer technology and software, community pharmacists have ready access to drug product information that can be helpful to patients. In many cases, they also have access to patient profile information that can help guide pharmacist counseling of patients.

Thus, pharmacists are in a key position to help address the mismedication problem noted above. In one sense, they can serve as a last line of defense, to identify and correct any prescription errors at the point of dispensing. In another, they can act in a proactive manner as a part of the patient care team to foster better patient understanding and use of prescription drugs.⁶ Such a role is in accord with the Food and Drug Administration's longstanding efforts to increase patient information about prescription drugs. It is also in accord with the prescription information action plan recently developed by a broadly based task force and approved by the Department of Health and Human Services (see appendix A).

State Patient Counseling Laws

In 1990, Congress underscored the counseling role of pharmacists by including it as one of the components of the Drug Utilization Review requirements it incorporated into the Medicaid program. It stipulated that pharmacists must offer to counsel each Medicaid beneficiary who presents a prescription and that State governments must establish standards for the counseling of these individuals.⁷

Nearly all States responded by enacting patient counseling laws that applied not only to Medicaid beneficiaries, but to all consumers. The scope of the laws is limited. For instance, in most States an offer to counsel can be extended in a written form handed to the patient by a pharmacy technician. Nevertheless, the laws have served to heighten the professional roles and responsibilities of community pharmacists. The States typically have given the responsibility of enforcing the laws to State Boards of Pharmacy, the entities responsible for licensing and, where necessary, disciplining pharmacists.

STATE PATIENT COUNSELING LAWS	
	States
Delivery	
Offer must be made verbally	17
Counseling, when performed, must be face-to-face by pharmacist	46
Scope	
Inclusive of all ambulatory patients	42
Inclusive of refills	17
Content	
Mandate patient profiles	43
Mandate minimum set of information	9

Source: Derived from information compiled by the National Association of Boards of Pharmacy, 1996.

Questionable Effects of the Laws

The actual effects of the laws in fostering useful patient counseling remains questionable. For instance, a July 1994 survey conducted by the National Association of Boards of Pharmacy indicated that patients reported offers to counsel only 38 percent of the time.⁸ Another survey conducted at about the same time by the New York City Office of the Public Advocate found that only 42 percent of independent community pharmacists and 27 percent of chain pharmacists extended offers to counsel.⁹

One of the most troubling and widely publicized signs that the laws may not be having the intended effect was provided in August 1996 in a national news magazine under a cover story entitled: "Danger at the Drugstore: Pharmacists are your last defense against risky drug interactions. Too many are blowing it."¹⁰ The story was based on the efforts of reporters who posed as consumers seeking to fill combinations of prescriptions which would be dangerous or even deadly if taken together. In the 245 pharmacies visited in 7 cities, more than one-half of the pharmacists failed to warn the reporters/consumers of the risks associated with mixing the drugs. A similar study conducted earlier in the District of Columbia by researchers at Georgetown University Medical Center found that more than 30 percent of the pharmacists filled the prescriptions without any warning.¹¹

This Inquiry

This inquiry focuses on the role of State pharmacy boards in overseeing compliance with State patient counseling laws. It is based on the premise that effective oversight can help foster the intent of the laws. It sets forth the extent and nature of the boards' educational and enforcement efforts, and closes with a review of what board officials regard as major obstacles to successful implementation of the laws.

The information we present comes from three sources. The primary source is a survey we conducted of all State pharmacy boards in the country. We administered the survey from November 1996 through January 1997. We sent questionnaires to 51 boards¹² and received responses from 46 of them, representing a response rate of 90 percent. (The survey results appear in appendix A).¹³ The second source is telephone interviews with board officials in 12 to 15 States. Typically, we initiated these interviews to obtain some elaboration on information provided on a returned questionnaire. Finally, mainly for context, we draw on a review of pertinent reports and literature concerning patient counseling by pharmacists and concerning problems associated with misuse of prescription drugs.

We conducted this inspection in accordance with the Quality Standards for Inspections issued by the President's Council on Integrity and Efficiency.

FINDINGS

State pharmacy boards have played an active role in explaining and urging pharmacist compliance with State patient counseling laws.

- ▶ During the past year, 38 of 46 responding boards (83 percent) have conducted educational efforts intended to help pharmacists understand or carry out the laws.
- ▶ Among these 38 boards, 28 have carried out three or more different types of educational efforts. Typically, they have involved the preparation and distribution of newsletters and other written materials, the presentation of information at professional association meetings, and the provision of information during pharmacy inspection visits.

This educational thrust of the boards is most apparent in the newsletters which they typically send to all pharmacists in their States. Through these newsletters they explain the key elements of the counseling law and remind pharmacists of the importance of counseling and how they might overcome some of the barriers associated with it. A particularly notable example of such educational outreach was an issue of the California board's newsletter. Drawing on information from the California Pharmacists Association and the California Society of Health System Pharmacists, it spelled out how pharmacists in seven different settings "have implemented pharmaceutical care by emphasizing patient counseling and pain management."¹⁴

Through appearances at professional association meetings, the boards get out the same message in a more personal way, with opportunity for give and take. The Texas board was particularly active in this regard, having made during the past year 29 presentations that reached 4,000 pharmacists. The Virginia board held four public forums that addressed how pharmacists' workloads affect their ability to comply with counseling requirements and to prevent dispensing errors. The Arizona board developed and provided for continuing education credit at professional meetings a live 2 to 3 hour program specifically aimed at preventing dispensing errors through patient counseling.¹⁵

Even more personal and direct are the face-to-face exchanges that pharmacy inspectors and pharmacists engage in during the course of board inspections of individual pharmacies.¹⁶ During these inspections, boards are primarily focused on compliance, but at least with respect to the counseling law they also tend to be attentive to the educational opportunity afforded by their visit. They reinforce the intent of the counseling law, answer questions concerning it, and sometimes leave informational materials.

In contrast to the above efforts directed to pharmacists, boards have devoted much less attention to educating patients about the counseling laws. Of 46 responding boards, only 11 (24 percent) undertook any such initiatives during the past year.¹⁷ However, some notable efforts have been made and more are being developed. The New York, Texas

and California boards have prepared information brochures directed to consumers. The Nevada board produced a series of public service announcements. The Louisiana, Ohio, and other boards are preparing informational postings on the Internet. And the Massachusetts board, at this writing, is preparing a guideline that will require all pharmacies to post a sign informing consumers of their right to counseling.

The boards' enforcement of the counseling laws has been minimal.

- ▶ They have made little use of "shopping" visits, whereby representatives of pharmacy boards pose as patients to assess compliance with counseling requirements. During the past year, only 17 of 46 responding boards (37 percent) made such visits--generally only to pharmacies against which a complaint had been lodged.

Shopping visits to pharmacies are an excellent enforcement tool to determine if and how well pharmacists are counseling patients. The Georgetown Medical School, as we noted earlier, used this approach to help draw attention to the fact that pharmacists often do not provide a sufficient front line of protection for patients. The pharmacy boards, however, make little use of this mechanism. Most do not use it at all; most of the others, do so sparingly. In a few cases, legal concerns about entrapment seem to inhibit its use. Much more often, the limited resources available to the board serve as the restraint. Shopping is a labor-intensive activity that can be quite costly if used on other than a highly selective basis.¹⁸

Thus, even among the 17 boards citing some recent experience with shopping, only a few have used the technique in a proactive manner, randomly visiting pharmacies in the State. And even in those cases, relatively few pharmacies were visited.¹⁹ Shopping, to the limited extent it is practiced by the boards, is used essentially as a tool of investigation of pharmacies that are the focus of special concern.²⁰

- ▶ Boards have relied on inspection visits as the primary means of enforcing patient counseling laws. Such visits are conducted with widely varying degrees of frequency among the states and even at best offer limited opportunities for assessing the extent and adequacy of counseling.

During these visits, inspectors must examine many different elements associated with the practice of pharmacy.²¹ They include, among other things, the adequacy of the facility itself, of the records and record-keeping procedures, of the prescription drug inventory, of the compounding practices, and of interactions with patients. The latter involves some tangible elements that can be examined, such as the physical area set aside for counseling or the type of written material distributed. But the dynamics of offering to counsel and then actually counseling are much less conducive to assessment. Pharmacy inspections are usually unannounced, but we are told that once the inspectors appear on site, pharmacy staff tend to be well aware of their presence. Accordingly, one board official noted: "Some of the best counseling in our State goes on when the inspectors are around."

How often the inspectors are around in any particular pharmacy varies greatly from State-to-State. Among 46 reporting boards, 8 (all among the least populated States) indicated that during the past year they had conducted site visits to all of the pharmacies in their State. On the other hand, 7 reported conducting no such visits and 8 (most among the most heavily populated States) reported visits to less than 50 percent of the pharmacies.

- ▶ They have taken few final, formal disciplinary actions involving violations of patient counseling laws. Of the 354 actions taken during the past year by 23 reporting boards, 208 (59 percent) were in just 3 States.

Pharmacy board officials, as we will note below, recognize the substantial constraints that limit the potential effectiveness of the patient counseling laws. Some also appear to believe that too punitive an approach to enforcement could be counterproductive. Whatever the rationales, the data we collected indicate that in most States the boards have taken few if any final, formal disciplinary actions against pharmacists for reasons that relate at least in part to violations of patient counseling laws. Further, of the actions taken, only a small percent have involved anything other than a fine or reprimand.

A number of boards note that while they invoke few if any formal disciplinary actions that concern counseling, they do take informal actions, which serve as warnings to pharmacists who they found were not sufficiently attentive to patient counseling. Such warnings, board officials note, can be an effective way of reminding the pharmacists and the pharmacy managers of the intent of these laws.

The Boards identified major obstacles to the successful implementation of patient counseling laws.

Economics of Pharmacy Practice. The most significant obstacles, according to the boards, is the economic reality of pharmacy practice in environments where payers are squeezing operating margins and pharmacies are consolidating, often as part of large national chains. Thus, about three-fourths of 44 responding boards cited as a major obstacle the limited reimbursement for counseling services and about one-half of 45 boards - the lack of owners' commitment to counseling.²² Making a point reiterated by many of his colleagues in other States, one board official said: "Staffing in corporate pharmacies is simply insufficient to allow routine counseling." The workload pressures on individual pharmacists are simply too great.²³

Limited Patient Demand. The demand side, boards emphasized, must not be overlooked. About 60 percent of 45 responding boards underscored that a major obstacle was a lack of patient knowledge about the counseling requirement; about one-half stressed the lack of a suitable physical area for counseling as a major impediment.

In their comments to us, boards surfaced two other, perhaps more basic factors inhibiting patient demand. One is that many patients tend to overlook the vital importance of drug information and just assume that their physicians and pharmacists will not allow anything bad to happen to them. Another related factor is that patients do not want to spend the

extra time that counseling entails. "The entire counseling process," said one board official, "is new and not within what most patients consider 'traditional practice.' Even when asked, they will refuse."²⁴ Of course, the relatively limited educational outreach efforts of boards (and other entities) do little to change this patient perspective.

Lack of Resources for Enforcement. Finally, boards stressed that insufficient resources are a major factor impeding their enforcement of patient counseling efforts. Close to one-half of 45 responding boards identified it as a major obstacle.²⁵ They stress that they have insufficient staff to engage in the long and tedious process of identifying those pharmacists and pharmacies that are not complying with the counseling laws and, where necessary, accumulating enough evidence to serve as the basis for disciplinary action.

One particularly irksome concern to some boards is that without any additional funding they are expected by the State Medicaid agency to serve as the chief entity responsible for enforcing the Federal counseling requirement directed to Medicaid beneficiaries. Boards note that while the Medicaid agency gets Federal reimbursement for a share of their costs, none of that reimbursement gets passed on to them.

On the other hand, a few officials noted developments that may contribute to increased interest attention to counseling. One is the acceleration of automation efforts that can free up more pharmacist time for counseling. Another is the threat imposed by large malpractice settlements in cases involving drug dispensing errors.²⁶

RECOMMENDATIONS

There is a substantial Federal interest in effective implementation and enforcement of patient counseling laws. The HHS Secretary and the FDA are committed to public-private efforts that will result by the year 2000 in at least 75 percent of the individuals receiving new prescriptions being given useful written information.²⁷ The HCFA is committed to Federal-State efforts that will result in fulfilling the intent of the Medicaid patient counseling requirements established by Congress.

At the State level, the pharmacy boards serve as the main body responsible for overseeing pharmacists' compliance with the Federal and State patient counseling laws. Our review indicates that there is much room for improvement in State oversight efforts and that there are major obstacles to the full-fledged integration of patient counseling into pharmacy practice. We offer two sets of recommendations intended to help address this situation. One is directed to the FDA; the other to HCFA. They follow:

The FDA should collaborate with State pharmacy boards to collect survey data on the usefulness of written information offered to individuals receiving new prescriptions.

The FDA is completing a survey assessing the extent to which patients are being given written information when receiving new prescriptions. To assess the "usefulness" of the information being offered, it will be conducting another survey. This survey effort offers a prime opportunity for the FDA and pharmacy boards to work collaboratively to foster mutual interests in patient counseling.

In particular, we suggest that a number of boards, working in concert with FDA, conduct "shopping" efforts to a sample of pharmacies to determine the extent and type of counseling being offered to patients. In conducting these visits, the boards could obtain information that would help them ensure compliance with their States' own patient counseling laws and at the same time collect and send to FDA the written information that pharmacists provided to the "shopper." The FDA could then assess the usefulness of this information in accord with the criteria established in the prescription information action plan approved by the HHS Secretary (see appendix B).

The prospects for a successful cooperative effort of this kind would appear to be good. Pharmacy boards have already been working with FDA in helping to enforce FDA regulations. Moreover, many board officials have been commissioned by FDA. This entitles them with access to communications and information that would otherwise be considered confidential.

The HCFA should facilitate State efforts to enforce the Medicaid patient counseling mandate.

The lead role in carrying out this mandate is with the States. But given the partnership nature of the Medicaid program, HCFA, the above-noted HHS agencies, and the State governments (including State Medicaid agencies and State pharmacy boards or their national federation) should work together cooperatively in fostering their common interest in patient counseling. Toward that end, we suggest two initiatives which HCFA could undertake:

Develop and assess State progress toward a patient counseling performance objective. Ideally, this objective would closely parallel the performance objective which the Secretary has already endorsed calling for 75 percent of patients by the year 2000 to receive useful written information and which the FDA is monitoring. (Given the nature of the Federal mandate, however, it probably should address oral as well as written information.) The HCFA could amend its Drug Utilization Review annual report instructions to State Medicaid agencies to require State updates, based on survey data, of progress being made in meeting the objective. At present, those instructions are much more general.

Develop guidelines on State oversight of the Federal patient counseling mandate. The authorizing statute calls upon the States to develop standards for counseling individuals. Federal guidelines governing how States ensure enforcement of the standards could facilitate State progress in meeting them. If based on input from and best practices currently being carried out by the States, these guidelines could be of considerable value to State pharmacy boards as they consider how to carry out their enforcement efforts in the most cost-effective manner possible.

COMMENTS ON THE DRAFT REPORT

Within the Department, we solicited and received comments on the draft report from FDA, HCFA, the Health Resources and Services Administration (HRSA), and the Assistant Secretary for Planning and Evaluation (ASPE). From external organizations, we requested and received comments from the National Association of Boards of Pharmacy, the Citizens' Advocacy Center, Public Citizen's Health Research Group, the American Pharmaceutical Association, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the American Society of Health-System Pharmacists. We include the complete text of comments in appendix B. Below we summarize the major thrust of the comments on our recommendations and, in italics, offer our responses. We made a number of minor edits in the report in response to the comments.

FDA, HCFA, HRSA, AND ASPE COMMENTS

The FDA, HCFA, and ASPE concurred with our recommendations. *In our draft report, we suggested that one initiative that HCFA could take in facilitating State efforts to enforce the Medicaid patient counseling mandate would be to "facilitate the convening of a national symposium on oral counseling by pharmacists." In this final report, we have eliminated that suggestion because pharmacy associations have decided to sponsor such a symposium in September 1997. We still suggest, however, that HCFA pay careful attention to the issues raised in the symposium and that it exert leadership in examining and even showcasing constructive ways of addressing the major obstacles to patient counseling that we identified in this report.*²⁸

The HRSA did not comment specifically on the recommendations, but it did note that the draft report made it appear that it was the responsibility of State pharmacy boards to enforce Federal Medicaid statutes. *We modified our introductory discussion to make it clear that States typically have chosen to rely on the boards as their enforcement arm. Further, in both the draft and final report our discussion concerning the lack of resources for enforcement addresses State board concerns that State Medicaid agencies look to them to enforce the Federal patient counseling law without sharing any of the Federal funds they receive under the Medicaid program.*

EXTERNAL ORGANIZATIONS' COMMENTS

These comments serve as an important complement to our report. They add useful perspective, especially with respect to the obstacles to patient counseling. The associations tend to emphasize the need for Federal initiatives to address these obstacles (especially with respect to the economics of pharmacy practice) while more generally expressing their concern about any broadening of the Federal role. The consumer-based organizations call for stronger Federal action in ensuring that patients are adequately

informed. We are sensitive to the scope of the obstacles inhibiting oral counseling by pharmacists and to the primary role of State government in enforcing existing counseling laws. At the same time, we must reemphasize that our survey reveals that the enforcement of Federal and State oral counseling laws has been minimal. It is vital, we believe, for both levels of government to give greater attention to the implementation of these laws and to support "shopping" and other techniques toward that end.

APPENDIX A

SURVEY OF STATE PHARMACY BOARDS

Response Rate to the Survey

Number of States Surveyed*	51
Number of Responses	46
Response Rate	90%
*Includes the District of Columbia Nonrespondents were: the District of Columbia, Kansas, Maine, Michigan and South Carolina.	

Survey Questions and Responses

In your view, how informed do pharmacists tend to be of their obligations under your State's patient counseling requirement?

	Number of States	Percent
Well Informed	24	53
Very Well Informed	11	24
Moderately Informed	10	22
Total	45	100
Percentages may not total to 100 due to rounding.		

Within the past year, has your Board conducted any educational efforts intended to help pharmacists understand and/or carry out the State's patient counseling requirements?

	Number of States	Percent
Yes	38	83
No	8	17
Total	46	100

If yes, please check (and briefly explain) any of following educational efforts that apply.

	Number of States Undertaking Effort	Percent of States
Made information available at on site inspections	33	89
Mailed information to pharmacists	31	84
Made information available at professional association meetings	30	81
Conducted other educational efforts	9	24
Issued media announcements	6	16
Mailed information to patients	5	14
Made information available on the Internet	3	8
Total Number of Efforts Reported	117	
N States Responding = 37 (Multiple responses permitted.)		

Number of Educational Methods Undertaken by States to Help Pharmacists Understand and/or Carry Out Patient Counseling Requirements		
Number of Methods	Number of States	Percent of States
1	2	5
2	7	19
3	18	49
4 or more	10	27
Total	37	100
Percentages may not add to 100 due to rounding.		

Does your State have any continuing education requirements specifically intended to help pharmacists conduct patient counseling?

	Number of States	Percent
No	43	94
Yes	3	7
Total	46	100

Within the past year, has your Board conducted any shopping efforts, whereby individuals pose as patients to assess compliance with patient counseling requirements?

	Number of States	Percent
No	29	63
Yes	17	37
Total	46	100

Within the past year, has your Board conducted site visits of pharmacies to assess their compliance with State pharmacy laws (including patient counseling requirements)?

	Number of States	Percent
Yes	39	85
No	7	15
Total	46	100

If yes, about what percent of pharmacies in the State has your Board visited?

Number of States	Mean	Median	Minimum	Maximum
37	71%	80%	10%	100%

Has your Board conducted other types of proactive enforcement efforts to assess compliance with patient counseling requirements?

	Number of States	Percent
No	29	63
Yes	17	37
Total	46	100

What is the most recent year for which your Board has compiled statistics concerning complaints and disciplinary activities?

	Number of States	Percent
1996	19	54
1995	15	43
1994	1	3
Total	35	100
Years reported were a combination of CY, FY, and YTD. Percentages may not add to 100 due to rounding.		

For that year, please provide the following:

A) Number of Complaints of Any Type Made to the Pharmacy Board:

Number of States	Mean	Median	Minimum	Maximum
30	269	106	6	1576

B) Number of Complaints Involving Possible Violations of Patient Counseling Requirements:

Number of States	Mean	Median	Minimum	Maximum
20	22	12	0	119

What would you say is the primary source of complaints involving possible violations of patient counseling requirements?

	Number of States	Percent
Consumers	28	76
Other	4	11
Law Enforcement	3	8
Pharmacists	2	5
Total	37	100
Percentages may not add to 100 due to rounding.		

For the prior year, please complete the following:

A) Number of Complaints of any Type Made to the Pharmacy Board:

Number of States	Mean	Median	Minimum	Maximum
28	228	89	0	1236

B) Number of Complaints Involving Possible Violations of Patient Counseling Requirements:

Number of States	Mean	Median	Minimum	Maximum
21	15	8	0	84

For the most recent year for which your Board compiled statistics concerning complaints and disciplinary activities, please provide the following:

A) Number of final, formal disciplinary actions taken against licensed pharmacists that were based at least in part on failure to adhere to patient counseling requirements.

Number of States	Mean	Median	Minimum	Maximum
34	7	3	0	80

B) Please indicate the number of such actions that have resulted in revocations, suspensions, fines, reprimands, or other disciplinary actions.

	Number of Actions	Percent
Fines	176	50
Reprimands	129	36
Other	24	7
Suspensions	16	5
Revocations	9	3
Total	354	100
Number of States responding = 23		
Percentages may not add to 100 due to rounding.		

Please indicate how much of an obstacle each of the following represents to effective enforcement of patient counseling requirements:

Categories Ranked by States	Not an Obstacle	Minor Obstacle	Moderate Obstacle	Significant Obstacle	Very Significant Obstacle	Totals
Complexity of the law	19 (42%)	15 (33%)	10 (22%)	1 (2%)	0 (0%)	45 (100%)
Higher priority enforcement issues for the board	7 (16%)	12 (27%)	15 (33%)	7 (16%)	4 (9%)	45 (100%)
Opposition from professional community	12 (27%)	16 (36%)	14 (31%)	3 (7%)	0 (0%)	45 (100%)
Lack of resources	6 (13%)	6 (13%)	12 (27%)	10 (22%)	11 (24%)	45 (100%)
Limited complaints/referrals to the board	9 (21%)	10 (23%)	15 (34%)	10 (23%)	0 (0%)	44 (100%)
Percentages may not add to 100 due to rounding.						

Please indicate how much of an obstacle each of the following represents to pharmacist compliance to patient counseling requirements:

Categories Ranked by States	Not an Obstacle	Minor Obstacle	Moderate Obstacle	Significant Obstacle	Very Significant Obstacle	Total
Lack of commitment from pharmacy owners/management	4 (9%)	5 (11%)	13 (29%)	18 (40%)	5 (11%)	45 (100%)
Underutilization of supportive personnel in pharmacies	6 (13%)	9 (20%)	19 (42%)	9 (20%)	2 (4%)	45 (100%)
Limited reimbursement for counseling services	1 (2%)	4 (9%)	5 (11%)	16 (36%)	18 (41%)	44 (100%)
Inadequate computer software	7 (16%)	22 (49%)	13 (29%)	3 (7%)	0 (0%)	45 (100%)
Insufficient counseling skills of pharmacists	7 (16%)	16 (36%)	19 (42%)	3 (7%)	0 (0%)	45 (100%)
Percentages may not add to 100 due to rounding.						

Please indicate how much of an obstacle each of the following represents to patients who wish to receive pharmacist counseling:

Categories Ranked by States	Not an Obstacle	Minor Obstacle	Moderate Obstacle	Significant Obstacle	Very Significant Obstacle	Total
Lack of patient knowledge about the counseling requirement	2 (4%)	5 (11%)	10 (22%)	22 (49%)	6 (13%)	45 (100%)
Lack of pharmacist availability	1 (2%)	6 (13%)	18 (40%)	18 (40%)	2 (4%)	45 (100%)
Prescription area not conducive to communication between patients and the pharmacist	0 (0%)	6 (13%)	15 (33%)	18 (40%)	6 (13%)	45 (100%)
Insufficient patient access to basic prescription drug information	4 (9%)	16 (36%)	18 (40%)	7 (16%)	0 (0%)	45 (100%)
Percentages may not add to 100 due to rounding.						

APPENDIX B

THE MEDGUIDE EFFORT

For about 30 years, the Food and Drug Administration (FDA) has sought to enable consumers to receive more and better information about the prescription drugs they use. Its first such effort was a requirement that written information be provided that made clear the dangers associated with certain inhalation products. Toward the end of the next decade, it proposed a rule that would have required drug manufacturers to include patient package inserts for 10 classes of drugs. In 1982, the FDA withdrew the proposed regulation in response to concerns about over-regulation.

Throughout the 1980s and into the 1990s, FDA continued to stress the importance of consumer education, particularly through the issuance of written materials that were distributed with the drugs and made clear the best ways to take a drug and any side effects associated with it. It conducted a number of surveys of patients assessing how often they were provided such information about their prescription drugs.

By the mid-1990s, FDA found that the rate at which such information was being provided had increased. But it felt that the progress was not nearly fast or thorough enough, given the continued high incidence of adverse drug events and patient noncompliance with prescribed drug regimens. Further, continued advancement in computer technology, it felt, made the provision of consumer information more efficient and economical than it would have been a decade or two ago.

Thus, in August 1995, it once again proposed a rule entitled, "Prescription Drug Labeling: Medication Guide Requirements." Widely cited as the "MedGuide" requirements, they called for manufacturers to produce written product inserts for certain categories of drugs posing particular dangers, encouraged the preparation and distribution of written information for all drugs, and established performance standards for both the distribution and quality of written information.

As the performance standard for distribution, FDA proposed using the pertinent goal already established by the Public Health Service in the "Healthy People 2000" set of performance goals. The goal set forth is that by the Year 2000 at least 75 percent of the people receiving new prescriptions would be given useful written patient information. For the Year 2006, the goal is 95 percent.

As the performance standard for determining what is "useful" information, FDA identified 7 components which must be satisfactory. They are: scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

In August 1996, Congress, as part of the FDA appropriations bill, included a provision giving private sector groups 120 days to "assess the effectiveness of current private-sector approaches used to provide oral and written information to consumers" and to submit to the HHS Secretary an alternative to FDA's Medguide plan. If an alternative plan that was acceptable to the Secretary was not produced, then FDA would be authorized to proceed in carrying out its MedGuide requirements.

The Secretary appointed the Keystone Group, a private firm, to appoint and develop a steering committee comprised of diverse interests. The 34 member Committee met on numerous occasions and produced its action plan in December 1996. In January 1997, the Secretary approved the plan, which essentially looks to the private sector to foster progress in providing more and better written information about prescription drugs to the public. It sets forth the performance target that action plan will result in "the distribution of useful information to 75 percent of individuals receiving new prescriptions by the year 2000 and to 95 percent by the year 2006. In determining the kind of information that would be regarded as "useful," it supplants FDA's 7 criteria with 11 distinct components.

With respect to oral counseling, the plan makes three recommendations. The first is that State pharmacy boards "continue their efforts to assess the quality of oral counseling provided by pharmacists in all settings in which prescription medicines are provided to ambulatory patients" "This assessment," it adds, "should include the nature and effectiveness of the 'offer to counsel' made to the patient."

The second recommendation is that "a National Symposium on Oral Counseling by Pharmacists about Prescription Medicines be convened in 1997 by pharmacists' groups, including NABP [the National Association of Boards of Pharmacy]. . . The purpose of this conference would be to assess the effectiveness of current oral counseling guidelines . . . and to assist State boards of pharmacy and NABP in enforcing existing guidelines and developing new guidelines, if necessary, for oral counseling."

Finally, the third recommendation is that FDA "should continue to conduct periodic consumer surveys to determine whether consumers are receiving oral counseling when they obtain their prescription medications." It adds that for oral counseling "the appropriate mechanism to assess the quality of the information being provided to consumers by pharmacists, as well as the offer to counsel, should be developed by individual State boards of pharmacy..."

APPENDIX C

COMPLETE COMMENTS ON DRAFT REPORT

In this appendix, we present in full the comments we received on the draft report.



Memorandum

Date: JUL 11 1997

From: Deputy Commissioner for Management and Systems

Subject: FDA Response to OIG Draft Report: "State Pharmacy Boards' Oversight of Patient Counseling Laws," OEI-01-97-00040

To: June Gibbs Brown, Inspector General
Department of Health and Human Services

We have reviewed the OIG Draft Report: "State Pharmacy Boards' Oversight of Patient Counseling Laws," and offer the following comments:

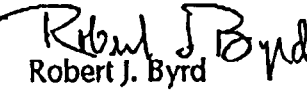
For over thirty years, FDA has sought to enable consumers to receive more and better information about the prescription drugs they use. We have recently conducted the fifth in a series of surveys of both oral and written information being given to consumers with their prescription medications. Our latest survey indicates that the level of verbal counseling is still very low and although written information being given to consumers has increased, only 67% of patients reported receiving written information from their pharmacists.

We strongly agree with your proposal to have the Food and Drug Administration collaborate with state pharmacy boards by collecting data about the usefulness of written information offered to patients by pharmacists. FDA could then assess the usefulness of this information in accord with the criteria established in the Prescription Information Action Plan developed by a diverse steering committee made up of health professionals, consumers, patient advocacy groups, drug information vendors and the pharmaceutical industry. This Plan was accepted by the Secretary on January 13, 1997. This joint effort would help FDA carry out its responsibility to measure progress being made in offering useful written information to patients.

FDA is committed to the public-private sector efforts in Healthy People 2000 where the objective is that at least 75% of individuals receiving new prescriptions be given useful, written information. FDA will continue to facilitate both oral and written information given to consumers by health professionals. Our Office of External Affairs has ongoing efforts to help make consumers and health professionals aware of the importance of this information. One of the new initiatives in this area is focused on providing information to women and encouraging this population to begin a dialogue with their health care professionals about medications.

Page 2 - June Gibbs Brown, IG

We agree with the premise of your Draft Report that encouraging health care professionals to improve their communications with consumers about prescription medicines will improve health outcomes and reduce preventable, medications-related problems. We also encourage activities to increase consumer understanding and awareness of the benefits and availability of written prescription medicine information, and the importance of oral communication between health care professionals and patients.


Robert J. Byrd



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Assistant Secretary
Washington, D.C. 20201

DATE: AUG -4 1997

TO: June Gibbs Brown
Inspector General

FROM: Bruce C. Vladeck *Bruce Vladeck*
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "State Pharmacy Boards'
Oversight of Patient Counseling Laws," (OEI-01-97-00040)

We reviewed the above-referenced report which assesses state pharmacy boards' oversight of patient counseling laws.

Our detailed comments on the report recommendations are attached for your consideration. Thank you for the opportunity to review and comment on this report.

Attachment

Comments of the Health Care Financing (HCFA) on
Office of Inspector General (OIG) Draft Report:
"State Pharmacy Boards' Oversight of Patient Counseling Laws"
(OEL-01-97-00040)

OIG Recommendation

The Food and Drug Administration (FDA) should collaborate with state pharmacy boards to collect survey data on the usefulness of written information offered to patients receiving new prescriptions.

HCFA Response

We defer to FDA for comments on specific initiatives.

OIG Recommendation

HCFA should assist with state efforts to enforce the Medicaid patient counseling mandate.

HCFA Response

We concur. We believe there is an urgency in addressing the problems states are having in their efforts to monitor compliance of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) patient counseling mandate. Problems such as lack of resources, reliance on sporadic pharmacy board inspection visits, and the lack of consumer education on their right to be counseled, have hampered the effectiveness of the pharmacy board/state Medicaid agency oversight of patient counseling laws.

Additional Comments on OIG Suggested Initiatives:

OIG Initiative #1

Develop and Assess state Progress Toward a Patient Counseling Performance Objective

HCFA Response

We concur. HCFA is committed to assisting states in fully adhering to Medicaid patient counseling requirements, and meeting that objective by year 2000. By doing so, at least 75 percent of individuals receiving new prescriptions will be given useful patient written information. We must recognize this objective is not mentioned in the OBRA 1990 law, nor is it mentioned in HCFA regulations. States can only be encouraged to use the

objective as a yardstick to improve the effectiveness of patient counseling each year. HCFA will assist states by amending the Drug Utilization Review (DUR) Annual Report instructions to collect more specific information regarding the compliance, monitoring efforts that have been performed and how effective these efforts have been. Questions concerning the progress of each state in monitoring compliance, as well as the level of compliance in the pharmacies with the counseling requirements, will be included in future report instructions. This information will be shared with states in HCFA's Medicaid DUR Newsletter.

Since many Medicaid beneficiaries read poorly and/or may not understand the need enough to take time reading drug information, it is crucial to have oral counseling standards as well. Also, since most repeat Medicaid drug users are elderly and/or chronically ill or disabled, hopefully high oral standards are attainable due to a traditionally more cooperative clientele and the fact that constant medication is a vital part of their daily routine. Counseling these individuals are the top priority.

OIG Initiative #2

Develop Guidelines on State Oversight of the Federal Patient Counseling Mandate

HCFA Response

We concur. HCFA is committed to Federal-state partnership. Therefore, we will solicit input from states on the practices they find most effective, and distribute this information to all pharmacy boards.

OIG Initiative #3

Facilitate the Convening of a National Symposium on Oral Counseling by Pharmacists

HCFA Response

We concur. Although Federal leadership is necessary in facilitating this meeting, Congress has not appropriated the resources necessary to lead this endeavor. Nevertheless, HCFA is fully committed to assisting state oversight of the counseling requirements, and thereby improving the quality of care of Medicaid patients. We believe including the activities described above will assist us in accomplishing this objective.

AUG 15 1997

TO: Inspector General, DHHS
FROM: Acting Deputy Administrator
SUBJECT: Office of Inspector General (OIG) Draft Report, "State Pharmacy Boards' Oversight of Patient Counseling Laws."
(CIN: OEI-01-97-00040)

In response to an informal request for comments on the subject report, we are providing HRSA's comments as listed below. This report was informally provided to HRSA on July 10, 1997.

GENERAL COMMENTS:

HRSA appreciates the opportunity to review and comment on the subject draft report. The report is timely and provides information on a subject that is of national interest. It is important for health care professionals to communicate with patients about prescription medications to improve outcomes and reduce medication misadventures.

One issue that was not addressed in the report that may serve as a barrier to counseling patients is the need to improve the communication skills of pharmacists. Another issue that was not addressed is the age, gender and culturally-sensitive barriers that exist in providing useful information to patients.

The OIG may want to consider the following published resources as references for inclusion in the draft report:

Manasse HR Jr. Medication use in an imperfect world. 1: drug misadventuring as an issue of public policy. Am J Hosp Pharm. 1989;46: 929-944.

Manasse HR Jr. Medication use in an imperfect world. 11: drug misadventuring as an issue of public policy. Am J Hosp Pharm. 1989;46: 1141-1152.

Johnson JA, Bootman JL. Drug-Related Morbidity and Mortality. Arch Intern Med/vol 155, Oct 9, 1995. 1949-1956.

With regard to the chain of responsibility, the premises of the report are plausible from the Federal perspective, but they look odd from the perspective of a reader in a State government. The draft text presumes that it is the clear duty of State pharmacy boards to enforce Federal Medicaid statutes. There is no direct

duty to do so. Instead, there is an indirect chain of responsibility that must be effectively transmitted from HCFA and a State Medicaid agency to that State's pharmacy board. The draft report should probably clarify this, placing the responsibility on the State Medicaid agency to deputize and fund the pharmacy board to perform the requisite tasks with respect to pharmacy counseling. Then, this report might discuss the relative merits of hard "enforcement" versus soft "education" approaches, setting the stage for the subsequent discussions of disciplinary actions. The inter-professional policy controversy mentioned in Appendix C, Endnotes 6 and 28 explains the softer educational approach chosen by most boards; this report should openly discuss the controversy in the background explanations, rather than in endnotes.

With regard to the findings on pages four through seven, the text assumes that optimal enforcement occurs through, "shopping visits, whereby representatives...pose as patients to assess compliance..." Opposing viewpoints, particularly regarding boards' concerns about entrapment, should be more fully discussed. The text further assumes that such "shopping" is cost-effective in combating minor quasi-violations like failure-to-counsel; in this regard, Endnote 18 might profitably be replaced by a relevant discussion, and the existing anecdote moved elsewhere. The report assumes that HCFA counseling regulations should take a high priority among enforcement activities. The draft report should reflect State pharmacy boards' concerns with security of drug storage, abuse of drugs, and prescription errors, which are more dangerous problems that they feel should take precedence for scarce enforcement resources.

The national symposium proposed on page nine would be best convened by HCFA and FDA, drawing on the perspectives of the other agencies mentioned.

It would also be helpful to the reader if an extract of the relevant portions of OBRA 1990 (Sec. 4401(g)(2)) were attached.

TECHNICAL COMMENTS:

Page i Executive Summary, Background, states "They also add as much as \$100 million a year to health care costs." Page 1, Introduction, Background, states "Costs associated with the waste in misused drugs and the results of not receiving intended therapy have been estimated to account for as much as \$100 billion a year." The \$100 billion appears to be the correct figure, so the \$100 million in the Executive Summary may need to be corrected if they are referring to the same cost figure.

Contained in the findings on pages six and seven of the report are different numbers for the responding boards (i.e., 45, 44 and 46). It is unclear as to which number is correct.

Page 8, paragraph 1 states, "The HHS Secretary and the FDA are committed to public-private efforts that will result by the year 2000 in at least 75 percent of the individuals receiving new prescriptions being given useful written information." *Healthy People 2000* objective supports oral counseling as well by its objective 12.8 "Increase to at least 75 percent of the proportion of people who receive useful information verbally and in writing for new prescriptions from prescribers and dispensers." Although the Keystone group did not come to a consensus, the steering committee "did recognize the very important role that oral counseling will play in achieving the goals of this Plan." It is unclear if the efforts are for only written information or if oral counseling is to be included.

On page 8, paragraph 5, line 7, reference is made to a, "...prescription information action plan approved by the HHS Secretary (see Appendix A)." The Appendix A in the draft I have is a collection of statistical tables titled "Survey of State Pharmacy Boards," and no "Prescription Information Action Plan" is attached. If Appendix B, "The Medguide Effort," is intended, the text should so state. If so, further editing is indicated, as that text is somewhat unclear and the "criteria" and the concreteness of an "Action Plan" are not obvious in it. If not, the real Action Plan that the authors had in mind should be attached and properly cited. The appropriate correction should be made in Endnote 6 as well.

Page 4 - Inspector General, DHHS

Staff questions may be referred to Michael Herbst in the Division of Grants and Procurement Management on 443-5256.


Thomas G. Morford

cc: Mr. Corrigan, w/attachment
Mr. Gearing, w/attachment
Mr. Clark, w/attachment
Dr. Paavola, w/attachment
Dr. Robinson, w/attachment
Dr. Mahoney, w/attachment
Dr. Snyder, w/attachment



nabp

National Association of Boards of Pharmacy

700 Busse Highway • Park Ridge, IL 60068
Tel: 847/698-6227 • Fax: 847/698-0124

July 18, 1997

June Gibbs Brown
Inspector General
Office of Inspector General
Department of Health & Human Services
Washington, DC 20201

RE: Draft Inspection Report "State Pharmacy Boards' Oversight of Patient Counseling Laws"

Dear Ms. Brown:

The National Association of Boards of Pharmacy (NABP) represents the state boards of pharmacy in all jurisdictions of the United States, Guam, Virgin Islands, Puerto Rico, nine provinces of Canada, three states in Australia, and New Zealand. NABP assists its member boards in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

The NABP compliments the Office of the Inspector General for researching this critical patient care area and concurs, in general, with the findings and subsequent recommendations. The state boards of pharmacy and NABP also agree with the Office of the Inspector General's assertion that pharmacists can help to reduce adverse drug reactions and the misuse of prescription drugs by "providing patients with oral and written information."

Studies conducted by NABP confirm the finding that too many patients, for many of the reasons noted in the report, are not being counseled about their prescription medications. We believe that counseling is a necessary responsibility of the pharmacist; a responsibility of the individual pharmacist, who must be competent and willing to counsel, and employer, who must provide the resources and support, to provide counseling to patients.

June Gibbs Brown
July 18, 1997
Page 2

SPECIFIC COMMENTS

FINDINGS

State pharmacy boards have played an active role in explaining and urging pharmacist compliance with State patient counseling laws.

The report accurately notes the efforts of the state boards of pharmacy to educate pharmacists, through a number of methods and avenues, about patient counseling laws and urge their compliance with these laws. The efforts of the boards in this area were exceptional and clearly demonstrated that state boards of pharmacy perform meaningful functions beyond licensing and discipline.

State boards, through NABP, did develop the Patient Bill of Rights (Attachment A) to educate patients about their rights under the new counseling laws. Although we agree with the report's conclusion that these efforts were less than those expended to educate pharmacists, the reason for such disparity is clearly resources and not an unwillingness to do so.

The boards' enforcement of the counseling laws has been minimal.

Although the actual disciplinary actions taken by state boards of pharmacy for failing to provide counseling may seem low, the activity of the boards of pharmacy to ensure that patients are counseled is significant. As noted in the report, a number of boards of pharmacy use informal conferences or written warnings to increase the compliance of pharmacists with state counseling laws/rules. These activities often do not result in a formal disciplinary action, such as the revocation or suspension of a pharmacist's license. Data from NABP's Disciplinary Clearinghouse indicate that the state boards of pharmacy are taking action in situations where counseling is not occurring or medication errors could have been prevented if counseling was provided and more actions than noted in previous years. We agree with the finding of the report that more effort needs to be devoted to this area and the use of "shoppers" increased.

June Gibbs Brown
July 18, 1997
Page 3

The report accurately identifies a major obstacle which impedes the ability of state boards of pharmacy to be more effective in enforcing counseling laws - funding. This factor is, in NABP's opinion, the single most limiting obstacle. We cannot emphasize enough the importance of state governments and Federal agencies providing additional resources to the state boards of pharmacy to enforce counseling laws properly and thereby, better protect the public health and welfare. Without adequate and additional funding, the state boards of pharmacy are restricted to a reactive regulatory stance and limited to responding to complaints or taking actions when violations occur and patients injured or inappropriately served.

RECOMMENDATIONS

The FDA should collaborate with State pharmacy boards to collect survey data on the usefulness of written information offered to individuals receiving new prescriptions.

NABP strongly supports this recommendation. Through the NABP, the state boards of pharmacy have worked collaboratively with the FDA on a number of projects and enforcement initiatives. We believe that a cooperative partnership which recognizes the separate authority of the state boards of pharmacy and FDA and creates a collective regulatory synergy will improve the enforcement of counseling laws and patient care.

June Gibbs Brown
July 18, 1997
Page 4

The HCFA should facilitate State efforts to enforce the Medicaid patient counseling mandate.

Develop and assess State progress toward a patient counseling performance objective.

Although NABP agrees that a performance objective needs to be established and recognizes that HCFA bears responsibility for the Drug Utilization Review provisions of the Medicaid program, we would urge that any such recommendation recognize the authority of the state boards of pharmacy and the report's recommendation be revised to extol HCFA to develop a performance objective in concert with the state boards of pharmacy. NABP would be glad to assist in this regard and help to represent the state boards of pharmacy.

Develop guidelines on State oversight of the Federal patient counseling mandate.

NABP does not agree that Federal standards for ensuring enforcement will necessarily assist states. If the guidelines are not developed in conjunction with the states and do not include Federal funding, the states will be faced with additional requirements and no means to satisfy them. The problems with lack of enforcement noted in this report will be further exacerbated. The state boards should set the standards and adopt these standards as a national, uniform policy as they have done so with other requirements and patient care standards. This can be accomplished through the collective efforts of the states and NABP. The standards for enforcement once developed, could then be recognized by HCFA and additional funding from HCFA provided to the states to ensure that the standards can be implemented.

Facilitate the convening of a national symposium on oral counseling by pharmacists.

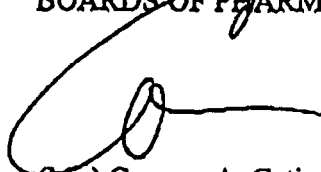
NABP strongly supports this recommendation.

June Gibbs Brown
July 18, 1997
Page 5

Thank you for the opportunity to comment on this report. If we can be of any further assistance to you, please do not hesitate to call upon me.

Respectfully yours,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

A handwritten signature in black ink, appearing to be 'Carmen A. Catizone', written over the printed name below.

(Mr.) Carmen A. Catizone, MS, RPh
Executive Director/Secretary

CC/mwg

Attachment A: Pharmacy Patient's Bill of Rights

Pharmacy Patient's **BILL OF RIGHTS**

PREAMBLE

IN ACKNOWLEDGMENT OF an increasingly informed and cost-conscious public, and with specific reference to the proliferation and complexity of drug therapy, Pharmacists have recognized the need for a "Pharmacy Patient's Bill of Rights." To reinforce their commitment to protect the health and well-being of their patients, Pharmacists need a common reference to describe their covenantal relationship with the public. In recognition of the public's right to freedom of choice and the Pharmacists' professional relationship with their patients, this document delineates: 1) the patient's rights and responsibilities with respect to appropriate drug therapy, and 2) the patient's responsibilities and Pharmacist's rights with respect to the quality of services provided. Such a charter is set forth with and shall be known as the "Pharmacy Patient's Bill of Rights."

PATIENT RIGHTS/PHARMACIST'S RESPONSIBILITIES

Patients have the right to expect their pharmacist to:

1. Be professionally competent and adhere to accepted standards of pharmacy practice.
2. Treat them with dignity, consistent with professional standards for all patients, regardless of manner of payment, race, sex, age, nationality, religion, disability, or other discriminatory factors.
3. Act in their best interest when making pharmaceutical care decisions.
4. Serve as their advocate for appropriate drug therapy and to make reasonable efforts to recommend alternative choices in coordination with the patients' other health care providers.
5. Maintain their medical records, keeping them confidential, using them routinely to maximize their care and making them available to the patient for review upon request.
6. Provide counseling, using the methods appropriate to the patients' physical, psychosocial and intellectual status.
7. Have their prescriptions dispensed and pharmacy services provided at a pharmacy of their choice in an atmosphere which allows for confidential communication and in an environment which is private, properly lighted, well ventilated and clean.
8. Monitor drug therapy within their medical regimen for safety and efficacy and make reasonable efforts to detect and prevent drug allergies, adverse reactions, contraindications or inappropriate dosage.
9. Monitor their compliance and proper drug use and institute remedial interventions when necessary.
10. Prominently post the Pharmacy Patient's Bill of Rights.

PATIENT RESPONSIBILITIES/PHARMACIST'S RIGHTS

In order for pharmacists to meet their responsibilities to patients as set forth in this "Pharmacy Patient's Bill of Rights," patients are responsible for:

1. Providing the personal demographics, medical history and payment mechanism including third party payor information necessary for Pharmacists to individualize care, the method of its provision and its reimbursement.
2. Implementing the drug therapy regimen conscientiously and reporting their clinical response to their pharmacist, especially untoward reactions and any changes in their health status and medical care.
3. Cooperating with the pharmacist and authorizing their physician or other health care practitioner to release the medical information necessary for the pharmacist to practice responsibly.



Citizen Advocacy Center

*A Training, Research, and Support Network for Public
Members of Health Care Regulatory and Governing Boards*

June 12, 1997

Ms. June Gibbs Brown
Inspector General
Department of Health and Human Services
Washington, DC 20201

Dear Inspector General Brown:

Thank you for asking for our comments on your draft report, "State Pharmacy Boards' Oversight of Patient Counseling Laws". The Citizen Advocacy Center (CAC) is a 501 (c) (3) training and support center for public members who serve on state health licensing boards, including boards of pharmacy. CAC participated as a member of the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information that submitted its Action Plan to Secretary Shalala in December 1996. CAC took a lead role in promoting the need for more and better oral counseling. In a February 26, 1997 letter to Secretary Shalala, CAC stated, "Certainly with regard to pharmacy, there is plenty of legislation already on the books in the form of OBRA 1990 requirements (under HCFA jurisdiction) and laws in over 40 states (under state pharmacy board jurisdiction) requiring pharmacists to offer to counsel patients. However, the actual delivery of oral counseling needs to be improved."

The new OIG report reinforces what many believed to be the case—that state patient counseling laws are not working. While recognizing that the state boards face major obstacles to the successful implementation of patient counseling laws (lack of resources for enforcement, economics of pharmacy practice, and limited patient demand), the report also finds that "the boards' enforcement of the counseling laws have been minimal". This finding cannot and must not be ignored. In three short paragraphs, the report pinpoints the problem of poor enforcement, as follows:

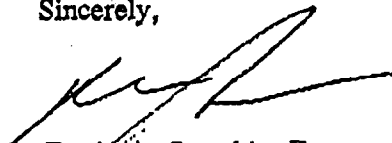
"They have made little use of "shopping" visits, whereby board representatives pose as patients to assess compliance with counseling requirements. In the past year, only 17 of 46 responding boards made such visits. Generally, they were made only to pharmacies against which a complaint had been lodged.

They have relied on inspection visits as the major means of enforcement. Such visits are conducted with widely varying degrees of frequency. At best they offer limited opportunities for assessing the extent and adequacy of counseling.

They have taken few final , formal disciplinary actions involving violations of patient counseling laws. Of the 354 actions taken during the past year by 23 reporting boards, 208 (59 percent) were in just 3 states."

That brings us to the recommendations. We agree with each of the 4 recommendations in the report - one addressed to FDA, the other 3 to HCFA. We believe, however, there is a need for a fifth recommendation - one addressed to the state boards of pharmacy. Such a recommendations should state bluntly that while there is a good understanding of the difficulties the state boards face in enforcing patient counseling laws, that cannot be used as an excuse for lax enforcement. Unenforced laws breed a contempt for government that eats away at the fabric of our society. Legislatures in 46 states have determined in their wisdom that citizens need to receive good offers to be counseled, and when they accept such offers to receive high quality counseling. They have directed the boards of pharmacy to see to it that these laws are enforced. All the sympathy and understanding in the world concerning the difficulties the boards face enforcing these laws cannot explain away the abysmal record to date. A strong statement to this effect in the final report would be appropriate. CAC has made overtures to the National Association of Boards of Pharmacy to help bring about better enforcement, and we have been pleased with the positive response of NABP. But NABP is not the enforcement agency. The state boards, individually, must be held accountable. A statement to that effect by the OIG would be most welcome.

Sincerely,



David A. Swankin, Esq.
President



Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

**Public Citizen's Health Research Group's Comments On:
State Pharmacy Boards' Oversight of Patient Counseling Laws (OEI-01-97-00040)**

Submitted - June 19, 1997

Public Citizen's Health Research Group sincerely appreciates the opportunity it has been given to comment on this topic of vital interest to the health of prescription drug consumers.

Since 1972, Public Citizen's Health Research Group has been promoting research-based, system-wide changes in health care policy as well as advocating for the appropriate prescribing and use of prescription drugs. The Health Research Group testifies before Congress and petitions the Food and Drug Administration (FDA) on issues such as banning or relabeling of drugs and the misleading advertising of prescription and non-prescription drugs by their manufacturers. Our publications help consumers make informed decisions about the health care they receive and the drugs they are prescribed.

This draft report identifies "mismedication," a term with no known definition, as a major national problem and promotes the irrational notion that failure of consumers to always be compliant (obedient) with their physicians' prescribed drug regimens is a major factor contributing to adverse drug reactions. This ambiguous articulation has led to an erroneous analysis and to unproductive recommendations that do not address the urgency or the seriousness of the most pressing problem faced daily by millions of prescription drug consumers - preventable drug induced injury.

The focus of this draft report is improving consumer access to useful prescription drug information¹ by effective implementation and enforcement of existing laws requiring pharmacists to counsel consumers about their prescriptions. It is Public Citizen's view, as a member of the steering committee responsible for developing the *Action Plan for the Provision of Useful Prescription Medicine Information*² (The Action Plan), that because of the small proportion of consumers receiving oral counseling about the risks of their prescriptions and the documented inconsistent and unreliable performance by pharmacists in warning of potentially fatal drug interactions, oral counseling cannot be considered a priority for consumers. It remains our view that written information meeting The Action Plan guidelines is the only source of accurate, consistent, comprehensive, and objective

information that a majority of consumers may receive in the foreseeable future about the risks of their prescriptions and how to protect themselves from potential harm. After 17 years³ of waiting consumers still have no reliable source of objective information about the risks of prescription drugs, how to recognize adverse effects and what steps to take should an adverse reaction appear. Written drug information is the essential "safety net" that consumers urgently need to protect themselves from the inappropriate prescribing and dispensing of prescription drugs.

We will concentrate the remainder of our comments on (1) the preventable problems facing prescription drug consumers; (2) pharmacists as counselors; (3) the distribution of oral and written information in pharmacies; and (4) who is the last line of defense in protecting consumers from preventable drug induced injury? Our recommendations will urge the Health Care Financing Administration (HCFA) to require that Medicaid beneficiaries receive useful written prescription drug information meeting the guidelines of The Action Plan. To ensure effective implementation there must be strong independent oversight and quality assurance by the FDA.

PREVENTABLE DRUG INDUCED INJURY: A NATIONAL PROBLEM

This reports use of the term mismedication has obscured the true nature of the problem faced daily by prescription drug consumers, the preventable causes of drug induced injury; the adverse drug reactions resulting from inappropriate prescribing^{4,5,6,7} and the improper dispensing^{8,9} of prescriptions. Compounding these risks is the distribution of inadequate,¹⁰ sometimes dangerous written drug information¹¹ by pharmacists.

By citing the failure of consumers to be compliant (obedient) to their physicians' prescribed drug regimens as a major contributing cause of adverse drug reactions, this report has blamed the victims and has failed to grasp the dimension of the public health problem facing prescription drug consumers. In the absence of useful prescription drug information, the present situation faced by consumers, to promote consumer obedience is irrational and potentially dangerous.¹²

The pharmaceutical industry has numerous opportunities to promote the use, over use, inappropriate use, and potential benefits of prescription drugs by spending millions of dollars advertising to doctors, pharmacists, and increasingly in direct to consumer advertising. Drug industry backed promotion of consumer compliance without ensuring consumer access to useful drug information only serves the interests of corporate sales, not the public's health. Citation 27 in this draft report illustrates precisely why there is an urgent need for accurate, consistent, comprehensive, and objective drug information for consumers meeting the guidelines of The Action Plan. The video tape referred to in this citation and its accompanying printed materials were distributed to members of The Action Plan steering committee by the American Pharmaceutical Association. These materials were funded by a major drug company, Pfizer Incorporated, and over promote consumer

compliance while minimizing the communication of risk information to consumers by pharmacists. Public Citizen finds it disturbing that citation 27 suggests this video tape be used as a training vehicle in a national symposium on oral counseling for pharmacists.

PHARMACISTS AS COUNSELORS

Public Citizen recognizes the ability and dedication of the many pharmacists who daily contribute to high quality health care by counseling consumers about the risks of their drugs. We also recognize the key role that pharmacists can play in reducing the incidence of preventable drug induced injury by providing consumers with useful drug information. However, we doubt the commitment of the owners and managers of pharmacies, particularly large, corporate chain pharmacies in providing a workplace environment, including adequate staffing, to allow pharmacists to counsel consumers about their prescription drugs. In this report, 23 of the 45 reporting State Boards of Pharmacy (51%) cited the lack of commitment from pharmacy owners/management as a significant or very significant obstacle to pharmacist compliance with consumer counseling laws.

The 34 of 45 reporting State Boards (71%) that felt limited reimbursement for counseling services was a significant or very significant obstacle to pharmacist compliance with counseling laws better reflects the level of commitment of pharmacy owners, managers, corporations and the trade groups representing their interests. In the deliberations that created The Action Plan the commitment of the pharmacy trade groups representing the interests of pharmacy owners and corporations was to reimbursement, no oversight, and no effective enforcement of the plan, not in contributing to a solution for a serious public health problem. If there were a professional commitment by pharmacy trade groups, then consumers would have had access to useful written drug information 17 years ago.

Public Citizen has little confidence that the community pharmacists dedicated to providing quality care to prescription drug consumers will be allowed to do so in the current market driven environment for health care.

THE DISTRIBUTION OF ORAL AND WRITTEN INFORMATION IN PHARMACIES

This report documents the minimal effects of the 1990 Omnibus Budget Reconciliation Act (OBRA '90) and subsequently enacted state laws to ensure consumer access to useful drug information by requiring pharmacists to offer to counsel consumers about their prescriptions. Results of FDA conducted national telephone surveys of randomly selected prescription drug consumers between 1982 and 1996¹³ substantiates this finding.

Pharmacist oral counseling to consumers concerning side effects (adverse effects) increased approximately three fold between 1982 and 1996, from eight percent to 23

percent respectively. During this same period oral information about a drug's precautions increased two fold, from 13 percent in 1982 to 26 percent in 1996. However, the distribution of written information in any form, regardless of quality, increased over four fold from 16 percent in 1982 to 71 percent in 1996. This figure of 71 percent approaches the goal of 75 percent mandated by The Action Plan. Only about one-quarter of consumers are receiving any oral information that could aid in reducing their chances of avoiding preventable drug induced injury while almost three-quarters of consumers are receiving written information, though of doubtful quality.

At the present rate Public Citizen estimates it will take pharmacists over 40 years to provide the same proportion of consumers with oral information about the precautions (26%) and side effects (23%) of their drugs as those receiving written information in 1996 (71%). We view it as highly unlikely that the extent of oral counseling in pharmacies will adequately address the problem of preventable drug induced injury in the foreseeable future.

Because pharmacists can now distribute some form of written information to 71 percent of prescription drug consumers, and consumers have already absorbed this cost through higher prescription prices, responsible public health policy dictates that HCFA must make its highest priority improving the poor quality of the information that is now being distributed by pharmacists and ensuring that 100 percent of Medicaid beneficiaries receive useful written drug information meeting the guidelines of *The Action Plan for the Provision of Useful Prescription Medicine Information* as soon as possible.

WHO IS THE LAST LINE OF DEFENSE?

This question was prophetically answered by John Gans, Executive Vice President of the American Pharmaceutical Association when he was quoted in the troubling *U.S. News & World Report* investigation, "Danger at the Drugstore"⁸, that patients have little choice but to look out for themselves and that "You have to manage your own care." Until a rational system of health care is adopted in the U.S., in the current chaos of competing corporations, health care consumers are the last line of defense against preventable drug induced injury.

This draft report cites two widely publicized studies^{8,9} showing the extent that pharmacists warn consumers of possibly fatal drug interactions. In the survey of 245 pharmacies in seven cities, more than one-half of the pharmacists failed to warn of potentially serious drug interactions.⁸ A similar survey conducted in Washington DC by researchers from the Georgetown University Medical Center found that more than 30 percent of pharmacists filled prescriptions for two potentially fatal interacting drugs without any warning.⁹ Clearly, the logic of consumer noncompliance with prescribed regimens as a cause of adverse drug reactions is fallacious. If the people participating in these two studies had been actual prescription drug consumers and had been compliant with the

directions written on their prescription containers the results may have been catastrophic.

The Georgetown University study⁹ used prescriptions for terfenadine (Seldane) and erythromycin to assess the extent that pharmacists warn consumers of possibly fatal drug interactions. Of the 10 pairs of prescriptions filled without comment by chain pharmacies, nine were accompanied by written information. Six of these nine suggested checking with the doctor if terfenadine and erythromycin were prescribed together, while three contained the general statement, "Report any other drugs you take or diseases you have." The written information distributed by these nine pharmacists lacked the contextual information necessary to adequately warn consumers of the seriousness of taking terfenadine with erythromycin and thus is dangerous. Distributing written information that does not adequately warn of a potentially life threatening risk can only be considered as professional dereliction by these pharmacists.

RECOMMENDATIONS

The first recommendation of this draft report that State Boards of Pharmacy collaborate with the FDA by collecting written information distributed to prescription drug consumers for quality evaluation by the agency is pointless. The FDA is required to evaluate if the distribution and quality goals for useful written drug information mandated by The Action Plan are achieved by 2000.

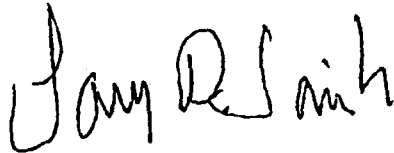
Given the Department of Health and Human Services (DHHS) and the FDA's stated commitment to ensure that consumers will receive useful prescription drug information we can find little purpose for the second recommendation, other than oral counseling must be addressed, because of its ill advised inclusion in the legislation¹⁴ establishing the process that created The Action Plan. OBRA '90 was enacted seven years ago to address the issue of oral counseling and has had minimal effect. When enacted, this legislation required that all Medicaid recipients receive an offer to counsel, and subsequently most states required that all consumers also receive an offer to counsel by pharmacists. By lowering the performance objective of 100 percent established in OBRA '90 to parallel the distribution objectives for written information in The Action Plan, 75 percent by 2000, and extending a deadline that is already four years old to 2000 is tacit acknowledgment of the failure of OBRA '90 to provide consumers with useful drug information.

Following a recommendation made in The Action Plan, this draft report recommends the convening of a national symposium on oral counseling by pharmacists to be facilitated by HCFA. However, HCFA need not follow recommendations that are unlikely to produce a productive result. The obstacles to consumer counseling are well understood, but the issue for consumers has remained for the past 17 years access to useful written prescription drug information.

Public Citizen recommends the following actions be taken by HCFA:

1. Require that all Medicaid beneficiaries receive useful written prescription drug information meeting the agreed upon guidelines of The Action Plan with each new and refill prescription.
2. Establish a deadline of January 1998 for meeting the distribution requirement. This would be one year after commercial information vendors agreed to The Action Plan guidelines for useful written drug information.
3. Guarantee strong independent oversight and quality assurance by the FDA. This would include giving the agency authority to remove written information not meeting The Action Plan guidelines from distribution and fining pharmacy owners and corporations for distributing written information not meeting The Action Plan guidelines.

Sincerely,



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ENDNOTES

1. Throughout our comments we will define "useful prescription drug information" as information that enables the consumer to use the drug properly and appropriately, receive the maximum benefit, and avoid harm as defined in the Action Plan for the Provision of Useful Prescription Medicine Information presented to Donna E. Shalala, Secretary of the Department of Health and Human Services, December 1996.
2. Action Plan for the Provision of Useful Prescription Medicine Information, presented to Donna E. Shalala, Secretary of the Department of Health and Human Services by the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, December 1996.
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6. Carlson AM, Morris LS. Coprescription of terfenadine and erythromycin or ketoconazole: an assessment of potential harm. *Journal of the American Pharmaceutical Association* 1996;NS36:263-269 and Thompson D, Oster G. Use of terfenadine and contraindicated drugs. *Journal of the American Medical Association* 1996;275:1339-1341.
7. Moore TJ. *Deadly Medicine*. New York: Simon & Schuster; 1995.
8. Headden S, Lenzy T, Kostyu P, Roebuck K, Locke L, Burgower Hordern B, et al. Danger at the drugstore. *U.S. News & World Report*, August 26, 1996.
9. Cavuto NJ, Woosley RL, Sale M. Pharmacies and prevention of potentially fatal drug interactions. *Journal of the American Medical Association* 1996; 275:1086[letter].
10. Sasich LD, Wolfe SM. Deficiencies in patient information leaflets concerning gastrointestinal complications of nonsteroidal anti-inflammatory drugs. *Journal of General Internal Medicine* 1997;12(suppl 1):79[abstract], and Department of Health and Human Services, Food and Drug Administration. Prescription Drug Product Labeling; Medication Guide Requirements, Proposed rule. *Federal Register* Vol. 60, No. 164, August 24, 1995, pages 44193 and 44194.

11. Public Citizen obtained drug information leaflets from a Washington DC pharmacy in late 1996 containing dangerous FDA disapproved-unapproved use information. A leaflet for short-acting nifedipine capsules (Adalat, Procardia) contained use information for hypertension. The use of short-acting nifedipine capsules to treat hypertensive emergencies was disapproved by the FDA in 1985. Current approved labeling for this drug warns in bold type that this form of nifedipine should not be used to treat hypertension for safety reasons. A leaflet for bromocriptine (Parlodel) contained information on the use of this drug to stop breast milk production in new mothers who choose not to breast-feed. The use of bromocriptine for this purpose was disapproved by the FDA because of heart attacks and strokes in young mothers.

12. Wynne HA, Long A. Patient awareness of the adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs). *British Journal of Clinical Pharmacology* 1996;42: 253-256.

13. Morris LA, Tabak ER, Gondek K. Counseling patients about prescribed medication: 12-year trends. *Medical Care* 1997 (In press).

14. *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1997*, PL 104-180 (August 6, 1996), Title VI, Section 601, Effective Medication Guides.



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The National Professional
Society of Pharmacists

August 6, 1997

The Honorable June Gibbs Brown
Inspector General
Department of Health and Human Services
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Washington, D.C. 20201

Dear Ms. Brown:

Thank you for the opportunity to comment on the draft report, *State Pharmacy Boards' Oversight of Patient Counseling Laws* (OEI-01-97-00040).

This report is remarkably timely. The past year has seen an unprecedented surge in the attention given by the Congress, the Secretary of Health and Human Services, the pharmacy profession, pharmacy store owners, and consumers themselves to the important problem of improving drug information provided to consumers. Your report is likely to contribute significantly to greater understanding of the need to solve this problem, and of the barriers that must be overcome before consumers can be assured of routinely receiving essential drug information from pharmacists.

Mismedication as a National Problem. The report does a fine job of citing several key studies documenting the human and financial cost of suboptimal prescribing, dispensing, and patient adherence to their prescribed drug regimen. While it is customary to cite the most recent studies to establish the nature and extent of a social problem, this approach may inadvertently lead policymakers to believe this problem has been only recently realized by health services researchers. Nothing could be further from the truth.

In fact, the great morbidity and mortality associated with poorly-managed pharmacotherapy has been documented in numerous studies for many years. For example, eight years to the day prior to the publication in *Archives of Internal Medicine* of the paper entitled "Drug-Related Morbidity and Mortality" by Johnson and Bootman, which reported the estimate of an expert pharmacist panel, *JAMA* published a similar estimate by an expert medical school panel entitled "Assuring the Quality of Health Care for Older Persons." The *JAMA* authors placed the "adverse effects of drugs" among the top five greatest priorities for quality improvement in care of the elderly -- along with four of the greatest sources of morbidity and mortality in our society: congestive heart failure, hypertension, pneumonia, and breast cancer.

Citing some of this older research will help to establish the grim reality that public and private policy may fairly be criticized as producing much more talk than action toward a solution. An annotated bibliography of several such studies is provided as an attachment.

Pharmacists as Counselors. One of the bright spots in this otherwise dismal picture of persistent preventable morbidity and mortality has been the dramatically improved performance of pharmacists in providing drug information to consumers. These educational services are a promising part of any effort to reduce the human and fiscal cost of mismanaged drug therapy. The pharmacist's contribution goes far beyond the written handouts discussed in the recommendations section of draft report.

Surveys performed at several intervals over the past fifteen years have shown direct pharmacist counseling of consumers has improved from 20 percent in an FDA survey conducted in 1982 (Federal Register, Volume 50, No. 164, page 44191) to 51 percent of consumers responding to the National Pharmacy Consumers' Survey, conducted by the American Pharmaceutical Association (APhA) in 1996.

The draft report is correct in its contention that these services, when provided, are valuable. Some readers of your report may not be aware of the evidentiary basis for this assertion, and for this reason we suggest that the report add numerous other citations to studies that confirm the effectiveness of the pharmacist as a source of drug therapy patient education and management. A brief annotated bibliography of several recent studies is attached for your reference and use. Copies of these articles are available upon request.

Board Enforcement of Counseling Laws. Use of the "shopping" technique is a potentially powerful tool for identifying inadequate counseling practices. The advantage of this approach is that it can discover directly the experience of the typical consumer who receives products and services in a pharmacy, if such "shoppers" are not identifiable as such.

"Shoppers" utilized for this purpose must be well-trained in counseling techniques, and must be well-supervised, to ensure validity and equity in their findings. A critically important aspect of such training should be in assessing the workplace circumstances of pharmacist employees, who may simply be unable to counsel given the level of staffing and the volume of dispensing they are required to perform by their employer. For these reasons, it may be helpful for State pharmacy boards to have a "best practices" model to inform their efforts in making wise use of this quality monitoring tool. APhA has been collaborating with the National Association of State Boards of Pharmacy (NABP) and appropriate physician and consumer organizations to cosponsor a conference to debate and develop guidelines, such as a model oral counseling assessment mechanism, and would urge the OIG and the Department to provide financial support for this conference.

Finally, APhA believes it makes sense, given the scant resources of pharmacy boards, to reserve such resource-intensive methods as "shopping" for investigating pharmacies and pharmacists about which complaints have been filed relating to the quality of counseling services.

Regulatory pressure on pharmacies and pharmacists to increase patient counseling may produce some small incremental reallocation of resources to improve pharmacist counseling. But it would be a mistake to expect a "crack down" on pharmacists or store owners to produce many benefits for the public because margins in the retail sector of pharmacy are extremely thin and getting thinner for reasons beyond the control of the pharmacist and many store owners. Already, financial pressures have forced approximately a thousand independent retail pharmacies to be sold or closed each year in the early 1990s, even without the additional pressure of a call by regulators to reassign pharmacists to counseling duties.

These realities are so broadly accepted as to be reflected not only in comments from store owners and pharmacists but, as the draft report indicates, in comments from most pharmacy regulators, who understand that the disincentives for counseling are formidable. What is needed is a concerted effort by those representing all stakeholders to convince payors, consumers, and store owners of the value of counseling services. The draft report can play a stronger role in awakening public policymakers to these realities of the marketplace.

Barriers to Patient Counseling. The OIG report correctly identifies the three major barriers impeding full implementation of section 4401(g) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90).

Relative Importance of the Barriers Identified by the OIG. In presenting these, we believe it makes the most sense to present these in order of the frequency with which they were mentioned by the State pharmacy board officials surveyed by the OIG:

- (1) Economics of Pharmacy Practice (cited by about 75% of respondents);
- (2) Limited Patient Demand (cited by about 60%); and
- (3) Lack of Resources for Enforcement (cited by just 50%, despite the direct incentive to emphasize this problem which might be ascribed to State board officials).

This sequence more accurately reflects State officials' awareness of the fundamental diseconomies dominating today's marketplace which punish, rather than reward, pharmacists for patient counseling activities. State officials understand that it would be both inequitable and ineffective to attempt to reverse these powerful economic disincentives solely by imposing ever greater financial or other civil penalties.

Patient Demand. APhA's 1996 National Pharmacy Consumer Survey assessed the views of a random sample of over 980 consumers who reported at least one visit to a pharmacy in the preceding six months. The survey validates to some extent the State board officials' perception that there is limited consumer demand for pharmacist counseling services, but paints a somewhat more complex picture. Consider the following evidence from the survey:

- The most important reason given by consumers for choosing their pharmacy is "convenience" (37% of respondents) – specifically, how close the pharmacy is to home or work (33%). This is more than twice the percentage identifying either "price" (18%) or "service" (16%) as the reason for their choice of pharmacy.
- Results from this survey revealed that between 76% and 93% of consumers believe that their needs for most dispensing-related services are already being met by their pharmacist. This high level of satisfaction with the current level of pharmacists' service indicates consumers believe pharmacists are already providing essential counseling services when these are needed, and may feel no need to ask for what is not already being provided.
- The survey does provide some evidence that about 20% of pharmacy consumers desire more contact with their pharmacist to discuss their prescription drug therapy, but significant barriers interfere with their obtaining these services:

Nearly half of those expressing a desire to have greater access to their pharmacist are daunted by the perception that the pharmacist is "too busy" to speak with them.

Over one-third of consumers have difficulty distinguishing pharmacist(s) from other pharmacy personnel.

Finally, the services consumers most often report they'd like to receive from the pharmacist are the services least likely to be performed at the time of dispensing: About 70 percent of consumers want the pharmacist (1) to remind customers by mail or telephone that it is time to have a prescription refilled, and (2) call to find out how the prescription is working. This suggests the greatest unmet demand for pharmacist counseling services are those which are provided to the consumer while they are not in the pharmacy.

- Relatively few consumers are willing to pay the entire cost of enhanced counseling services out of pocket, suggesting that these services will not be used at an optimal level by the consumer until the expense is covered by health plans in the same manner as other health care services.

The National Pharmacy Consumers' Survey does supply evidence that most consumers are open to a more intensive level of service from their pharmacist. Over two-thirds of consumers would view "somewhat favorably" or "very favorably" a new, higher level of service in which the pharmacist would provide more counseling before and after the filling of prescriptions, as well as engage in greater interaction with their physician to facilitate any needed adjustments to their drug regimen. Fully 31% of pharmacy consumers expressed a willingness to switch pharmacies to gain access to this higher level of service, if there was no cost to the consumer.

Economic Barriers in Pharmacy Practice. The report accurately depicts the dilemma of pharmacists and their employers in the current marketplace. There are two major economic barriers standing in the way of consumers receiving more and better counseling from their pharmacist. Both are the result of drug *product* reimbursement reductions that are squeezing pharmacist counseling *services* out of the pharmacy. These barriers deserve more explanation in the report, even though it is unlikely that the market will embrace higher drug product reimbursement as a solution.

In the past, pharmacists were able to finance patient counseling activities from the margin they received from selling pharmaceuticals. Demands from within the profession and from the Federal and State governments for greater pharmacist counseling have coincided with the increasing domination of the market by third party payors, who have been increasingly successful in demanding drug product discounts from pharmacists. By 1995, a senior Blue Cross/Blue Shield Association official was able to report that reduced reimbursement to pharmacies accounted for fully 60% of all savings achieved by the Association in managing the drug benefits offered through the Federal Employees Health Benefits Program (FEHBP).

Such reimbursement reductions inevitably spur changes in pharmacy practice. In a market dominated by slim and declining margins, pharmacies that can dispense more prescriptions per hour are economically advantaged over those which cannot. Pharmacies where pharmacist employees spend time on non-revenue generating counseling of patients can only expect to benefit if patients select that pharmacy on the basis of service – which the draft report has correctly identified as an area of soft consumer demand.

One remedy for this situation would be for private and public sector payors, such as the Federal and State governments – through the FEHBP, State employee, Medicare, and Medicaid programs – to pay for some or all pharmaceutical care services. Data from the Washington State Medicaid Drug Use Review demonstration project show that paying pharmacists for counseling activities easily pays for itself out of drug product costs *alone* if payment is tied to documented, clinically necessary changes in drug therapy which have been suggested to the physician by the pharmacist. Additional savings from reduced morbidity and mortality may reasonably be expected, though that demonstration project was not designed to capture evidence of such savings from reduced health care utilization.

A large controlled study done by the University of Southern California and Kaiser Permanente (publication pending) found that either of two different models of pharmacist counseling significantly reduce hospitalizations compared to the control group. The two models of pharmacist counseling were the "OBRA '90" counseling model and Kaiser Permanente's own counseling program, in which pharmacists are instructed to focus counseling efforts on high risk drug products and related patient populations.

Patients who received "OBRA '90" counseling services from Kaiser pharmacists were interviewed for the USC/Kaiser study about the frequency of counseling they received. These patients reported receiving "OBRA '90" counseling interventions at over twice the rate of patients served in community pharmacies during the course of the study. It appears that these Kaiser pharmacists, serving under the same legal obligations as their professional colleagues in community pharmacies, provided a substantially higher level of service. Why? The most likely explanation for this is that Kaiser pharmacists enjoyed a significant infusion of resources in the form of more technicians and management encouragement and support for counseling. Financial incentives support effective counseling by Kaiser and its employee pharmacists, inasmuch as staff receive bonuses if their efforts result in reduced preventable health care utilization.

The existence or absence of financial incentives for pharmacy owners and pharmacists has a powerful impact on whether certain pharmacy practice innovations produce more counseling service, or simply result in reduced professional staffing. For example, the draft report suggests that increased use of technicians, as well as automation of the dispensing aspect of pharmacy practice, can theoretically free up the pharmacist to provide counseling services. This is certainly true, however, if the owner of the pharmacy does not realize revenue from the services of the pharmacist, the owner has an incentive to replace the pharmacist with automation and/or technicians and pocket the savings, rather than continue to pay the pharmacist to provide unpaid drug therapy management to consumers.

A related barrier deserving mention and follow up study is that some State pharmacy boards limit, by regulation, the use of technicians that might be used to free up the pharmacist for counseling services.

Additional Studies on Economic Barriers. Several studies confirm the impression of the State pharmacy board executives surveyed by the OIG that there are significant economic barriers to pharmacists spending time with patients. These studies should be cited in the report:

- Barnes et al, in a 1996 survey of 400 pharmacists published in *The Annals of Pharmacotherapy* found that the most significant barriers to implementation of the

OBRA '90 patient counseling requirements were (1) excessive workload; (2) lack of financial compensation; (3) patients' attitudes (e.g., lack of interest in counseling).

- Rupp et al, in a 1992 study published in *Medical Care*, documented that there is a statistically significant inverse relationship between greater volume of prescriptions dispensed and the amount of pharmacist oversight and counseling of those prescriptions. The authors noted in this study:

"this finding suggests that pharmacists' willingness or ability to intervene in problematic new prescription orders decreases as the volume of prescriptions they dispense per hour increases."

- According to the May 8, 1995 issue of *Forbes* magazine, "the growing power of [insurance plans] to dictate the price of prescription drugs has slashed retail pharmacy gross margins to 25%, from 35% in 1989. That's \$5.5 billion carved right out of operating profits." Declining per unit profits create a powerful incentive for pharmacy owners to increase volume and improve the productivity of their employee pharmacists in performing those activities for which the store receives revenue. This directly affects the time available for counseling.
- Results from the 1996 APhA National Pharmacy Consumers' Survey indicate that nearly 60% of those desiring greater access to their pharmacist reported that these health professionals appear "too busy" to talk with them.

Additional Recommendations Regarding Federal Government Action. The draft report properly notes that there is a substantial Federal interest in improving the quantity and quality of pharmacist counseling of consumers. The draft recommendations fall short of addressing the key economic incentives discussed in the body of the report, however. APhA has several additional recommendations to suggest, described below.

(a) Federal Costs Associated with Drug-related Morbidity & Mortality. An important Federal interest which is not mentioned is the cost of suboptimal drug therapy which is charged to Medicare, Medicaid, FEHBP, CHAMPUS and other insurance or health plan arrangements sponsored or financed by the Federal Government. Although the report mentions the scientific and clinical literature (including estimates from FDA) which estimate substantial costs associated with preventable drug-related morbidity and mortality, these costs should be projected to the large patient populations covered under these health care programs, even if these estimates are only based on the approximate drug utilization of these populations.

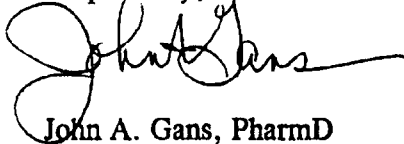
(b) Economic Incentives to Counsel are Appropriate and Timely. APhA believes the OIG report should recommend that fee for service programs, beginning with those operated or funded by the Federal Government, provide financial incentives for these services as well. These payments could be conditioned on documentation that a prescriber has accepted a clinically-relevant drug therapy change recommended by a pharmacist. Such a program could be put into place today, using existing electronic claims coding standards. The entire objective of such a program should be to reduce drug-related morbidity and mortality in key populations of interest to the Federal Government, such as older Americans.

(c) Oral Counseling Objectives of the Secretary. The draft report discusses the HHS Secretary's support for increased distribution of written information to pharmaceutical consumers. It is important to note that the Secretary has for several years embraced the Health People 2000 goals, which were updated in 1995 to call for -

"[Objective 12.8] Increase to at least 75 percent the proportion of people who receive useful information *verbally and in writing* for new prescriptions from prescribers or dispensers." [emphasis supplied]

APhA believes this report will help encourage pharmacy boards, consumers, pharmacy owners and pharmacists to begin an unprecedented cooperative effort to enhance the quality and frequency of pharmacist service received by the public. Once again, thank you for your consideration of the views of America's pharmacy profession.

Respectfully,



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Executive Vice President

Enclosures
JAG/dgs



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The National Professional
Society of Pharmacists

OLDER AMERICANS NEED PHARMACEUTICAL CARE SERVICES

PROBLEM: Preventable drug related problems inflict substantial morbidity and mortality, costing Medicare, employers, and health insurers billions every year.

- o Drug-related morbidity and mortality are estimated to cost \$77 billion in the U.S. each year. -- Archives of Internal Medicine, October 1995.
- o Adverse drug events are among the top five greatest and most preventable threats to the health of elderly Americans, after Congestive Heart Failure, Breast Cancer, Hypertension, & Pneumonia. -- JAMA, October 1987.
- o Twenty-eight percent of hospitalizations of elderly Americans are due to noncompliance with drug therapy (11%) and adverse drug reactions (17%). -- Archives of Internal Medicine, April 1990.
- o Patient compliance with drug therapy deteriorates as the number of drugs taken by the patient increases. Because 25% of the elderly use three or more drugs daily, the elderly are particularly at risk. -- The Gerontologist, March 1994.
- o Of elderly patients taking three or more chronic prescription drugs, over one-third are re-hospitalized within six months of discharge from a hospital. Twenty percent of readmissions are due to drug problems, principally undertreatment, noncompliance, and adverse drug reactions. -- Medical Care, October 1991.
- o 32,000 senior citizens each year suffer hip fractures from falls caused by adverse drug events. -- New England Journal of Medicine, February 1987.
- o The inappropriate use of prescription drugs is a potential health problem that is particularly acute for the elderly. The U.S. General Accounting Office analyzed 1992 Medicare data and found that about 5.25 million of noninstitutionalized elderly Medicare enrollees used at least one drug identified as generally unsuitable for elderly patients given that safer drugs exist. -- GAO, July 1995.
- o In an average year, 32,800 people die from pneumococcal disease and 20,000 die from influenza--almost all elderly. Medicare spends as much as \$1 billion for treatment of influenza-associated diseases each year. Seventy-three percent of the elderly have never been immunized for pneumococcal pneumonia; 49% of the elderly have not been vaccinated against influenza. -- GAO, June 1995.
- o Influenza vaccination reduced hospitalization costs an average of \$117 for each of the 41,418 elderly people immunized during a three year period. -- The New England Journal of Medicine, September 1994.

PROBLEM: Perverse incentives. Until pharmacists are paid for pharmaceutical care, their livelihood depends on faster dispensing of prescriptions, making it uneconomical for them to spend time with patients & physicians solving drug therapy problems.

PHARMACEUTICAL CARE IMPROVES PATIENT CARE AND OUTCOMES

- o Pharmacist teaching and monitoring of drug therapy in a group of African-American asthma patients reduced emergency department (ED) visits by over 70% and hospitalizations by 80%, compared with no significant reduction in ED visits and a 50% reduction in hospitalizations in a control group receiving "usual care from local physicians." [Kelso TM, et al, Am Jrnl of Med Sciences, June 1996]
- o Asthma patients who are high users of hospital emergency departments experienced an 80% decline in ED visits after ongoing pharmacist counseling. [Pauley TR, et al, Annals of Pharmacotherapy, Jan 1995]
- o Geriatric consumers, who account for about 30% of drug use in the U.S., were able to reduce the number of drugs taken and achieve significantly better compliance with their drug regimen after counseling by pharmacists, with no increase in costs. [Lipton HL, and Bird JA, Gerontologist, March 1994].
- o Ambulatory patients used significantly fewer health services, saving over \$640 a year in health costs per individual, as a result of comprehensive pharmacist counseling. [Borgsdorf LR, et al, Am Jrnl of Hosp Pharm, March 1994].
- o Community pharmacists counseling patients identified and resolved problem drug therapy in ~2% of new prescription orders, with about 28% of these judged capable of causing "patient harm" if the pharmacist had not intervened. [Rupp MT, et al, Medical Care, Oct 1992].
- o Physicians accepted about 83% of pharmacists' recommendations for drug therapy changes in an ambulatory care clinic. For 80% of recommendations, "improvement or resolution of a patient's disease state" occurred. Cost reductions were noted. [Lobas NH, et al, Am Jrnl of Hosp Pharm, July 1992].
- o Medicare would realize net savings of \$280,000, 139 hospitalizations, and 63 deaths per 100,000 enrollees each year if it paid pharmacists to advise enrollees to be vaccinated for influenza, according to an estimate based on an experiment in North Carolina. [Grabenstein JD, et al, Medical Care June 1992.]
- o The addition of a clinical pharmacist to a hospital-based geriatric clinic reduced the number of medications associated with an adverse drug reaction by 42%, and produced direct cost savings of \$54/patient, in the first six months. [Phillips SL, Carr-Lopez SM. Am Jrnl of Hosp Pharm, May 1990]
- o Hypertensive patients who received pharmacist counseling were more compliant with their treatment, and achieved better blood pressure control, than a control group. [McKenney JM, et al, Circulation, Nov. 1973; McKenney JM, et al,

Contemp Pharm Pract, Fall 1978]

- o Relative to a control group, diabetic patients who received pharmaceutical care were more compliant in keeping clinic appointments, made fewer medication errors, saw symptoms improve in 5 of 8 variables measured, and had a lower incidence of hospital admissions and "medical contacts". [Sczupak CA, Conrad WF, Am Jnl of Hosp Pharm, Nov 1977].

NACDS

National Association of Chain Drug Stores

Thomas M. Ryan
Chairman of the Board

Ronald L. Ziegler
President & CEO

June 30, 1997

The Honorable June Gibbs Brown
Inspector General
United States Department of Health and Human Services
Room 5250 Cohen Building
Washington, DC 20201

RE: OEI-01-97-00040

Dear Ms. Brown:

On behalf of the National Association of Chain Drug Stores (NACDS), I am pleased to include the attached document which provides our perspectives on the draft report, "*State Pharmacy Boards' Oversights of Patient Counseling Laws.*" We appreciate the opportunity to comment on this draft report.

NACDS membership consists of more than 130 retail chain community pharmacy companies. Collectively, chain community pharmacy accounts for the largest component of pharmacy practice with over 86,000 pharmacists. Chain community pharmacy is comprised of 18,500 traditional chain drug stores, over 6,000 supermarket pharmacies and nearly 5,000 mass merchant pharmacies. The NACDS membership base operates nearly 30,000 retail community pharmacies with annual sales totaling over \$110 billion in prescription drugs, over-the-counter (OTC) medications and health and beauty aids (HBA). Chain operated community retail pharmacies fill approximately 60 percent of the more than 2.5 billion prescriptions dispensed annually in the United States.

Thank you for the opportunity to comment on this report. Please call on us if we can provide any additional information to your office about this or other issues.

Sincerely,



Ronald L. Ziegler
President and Chief Executive Officer

COMMENTS OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES
DRAFT REPORT
"STATE PHARMACY BOARDS' OVERSIGHT OF PATIENT COUNSELING LAWS"

General Overview

Consumers of prescription medications are entitled to a meaningful offer to be counseled, consistent with state law. Interaction with the pharmacist should help consumers better understand how to take their medications.

NACDS also believes that consumers are entitled to receive comprehensive written information about their prescription medications that reinforces and supplements the oral information provided to the consumer by health professionals. Such written information can also serve as a reference source for the consumer during the course of prescription use.

The OIG report clearly identifies current issues relating to state board of pharmacy enforcement of patient counseling laws. However, NACDS believes that the report describes the situation as a "glass half empty" rather than a "glass half full." While there are clearly strides to be made in improving the quality and quantity of oral counseling, FDA's own data illustrate the progress that has been made to date by pharmacists in providing oral counseling to consumers.

While the oral counseling provisions were included in Medicaid legislation enacted in 1990, the law required that these provisions take effect January 1, 1993. Since that time, consistent and appreciable strides have been made in improving the quantity and quality of oral counseling. In fact, FDA reported that 32 percent of consumers reported that they received oral counseling in 1992, which increased to 42 percent in 1994 and 47 percent in 1996.

Therefore, substantial progress in complying with oral counseling laws has already been made by pharmacy in just three short years, in spite of multiple challenges to the development of this practice. As with any significant and substantive change in the practice of a health professional, a period of adjustment must be expected by all parties involved, including consumers. Moreover, the success of oral counseling depends upon a complex dynamic of multiple factors in the health care system working well together. These include boards of pharmacy, pharmacists, consumers, pharmacy benefit managers (PBMs), and other third parties, all of whom have a vested interest in its success, and all of whom have to contribute to making it successful.

The practice, economic and social barriers and challenges that must be addressed to increase meaningful oral counseling by pharmacists are described below.

Practice Challenges: Many state boards impose outdated and antiquated practice requirements on pharmacies, requirements that shift pharmacists' focus to prescription dispensing rather than consumer interaction. That is, many state boards impose unrealistic technician-to-pharmacist ratios, and some states require that only pharmacists perform non-judgmental tasks that could be performed by well-trained technical personnel. NACDS is working to revise these antiquated and outdated practice acts so that pharmacists can spend more time with consumers on such

activities as oral counseling. This movement will also be facilitated by the evolution of automated pharmacy dispensing systems.

An additional practice barrier is the fact that pharmacists are often unaware of the intended use of the prescription medication, or the patient's diagnosis. Knowledge of the prescriber's intended use of the drug would facilitate the interaction between the pharmacist and the consumer, especially when the drug is being used for an off-label use.

To facilitate and encourage oral counseling, many chain pharmacies are restructuring their prescription departments to provide a private area for the consumer to talk with the pharmacist about the medication.

Economic Challenges: We concur with the draft report's finding that a significant obstacle to providing oral counseling is the economics of pharmacy practice, where, according to the report, "payers are squeezing operating margins." When OBRA 90 was enacted, no additional provisions for payment were provided to states to defray pharmacists' costs of providing counseling to Medicaid recipients, essentially resulting in an unfunded mandate on pharmacists and the states.

As the report also indicates, OBRA 90 vested the enforcement of these new laws with the states without providing for additional resources. In addition, most states extended the counseling requirements to non-Medicaid recipients, meaning that the unfunded mandate was extended in most states to all pharmacy consumers, not just Medicaid recipients.

At this point, almost 70 percent of all prescriptions are paid for by third party plans. These plans are paying pharmacies less per prescription, not more, and are squeezing pharmacy margins. In almost all cases, third-party plan reimbursement, including Medicaid, does not even compensate pharmacies adequately for the cost of filling the prescription, much less for providing counseling.

In 1991, before the pharmacy counseling provisions were implemented, HCFA found that the average cost of dispensing a Medicaid prescription was about \$5.50. This amount did not include the cost of counseling. In its final rule implementing the patient counseling guidelines, HCFA itself indicated that the cost of a counseling session was about \$2.50-\$3.00.

When the HCFA-estimated additional costs of counseling are added to the cost of providing the prescription, it increases the cost of dispensing to, on average \$8-\$8.50 per prescription, well below the current average per-prescription Medicaid payment to pharmacies. At this point, Medicaid's average dispensing fee per prescription has declined by 14.4% in 1996 inflation-adjusted dollars from \$4.93 in 1991 to \$4.22 today. This underscores the economic challenge to the provision of oral counseling by community retail pharmacies.

Consumer Challenges: Consumers need to better understand and appreciate the value of the pharmacist in helping them manage their medications. Physicians and other health care professionals also have to sensitize consumers to the need to obtain as much information about their medications as possible, including through oral communications.

Consumers can also help their own cause by demanding that their health benefit plans cover the cost of pharmacists providing oral counseling as a part of the prescription drug benefit. Unfortunately, third party prescription benefit plans continue to focus on reducing reimbursement for the product cost.

Instead, health benefit plans and PBMs should adopt reimbursement policies that encourage the delivery of pharmacy services which reduce overall drug expenditures through better drug use. Community pharmacy is eager to work with consumer and patient advocacy groups to increase consumer demand for oral counseling at local pharmacies.

Response to OIG Suggestions

NACDS would like to offer brief comments on the suggestions made by the OIG in its draft report relative to methods to improve oral counseling. NACDS is participating with almost every other national pharmacy organization in cosponsoring a national symposium on pharmacy oral counseling. The symposium is scheduled to be held this fall, which will help implement part of the "Action Plan for the Provision of Useful Prescription Medicine Information."

This plan was developed in lieu of the MedGuide action plan proposed by the FDA. This upcoming symposium will assess the current array of pharmacy oral counseling guidelines, evaluate the need for any refinement to these guidelines, and seek to develop an action plan to address many of the challenges to the further provisions of oral counseling as described above.

NACDS has serious reservations, however, about other recommendations made in the report that would prescribe a broader role for the Federal government, notably HCFA and FDA, in setting performance objectives for oral counseling by pharmacists, as well as Federal oversight of such counseling. NACDS believes that the regulation of the practice of pharmacy is the purview of the states. Any additional performance objectives or standards that are needed, including any necessary oversight mechanisms, should be developed by the state boards of pharmacy in conjunction with the profession of pharmacy.

It is important to recognize that, while an increase in the quality and quantity of oral counseling is a goal that is desirable and achievable, any further efforts to establish additional standards or oversight must be accompanied by an equally-committed and forceful effort to address some of the challenges that currently impede the further development of oral counseling.

[u/s/gov/fda/oirp2](http://www.fda.gov/oc/oirp2)

June 13, 1997



National
COMMUNITY
PHARMACISTS
Association

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June Gibbs Brown
Inspector General
Department of Health & Human Services
Wilbur J. Cohen Building, Suite 5250
330 Independence Ave., SW
Washington, D.C. 20201

RE: Draft inspection report, "State Pharmacy Boards' Oversight
of Patient Counseling Laws." *OEI-01-97-00040*

Dear Inspector General, June Gibbs Brown:

We agree with your basic premise that effective oversight can help foster the intent of the federal and state patient counseling laws. We commend your office for doing this study and your recognition that proper use of medicine is a major public policy issue. We also agree with your view that pharmacists are in a key role to assure the appropriate use of medication, both through identifying and correcting prescription errors, and through effective interaction with patients to foster better patient understanding and use of medicine. Incidentally, several studies have documented the cost of inappropriate medication well in excess of \$100 million a year noted in your report. (See attached *The 76 Billion Dollar Question*.)

The oversight of the non-Medicaid laws, of course, rests exclusively with the state pharmacy boards. Your investigation has determined that "their enforcement of the laws has been minimal". We believe it is particularly important that your investigation of obstacles to effective pharmacist counseling found that the principle barrier was "limited reimbursement for counseling services." The Prescription Information Action Plan approved by Secretary Shalala, at page 33, concludes that..."third-party payors (including government agencies) should consider the health care and economic benefits they will likely receive due to improved oral and written communication and are strongly encouraged to provide payment to health care professionals for providing these services." Your department has a wide range of options available to help facilitate the removal of this principle barrier to more effective patient counseling.

Another particularly enlightening aspect of your investigation is that 94% of the state pharmacy boards indicated that their state had no continuing education requirements specifically intended to help pharmacists conduct patient counseling. Under the prospective drug review provisions of the 1990 Medicaid amendments, each state's program is required to conduct active and ongoing educational outreach programs to educate practitioners, pharmacists

Inspector General Brown
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and doctors, on common drug therapy problems. We recommend that your department encourage state Medicaid programs through funds made available to state pharmacist association to conduct the relevant continuing education programs.

Considering your finding that lack of patient knowledge about the counseling requirement is also a major obstacle; it would seem that similar Medicaid patient education programs would be appropriate. Of course the development of state standards called for in the '90 amendments could help achieve these and other objectives.

The planning for the National Symposium on Oral Counseling by pharmacists called for in the Secretary Shalala's Prescription Information Action Plan is well underway. In fact, several weeks after the plan approval, we hosted a meeting of the CEOs of the major national pharmacy organizations where a consensus was developed in support of convening the private sector sponsored symposium.

The Center for Drugs and Public Policy has been contracted to assist with the symposium, and recently an advisory committee met in our offices to help assure that consumer, private third-party payor and other interested parties are involved both in the development of the program and participation at the symposium which will be held September 19-21 at the Landsdowne Conference Center in Leesburg, Virginia. (See enclosed related materials). It is particularly exciting to see all of pharmacy supporting this effort.

HCFA is encouraged to designate a representative for the Advisory Committee and to suggest appropriate individuals to the Center on Drugs and Public Policy to participate at the symposium. It is important, however, to note that while support for the symposium by HCFA is important, it is a private sector pharmacy led initiative.

Incidentally, the purposes of the symposium include an assessment of guidelines as noted in your report (see B-2), but are per Secretary Shalala's Prescription Information Action Plan more comprehensive:

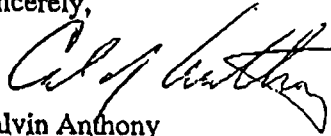
- the effectiveness of current oral counseling guidelines relating to prescription medicines
- identification of "best practices" for oral counseling
- suggestions for refinement to current guidelines, if needed, with referral to State boards of pharmacy.
- strategies to reduce the economic, practice, and social barriers relating to providing useful oral information about prescription medicines.

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Page Three

Regarding the FDA, we certainly support their involvement in an assessment of the "usefulness" of written information provided to patients and would encourage a similar assessment of written information provided by the boards of pharmacy to pharmacists.

Again, thank you for the opportunity for community pharmacy to comment on this report, and its significant findings. We stand ready to assist your department in taking meaningful steps to address the findings.

Sincerely,



Calvin Anthony
Executive Director

CA:dj
Enclosures



AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Pharmacists in health systems helping people make the best use of medications

July 10, 1997

Ms. June Gibbs Brown
Inspector General
Department of Health and Human Services
5250 Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

RE: Draft Report, "State Pharmacy Boards' Oversight of Patient Counseling Laws."

Dear Ms. Brown:

The American Society of Health-System Pharmacists (ASHP) appreciates the opportunity to comment on this draft report. ASHP is the 30,000-member national professional organization that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care organizations, and other components of health care systems.

As a long-time proponent of patient counseling, ASHP has a particular interest in the subject matter of the draft report. Because of its strong commitment to patient counseling, ASHP has taken an active role in supporting this aspect of patient care as part of its mission to help pharmacists provide pharmaceutical care that results in positive patient-care outcomes. In the 1970s, ASHP established "Guidelines on Pharmacist-Conducted Patient Counseling." These guidelines have been revised and expanded over the years, and a copy of the most recent (1996) revision is enclosed. The guidelines indicate ASHP's commitment to the principle that pharmacists should educate and counsel all patients to the fullest extent possible, going beyond the minimum requirements of laws and regulations. Anything less is inconsistent with pharmacists' responsibilities and talents.

The importance of informing consumers about the vital patient care role of pharmacists and expanding efforts to prevent medication errors and other drug-related problems are also prominent portions of our 1997-1998 Leadership Agenda (also enclosed). ASHP has provided input to state boards of pharmacy when those boards develop patient-counseling rules. ASHP was represented on the steering committee that developed the *Action Plan for the Provision of Useful Prescription Medicine Information* that was approved by Secretary Shalala in January of this year. And ASHP is one of the eight organizations planning and providing funding for the National Symposium on Oral Counseling that was called for by the Action Plan.

We shared the executive summary of the report with our Board of Directors and leaders of our Affiliated State Societies. The comments below are partly a result of the responses received from these members.

BACKGROUND SECTION (Pages 1-3 of the Draft Report)

Page 1 of the report states that pharmacists can help patients "as a last line of defense, to identify and correct prescription errors" and "in a proactive manner to foster better patient understanding and use of prescription drugs." ASHP encourages the Inspector General to stress pharmacists' proactive and prospective abilities for intervention as a vital and productive member of the patient care team.

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Page 2

FINDINGS SECTION (Pages 4-7 of the Draft Report)

While ASHP is in general agreement with the findings of the Inspector General contained in the draft report, we would like to bring the following concerns to your attention:

Although the data used to prepare the draft report came primarily from a survey of state boards of pharmacy conducted as recently as November 1996 to January 1997, we would argue that the information from your survey is not completely accurate and up-to-date. For example, a coalition of pharmacy groups in Illinois has been working with that state's Board of Pharmacy to establish rules and regulations enhancing pharmaceutical care and patient counseling. In May of this year, the Illinois Board of Pharmacy accepted the coalition's recommendations for revising that state's rules for patient counseling. Although the state board's adoption of these recommendations is only the first step in the process of establishing better patient counseling rules in Illinois, and implementation of those rules cannot occur without the appropriate infrastructure and funding, it is an example of how state pharmacy organizations are dealing with the problem.

Pharmacy organizations in other states have had similar successes. Through the work of pharmacy groups in Texas within the last three months, that state has expanded its counseling requirements to include a once-a-year consultation on refills and maintenance medications, but this has not been enforced yet due to its recency. Texas pharmacy groups are currently holding meetings to discuss the affect pharmacists' working conditions have on their ability to offer counseling.

ASHP applauds these efforts by state pharmacist organizations and state boards of pharmacy to improve the dissemination of medication information to patients. We suggest that the Inspector General conduct follow-up surveys to determine what recent and on-going efforts have been initiated to solve the problems noted in the draft report.

Pharmacy Boards' Enforcement of Counseling Laws

ASHP agrees with the finding, noted on page 5 of the draft report, that board of pharmacy enforcement of counseling laws has been minimal. This is due, partly, to differences in how pharmacy boards deal with complaints and implement enforcement of state laws and regulations, a factor that the draft report does not seem to address. In addition to differences in how pharmacy boards implement enforcement of pharmacist counseling, there are differences, as noted on page 6 of the draft report, in how punitive boards are. Some are funded solely by the fines they issue, and these may be more inclined to carry out enforcement procedures.

ASHP believes strongly that implementation and enforcement of pharmacy practice laws and regulations should be left up to the individual states, and we recommend that a study or studies be conducted to determine what factors, related to state board of pharmacy operations and funding, have a positive influence on effective enforcement of counseling laws.

State Boards' Identification of Obstacles to Implementing Patient Counseling Laws

Lack of Resources for Enforcement

ASHP agrees that state boards of pharmacy lack sufficient staff and funding to investigate and enforce federal and state counseling requirements. While some state boards are funded by the fines they impose, others are not reimbursed for any costs related to the enforcement of counseling requirements, and even have limited funding to disseminate educational information about counseling.

Economics of Pharmacy Practice

On page 6, the draft report lists "Economics of Pharmacy Practice" as one of the obstacles state pharmacy boards identified as impediments to patient counseling. This includes "limited reimbursement for counseling services" and "lack of owners' commitment to counseling." ASHP and its members agree with both of these observations.

In today's marketplace, pharmacists are expected to increase the number of prescriptions they fill and patients they serve while simultaneously cutting costs and, in many cases, staff. This leads to patients equating the quality of pharmaceutical care and services with the quick delivery of prescriptions, which further lowers the priority of counseling as a service that can and should be provided by pharmacists. If the numbers cited in the draft report are correct -- that as much as \$100 billion a year is added to health-care costs due to patients misusing drugs and not receiving intended therapy¹ -- some consideration must be given to increasing insurance carriers' and other payors' (e.g., government) motivation to pay more at the pharmacy counseling level to encourage compliance with medication therapy and thereby reduce the overall cost of providing health care.

ASHP has received some interesting comments regarding what the draft report calls "lack of owners' commitment to counseling." In Endnote 28 (page C-4), the draft report states that "owners and managers of pharmacies, particularly large, corporate chain pharmacies, express considerable concern that without reimbursement for cognitive services offered by pharmacists, oral counseling could have undesirable financial effects on their operations." ASHP members who provided us with comments on the Executive Summary of the draft report, while agreeing that a reimbursement mechanism should be established for cognitive services, noted that a major impediment to proper pharmacist involvement in patient medication education is the attitude of non-pharmacist owners of pharmacies, particularly chain store owners, who have little interest in promoting counseling activities that may decrease the volume of prescriptions dispensed.

Some ASHP members contend that the reason some state pharmacy boards do not enforce counseling laws is because these boards have members who represent certain corporate interests that resist efforts at stronger enforcement. They believe that this situation will not change until boards are restructured to

¹Some minor corrections need to be made to the draft report. Page 1 of the report correctly cites the estimated costs as \$100 billion a year. Page i of the Executive Summary incorrectly states the cost as \$100 million a year. The date of the source for this estimate -- an article in the *Journal of the American Medical Association* -- is cited incorrectly in Endnote 2 (page C-1 of the report) as June 21, 1996; the article actually appeared in *JAMA* on June 21, 1995.

provide more input from practitioner pharmacists and consumers. One member noted that "economic reality places an unfair burden on a pharmacist who may choose to question company policy.... Proper counseling will not become universal or even widespread until the laws are changed to place sanctions on pharmacy owners who do not require their employed pharmacists to counsel patients." The consensus is that ways should be found to fine and discipline corporate owners as well as individual pharmacists for not complying with patient counseling laws.

Limited Patient Demand

On page 7, the draft report lists "Limited Patient Demand" as another obstacle identified as an impediment to patient counseling. ASHP believes that this is more of a perception than a reality. *Demand* should not be a barrier to counseling. Federal regulations and state laws require that pharmacists offer to counsel patients, not that the patients should ask. Pharmacists are often told by patients that they prefer to go to particular pharmacies because of the *printed* material the pharmacists provide there. Personal discussions with pharmacists could have an even greater impact on patient satisfaction.

Counseling must be a part of the prescription process and not a separate task performed by the pharmacist. While offering counseling as an "extra" service requiring additional time might be discouraging to some, our experience indicates that patients will spend the time needed for counseling if it is built into the process and is routinely performed. Clearly, patients require oral and written reinforcements to assure safe use and compliance with the prescribed drug regimen.

RECOMMENDATIONS SECTION (Pages 8-9 of the Draft Report)

Recommendations Directed to the Food and Drug Administration

On page 8, the draft report recommends that the FDA collaborate with state boards of pharmacy to collect survey data -- particularly through "shopping" visits -- "to determine the extent and type of counseling being offered to patients." While ASHP agrees that "shopping" visits may be helpful indicators of the amount of counseling that is provided (or if it is even offered), this is only one approach to fact-finding, and it is a labor-intensive and costly approach. Other survey methods should be considered, such as customer satisfaction surveys, which might be a better indicator of whether the patient has received any counseling at all, and whether the patient is pleased with the information provided by the pharmacist. Surveys could also be used to examine whether the pharmacy environment is appropriate for the interaction between pharmacists and patients, and they could identify and offer suggestions to correct structural deficiencies and procedures that can improve the delivery of healthcare information.

Recommendations Directed to the Health Care Financing Administration

On page 8, the draft report recommends that the HCFA should "facilitate State efforts to enforce the Medicaid patient counseling mandate." Unfortunately, it is likely that this "facilitation" will be largely ineffective unless pharmacists and state boards receive some type of economic incentive to comply with the federal mandate. One solution would be for HCFA to ensure that reimbursement for pharmacy services be adequate enough to cover counseling. The Inspector General's final report needs to

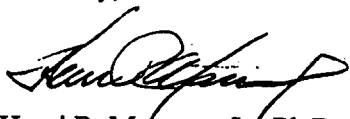
Ms. June Gibbs Brown
July 10, 1997
Page 5

address the important issue of how to fund the initiatives it recommends. ASHP suggests, as an initial phase, that HHS and HCFA measure the true costs of providing complete medication distribution and education, and then assist in developing a plan to make the appropriate resources available.

On page 9, the draft report recommends that HCFA should play a "stimulative role" in convening the national symposium on oral counseling by pharmacists recommended by the *Action Plan for the Provision of Useful Prescription Medicine Information* that was approved by Secretary Shalala. As noted above, ASHP and seven other organizations -- the Academy of Managed Care Pharmacy, the American Pharmaceutical Association, the American Society of Consultant Pharmacists, the National Community Pharmacists Association, the National Association of Boards of Pharmacy, the National Association of Chain Drug Stores, and the Pharmaceutical Care Management Association -- are sponsoring this symposium under the auspices of the Center on Drugs and Public Policy, University of Maryland School of Pharmacy. Most of the constructive work of the symposium, which is scheduled to be held on September 19-21, 1997, will be conducted through small group workshops that will address three major issues: consumers, pharmacy practice, and compensation. The goal of the symposium is to develop a common set of specific strategic plans for action that can be implemented by pharmacists to provide effective oral counseling to consumers. The sponsoring organizations plan to invite HCFA representatives to participate in the symposium on various levels.

ASHP looks forward to working with the Department of Health and Human Services, the Food and Drug Administration, the Health Care Financing Administration, and private-sector pharmacy organizations to address the concerns raised in the Inspector General's draft report. Our Affiliated State Chapters are prepared to work with their boards of pharmacy on this issue. Please call us if you have any questions about our comments, and we can discuss a further role that national and state professional pharmacy organizations may play in ensuring compliance with this important practice issue.

Sincerely,



Henri R. Manasse, Jr., Ph.D., Sc.D.
Executive Vice President

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Enclosures

cc: Board of Directors

G-103

ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling

Am J Health-Syst Pharm. 1997; 54:431-4

Purpose

Providing pharmaceutical care entails accepting responsibility for patients' pharmacotherapeutic outcomes. Pharmacists can contribute to positive outcomes by educating and counseling patients to prepare and motivate them to follow their pharmacotherapeutic regimens and monitoring plans. The purpose of this document is to help pharmacists provide effective patient education and counseling.

In working with individual patients, patient groups, families, and caregivers, pharmacists should approach education and counseling as interrelated activities. ASHP believes pharmacists should educate and counsel all patients to the extent possible, going beyond the minimum requirements of laws and regulations; simply offering to counsel is inconsistent with pharmacists' responsibilities. In pharmaceutical care, pharmacists should encourage patients to seek education and counseling and should eliminate barriers to providing it.

Pharmacists should also seek opportunities to participate in health-system patient-education programs and to support the educational efforts of other health care team members. Pharmacists should collaborate with other health care team members, as appropriate, to determine what specific information and counseling are required in each patient care situation. A coordinated effort among health care team members will enhance patients' adherence to pharmacotherapeutic regimens, monitoring of drug effects, and feedback to the health system.

ASHP believes these patient education and counseling guidelines are applicable in all practice settings—including acute inpatient care, ambulatory care, home care, and long-term care—whether these settings are associated with integrated health systems or managed care organizations or are freestanding. The guidelines may need to be adapted; for example, for use in telephone counseling or for counseling family members or caregivers instead of patients. Patient education and counseling usually occur at the time prescriptions are dispensed but may also be provided as a separate service. The techniques and the content should be adjusted to meet the specific needs of the patient and to comply with the policies and procedures of the practice setting. In health systems, other health care team members share in the responsibility to educate and counsel patients as specified in the patients' care plans.

Background

The human and economic consequences of inappropriate medication use have been the subject of professional, public, and congressional discourse for more than two decades.¹⁻³ Lack of sufficient knowledge about their health problems and medications is one cause of patients' nonadherence to their pharmacotherapeutic regimens and monitoring plans; without adequate knowledge, patients cannot be effective partners in managing their own care. The pharmacy profession has accepted responsibility for providing patient education

Approved by the ASHP Board of Directors, November 11, 1996. Revised by the ASHP Council on Professional Affairs. Supersedes the ASHP Statement on the Pharmacist's Role in Patient-Education Programs dated June 3, 1991, and ASHP Guidelines on Pharmacist-Conducted Patient Counseling dated November 18, 1992.

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and counseling in the context of pharmaceutical care to improve patient adherence and reduce medication-related problems.^{6,9}

Concerns about improper medication use contributed to the provision in the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) that mandated an offer to counsel Medicaid outpatients about prescription medications. Subsequently, states enacted legislation that generally extends the offer-to-counsel requirement to outpatients not covered by Medicaid. Future court cases may establish that pharmacists, in part because of changing laws, have a public duty to warn patients of adverse effects and potential interactions of medications. The result could be increased liability for pharmacists who fail to educate and counsel their patients or who do so incorrectly or incompletely.¹⁰

Pharmacists' knowledge and skills

In addition to a current knowledge of pharmacotherapy, pharmacists need to have the knowledge and skills to provide effective and accurate patient education and counseling. They should know about their patients' cultures, especially health and illness beliefs, attitudes, and practices. They should be aware of patients' feelings toward the health system and views of their own roles and responsibilities for decision-making and for managing their care.¹¹

Effective, open-ended questioning and active listening are essential skills for obtaining information from and sharing information with patients. Pharmacists have to adapt messages to fit patients' language skills and primary languages, through the use of teaching aids, interpreters, or cultural guides if necessary. Pharmacists also need to observe and interpret the nonverbal messages (e.g., eye contact, facial expressions, body movements, vocal characteristics) patients give during education and counseling sessions.¹²

Assessing a patient's cognitive abilities, learning style, and sensory and physical status enables the pharmacist to adapt information and educational methods to meet the patient's needs. A patient may learn best by hearing spoken instructions; by seeing a diagram, picture, or model; or by directly handling medications and administration devices. A patient may lack the visual acuity to read labels on prescription containers, markings on syringes, or written handout material. A patient may be unable to hear oral instructions or may lack sufficient motor skills to open a child-resistant container.

In addition to assessing whether patients know *how* to use their medications, pharmacists should attempt to understand patients' attitudes and potential behaviors concerning medication use. The pharmacist needs to determine whether a patient is willing to use a medication and whether he or she intends to do so.^{13,14}

Environment

Education and counseling should take place in an

environment conducive to patient involvement, learning, and acceptance—one that supports pharmacists' efforts to establish caring relationships with patients. Individual patients, groups, families, or caregivers should perceive the counseling environment as comfortable, confidential, and safe.

Education and counseling are most effective when conducted in a room or space that ensures privacy and opportunity to engage in confidential communication. If such an isolated space is not available, a common area can be restructured to maximize visual and auditory privacy from other patients or staff. Patients, including those who are disabled, should have easy access and seating. Space and seating should be adequate for family members or caregivers. The design and placement of desks and counters should minimize barriers to communication. Distractions and interruptions should be few, so that patients and pharmacists can have each other's undivided attention.

The environment should be equipped with appropriate learning aids, e.g., graphics, anatomical models, medication administration devices, memory aids, written material, and audiovisual resources.

Pharmacist and patient roles

Pharmacists and patients bring to education and counseling sessions their own perceptions of their roles and responsibilities. For the experience to be effective, the pharmacist and patient need to come to a common understanding about their respective roles and responsibilities. It may be necessary to clarify for patients that pharmacists have an appropriate and important role in providing education and counseling. Patients should be encouraged to be active participants.

The pharmacist's role is to verify that patients have sufficient understanding, knowledge, and skill to follow their pharmacotherapeutic regimens and monitoring plans. Pharmacists should also seek ways to motivate patients to learn about their treatment and to be active partners in their care. Patients' role is to adhere to their pharmacotherapeutic regimens, monitor for drug effects, and report their experiences to pharmacists or other members of their health care teams.^{12,15} Optimally, the patient's role should include seeking information and presenting concerns that may make adherence difficult.

Depending on the health system's policies and procedures, its use of protocols or clinical care plans, and its credentialing of providers, pharmacists may also have disease management roles and responsibilities for specified categories of patients. This expands pharmacists' relationships with patients and the content of education and counseling sessions.

Process steps

Steps in the patient education and counseling proc-

ess will vary according to the health system's policies and procedures, environment, and practice setting. Generally, the following steps are appropriate for patients receiving new medications or returning for refills¹²⁻²¹:

1. Establish caring relationships with patients as appropriate to the practice setting and stage in the patient's health care management. Introduce yourself as a pharmacist, explain the purpose and expected length of the sessions, and obtain the patient's agreement to participate. Determine the patient's primary spoken language.
2. Assess the patient's knowledge about his or her health problems and medications, physical and mental capability to use the medications appropriately, and attitude toward the health problems and medications. Ask open-ended questions about each medication's purpose and what the patient expects, and ask the patient to describe or show how he or she will use the medication.

Patients returning for refill medications should be asked to describe or show how they have been using their medications. They should also be asked to describe any problems, concerns, or uncertainties they are experiencing with their medications.

3. Provide information orally and use visual aids or demonstrations to fill patients' gaps in knowledge and understanding. Open the medication containers to show patients the colors, sizes, shapes, and markings on oral solids. For oral liquids and injectables, show patients the dosage marks on measuring devices. Demonstrate the assembly and use of administration devices such as nasal and oral inhalers. As a supplement to face-to-face oral communication, provide written handouts to help the patient recall the information.

If a patient is experiencing problems with his or her medications, gather appropriate data and assess the problems. Then adjust the pharmacotherapeutic regimens according to protocols or notify the prescribers.

4. Verify patients' knowledge and understanding of medication use. Ask patients to describe or show how they will use their medications and identify their effects. Observe patients' medication-use capability and accuracy and attitudes toward following their pharmacotherapeutic regimens and monitoring plans.

Content

The content of an education and counseling session may include the information listed below, as appropriate for each patient's pharmacotherapeutic regimen and monitoring plan.^{6,9,20} The decision to discuss specific pharmacotherapeutic information with an individual patient must be based on the pharmacist's professional judgment.

1. The medication's trade name, generic name, common synonym, or other descriptive name(s) and, when appropriate, its therapeutic class and efficacy.
2. The medication's use and expected benefits and action. This may include whether the medication is

intended to cure a disease, eliminate or reduce symptoms, arrest or slow the disease process, or prevent the disease or a symptom.

3. The medication's expected onset of action and what to do if the action does not occur.
4. The medication's route, dosage form, dosage, and administration schedule (including duration of therapy).
5. Directions for preparing and using or administering the medication. This may include adaptation to fit patients' lifestyles or work environments.
6. Action to be taken in case of a missed dose.
7. Precautions to be observed during the medication's use or administration and the medication's potential risks in relation to benefits. For injectable medications and administration devices, concern about latex allergy may be discussed.
8. Potential common and severe adverse effects that may occur, actions to prevent or minimize their occurrence, and actions to take if they occur, including notifying the prescriber, pharmacist, or other health care provider.
9. Techniques for self-monitoring of the pharmacotherapy.
10. Potential drug-drug (including nonprescription), drug-food, and drug-disease interactions or contraindications.
11. The medication's relationships to radiologic and laboratory procedures (e.g., timing of doses and potential interferences with interpretation of results).
12. Prescription refill authorizations and the process for obtaining refills.
13. Instructions for 24-hour access to a pharmacist.
14. Proper storage of the medication.
15. Proper disposal of contaminated or discontinued medications and used administration devices.
16. Any other information unique to an individual patient or medication.

These points are applicable to both prescription and nonprescription medications. Pharmacists should counsel patients in the proper selection of nonprescription medications.

Additional content may be appropriate when pharmacists have authorized responsibilities in collaborative disease management for specified categories of patients. Depending on the patient's disease management or clinical care plan, the following may be covered:

1. The disease state: whether it is acute or chronic and its prevention, transmission, progression, and recurrence.
2. Expected effects of the disease on the patient's normal daily living.
3. Recognition and monitoring of disease complications.

Documentation

Pharmacists should document education and counseling in patients' permanent medical records as consistent with the patients' care plans, the health system's policies and procedures, and applicable state and

federal laws. When pharmacists do not have access to patients' medical records, education and counseling may be documented in the pharmacy's patient profiles, on the medication order or prescription form, or on a specially designed counseling record.

The pharmacist should record (1) that counseling was offered and was accepted and provided or refused and (2) the pharmacist's perceived level of the patient's understanding.⁹ As appropriate, the content should be documented (for example, counseling about food-drug interactions). All documentation should be safeguarded to respect patient confidentiality and privacy and to comply with applicable state and federal laws.¹⁰

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ASHP Leadership Agenda, 1997-98

Rationale and Implementation

Increase awareness among the public in general and among health-system decision-makers specifically about the vital patient care role of pharmacists.

Rationale. A new mission for pharmacists--helping people make the best use of medications--has been declared, but pharmacists need public understanding and support in order to achieve widespread acceptance and recognition for this role. Decision-makers in health systems do not fully appreciate the value of pharmacists in patient care and in the continuity of care. There is a risk in today's cost-cutting environment that some health-system executives may compromise the quality of patient care by simply curtailing their employment of pharmacists without seeking ways for pharmacists to help improve patient outcomes while lowering costs.

Implementation. ASHP has expanded its efforts to increase the general public's awareness of the value of health-system pharmacists. An aggressive, proactive public relations program is being developed with the assistance of a communications firm and with the involvement of affiliated state societies. In 1996-97, ASHP launched a communications campaign to increase the awareness of health-system decision-makers about the vital patient care role of pharmacists. One thrust of the campaign, which will continue in 1997-98, is communicating directly with health-system executives and another is developing tools that individual ASHP members can use to help them demonstrate the value of pharmacists in their practice settings.

Foster expanded efforts by health systems to prevent medication errors and other drug-related problems.

Rationale. The safety of medication use is a growing public concern as reflected by the news media and by the scientific and professional literature. In the health-system environment, responsibility for the safety of the medication-use process is shared by many persons in addition to pharmacists, including physicians, nurses, administrators, various technical personnel, and patients. Health systems are not consistently applying proven methods for reducing medication errors. By virtue of their education and training, pharmacists are in a position to lead efforts within health systems to assess and improve the safety of medication use. Highly visible activity by health-system pharmacists on this issue will enhance public awareness of the patient care role of pharmacists.

Implementation. ASHP will build on its previous work and launch new initiatives to foster safe medication use in health systems. In doing so, it will collaborate with the ASHP Research and Education Foundation and other health professions and organizations.

**Accelerate efforts to help health-system pharmacists
serve patients across the continuum of care.**

Rationale. The ongoing formation of integrated health care delivery systems will require ASHP members to be well equipped to serve the needs of patients in all components of integrated systems and to foster continuity of care across those components. The demand for health-system pharmacists in certain areas such as ambulatory care may grow faster than in acute care, presenting new opportunities for pharmacists to improve patient outcomes. Health systems will be giving more attention to disease prevention and health promotion, activities that are relatively underdeveloped in pharmacy education and practice.

Implementation. ASHP will identify and begin development of initiatives to ensure that pharmacists are well equipped for their evolving roles in all components of health systems, including ambulatory care, chronic care, long-term care, disease prevention, and health promotion. These initiatives will cover pharmacy management and leadership as well as clinical practice.

**Build strategic partnerships that will advance the health-system pharmacist's
role in the medication-use process.**

Rationale. The providers of health care services will continue to consolidate through the development of integrated delivery systems that cover all components of health care. In this environment, ASHP must actively seek new types of collaborative relationships that will create opportunities for advancing the health-system pharmacist's role in coordinating the medication-use process as well as expanding ASHP's capacity to serve members.

Implementation. ASHP has identified existing and desirable partnerships (organizational, interdisciplinary, business) that offer strategic possibilities and has determined which offer the best potential for strategic alliances. ASHP is systematically pursuing the establishment of strong working relationships with several key groups. The top priorities are medical organizations, managed care provider organizations, and standard-setting and performance-measurement organizations in health care.

ASHP Mission Statement

The mission of ASHP is to represent its members and to provide leadership that will enable pharmacists in organized health-care settings to

- (1) extend pharmaceutical care focused on achieving positive patient outcomes through drug therapy;
- (2) provide services that foster the efficacy, safety, and cost-effectiveness of drug use;
- (3) contribute to programs and services that emphasize the health needs of the public and the prevention of disease; and
- (4) promote pharmacy as an essential component of the health-care team.

--Approved by the ASHP House of Delegates, June 3, 1992

APPENDIX D

ENDNOTES

1. For studies addressing the quality of care impacts associated with mismedications, see A.J. Wood and J.A. Oates, "Adverse Reactions to Drugs," in R. Petersdorf et al., *Harrison's Principles of Internal Medicine*, 12th ed. (New York: McGraw Hill, 1991), 373-9; Stephen H. Long, "Prescription Drugs and the Elderly: Issues and Options," *Health Affairs* 158 (Spring II, 1994), 157-74; U.S. General Accounting Office, *Prescription Drugs and the Elderly: Many Still Receive Potentially Harmful Drugs Despite Recent Improvements*, GAO/HEHS-95-152, July 1995; Jeffrey A. Johnson et al., "Drug-Related Morbidity and Mortality: A Cost-of-Illness Model," *Archives of Internal Medicine*, 155 (October 9, 1995), 1949-56; *Adverse Drug Reactions in the Elderly: Hearing before the Special Committee on Aging*, United States Senate, 104th Cong., 2nd Sess., March 28, 1996; and Robert McCarthy, "Patient Compliance: Strategies to Overcome a Costly Problem," *Medical Utilization Management* 24 (July 11, 1996) 14, 5-8.
2. This assessment was made by Paul Rogers, chair of the National Conference on Prescription Medicine Information and Education. See "FDA Pushes for Prescription Drug Information," *Journal of the American Medical Association* (273) 23, June 21, 1995, 1815-16. The FDA Commissioner has estimated that failure to get consumers adequate information about prescription drugs costs about \$20 billion a year in direct costs associated with patients who have not adhered to a prescribed drug regimen and about \$80 billion in indirect costs such as those associated with days lost from work. See Philip J. Hilts, "F.D.A. Seeks Clear Information Inserts with Prescription Drugs," *New York Times*, August 24, 1995, A21.
3. On the basis of a review of 50 studies, the FDA concluded that noncompliance rates averaged from 30 to 50 percent. See "Prescription Drug Product Labeling: Medication Guide Requirements; Proposed Rule," Department of Health and Human Services, Food and Drug Administration, *Federal Register*, 21 CFR Part 201, wt al., August 24, 1995, 44186.
4. See, for instance, Timothy S. Lesar, et al., "Factors Related to Errors in Medication Prescribing," *Journal of the American Medical Association*, (277) 4, January 22/29, 1997, 312-17.
5. See Office of Inspector General, "The Clinical Role of the Community Pharmacist," OEI-01-89-89160, November 1990.
6. The American Pharmaceutical Association and other pharmacy professional organizations are encouraging the development of "pharmaceutical care" - whereby pharmacists play an important role in counseling patients. Professional medical associations support pharmacist roles in helping ensure that patients understand and adhere

to drug therapy prescribed by physicians. However, they tend to be wary of more activist roles by community pharmacists. This was most apparent in the minority report of the American Medical Association, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists to the private-sector action plan recently approved by the Secretary of Health and Human Services (see appendix B). In their comments, they express concern that pharmacy organizations have sought to use the action plan "as a mechanism to legitimize the role of the pharmacist as a primary counselor of patients about prescription drugs." "It is," they add, "the unwavering view of the physician organizations that this is inappropriate as it distorts the reality of actual practice."

7. The Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508).
8. The National Association of Boards of Pharmacy, *Consumer Patient Counseling Survey*, 1996.
9. New York City Office of the Public Advocate, *Prescription for Danger: Drugstore Counseling Routinely Ignored*, 1996.
10. *U.S. News and World Report* (121) 8, August 26, 1996, 46-53. At about the same time, a television news show ran a major segment on the same topic.
11. Nicholas John Cavuto, et al., Letter to the Editor, "Pharmacies and Prevention of Potentially Fatal Drug Interactions," *Journal of the American Medical Association* (275) 14, April 10, 1996, 1086-7.
12. We sent the survey to the 50 State pharmacy boards and the pharmacy board of the District of Columbia.
13. Three boards did not respond to our survey: Maine, Kansas, and District of Columbia. Two, Michigan and South Carolina, suggested that we contact the State Medicaid agency to discuss enforcement of the Medicaid counseling law. In those two cases, we did conduct discussions with Medicaid agency representatives, but we regarded those two States as nonrespondents for our survey of pharmacy boards.
14. California State Board of Pharmacy, Department of Consumer Affairs, Fall 1995.
15. Although this and other such outreach efforts by boards would provide pharmacists with opportunities to obtain continuing education credits, only 3 of 46 reporting boards indicated that their State had a continuing education requirement for pharmacists that was specifically intended to help them conduct patient counseling.
16. During the past year, 39 of 46 reporting boards (85 percent) conducted on-site visits of pharmacies. In these States, the median percentage of pharmacies visited was 80 percent.

17. Our reference here and throughout the report is to boards responding to a particular question. Thus, while 46 boards responded to some or all of our survey, the number responding to any particular question varies slightly.

18. One board official commented as follows: It is virtually impossible to make a "paper case." Each disciplinary action requires more than one undercover shopping visit and is very labor intensive. This is a problem for an agency that is short on personnel."

19. One board noted that several shopping efforts have been undertaken in the past year and that in almost all cases pharmacists are complying with the OBRA 1990 legislation. Two other boards were less positive in describing their results. One noted an overall compliance rate of 70 percent. One simply noted that the results of shopping visits to three dozen pharmacies "were not satisfactory." He noted that they found that pharmacists tend to skip counseling on patients they didn't know.

20. Even though the investigation may involve "shopping," the complaint/concern leading to it does not necessarily involve a possible counseling violation.

21. Pharmacy boards also enforce patient counseling laws through their response to complaints. In our survey, we asked how often such complaints were related to patient counseling. We present the responses in appendix A. However, upon follow-up discussions with a number of board officials we determined that boards had widely varying interpretations of "counseling-related;" thus any generalizations on this matter would be suspect. It may be pertinent to note though that among 37 reporting boards, 28 (76 percent) estimated that consumers were the primary source of complaints involving possible violations of patient counseling requirements.

22. The economic barriers to counseling were also emphasized in a prior Office of Inspector General study. See OEI-89-89160, "The Clinical Role of the Community Pharmacist," November 1990.

23. A few officials, however, suggested that the "attitudes" of pharmacists also contributed to a lack of counseling.

24. This perception has been documented in many prior studies over many years. For instance, a 1982 Schering Laboratory study found that among 15 possible reasons offered for choosing a pharmacy, consumers they surveyed ranked the following as the first reason: "Pharmacist fills prescriptions promptly." See Schering laboratories, "Pharmacist Perceptions vs. Consumer Realities: Updating the View from Both Sides of the Counter," The Schering Report IV, Kenilworth, New Jersey, 1982.

25. Here, and throughout the text, we use the term "major" to describe responses identified by respondents as "significant" or "very significant."

26. For instance, an October 1996 verdict a South Carolina case resulted in a \$16 million settlement against a chain pharmacy for an improperly filled prescription leading to severe brain damage for a child. (Court of Common Pleas, York County, South Carolina. Docket Numbers: 95-CP-46-405 and 95-CP-46-406.)

27. The national health promotion and disease prevention objectives issued by the Department of Health and Human Services in its report entitled, "Healthy People 2000," calls for a commitment to written and oral counseling. Objective 12.8, added in 1995, states: "Increase to at least 75 percent the proportion of people who receive useful information verbally and in writing for new prescriptions from prescribers and dispensers."

28. Physician groups, as we have noted, express considerable concern that oral counseling initiatives could lead to undesirable intrusions into the practice of medicine. Similarly, owners and managers of pharmacies, particularly large, corporate chain pharmacies, express considerable concern that without reimbursement for cognitive services offered by pharmacists, oral counseling could have undesirable financial effects on their operations. The HCFA and pharmacy associations could help address these concerns by showcasing ways in which pharmacists and physicians are working together in some community settings. Similarly, they could help draw attention to initiatives such as the one in Wisconsin where the Medicaid program is reimbursing pharmacists for "pharmaceutical care" at varied levels, depending on the extent of care being provided to patients.