

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Experiences of Health Maintenance Organizations
with
Pharmacy Benefit Management Companies**



**JUNE GIBBS BROWN
Inspector General**

April 1997
OEI-01-95-00110

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EXECUTIVE SUMMARY

PURPOSE

To examine the experiences of health maintenance organizations, particularly those participating in Medicare or Medicaid, in contracting with pharmacy benefit management companies.

BACKGROUND

MEDICAID AND MEDICARE COVERAGE OF PRESCRIPTION DRUGS

In 1994, national expenditures on prescription drugs were \$52 billion, up from \$21 billion in 1985. The Medicaid program accounted for \$9 billion of these expenditures (8 percent of all Medicaid expenditures). The Medicare program has limited its coverage of outpatient prescription drugs to a few specific categories of drugs. But recently, many beneficiaries have been receiving broader outpatient drug coverage as an additional benefit offered by Medicare-risk health maintenance organizations (HMOs).

PHARMACY BENEFIT MANAGEMENT COMPANIES

Pharmacy benefit management companies (PBMs) have emerged as significant players that can help payers and health plans control rising drug costs and improve drug therapy of their providers and to their patients. The HMOs, among others, can contract with PBMs for services ranging from claims processing to disease management programs involving patients, pharmacists, and physicians.

THIS INQUIRY

This inquiry focuses on the experiences of HMOs in using PBMs. As enrollment in managed care continues to grow and because PBMs can significantly affect patients' use of prescription drugs, it is important for the Health Care Financing Administration (HCFA), as well as private payers, to be informed about the HMOs' experiences with them.

This report is based primarily on data from a mail survey of all HMOs in the country, for which we had a 71 percent response rate. We also drew on discussions with staff from the U.S. Department of Health and Human Services (HHS) and several State Medicaid agencies; with non-government experts; and on a review of the literature.

EXPERIENCES OF HMOs WITH PBMs

WIDESPREAD AND GROWING USE OF PBMs

Three-fourths of the 263 HMOs responding to our survey contract with PBM companies. The number using PBMs has nearly tripled since 1993. A majority (74 percent) of these HMOs serve Medicare and/or Medicaid beneficiaries.

Nearly all HMOs use PBMs for services that affect patients' use of prescription drugs, such as managing formularies and reviewing drug therapy decisions of physicians, pharmacists, and patients.

In the future, many HMOs will use PBMs in ways that influence patient care even more directly through purchasing more clinically focussed services and through negotiating more capitated or risk-sharing contracts.

POTENTIAL COST-SAVINGS: THE BIGGEST BENEFIT

The HMOs describe the benefits of using PBMs mainly in terms of controlling costs of prescription drugs. They also consider other important benefits to be improving physicians' prescribing practices and patients' access to pharmacy services.

POTENTIAL BIAS: THE BIGGEST CONCERN

The HMOs' biggest concern about PBMs is the potential for bias resulting from the PBMs' alliances with drug manufacturers. One-half (52 percent) of the HMOs contract with one of the five, large PBMs, each of which is owned by or allied with drug manufacturers.

Other concerns to HMOs include confidentiality of data, disclosure of information to patients, and the HMOs' own oversight of the PBMs' performance.

MINIMAL OVERSIGHT OF PERFORMANCE

The HMOs rely primarily on PBM-supplied data and reports for overseeing their PBMs' performance. They rely less on independent assessments from their own clinicians and patients.

The HCFA and State Medicaid agencies we contacted provide minimal oversight of their Medicare and Medicaid HMOs' subcontracts with PBMs or their HMOs' pharmacy programs in general.

The major, private accreditation programs for managed care organizations neither accredit PBMs nor review HMOs' pharmacy programs and the arrangements they may have with PBMs. In part, this inattention reflects a lack of quality measures suitable for assessing pharmacy programs in these settings.

RECOMMENDATIONS

The HCFA should take steps to ensure that its Medicare HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries.

The HCFA could take steps toward this end by strengthening its contract requirements for Medicare HMOs and by incorporating reviews of pharmacy programs in its oversight of the HMOs' performance.

Similarly, State Medicaid agencies should take steps to ensure that their Medicaid HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries.

State Medicaid agencies could take steps similar to those suggested above for HCFA and its Medicare HMOs. The HCFA could work with States towards this end.

The HCFA, the Food and Drug Administration, and the Health Resources and Services Administration, working together with external organizations, should build on existing efforts to develop quality measures for pharmacy practice that can be used in managed care settings.

The pharmacy profession has begun to develop a framework of standards and measures that can be used to assess the quality of pharmacy services and programs. Continued development of this framework is essential. It needs to involve the significant parties who have responsibility for ensuring that pharmacy programs rest on foundations that are clinically sound, widely accepted, and promote improved patient care. These parties include the professional pharmacy and medical organizations, the private accreditation organizations, consumer groups, and the managed care industry.

COMMENTS ON THE DRAFT REPORT

We received comments on the draft report from the Health Care Financing Administration (HCFA), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA). We also solicited and received comments from the Academy of Managed Care Pharmacy (AMCP), the American Medical Association (AMA), the American Pharmaceutical Association (APHA), the American Society of Health Systems Pharmacists (ASHP), the Consumer Coalition for Quality Health Care, and HCFA's Medicaid Pharmacy Technical Advisory Group. We include the complete text of the detailed comments in appendix D. Below we summarize the major thrust of the comments and, in italics, offer our responses. We made a few minor edits in the report in response to the comments.

HCFA, FDA, HRSA COMMENTS

All three agencies concurred with our recommendations.

In concurring with the first recommendation, HCFA identified current requirements for its contracts with HMOs and summarized its current approaches for monitoring their performance. *In our view, this response does not substantively address a central concern raised in this report about HCFA's minimal oversight of its HMOs' pharmacy programs and their subcontracts with PBMs. We believe our findings warrant more attention by HCFA. Its HMO contract, as we point out, could be an important vehicle for strengthening Medicare HMOs' accountability for their pharmacy programs.*

The third recommendation, for HCFA, FDA, and HRSA to work with external organizations on developing quality measures for pharmacy practice, was favorably received by all three agencies. We encourage the agencies to meet together and to identify one among them to assume lead responsibility, so that enhanced communication

and coordination may facilitate continued progress in developing these measures.

EXTERNAL ORGANIZATIONS' COMMENTS

All the outside organizations concurred with our recommendations. Some call for revisions to the report or other actions on our part. *We appreciate that these organizations support our recommendations. Unfortunately, many of the comments suggest actions beyond the scope of this inquiry.*

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INTRODUCTION

PURPOSE

To examine the experiences of health maintenance organizations, particularly those participating in Medicare or Medicaid, in contracting with pharmacy benefit management companies.

BACKGROUND

The Growth of Managed Care

During the 1990s, America's health care system has been transformed by the rapid growth of managed care systems for financing and delivering health services. Enrollments in managed care plans, particularly health maintenance organizations (HMOs), are increasing dramatically as payers, both public and private, and consumers seek to contain the rising costs of health care.¹

This shift to managed care has moved to center stage for both the Medicare and Medicaid programs as well. As public payers of health care for the elderly, disabled, and indigent, States and the Federal Government, through the Health Care Financing Administration (HCFA), have encouraged the enrollment of Medicare and Medicaid beneficiaries into managed care arrangements. The number of Medicare beneficiaries receiving services through managed care plans has tripled since 1990 (now around 4.5 million or 12 percent of all beneficiaries), and the number of Medicare-risk managed care programs is increasing rapidly.² Similarly, enrollment of Medicaid beneficiaries in managed care arrangements was around 39 percent as of June 1996, up from 10 percent in 1991.³ Enrollment continues to grow.

The Rising Costs of Prescription Drugs

Spending on prescription drug costs has been increasing annually; in 1994, expenditures on drugs was nearly \$52 billion, up from \$21 billion in 1985. The proportion of these costs borne by third-party payers was 58 percent, up from 45 percent in 1985.⁴

Medicare and Medicaid beneficiaries together constitute the largest segments of the outpatient prescription drug market. All States' Medicaid programs cover outpatient prescription drugs for beneficiaries enrolled in managed care plans and in the fee-for-service system. The costs of prescription drugs to Medicaid was nearly \$9 billion, or 8 percent of total Medicaid spending in 1994.⁵ The Medicare program, on the other hand, has limited its outpatient drug coverage to a few categories of drugs, such as immunosuppressants and cancer drugs. However, Medicare is now, in effect, supporting broader outpatient prescription drug coverage as its risk HMOs rely more and more on this additional benefit to attract Medicare enrollees, many of whom have no drug coverage at all.⁶

To the rising costs of prescription drugs can also be added the estimated billions of dollars annually in health costs resulting from mismedication of patients and their noncompliance with drug therapies. These problems are particularly acute among the elderly and are costly for Medicare.⁷

The Evolution of Pharmacy Benefit Management Companies

Pharmacy benefit management companies (PBMs) have emerged as important players in the health care system. They are relied upon by many payers and health plans to contain rising pharmacy costs. PBMs bring to the table sophisticated, on-line computer systems that enable them to verify immediately enrollees' eligibility and to rapidly process prescription claims for payment. Many PBMs offer other services helpful in managing prescription drug benefits such as systems for delivering prescriptions by mail and networks of community pharmacies that participate in particular health plans. Some PBMs have teamed their computer capabilities with their massive databases of prescription claims to offer more sophisticated services such as formulary management services, drug use reviews, and education programs. Finally, a few are now pioneering disease state management programs as well as research programs to assess cost-effectiveness and outcomes of drug therapies.

The influence of PBMs in the marketplace has been growing steadily. They managed benefits, in 1993, for an estimated 100 million people, around 40 percent of the U.S. population. While several dozen PBMs are active in the marketplace, a handful of firms dominate. Estimates suggest that, in 1995, the 5 largest PBMs managed benefits for 80 percent of all health plan enrollees served by PBMs.⁸

The Potential in Using Pharmacy Benefit Management Companies

PBMs are attractive to payers and health plans, such as HMOs, because of their potential to contain escalating pharmacy costs. And PBMs can help improve health outcomes for patients by influencing physicians' prescribing, pharmacists' dispensing, and patients' compliance with their drug therapies.

At the same time, the financial imperatives driving managed care arrangements have potential for compromising the quality of pharmacy programs. Quality can be compromised by the way payers and plans structure the pharmacy benefit and by the approaches they use to manage it.⁹

Concerns about the effect of PBMs on the quality of pharmacy programs have intensified because of the business relationships that exist between PBMs and drug companies. In fact, 3 of the 5 largest PBMs are now owned by drug companies.¹⁰ Questions of bias and conflict of interest have been raised about the relationships between PBMs and drug companies. And issues of potential anti-competitive trade practices associated with the mergers, in particular, have been of concern to the Federal Trade Commission.¹¹

THIS INQUIRY

This inquiry focusses on the recent experiences of HMOs who contract with PBMs. As managed care plans continue to grow, HMOs are increasingly important purchasers of PBM services. The relationships between HMOs and PBMs are especially significant to the Department of Health and Human Services (HHS) because of the growing number of its beneficiaries enrolling in HMO programs. The Food and Drug Administration (FDA) has questioned the adequacy of drug product information disseminated by PBMs to physicians, pharmacists, and patients as they manage formularies and influence the drug products prescribed and sold.¹² And the Office of Inspector General (OIG) also questioned prescription drug marketing practices in a 1994 Special Fraud Alert.

We intend this inspection to provide pertinent information to HCFA, State Medicaid agencies, and other payers who need to be well informed about the extent, nature, and consequences of HMOs' arrangements with PBMs.

METHODOLOGY

We relied on four sources of information for this report (a fuller description of our methodology is presented in appendix A).

- ▶ A mail survey of all HMOs in the country is the primary source of information. We surveyed 368 decisionmakers (either the chief executive or the head of pharmacy services) responsible for decisions about PBMs for their HMOs. Our universe included 26 executives from national or regional managed care organizations who represent their organizations' 283 affiliated local plans. The remaining 342 executives each represent local HMO plans unaffiliated with any national or regional managed care organizations. These 368 decisionmakers represent 625 local plans nationwide, which served nearly 54 million enrollees in 1995. Overall, 263 of 368 decisionmakers (whom we refer to as "HMOs" in this report) responded to our survey. This is a response rate of 71 percent.
- ▶ Telephone discussions with HCFA staff in both headquarters and 6 regional offices and with Medicaid officials from 9 States.
- ▶ Discussions with experts and analysts knowledgeable about managed care, pharmaceutical care, and pharmacy benefit management.
- ▶ A literature review including journals and newsletters, reports and analyses, government documents, documents from professional and trade organizations.

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

PHARMACY BENEFIT MANAGEMENT COMPANIES: THE BASICS

The demands for efficiencies and savings in the managed health care marketplace have spawned a new player: the pharmacy benefit management company.¹³ Evolving from their early years as prescription claims processors, PBMs are now major actors on the pharmacy scene with complex, influential roles in the mix of payers, health plans, consumers, physicians, pharmacists, pharmacies, and drug manufacturers. Health plans, among others, contract with PBMs for particular benefit management services. PBMs' services typically fall into three categories:

The Basic Services focus primarily on the systems management functions of a pharmacy benefit:

- *Claims processing:* processing individual prescription claims for payment; may also involve confirming the patient's eligibility and the compliance of the drug with the benefit's formulary.
- *On-line pharmacy networks:* contracting with individual community-based pharmacies to form a network of providers participating in the health plan.
- *Mail order services:* using mail order pharmacies to supply prescription drugs via mail rather than through retail pharmacy settings.

The Intermediate Services focus on the purchasing power of PBMs and their capacity to screen large databases of prescription claims for utilization and quality issues. These services can have greater impact on patient care than the basic services.

- *Formulary development and management:* evaluating and selecting which drugs to include on the lists of preferred drugs (formularies) for use by the health plans' enrollees. PBMs decide which drug classes to include as well as which drugs within those classes and the priority ranking for each. The process involves applying cost and clinical criteria for choosing among the many drugs available from different manufacturers. PBMs can also manage the formularies on behalf of health plans. They use practices agreed to by the health plans such as requirements for authorization prior to dispensing a particular drug; limits on the frequency or numbers of prescriptions or refills allowed; and drug product substitution programs by which pharmacists, acting on behalf of the PBM, dispense different drugs from those initially prescribed.

- *Drug use review:* examining the use of prescription drugs using pre-determined cost and/or quality criteria. Prospective review screens individual prescriptions before they are filled to identify quality or utilization problems. Retrospective review occurs after prescriptions are filled and the claims submitted for payment. It involves screening large numbers of claims to identify inappropriate prescribing or dispensing practices, possible fraudulent activity, or noncompliance by patients with their drug therapies.

- *Education:* intervening with physicians, pharmacists, and patients to change drug therapy practices.

The Enhanced Services are the most recently developed services that involve PBMs substantively in the ways drugs are used and in managing patients' care.

- *Outcomes/cost-effectiveness research:* using the PBMs' massive databases to inform research on the cost-effectiveness or outcomes of drugs and drug therapies.

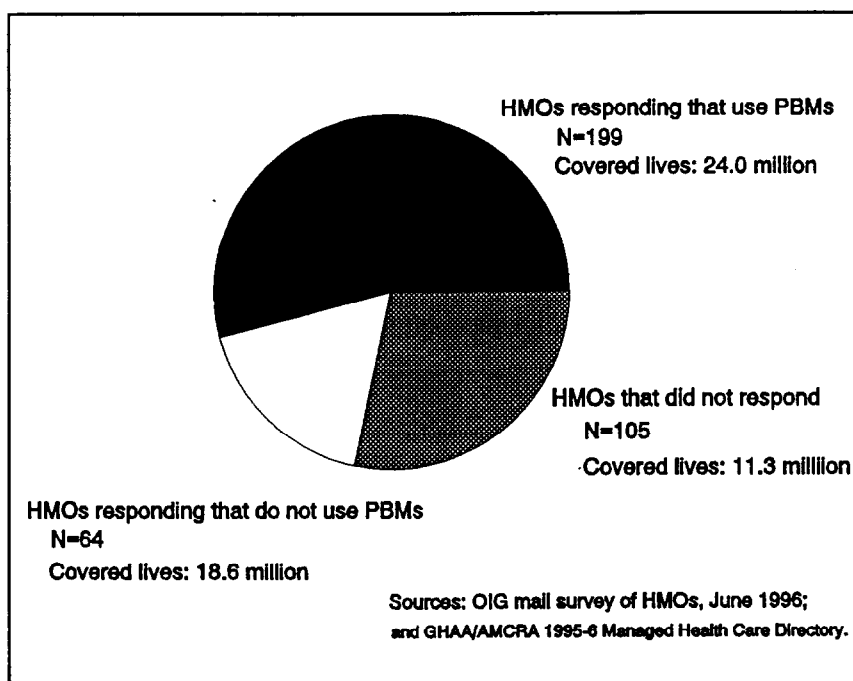
- *Disease state management:* managing the diseases of groups of patients through improved drug therapies, particularly focussing on those chronic diseases, such as diabetes and asthma, which can be effectively treated by prescription drugs but which can result in costly illness without adequate management.

WHICH HMOs USE PBMs

Three-fourths of the 263 HMOs responding to our survey contract with PBM companies. The number using PBMs has nearly tripled since 1993. They served 45 percent of all enrollees in HMOs in 1995.

Figure 1

EXTENT OF USE OF PBMs BY HMOs



A majority of the HMOs using PBMs:

- ▶ serve Medicare and/or Medicaid beneficiaries (74 percent);¹⁴
- ▶ contract with one of the five, large PBMs, each of which is owned by or allied with drug manufacturers (52 percent); and
- ▶ are for-profit plans (61 percent).¹⁵

A larger proportion (77 percent) of the unaffiliated, local HMOs use PBMs than do the local plans affiliated with national or regional managed care organizations (46 percent).¹⁶

The number of enrollees affected by PBMs is significant and will likely continue to be so. The HMOs indicating that they use PBMs covered 24 million lives in 1995. This estimate no doubt underreports the actual number, because data were not reported by all HMOs, and, since then, enrollments in HMOs have been increasing steadily.¹⁷

HOW HMOs USE PBMs

Nearly all HMOs use PBMs for services that affect the use of prescription drugs by patients. Most rely on PBMs to develop or manage their formularies and to review drug use by physicians, pharmacists, and patients.

All but four HMOs use their PBMs for services other than claims processing. Nearly all HMOs contract for multiple services: an average and a median per HMO of 7 of 11 different types of services (see service types in Figure 2). Nearly all HMOs use at least one of the basic services (97 percent) and at least one of the intermediate services (96 percent). Far fewer (41 percent) contract for either of the enhanced services. Those HMOs that serve Medicare and/or Medicaid beneficiaries do not differ significantly in their use of services from those HMOs that do not.¹⁸

Figure 2

PROPORTION OF HMOs USING PBM SERVICES, BY TYPE OF SERVICE

<u>Basic services</u>	
94 %	Claims Processing
74 %	Pharmacy networks
46 %	Mail order services
<u>Intermediate services</u>	
84 %	Retrospective DUR
81 %	Prospective Drug Use Review (DUR) management
71 %	Formulary management
62 %	Formulary development
56 %	Education of individual providers and/or patients
42 %	Education through broadly based outreach programs
<u>Enhanced services</u>	
35 %	Disease state management programs
28 %	Outcomes/cost effectiveness research
N = 199 HMOs	
Source: OIG mail survey of HMOs, June 1996.	

In the years ahead, many HMOs expect to use PBMs in ways that influence patient care even more directly. They are likely to use services that are more clinically focussed and to use more capitated or risk-sharing contract arrangements.

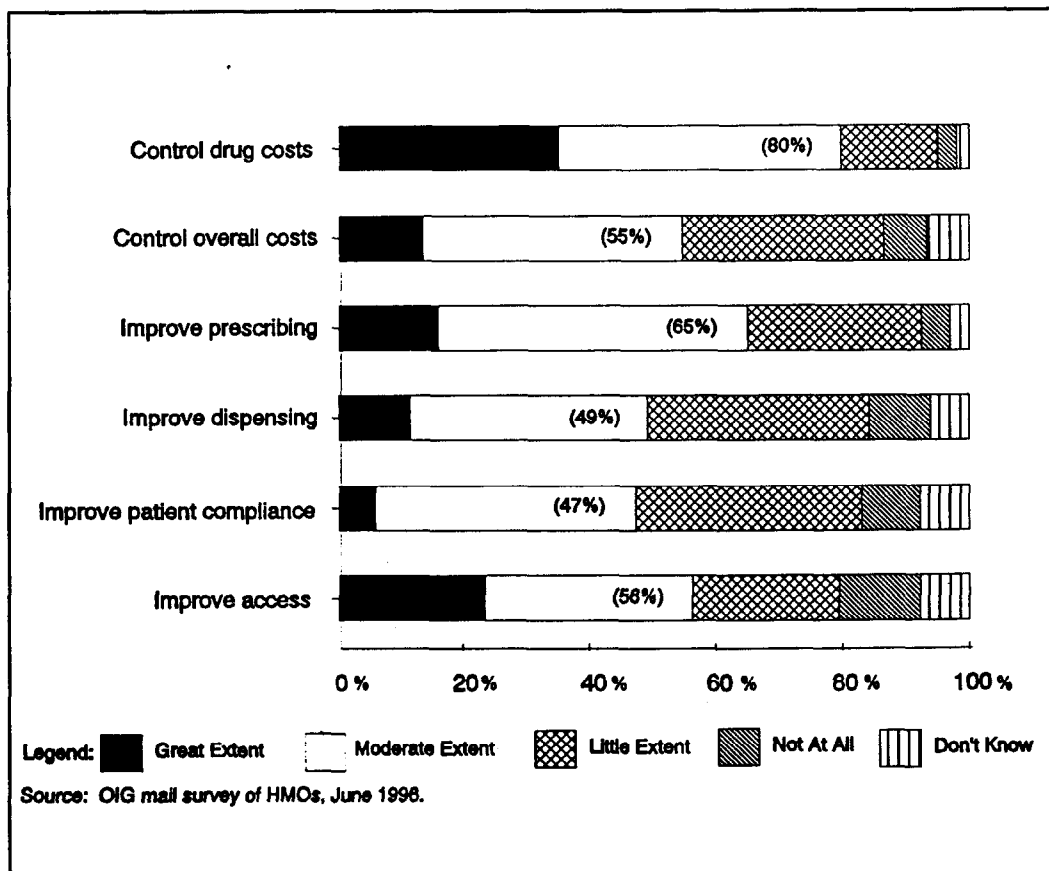
Fifty-two percent of the HMOs are considering changes in the mix of services they will purchase from PBMs. Most commented specifically about adding disease state management programs and various educationally focussed intervention programs targeted to providers and patients. Approximately 40 percent may negotiate contracts that increase their PBMs' share of financial risk.

POTENTIAL BENEFITS OF USING PBMs

HMOs describe the benefits of using PBMs mainly in terms of controlling prescription drug costs and, to a lesser extent, overall health care costs. Improving physician prescribing is the second most important benefit to the HMOs.

Figure 3

POTENTIAL BENEFITS OF USING PBMs



Containing costs: The HMOs report that the biggest benefit of using PBMs is their ability to help control prescription drug costs. Nearly all (80 percent) think PBMs help them contain these costs to either a great extent (35 percent) or a moderate extent (44 percent). Slightly more than half (55 percent) think PBMs help to either a great or a moderate degree in containing overall health care costs.

Drug Costs: The formularies developed by PBMs have the potential to realize savings in drug product costs.¹⁹ PBMs negotiate with manufacturers for discounts and rebates on drugs in return for including the companies' products on the PBMs'

formularies.²⁰ The PBMs, in turn, can share a portion of these rebates with the HMOs. PBMs also negotiate with community pharmacies for lower dispensing fees and drug reimbursement levels. In return, the pharmacies become participating providers in the retail networks managed by the PBMs for the HMOs.²¹

In addition, HMOs can purchase other services from PBMs that have the potential to lower costs. PBMs can manage formularies for HMOs using techniques such as prior approval programs or substitution programs that favor lower priced drugs. And by profiling physicians' prescribing practices to identify patterns of costly drug use, PBMs can help HMOs lower utilization of high priced drugs.²²

Several HMOs specifically commented to us about the ways they had realized savings from their PBMs. Only one HMO specified an estimate of actual savings achieved: "10 to 25 percent gross savings from pharmacy discounts and formulary rebates." A recent study of PBMs, conducted under contract with HCFA, found it difficult to determine and substantiate cost savings attributable to PBMs. Often the data are unavailable because PBMs consider them proprietary, and common baselines for comparing data do not exist.²³

Overall health costs: PBMs may lower health costs overall as they improve patients' drug use more generally. Some PBMs are launching disease state management programs,²⁴ which, as noted above, are increasingly attractive to HMOs for their potential to lower overall health care costs for patients targeted for these initiatives. The extent of savings in health care costs, like savings in drug costs, has been difficult to document.²⁵

Improving drug therapy: The HMOs think that PBMs are helpful in improving the prescribing practices of physicians. Nearly two-thirds (65 percent) think PBMs help physicians to either a great extent (16 percent) or a moderate extent (49 percent). They see PBMs as less helpful in improving the care provided by pharmacists or the compliance of patients with their drug regimens.

PBMs have the capacity, with their sophisticated, on-line computer systems and their large databases of prescription information, to help HMOs improve the quality of drug therapy of physicians, pharmacists, and patients. They can identify poor prescribing and dispensing practices of providers and can identify those patients who are not complying with their drug regimens.²⁶ They can identify potential problems before prescriptions are dispensed; they can profile patterns of drug use retrospectively. And, once having identified inappropriate drug use, PBMs can intervene individually with patients, pharmacists, or physicians through one-on-one interventions or through broadly based education programs such as newsletters or targeted mailings to groups of providers or patients.

Yet HMOs do not report making extensive use of PBMs for educating patients and providers about drug therapy. Not quite half (43 percent) report they use PBMs to intervene with individual physicians to improve the quality of their prescribing. Very

few (15 percent) use PBMs to intervene with individual patients identified as being noncompliant with the prescribed drug therapy. Most do not use PBMs to conduct broadly based education to improve drug therapy that is targeted to the HMOs' providers (62 percent) or to their enrollees (78 percent).

Disease management programs, as noted above, have potential to lower overall health care costs by targeting specific groups of patients with expensive chronic illnesses that are amenable to treatment with prescription drugs. These programs are still in their infancy in most settings. Their potential for containing costs and improving therapy is, as yet, unproven.

The HMOs report using PBMs most frequently for profiling physicians' prescribing patterns (79 percent); profiling dispensing patterns of pharmacies/pharmacies (66 percent); and for screening individual prescriptions for therapeutic contraindications at the point of dispensing (76 percent).

***Improving access:** Slightly more than one-half (56 percent) of the HMOs think PBMs are at least moderately useful in improving access to pharmacy services. But HMOs rate this benefit as least useful of all: approximately 20 percent think PBMs either are not at all useful (13 percent) in improving access or respond that they do not know (8 percent).*

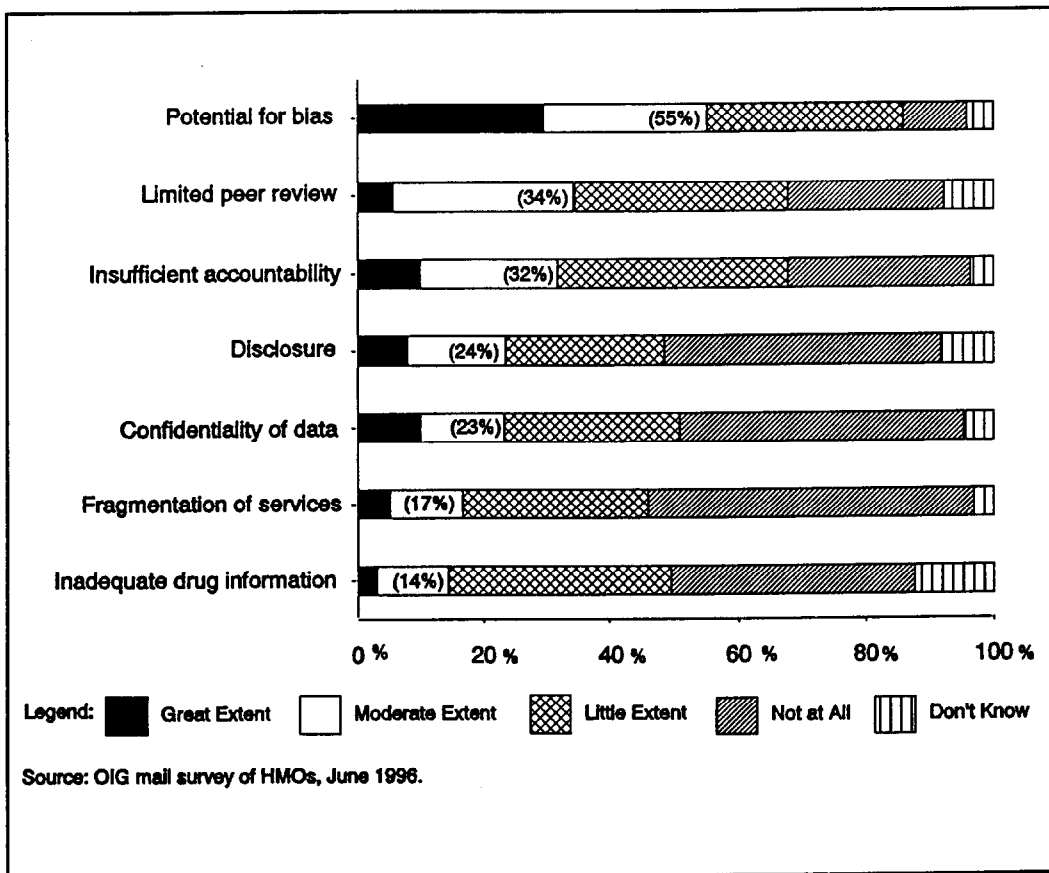
In using PBMs for mail order services or for the PBMs' networks of retail pharmacies, HMOs can expand the access of consumers to drug products. Yet some argue that these arrangements are reducing the profitability of retail pharmacies, thereby forcing many to close.²⁷

CONCERNS ABOUT USING PBMs

The HMOs' biggest concern about PBMs is the potential for bias resulting from their alliances with drug manufacturers. They are also concerned about confidentiality issues and about their own oversight of the PBMs' performance.

Figure 4

CONCERNS ABOUT USING PBMs



Potential for bias: Thirty (30) percent of the HMOs are very concerned about bias. The HMOs identify bias as their most serious concern 3 times as often as any other concern.

This high degree of concern is all the more striking when one considers that these HMOs are among those who are currently contracting with PBMs; they are not among those who have chosen to manage the benefit themselves.²⁸

The concern is that PBMs may bias their programs to favor their industry partners and, in so doing, compromise the quality of the HMOs' drug use practices and the

patient care they provide. Particularly vulnerable areas include formularies, drug use review programs, educational interventions, and cost-effectiveness research.

Formularies: Vulnerabilities can arise if PBMs are not sufficiently independent of the manufacturers' interests when developing their formularies and if they do not pay sufficient attention to therapeutic considerations when choosing which drugs to include.²⁹ Similarly, when managing formularies for the HMOs, PBMs can use substitution programs in which the drugs dispensed differ from those prescribed. The quality of patient care can be compromised if these programs are primarily marketing efforts conducted by PBMs on behalf of their industry partners³⁰ rather than clinically sound practices, guided by predetermined protocols that promote quality drug use.

Drug use review programs: The underpinnings of drug use review programs are the criteria and standards that guide the screening of claims and the profiling of prescribing and dispensing patterns of providers. The frameworks underlying the reviews can be structured to emphasize cost savings factors over quality considerations. Vulnerabilities can arise when PBMs choose the criteria and interpret the data for the HMOs while also having financial interests in the results of these reviews.³¹

Educational interventions: PBMs can intervene directly with providers and patients to educate them about drug products, drug use, and, increasingly, about managing particular diseases. These interventions are guided by protocols for drug use and information about drug products. The quality of patient care can be compromised if these efforts become marketing tools for PBMs and manufacturers rather than clinical tools for improving drug therapies.³² The quality of drug product information disseminated by PBMs to physicians, pharmacists, and patients is a minor issue for the HMOs responding to our survey (see Figure 4). But government regulators and some professional organizations have concerns about the product information distributed by PBMs.³³

Cost-effectiveness research: The PBMs' databases have significant value for outcomes studies and cost-effectiveness research on drugs and drug therapies. This kind of research is becoming more and more important in drug product marketing and for decision-making by PBMs, among others, about which drugs to position on formularies or which drugs to use when treating specific illnesses. The potential for bias in this research poses vulnerabilities for these kinds of clinically significant decisions.³⁴

Confidentiality issues: The HMOs are somewhat concerned about confidentiality issues associated with using PBMs. About one-fourth (23 percent) are concerned, to either a moderate or a great extent, about PBMs disclosing confidential patient information. And about one-fourth (24 percent) are equally concerned about HMOs' not disclosing their arrangements with PBMs to enrollees.

Confidentiality of patient data: The PBMs' databases are rich sources of information about which patients are using which drugs and which physicians are prescribing which drugs.³⁵ Increasingly, PBMs are gaining access to patients' medical data as well as their pharmacy records, so the databases can be linked for clinical services such as disease management programs.³⁶ Questions arise about whether PBMs adequately safeguard these data, particularly patient-identifiable information, from employers or drug manufacturers, for example.³⁷ Most HMOs are not concerned about this issue (see Figure 4). Several said they secure patient information through specific language in their PBM contracts. Yet questions linger, because HMOs, as one indicated to us, would not necessarily know of breaches of these confidentiality provisions by their PBMs.

Disclosure to patients: How much information HMOs should disclose to enrollees about their use of PBMs and their practices for managing the drug benefit is germane to the larger, national debate over patients' rights to know details of their HMOs' policies and practices. Disclosing pharmacy-related information is relevant here, because, as we have seen, physicians' prescribing choices, and thus the quality and extent of drug therapies available to patients, are significantly influenced by the ways in which HMOs structure and manage their pharmacy program with the PBMs.³⁸

Insufficient accountability and limited peer review: The HMOs' second most serious concern about PBMs deals with the adequacy of their own oversight of the PBMs' performance. Nearly one-third (32 percent) are concerned, to either a moderate or a great extent, that HMOs receive information from PBMs that is insufficient for holding them accountable. And one-third (34 percent) are similarly concerned that the HMOs' peer reviews of PBM programs are limited.

The number of HMOs greatly concerned about oversight are fewer than those similarly concerned about potential bias. But about the same number are moderately concerned about the adequacy of peer review and accountability (see Figure 4). It is noteworthy, however, that among those HMOs who have few concerns about using PBMs, several specifically commented that they would be much more concerned were it not for the protections their HMOs have adopted. These include such practices as tight contractual language, using their own clinicians to review PBM programs, or not relying on PBMs for particular services like educational interventions or formulary development.

OVERSEEING PBMs' PERFORMANCE

The HMOs rely primarily on PBM-supplied data and reports for overseeing their PBMs' performance. They rely less on independent assessments of the PBMs' performance from their own clinicians and patients.

In overseeing the performance of their PBMs, almost all HMOs (1) receive written reports from their PBMs (99 percent) and (2) use their own staff to analyze these data (97 percent).³⁹ Most HMOs (approximately 82 percent) consider these approaches either moderately or very useful. Some buy the PBMs' reports "off the shelf." Others customize them or develop their own; a few said they can access the PBMs' raw data to do their own analyses. The reports typically feature utilization and cost data or profiles of drug use. Nearly two-thirds (63 percent) of the HMOs use performance measures or guarantees to oversee their PBMs; a few commented specifically that they use these indicators and other data to benchmark their PBMs' performance with those of other HMOs.

A few HMOs commented specifically about the importance of an HMO conducting its own independent assessments of its PBM's programs. These include such approaches as using its own clinicians to review the PBM's formularies, drug use protocols or drug product information the PBM sends to clinicians and patients. They also include approaches, such as surveys and grievance procedures, that enable the HMO's physicians, pharmacists, and patients to give feedback on the PBM's programs.

Our data indicate, however, that the HMOs rely less on these kinds of independent assessments than they do on PBM-supplied data and reports. For example, 24 percent of the HMOs do not use their own Pharmacy and Therapeutics Committee to peer review their PBMs' programs; 38 percent do not perform their own drug use reviews of PBMs' analyses; 51 percent do not conduct on-site monitoring visits; and 65 percent do not use outside consultants to review their PBMs' programs.

Overall, it is not clear from our review just how substantive and independent are the efforts by HMOs to oversee the performance of their PBMs. Nor is it clear the extent to which HMOs balance their concerns about cost containment with the effects their PBMs may have on the quality of their pharmacy programs.⁴⁰

The HCFA and State Medicaid agencies we contacted provide minimal oversight of their Medicare and Medicaid HMOs' subcontracts with PBMs or their HMOs' pharmacy programs in general.

The HCFA does not have requirements specific to the content or management of the pharmacy benefits offered by its Medicare HMOs. Neither does it include clinical or management reviews of the HMOs' pharmacy benefit during its certification or annual monitoring of the HMOs. The HCFA does have guidelines for the content of the

HMOs' marketing materials, and it does address pharmacy benefits in its reviews of these materials.

The Medicaid agencies we contacted, in those States that include pharmacy services in their Medicaid HMO contracts, also have no requirements specific to the HMOs' subcontracts with PBMs, and few for the HMOs' pharmacy programs generally. Most typically, the States require only that the HMOs not use formularies more restrictive than the Medicaid fee-for-service formularies. They generally do not monitor either the PBMs' activities or the HMOs' pharmacy programs.

The major, private accreditation programs for managed care organizations neither accredit PBMs nor review HMOs' pharmacy programs and the arrangements they may have with PBMs. In part, this inattention reflects a lack of quality measures suitable for assessing pharmacy programs in these settings.

These accreditation programs include those of the Joint Commission on Accreditation of Health Organizations (JCAHO), the National Committee for Quality Assurance (NCQA), and the Utilization Review and Accreditation Commission (URAC).^{41 42} This lack of attention to pharmacy issues results, in part, from these organizations having focussed initially on establishing a process suitable for medical operations in managed care settings. Of necessity, pharmacy-related issues have not been a top priority.

To some extent, too, their inattention reflects an underappreciation of the contributions of pharmacy to patient care and a lack of quality measures suitable for assessing pharmacy programs in these settings. In recent years, several pharmacy organizations have been working to redefine the essence of outpatient pharmacy practice to emphasize the clinical contribution of pharmacists as members of the health care team. This process continues; it is a major, long-term effort involving restructuring academic curricula, negotiating reimbursement systems for pharmacists' clinical services, and educating accreditation groups and other health care providers, payers, and the public about the role and significance of pharmaceutical care.

Pharmacy has been slow to develop quality measures of performance that can be used by these accrediting groups, by payers, and by health plans. The process is inherently difficult. It has been perhaps more so for pharmacy, which has been focussed on redefining the essence of outpatient practice. The process has also demanded input from several large, national pharmacy organizations, which, at times, have had different and sometimes competing interests. Nonetheless, these organizations, concerned with quality issues in outpatient settings, recognize the importance of developing quality assurance programs for the clinical dimensions of pharmacy practice. Several have developed guidelines or standards for use among their own membership.⁴³ And they have begun recently to meet together to explore areas of commonality and to reach out to major payers and the national accreditation organizations.

RECOMMENDATIONS

Our inspection does not provide a basis for assessing the effectiveness of PBM services purchased by HMOs. Nor does it provide a basis for determining that pharmacy benefit management by PBMs is more or less preferable for achieving high quality pharmacy programs in HMOs. Our inquiry does, however, offer sufficient basis for concluding that payers, when overseeing the performance of their HMOs, need to devote attention to their HMOs' pharmacy programs and their use of PBMs. We base this conclusion on the following:

- ▶ The HMOs use various approaches for overseeing their PBMs' performance. But the effectiveness of these efforts in holding PBMs accountable for the quality of their services is not clear.
- ▶ The Medicare and Medicaid programs, both large public payers, devote little attention to the arrangements of their HMOs with PBMs or to their HMOs' pharmacy programs more generally.⁴⁴ And, as we have seen, neither payers nor the public can count on the private accreditation organizations for assurances of quality and accountability in the HMOs' pharmacy programs.
- ▶ Yet, pharmacy programs have a significant impact on the quality of patient care. This is true whether HMOs manage these programs using PBMs or internally by themselves. This impact can be positive or detrimental. It is not surprising that the HMOs described here, who are demonstrably committed users of PBMs, are generally positive about their experiences.

What is significant to us is the degree to which they have concerns about PBMs in areas that bear directly on the quality of patient care. Yet many of these HMOs are using PBMs for more clinically oriented services and will be negotiating more capitated or risk-sharing contracts with them. These trends signal the PBMs' growing involvement with and responsibility for patient care.

These observations lead us to emphasize the importance of HMOs being accountable for the quality of the pharmacy programs managed by their PBMs. Payers have responsibility for ensuring that their HMOs offer high quality care to patients. Accordingly, we offer three recommendations. The first two address the Medicare and Medicaid programs funded by HCFA and the States; they call for operational action steps that can be undertaken now. The third addresses a larger issue of pharmacy practice that requires attention of public and private organizations over the long term.

THE MEDICARE PROGRAM

The HCFA should take steps to ensure that its Medicare HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries.

It is important for HCFA to pay more attention to pharmacy issues in its Medicare HMOs for several reasons. First, as noted elsewhere, mismedication problems affect the elderly especially, and the Medicare program, in large measure, bears the costly consequences of these problems. Second, an increasing number of Medicare-risk HMOs are offering prescription drug coverage as an additional benefit because of its popularity with beneficiaries. While coverage for these benefits is not included in the basic capitated rate paid to the HMOs, the plans fund these benefits with savings from the HCFA capitated payments. And, finally, as we have seen here, many HMOs use PBMs to help manage the prescription drug use of Medicare beneficiaries.

The HCFA could take steps to ensure greater accountability by strengthening its contract requirements for Medicare HMOs and by incorporating pharmacy reviews in its oversight of the HMOs' performance. It could, for example:

- ▶ develop language for Medicare contracts that sets forth assurances that the HMOs should obtain in their subcontracts with PBMs and that specifies the responsibilities the HMOs must assume in overseeing their PBMs' performance.

This language could address specific approaches for reducing the vulnerabilities the HMOs associate with the use of PBMs that we report here. The HCFA could take such steps as requiring rigorous and systematic evaluation of the PBMs' services, independent review of the PBMs' formularies, drug use protocols, and education materials about drug products. It could specify language to protect the confidentiality of patient-identifiable information contained in the PBMs' databases.

- ▶ include, as part of the ongoing oversight of Medicare contracts, a review of the effectiveness of the HMOs' oversight of the quality of PBM services.

It could take such steps as reviewing the HMOs' subcontracts with PBMs to ensure that the HMOs are complying with the contractual requirements or reviewing the HMOs' evaluations of PBM services including the appropriateness of drug formularies for the elderly. And it could incorporate questions about satisfaction with the pharmacy benefit in the surveys being developed for use with beneficiaries enrolled in HMOs.

THE MEDICAID PROGRAM

State Medicaid agencies should take steps to ensure that its Medicaid HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries.

It is important for States to pay more attention to the pharmacy programs in their Medicaid HMOs. Pharmacy benefits continue to be a significant component of the Medicaid programs in all States. As States transition to managed care arrangements for beneficiaries, their risk contracts with HMOs typically include pharmacy services. As we have seen here, many HMOs report using PBMs to manage the drug benefit

for their Medicaid beneficiaries.

State Medicaid agencies could take steps similar to those suggested above for HCFA and its Medicare HMOs. The States rely on approaches for holding their HMOs accountable that are similar to those used by HCFA with its Medicare contracts. The States have requirements, for example, for the HMOs' quality assurance programs and for their subcontracts. The States, too, monitor the HMOs and oversee their marketing activities. The HCFA could work with the States in achieving greater accountability for their Medicaid HMOs.

THE PRACTICE OF PHARMACY

The HCFA, the FDA, and the Health Resources and Services Administration (HRSA), working together with external organizations, should build on existing efforts to develop quality measures for pharmacy practice that can be used in managed care settings.

We have called here for greater accountability for the quality of the pharmacy programs managed for HMOs by PBMs. Although ours has not been a study of pharmacy practice per se, our consideration of the quality issues associated with PBMs has led us inevitably to consider the HMOs' accountability for the quality of their pharmacy practices. We conclude that developing an underlying framework of standards and measures for assessing the quality of pharmacy services and programs is essential. Lacking such a framework, HMOs will find it more difficult to hold their PBMs accountable, and the payers and the public will find it more difficult to assure themselves of the quality of these pharmacy programs.

This task will not be an easy one. We have noted in the report some of the difficulties facing the pharmacy profession as it struggles with these issues. Their efforts are further complicated by the need for these quality measures to take into account individual practice as well as organizational practices, management processes as well as clinical processes, and closed practice settings, such as staff model HMOs, as well as more open arrangements.

Developing this framework will require leadership from both the public and private sectors, especially the profession of pharmacy itself which has responsibility as a profession to ensure that the payers and the public receive quality pharmacy care. The HCFA, as the single, largest payer for health care in the country; the FDA, with its responsibilities for drug product information and dissemination; and HRSA, which has long-standing interest in the health professions, can encourage and support the efforts of the pharmacy organizations. It is important for this process to engage other payers, professional medical organizations, private accreditation organizations, consumer groups, and the managed care industry. All have important perspectives to contribute. All these parties have responsibility to ensure that pharmacy programs rest on foundations that are clinically sound, widely accepted, and promote improved patient care.

COMMENTS ON THE DRAFT REPORT

We received comments on the draft report from the Health Care Financing Administration (HCFA), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA). We also solicited and received comments from the Academy of Managed Care Pharmacy (AMCP), the American Medical Association (AMA), the American Pharmaceutical Association (APHA), the American Society of Health Systems Pharmacists (ASHP), the Consumer Coalition for Quality Health Care, and HCFA's Medicaid Pharmacy Technical Advisory Group (P-TAG). We include the complete text of the detailed comments in appendix D. Below we summarize the major comments and, in italics, offer our responses. We made a few minor edits in the report in response to the comments.

HCFA, FDA, HRSA Comments

All three agencies concurred with our recommendations.

The first recommendation, addressed to HCFA, called for steps to strengthen the accountability of Medicare HMOs for the quality of services provided by PBMs to beneficiaries. In its concurrence, HCFA identified current requirements for its contracts with HMOs and summarized its current approaches for monitoring their performance.

In our view, this response does not substantively address a central concern raised in this report about HCFA's minimal oversight of its HMOs' pharmacy programs and their subcontracts with PBMs. Although HCFA concurs with the recommendation, its comments suggest that it sees no need to strengthen either its requirements of Medicare HMOs for their pharmacy programs and their use of PBMs or its approaches to monitoring these programs. Yet, we believe our findings warrant more attention by HCFA. We have suggested several steps HCFA could take that are within its current regulatory responsibilities. As we point out, the HMO contract, for example, could be an important vehicle for strengthening Medicare HMOs' accountability for their pharmacy programs. We suggest that HCFA consider taking additional steps to address these concerns that bear directly on quality of care.

The second recommendation urges that State Medicaid agencies, too, should strengthen the accountability of their Medicaid HMOs for the quality of PBM services to beneficiaries. The HCFA concurs with this recommendation.

We are pleased that HCFA concurs with this recommendation and urge that it work in consultation with the State Medicaid agencies, which have primary responsibility for the contracts with Medicaid HMOs.

The third recommendation, which calls for HCFA, FDA, and HRSA, to work with external organizations on developing quality measures for pharmacy practice in

managed care settings, was favorably received by all three agencies.

We encourage the agencies to meet together and to identify one among them to assume lead responsibility, so that enhanced communication and coordination may facilitate continued progress in defining these measures. We agree with the comment of HCFA's P-TAG that States be involved with this effort.

The HCFA and HRSA each offered technical comments on the report. *In response to HCFA's comments, we updated the Medicaid managed care statistic to reflect enrollment as of June 1996. We did not, however, recast the statistics we present in our discussion of the HMOs' approaches for overseeing their PBMs' performance. We believe our presentation is valid and correctly emphasizes the point we make about the degree to which HMOs rely on independent assessments of various kinds. We also chose not to elaborate on the nature of quality measures for pharmacy practice as HRSA suggested; we think such definition is more appropriately considered as part of the larger task to be accomplished under this recommendation.*

External Organizations' Comments

All the outside organizations concurred with our recommendations. Most offer elaboration of points made in our report or related to them. Some call for revisions to the report or other actions on our part.

For the most part, we have not revised the report in response to these comments, which, we believe, call for changes beyond the scope of this inquiry. We are pleased that the comments of the AMA, ASHP, APHA, and the Consumer Coalition support many of the points made in the report or elaborate on related issues. We appreciate the comments of AMCP but find many of the points raised are beyond the scope and purpose of our inquiry. Our focus on those HMOs contracting with PBMs is important to the Department and to other payers of managed health care services. Our findings, and the recommendations that spring from them, reflect in large measure the perspectives and insights from this increasingly significant group of health care providers.

APPENDIX A

METHODOLOGY

We relied on four primary sources of information for this report: (1) responses to a mail survey of all HMOs in the country; (2) telephone discussions with HCFA staff in headquarters and 6 regional offices and with Medicaid officials from 9 States; (3) discussions with experts and analysts on managed care, pharmacy and pharmaceutical care, and pharmacy benefit management; and (4) a literature review including journals and newsletters, reports and analyses, government documents, documents from professional and trade organizations. Below, we provide a detailed description of each source.

(1) MAIL SURVEY OF HMOS

Universe of HMOs

We relied initially on the listing of HMOs contained in the *GHAA/AMCRA Managed Health Care Directory, 1995-96*, which contained data on 639 HMOs across the country. These HMOs included the affiliated sites of 24 national and regional managed health care organizations as well as HMOs that were not affiliated with these national and regional organizations.

We telephoned each of the national and regional managed health care organizations listed in this directory to (1) determine whether decisions about the organizations' use of PBMs are made centrally and apply to all affiliated sites or whether these decisions are delegated to the affiliated sites, (2) confirm the number of HMO sites affiliated with each organization, and (3) identify the key decisionmakers.

Thus we refined the initial AMCRA listing of HMOs and ultimately defined a universe of 368 HMO decisionmakers to whom we sent our surveys. When we refer to "HMOs" in our report, we are speaking about these HMO decisionmakers, either the chief executive or the head of pharmacy services responsible for decisions about PBMs for their HMOs. Our universe included 26 HMO decisionmakers from national or regional managed care organizations who represent their organizations' 283 affiliated local plans. The remaining 342 HMO decisionmakers each represent local HMO plans unaffiliated with any national or regional managed care organizations. These 368 HMO decisionmakers represented 625 local plans nationwide.

Survey Process

All HMO decisionmakers received the same survey questionnaire. We mailed the survey first in June 1996; we mailed a follow-up survey to nonrespondents in July 1996. Overall, 263 of 368 HMO decisionmakers (whom we refer to as "HMOs" in this report) responded to our survey. This is a response rate of 71 percent.

Database construction

We grouped the HMOs listed in AMCRA’s directory into 5 categories based on whether or not they are affiliated with national/regional organizations and whether or not decisionmaking is centralized (see Figure A). Thus, we collapsed AMCRA’s data for HMOs into 368 records, each representing one HMO decisionmaker.

For the three types of HMOs (*plan types #1, #2, and #4b*) in which decisions to use a PBM are made at the local level, each HMO decisionmaker was counted as one record in the database. For the two types of HMOs (*plan types #3 and #4a*) in which the decision to use a PBM is made at the corporate level, we collapsed all data for affiliated plans into one record for each HMO decisionmaker.

In categorizing the HMOs, we relied on information from our telephone calls and on written comments from survey respondents. If we learned from a respondent that an independent plan had merged with a regional or national HMO, or that it was no longer in existence, we changed our database accordingly. We did not change AMCRA’s data in any other way.

**FIGURE A
TYPOLOGY OF HMOS**

Type of HMO	Number of HMOs Surveyed	Number of Affiliated Plans Represented
Plan type #1 Independent HMO. Decisions about using a PBM are made at the local level for each affiliated plan. One survey is sent to each local plan.	238	238
Plan type #2 National or regional HMO. Decisions about using a PBM are made at the local level for each affiliated plan. One survey is sent to each local plan.	95	95
Plan type #3 National or regional HMO. Decisions about using a PBM are made at the corporate level for all affiliated plans. One survey is sent to headquarters representing all affiliated plans.	18	227
Plan type #4a Hybrid model. Decisions about using a PBM are made at the corporate level for affiliated plans. One survey is sent to headquarters for these affiliated plans.	8	56
Plan type #4b Hybrid model. Decisions about using a PBM are made at the local level for affiliated plans. One survey is sent to each local plan.	9	9
Totals:	368	625

Figure B illustrates the number of HMOs responding to the OIG survey, and whether or not they use an external PBM. The chart presents the number of local plans represented by these local and national HMOs.

**FIGURE B
RESPONSES FROM HMO DECISIONMAKERS**

	Local HMOs (plan types #1, #2, and #4b)	National HMOs (plan types #3 and #4a)	Totals
Number of HMOs surveyed	342 HMOs (342 plans)	26 HMOs (283 plans)	368 HMOs (625 plans)
Number of HMOs responding to survey	241 HMOs (241 plans)	22 HMOs (254 plans)	263 HMOs (495 plans)
Number of HMOs responding to survey that use an external PBM	185 HMOs (185 plans)	14 HMOs (118 plans)	199 HMOs (303 plans)
Number of HMOs responding to survey that do not use an external PBM	56 HMOs (56 plans)	8 HMOs (136 plans)	64 HMOs (192 plans)
Number of HMOs not responding to survey	101 HMOs (101 plans)	4 HMOs (29 plans)	105 HMOs (130 plans)

Use of AMCRA data in OIG analysis

Although the OIG survey results served as the foundation for this report, we used AMCRA data for three of our analyses: 1) analysis of the nonrespondents, 2) analysis of the tax status of an HMO, and 3) analysis of the number of lives covered by an HMO.

In assigning a tax code to an HMO, we reviewed the tax status for all of its affiliated plans. If all the affiliated plans reported a for-profit tax status, we called the tax status of that HMO "for-profit;" if all the affiliated plans reported a non-profit tax status, we called the tax status of that HMO "non-profit"; and if some of the affiliated plans reported for-profit tax status and others reported non-profit tax status, we called the tax status of that HMO "mixed." For the sake of clarity, we chose to eliminate from any analyses involving tax status the eight HMOs that we designated as having a "mixed" tax status. To determine the number of covered lives for each HMO, we summed the total number of covered lives for all of the HMO's affiliated plans.

Caveats

The information drawn from the AMCRA database and from the OIG mail survey is self-reported by the HMOs. We did not verify this information. The AMCRA data are based on that organization's survey of HMOs which had a 76.8 percent response rate.

(2) TELEPHONE INTERVIEWS WITH MEDICARE AND MEDICAID OFFICIALS

We spoke with HCFA staff in Baltimore for both the Medicare and Medicaid managed care programs. We contacted Regional Medicare HMO staff in Boston (Region I), Atlanta (Region IV), Chicago (Region V), Dallas (Region VI), Denver (Region VIII), and San Francisco (Region IX). These Regions include those with the largest numbers of Medicare HMOs.

We also spoke with Medicaid officials in 9 States: Arizona, California, Florida, Massachusetts, Minnesota, Missouri, New York, Ohio, and Rhode Island. These States are among those most experienced with enrolling beneficiaries in Medicaid HMOs. These States, too, include pharmacy services in their HMOs' contracts.

(3) DISCUSSIONS WITH EXPERTS AND ANALYSTS

During the course of this inquiry, we had discussions with many experts and industry analysts about PBMs and the issues associated with their use. We spoke with representatives from PBMs, from health benefits consulting firms and large employer groups, from professional pharmacy and medical organizations, with organizations representing the managed care industry, with several national, private accreditation groups, and with Federal government agencies such as the General Accounting Office and the Federal Trade Commission.

(4) DOCUMENT AND LITERATURE REVIEW

Among the written materials we have reviewed are government and non-government studies on quality assurance systems and on pharmacy, managed care pharmacy, and pharmacy benefit management companies; position papers and guidelines from professional pharmacy and medical organizations; national accreditation standards; court cases and legal settlements; newsletters, newspapers, and professional journals.

APPENDIX B

NONRESPONDENT ANALYSIS

An important consideration with research based on surveys of the type we have conducted is the bias that may be introduced into the results if the nonrespondents differ from survey respondents in systematic ways. To test for the presence of bias, we relied on the following sources of data: information contained in the *GHAA/AMCRA Managed Health Care Directory, 1995-96* and an OIG typology of HMO decisionmakers.

In collapsing the data from AMCRA's directory for the nonrespondent analysis, we concluded that an HMO served Medicare beneficiaries if at least one of its affiliated plans served them. We followed a similar process for determining an HMO's Medicaid status. For this analysis we relied on data reported by the HMOs to AMCRA.

The Chi-square statistic was used to test differences between respondents and nonrespondents by 1) tax status of an HMO; 2) number of lives covered by the HMOs; 3) type of HMO according to the OIG typology; 4) whether or not an HMO serves Medicare beneficiaries; and 5) whether or not an HMO serves Medicaid beneficiaries.

We determined that the HMO decisionmakers responding to our survey did not differ significantly from those not responding in terms of the following four variables: the number of lives covered by the HMOs, the type of HMO according to our typology, whether or not the HMO decisionmaker serves Medicare beneficiaries, and whether or not the HMO decisionmaker serves Medicaid beneficiaries.

However, when we tested for a relationship between the response of an HMO decisionmaker and the HMO's tax status, we found that the chi-square statistic was significant (6.453) at the .01 level. When one finds that there is a statistically significant relationship between the response rate and a key variable, it is important to determine the extent of the impact of the nonresponse bias on the entire survey. We estimated the nonresponse bias for our key question "Do you contract with an external PBM?" and found that taking into account the tax status of nonrespondents changed the answer by less than one percentage point. Because the impact was not significant, it was not necessary to our adjust other analyses to reflect the nonresponse bias.

CHI-SQUARE FOR TYPE OF TAX STATUS

	Respondents	Nonrespondents	Total	% Respond
Profit	148 (56.9%)	42 (42.0%)	190	77.9%
Non-Profit	112 (43.1%)	58 (58.0%)	170	65.9%
Overall	260	100	360**	72.2%

CHI-SQ.=6.453* DF=1

*=This was significant at the .01 level.

**=Eight HMOs were eliminated because they either did not respond to the question about tax status in AMCRA's survey, or they responded but showed a "mixed tax status" when we collapsed AMCRA's records.

CHI-SQUARE FOR SIZE OF HMO

	Respondents	Nonrespondents	Total	% Respond
0 - 49,999	127 (52.0%)	52 (55.9%)	179	70.9%
50,000 - 99,999	47 (19.3%)	16 (17.2%)	63	74.6%
100,000 - 799,999	58 (23.8%)	22 (23.7%)	80	72.5%
800,000+	12 (4.9%)	3 (3.2%)	15	4.9%
Overall	244	93	337***	72.4%

CHI-SQ.=0.775 DF=3

***=Thirty-one HMOs were eliminated because they did not respond to the question about covered lives in AMCRA's survey.

CHI-SQUARE FOR TYPE OF CONTROL (NATIONAL VS. LOCAL CONTROL)

	Respondents	Nonrespondents	Total	% Respond
Local	241 (91.6%)	101 (96.2%)	342	70.5%
National/ Regional	22 (8.4%)	4 (3.8%)	26	84.6%
Overall	263	105	368	71.5%

CHI-SQ.=2.372 DF=1

CHI-SQUARE FOR WHETHER HMO SERVES MEDICARE

	Respondents	Nonrespondents	Total	% Respond
Do <u>not</u> serve Medicare	190 (72.2%)	80 (76.2%)	270	70.4%
Serve Medicare	73 (27.8%)	25 (23.8%)	98	74.5%
Overall	263	105	368	71.5%

CHI-SQ.=0.598 DF=1

CHI-SQUARE FOR WHETHER HMO SERVES MEDICAID

	Respondents	Nonrespondents	Total	% Respond
Do Not Serve Medicaid	201 (76.4%)	80 (76.2%)	281	71.5%
Serve Medicaid	62 (23.6%)	25 (23.8%)	87	71.3%
Overall	263	105	368	71.5%

CHI-SQ.=0.002 DF=1

APPENDIX C

SUMMARY OF HMOS' RESPONSES TO OIG MAIL SURVEY

All data presented in this appendix are derived from an OIG mail survey of HMOs conducted in June 1996.

1. Does your HMO currently contract with an external PBM to help manage pharmacy benefits for any of your HMO's enrollees?

Yes	No	N
199 (75.7%)	64 (24.3%)	263

Those HMOs that responded "Yes" to question 1 also answered questions 2-13.

Those HMOs that responded "No" to question 1 also answer questions 14-16.

2. What was the enrollment of your HMO in June, 1996?

Mean	Median	Std. Deviation	Minimum	Maximum	N
180,918	70,000	377,708	350	395,3400	189

3. Does your HMO:

	Yes	No	Don't Know	N
a. Serve Medicare beneficiaries?	107 (53.8%)	89 (44.7%)	3 (1.5%)	199
b. Serve Medicaid beneficiaries?	111 (55.8%)	87 (43.7%)	1 (0.5%)	199
c. Serve commercial enrollees?	191 (96.0%)	7 (3.5%)	1 (0.5%)	199
d. Use a PBM contract for Medicare beneficiaries?	89 (44.7%)	106 (53.3%)	4 (2.0%)	199
e. Use a PBM contract for Medicaid beneficiaries?	96 (48.2%)	103 (51.8%)	--	199
f. Use a PBM contract for commercial enrollees?	190 (95.5%)	8 (4.0%)	1 (0.5%)	199

4. For how many years altogether has your HMO used any PBM for services other than claims processing?

Mean	Median	Std. Deviation	Minimum	Maximum	N
4.1	3	3.2	0	20	190

5. Which PBM(s) has a contract with your HMO for 1996?

Contracts with one of the big 5 PBMs (includes PCS, DPS, Medco, Value Health, and Caremark)	Contracts with any other PBM	N
103 (52.3%)	94 (47.7%)	197

6. Has your HMO changed PBMs since 1993?

Yes	No	Don't Know	N
29 (43.3%)	38 (56.7%)	--	67*

*= Those HMOs which reported contracting with a PBM for four years or less were eliminated.

7. Which of the following services does your HMO purchase from the PBM?

Service	Use Service	N
Claims processing	188 (94.5%)	199
Pharmacy networks	147 (73.9%)	199
Mail order services	91 (45.7%)	199
Formulary development	123 (61.8%)	199
Formulary management	142 (71.4%)	199
Prospective Drug Use Review (DUR) programs	155 (77.9%)	199
Screening individual prescriptions for therapeutic contraindications at the point of dispensing	151 (75.9%)	199
Counseling individual patients about a prescribed drug therapy	46 (23.1%)	199
Retrospective DUR programs	158 (79.4%)	199
Profiling physicians' prescribing patterns	157 (78.9%)	199
Profiling dispensing patterns of pharmacists/pharmacies	132 (66.3%)	199
Profiling patients' compliance with drug regimens	87 (43.7%)	199
Profiling patterns to identify fraud and abuse	137 (68.8%)	199
Education Interventions	103 (51.8%)	199
Intervening with individual patients identified as being noncompliant with the prescribed drug therapy	29 (14.6%)	199
Intervening with individual physicians to improve the quality of their prescribing	85 (42.7%)	199
Conducting broadly based education programs to improve drug therapy that are targeted to:	77 (38.7%)	199
Your HMO's providers	76 (38.2%)	199
Your HMO's enrollees	43 (21.6%)	199
Outcomes/Cost-effectiveness research	55 (27.6%)	199
Disease-state management programs	69 (34.7%)	199
Other services	20 (10.1%)	199

8. Is this service mix significantly different from 2-3 years ago?

Yes	No	Don't Know	N
40 (28.0%)	101 (70.6%)	2 (1.4%)	143*

* = Those HMOs which reported contracting with a PBM for two years or less were eliminated.

9. Do you think your HMO will change the current service mix over the next couple of years?

Yes	No	Don't Know	N
104 (52.3%)	72 (36.2%)	23 (11.6%)	199

10. How useful, if at all, do you think any of these approaches have been for your HMO in overseeing the PBM's performance?

	Very Useful	Moderately Useful	A Little Useful	Not At All	Don't Use Approach	Don't Know	N*
a. Information reports submitted by the PBM	60 (33.7%)	84 (47.2%)	26 (14.6%)	4 (2.2%)	2 (1.1%)	2 (1.1%)	178
b. Analyses by your HMO of data from the PBM	70 (39.3%)	72 (40.4%)	23 (12.9%)	3 (1.7%)	6 (3.4%)	4 (2.2%)	178
c. Reviews of PBM performance by outside consultants	6 (3.4%)	10 (5.6%)	24 (13.5%)	12 (6.7%)	115 (64.6%)	11 (6.2%)	178
d. On-site monitoring visits conducted by your HMO	14 (7.9%)	24 (13.6%)	27 (15.3%)	13 (7.3%)	91 (51.4%)	8 (4.5%)	177
Peer reviews of PBM programs by your HMO's physicians or pharmacists	--	--	--	--	--	--	--
f. Using your HMO's Pharmacy and Therapeutics Committee	50 (28.6%)	54 (30.9%)	19 (10.9%)	4 (2.3%)	42 (24.0%)	6 (3.4%)	175
g. Using your HMO's own DUR programs	30 (17.4%)	46 (26.7%)	16 (9.3%)	7 (4.1%)	66 (38.4%)	7 (4.1%)	172
Direct feedback about PBM programs from:							
h. Your HMO's physicians	48 (27.3%)	39 (22.2%)	44 (25.0%)	3 (1.7%)	31 (17.6%)	11 (6.3%)	176
i. Your HMO's pharmacists	43 (24.4%)	50 (28.4%)	26 (14.8%)	8 (4.5%)	38 (21.6%)	11 (6.3%)	176
j. Your HMO's enrollees	54 (30.7%)	43 (24.4%)	31 (17.6%)	8 (4.5%)	28 (15.9%)	12 (6.8%)	176
k. Reviews of your PBM's performance through established performance measures or guarantees	33 (19.0%)	42 (24.1%)	20 (11.5%)	5 (2.9%)	64 (36.8%)	10 (5.7%)	174

* = Those HMOs which report contracting with a PBM for less than one year and/or report using a PBM for only claims processing were eliminated.

11. Based on your own experiences, to what extent, if at all, do you think using PBMs helps HMOs realize any of these potential benefits?

	To a Great Extent	To a Moderate Extent	To a Little Extent	Not at All	Don't Know	N
Contain costs:						
a. Using PBMs may help contain prescription drug costs.	70 (35.4%)	88 (44.4%)	30 (15.2%)	6 (3.0%)	4 (2.0%)	2198
b. Using PBMs may help contain overall health care costs.	27 (13.8%)	80 (41.0%)	62 (31.8%)	13 (6.7%)	13 (6.7%)	195
Improve drug therapy:						
c. Using PBMs may help improve physicians' prescribing practices.	32 (16.2%)	97 (49.0%)	54 (27.3%)	9 (4.5%)	6 (3.0%)	198
d. Using PBMs may help improve the pharmaceutical care provided by pharmacists.	23 (11.7%)	74 (37.6%)	69 (35.0%)	19 (9.6%)	12 (6.1%)	197
e. Using PBMs may help improve enrollees' compliance with their drug therapies.	12 (6.1%)	81 (41.3%)	70 (35.7%)	18 (9.2%)	15 (7.7%)	196
Improve access to pharmaceutical services:						
f. PBMs may help improve access to pharmaceutical services for HMO enrollees.	46 (23.6%)	64 (32.8%)	45 (23.1%)	25 (12.8%)	15 (7.7%)	195

12. Based on your own experiences, to what extent, if at all, do you share any of the following concerns about using PBMs?

	To a Great Extent	To a Moderate Extent	To a Little Extent	Not at All	Don't Know	N
a. Potential for bias. PBMs' alliances with drug manufacturers may influence decisions about drug products in ways that compromise optimal drug therapy.	59 (29.6%)	51 (25.6%)	61 (30.7%)	20 (10.1%)	8 (4.0%)	199
b. Fragmentation of services. Using PBMs may contribute to fragmentation of patients' health care.	10 (5.1%)	23 (11.6%)	58 (29.3%)	101 (51.0%)	6 (3.0%)	198
c. Limited peer review. Users of PBMs may not exercise sufficient independent peer review of the PBMs' clinical decisions.	11 (5.6%)	57 (28.8%)	66 (33.3%)	49 (24.7%)	15 (7.6%)	198
d. Inadequate drug-product information. HMOs' physicians and patients may base drug therapy decisions on product-specific information from PBMs which, unlike drug manufacturers, need not comply with the Federal requirements for drug labeling and advertising.	6 (3.1%)	22 (11.2%)	69 (35.2%)	75 (38.3%)	24 (12.2%)	196
e. Safeguarding the confidentiality of patient data. Confidential, patient-identifiable information contained in PBM databases may be disclosed to others, such as employers or drug manufacturers, without the fully informed consent of patients.	20 (10.1%)	26 (13.1%)	55 (27.6%)	89 (44.7%)	9 (4.5%)	199
f. Disclosure. HMOs may not inform enrollees about using a PBM and its alliances with drug manufacturer(s).	16 (8.0%)	31 (15.6%)	50 (25.1%)	86 (43.2%)	16 (8.0%)	199
g. PBM accountability. The information HMOs receive from PBMs may be too limited for HMOs to hold them sufficiently accountable for their performance.	20 (10.1%)	43 (21.7%)	71 (35.9%)	57 (28.8%)	7 (3.5%)	198

13. In which of the following ways, if any, do you think your HMO might change its present PBM contract over the next couple of years?

Type of change	HMO checks "yes"	N
Contracting with a different PBM	89 (44.7%)	199
Sharing with PBM of increased financial risk	81 (40.7%)	199
Managing drug benefit internally	53 (26.6%)	199
Other changes	23 (11.6%)	199

Questions 14-16 were asked only of those 64 HMOs that responded "No" to question 1, i.e., HMOs that do not currently contract with an external PBM.

14. Has your HMO ever had a contract with an external PBM for other than claims processing services?

Yes	No	Don't Know	N
4 (6.5%)	57 (91.1%)	1 (1.6%)	62

15. Do you think that your HMO will contract with an external PBM within the next two years?

Yes	No	Don't Know	N
14 (22.2%)	39 (61.9%)	10 (15.9%)	63

16. Does your HMO use an internal PBM to manage its pharmacy programs?

Yes	No	Don't Know	N
30 (49.2%)	30 (49.2%)	1 (1.6%)	61

APPENDIX D

COMMENTS ON THE DRAFT REPORT

In this appendix, we present in full the comments from the Health Care Financing Administration, the Food and Drug Administration, and the Health Resources and Services Administration. We also solicited and received comments from the Academy of Managed Care Pharmacy, the American Medical Association, the American Pharmaceutical Association, the American Society of Health Systems Pharmacists, the Consumer Coalition for Quality Health Care, and the Medicaid Pharmacy Technical Advisory Group of the Health Care Financing Administration.



DATE: MAR 11 1997

FROM: Bruce C. Vladeck *Bruce Vladeck*
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies" (OEI-01-95-00110)

TO: June Gibbs Brown
Inspector General

We reviewed the above-referenced report pertaining to the use of pharmacy benefit management companies by health maintenance organizations. Our detailed comments on the report recommendations are attached. Thank you for the opportunity to review and comment on this report.

Attachment

Health Care Financing Administration (HCFA) Comments on
Office of Inspector General (OIG) Draft Report: "Experiences of Health
Maintenance Organizations (HMOs) with Pharmacy Benefit Management Companies
(PBMs)." (OEI-01-95-00110)

OIG Recommendation

HCFA should take steps to ensure that its Medicare HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries.

HCFA Response

We concur. HCFA conducted an assessment of the PBM industry and its impact on costs and quality of care on Medicaid and Medicare services, as well as on the larger pharmaceutical market. The PBM industry has experienced considerable growth, both in terms of number of firms and number of people for whom the PBMs provide services. As a beneficiary-centered purchaser of health services, HCFA is entirely focused on achieving the optimal value for our beneficiaries in terms of cost and quality. However, HCFA is limited in its regulatory oversight and evaluation of pharmacy in Medicaid and Medicare managed care programs. Under Medicare, HCFA currently requires contracting HMOs to include specific provisions in their contracts with subcontractors that detail a listing of services covered for Medicare enrollees, a description of payment or incentive arrangements, an agreement not to bill Medicare members except for applicable copays, deductibles or coinsurance, and an agreement to participate in HMO quality assurance and utilization review activities. These provisions apply to all subcontracting relationships, including PBMs. HCFA monitors HMOs on a periodic basis during which random samples of all subcontracts are reviewed to ensure compliance. HCFA can encourage states to strengthen their contractual arrangements to ensure that oversight mechanisms are in place. HCFA will also continue to monitor managed care organizations' oversight of PBMs' performance as well as ensure that subcontracting relationships meet HCFA's contracting requirements.

OIG Recommendation

State Medicaid agencies should take steps to ensure that their Medicaid HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries.

HCFA Response

We concur. Given HCFA's regulatory limitations for oversight of pharmacy in Medicaid and Medicare managed care programs, we believe the best way to address this issue is to develop guidelines that would provide states with technical assistance in developing their contractual language and performance standards for the subcontractor relationship between HMOs and PBMs.

OIG Recommendation

HCFA, the Food and Drug Administration, and the Health Resources and Services Administration, working together with external organizations, should build on existing efforts to develop quality measures for pharmacy practice that can be used in managed care settings.

HCFA Response

We concur. This is an excellent opportunity for these Federal agencies to work together to improve the management of the drug benefit to beneficiaries through developing quality measures as well as monitoring the quality of service delivered to ensure feedback of results. In this regard, HCFA can ensure performance measures for pharmacy services are included in its strategy for quality assurance for HMOs. Further, the group can also identify incentives that ensure measurable improvements in outcomes of patient care, ensure increased accountability, and achieve higher beneficiary satisfaction.

Technical Comments

Page 1 - Medicaid managed care enrollment statistic of 24 percent is outdated. The more recent number would be 39 percent as of June 30, 1996.

Page 13 - You state that "24 percent of HMOs do not use their own Pharmacy Therapeutic Committees to peer review their PBMs' programs." It also holds that 76 percent do conduct this type of activity. In your report, you indicate that 38 percent do not perform their own drug use reviews of PBMs' analyses, but this indicates that 62 percent do conduct this type of analysis. Further, you cite that 51 percent do not conduct on site review. This means that 49 percent do conduct on site reviews. These statistics could be cited based on order of magnitude so as to avoid negative overcast.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Memorandum

Date FEB 20 1997

From Deputy Commissioner for Management and Systems, FDA

Subject FDA Comments on the OIG Draft Report "Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies," - OEI-01-95-00110

To June Gibbs Brown
Inspector General

We have reviewed the Office of Inspector General's draft report, "Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies," and submit the attached FDA comments on the report's recommendation.


Robert J. Byrd

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

JAN 30 1997

TO: Inspector General

FROM: Acting Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report -
"Experiences of Health Maintenance Organizations with Pharmacy Benefit
Management Companies" - OEI-01-95-00110

Attached, in accordance with your December 12, 1996 request, are HRSA's comments on the subject draft report.

Thomas G. Morford

Attachment

**HEALTH RESOURCES AND SERVICES ADMINISTRATION
COMMENTS ON
OFFICE OF INSPECTOR GENERAL (OIG)
EXPERIENCES OF HEALTH MAINTENANCE ORGANIZATIONS
WITH PHARMACY BENEFIT MANAGEMENT COMPANIES
OEI-01-95-00110**

GENERAL COMMENT

The report provides a description of pharmacy benefit management companies (PBMs), and the services they provide to payers and health plans. The main use of PBMs is in controlling costs of prescription drugs. While costs should be an important consideration, costs should not be the only factor considered in the decision making process. Also the report points out the lack of sufficient accountability for the quality of services provided to beneficiaries. Various publications have documented drug misadventuring and the associated cost to the health care system, as well as pharmacists filling prescriptions that would produce a potentially harmful adverse reaction. The Department recently launched a public-private plan designed to improve patient understanding of prescription drugs and reducing misuses of medications.

OIG RECOMMENDATION

HCFA, FDA and HRSA working together with external organizations, should build on existing efforts to develop quality measures for pharmacy practice that can be used in managed care settings.

HRSA RESPONSE

We concur. HRSA has a variety of initiatives underway to evaluate the role and effectiveness of managed care in a reformed health care system insuring access to quality health care services. This recommendation is a reasonable extension of these ongoing activities.

TECHNICAL COMMENTS

Page iii., second paragraph. Insert the following after "...improved patient care." Quality measures should reflect, as a minimum, consumer perception, clinical measure payout/revenue ratios and provider evaluations.

ACADEMY OF AMCP MANAGED CARE PHARMACY®

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January 3, 1997

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

Dear Ms. Brown:

The Academy of Managed Care Pharmacy (AMCP) is pleased to have the opportunity to offer comments on the Office of Inspector General's (OIG) draft report, OEI-01-95-00110, entitled *Experience of Health Maintenance Organizations with Pharmacy Benefit Management Companies*.

AMCP is the national professional society dedicated to the concept and practice of pharmaceutical care in managed health care environments. AMCP's mission is to promote the development and application of pharmaceutical care in order to ensure appropriate health care outcomes for all individuals. Its sole purpose is to represent the views and interests of managed care pharmacy. The Academy has more than 3,500 members nationally who are part of more than 600 health care organizations, including the leading health maintenance organizations (HMOs) and pharmacy benefit management (PBMs) companies, that provide comprehensive pharmacy coverage to the millions of Americans served by managed care.

We commend the Inspector General's Office for turning its attention to the role that PBMs play in the delivery of quality, cost-effective pharmaceutical care. We believe the draft report begins to explore the substantive interaction between PBMs and their HMO clients and agree, in general, with the three recommendations the report makes. However, we recognize that since the report is based primarily on responses to survey questions by HMO administrators, a full understanding of the relationships that exist between PBMs and their HMO clients may not have been possible to achieve. We offer our comments in the spirit of expanding on that understanding and clarifying some items that may be misinterpreted.

1. There is general satisfaction with the level of performance HMOs receive from PBMs as evidenced by the extent of use of PBMs by managed care organizations. PBMs have a level of performance and quality that is attractive to HMO clients not only for their cost-savings potential, but also for optimizing patient care through use of patient and provider profiling, academic detailing, and automated advisories to prescribers and dispensers. Often PBMs offer disease state management services to clients so that drug regimens produce the best patient outcomes; this may entail greater, rather than reduced, outlays for prescription items, but with cost savings ramifications for total patient expenditures by clients. PBMs offer expertise in the management of the pharmacy benefit not always available within individual health care organizations. These include a focus on pharmaceutical care tools such as monitoring for patient drug compliance, drug interaction, allergies and identifying potential or actual drug related problems. They also include the use of sophisticated, automated databases and information systems.

2. In order to comprehend the entire operating environment within which PBMs function, it is necessary to broaden the scope of inquiry for input. We believe that to achieve a true understanding of the dynamics at work, the following parties need to have opportunity to explain how they interact with PBMs:

PBM administrators: the report suffers from not having comments from people who work in PBMs and who can be responsive first-hand to such issues as accountability, oversight, safeguards, patient satisfaction, and value-added services demanded by HMO and non-HMO clients.

Employer group purchasers: This prevalent sector of PBM clients helps shape how PBMs operate. Employer purchasers recognize the buyers market they operate in regarding purchase of PBM services. Fueled by competitive pressures, PBMs listen carefully to what this important client base asks for in terms of both base-line cost considerations and provision of quality services to their employees. Because employers are making purchasing decisions based on what will be made available to their own personnel, they are very sensitive to performance/quality concerns. Many of the innovations PBMs introduce into their operating procedures spring from requests made by employers who demand accountability in a number of different ways.

Pharmacies in the community under contract with PBMs: PBMs cannot operate without extensive networks of participating retail pharmacies. These are the backbone of the delivery mechanism. As they provide the means for the HMO to provide the pharmacy benefit to enrollees, the interaction between the PBM and pharmacies under contract have a direct impact on the relationship between PBMs and their HMO clients.

Individual providers: PBMs, through use of their patient and provider profiles, are able to alert physicians and pharmacists to potentially dangerous situations that would alter the prescriber's choice of drug. Providers' views of PBM/HMO interactions could be enlightening.

3. Contrary to statements in the report, PBMs are held accountable by their clients. The keen competitive marketplace that PBMs operate in demands that they be responsive to client concerns. If PBMs cannot demonstrate quality performance, their clients go to their competitors.

Accountability, forced by competitive pressures, is further demanded by an array of external entities. In the case of HMO clients, the PBM routinely must answer to HMO representatives responsible for the quality of care provided to enrolled populations. This may be the medical director, the pharmacy director, or the quality assurance team. These individuals are responsible for the health plan meeting quality standards set by such respected external accrediting bodies as the National Committee for Quality Assurance or by state oversight agencies concerned about both quality of care and financial solvency. Also, state Boards of Pharmacy have increased their oversight of PBMs due to nonresident licensure statutes in some states which cause all PBMs with dispensing facilities to come under the scrutiny of multiple boards.

Both HMO and employer group clients are particularly sensitive to achieving both cost efficiencies and patient satisfaction. Often such performance/quality accountability mechanisms are spelled out in the contracts between PBMs and their clients. These accountability mechanisms typically include:

- accessibility of pharmacies to the covered population
- information systems capabilities and consistency
- provision of clinical services such as formulary management assistance, alerts to prescribers of potential and actual drug-related problems, and drug use evaluation
- profiling of patient usage
- profiling of prescriber patterns
- provision of academic detailing to physicians to help them become acquainted with the capabilities and limitations of certain prescription products
- jointly administered PBM/client patient satisfaction surveys
- client discounts through passing on of manufacturer rebates
- negotiated standards for such performance factors as dispensing error rates, telephone answering speed, and dispensing turn-around times.

In order to forestall costs associated with redundant performance/quality review, the Health Care Financing Administration should look for ways to partner with existing approaches used by PBMs and their clients to assure quality and performance for Medicare and Medicaid beneficiaries.

4. The report leads the reader to assume, incorrectly, that PBMs develop a formulary that clients must operate under. This is not the case. Most established HMOs retain authority for formulary decisions; the PBM provides advice in implementing the individual plan's formulary. The plan's formulary is the product of intensive, ongoing work by a Pharmacy and Therapeutics (P&T) Committee comprised of health care professionals involved in patient treatment. Changes to a plan's formulary are not discretionary and must be made only by the P&T Committee. It is the responsibility of the PBM to manage the client-developed formulary.

Where the PBM's client is an employer-based group, that client, in some cases, may not have the ability or desire to provide its own P&T Committee and formulary program. In those situations, it will utilize the PBM's P&T Committee recommendations, and, adopt one of a variety of formularies which the PBM may offer. To service this need, most PBMs regularly maintain a P&T Committee composed of independent health care professionals to evaluate therapeutic products for inclusion on the preferred list of drugs.

5. The report mistakenly suggests that PBMs retain most of the rebates paid by manufacturers; this is not the case. Ordinarily the disposition of manufacturer rebates is decided by contract negotiation between the PBM and the individual client. One of the nation's largest PBMs with the most experience with HMOs reports that 100% of the rebates are returned to the HMO, unless they specifically agree to a different arrangement.

6. We believe the report should be explicit in stating that PBMs are not empowered to make therapeutic substitutions to prescriptions without receiving authorization from the prescriber, and, in some instances, from the patient.

7. The report cites confidentiality of patient data as one potential concern of using PBMs, but fails to note the benefits that result from the appropriate use of patient prescription and medical data. As the report notes, PBM databases are rich sources of information about which patients are using which drugs. This information, used by physicians, pharmacists, and health plan and PBM administrators, benefits patients by assuring proper drug selection. This is particularly effective when the information is transferred electronically. Access to such data helps health care professionals share practical information regarding how the prescribed drug may either benefit or harm the patient because of potential drug interactions, similarity with other prescription drugs the patient may already be taking, or compliance with drug therapy. This information helps physicians and pharmacists make informed decisions about whether or not a particular medication is appropriate for a particular patient.

Managed care organizations and PBMs recognize and respect patient confidentiality as a desirable and firmly-established principle. AMCP supports steps that health plans and PBMs already take to protect patient privacy regarding their medical and prescription records, including use of computer passwords and secure networks. AMCP believes managed care organizations and PBMs must not release personally-identifiable data without the prior knowledge and consent of the patient. (See enclosed position statement on electronic transfer of prescription information.) Additionally, PBMs are subject to the laws of various states governing confidentiality of patient information. As such, they are very conscious of their responsibility with regard to protecting the confidentiality patient records.

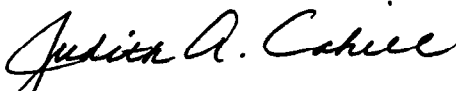
8. Ownership of a PBM by a drug manufacturer is irrelevant to the question of whether quality care is being provided. The report states that drug company ownership of a PBM may represent a conflict of interest and raise concerns about anti-competitiveness. While we believe this is a valid concern, we believe safeguards already exist that prevent its happening. Regulatory oversight by both state courts and the Federal Trade Commission have prompted strict adherence to these safeguards so that PBMs and their owners operate independently. Additionally, the P&T Committee composition and decision-making authority over formularies assures an independent group of clinical experts controls the choice of preferred drugs. We recommend the report reinforce the need for PBMs to have quality safeguards in place to avoid conflict of interest, rather than suggest PBM ownership by drug companies is *prima facie* evidence of anti-competitive actions.

9. The report's bibliography would lead a reader to some very negative pieces on managed care. AMCP would be pleased to suggest additions for the listing that would result in a more balanced literature reference set.

In conclusion, we look forward to working with the Department of Health and Human Services as it pursues its objectives of assuring that quality, responsible health care is made available to its constituents. We would be pleased to meet with representatives of the agency to describe the efforts AMCP's Task Force on Quality Initiatives is developing and explain the work of the AMCP-led Quality Council comprised of representatives from all of the national pharmacy associations.

Thank you again for the opportunity to offer our comments.

Sincerely,



Judith A. Cahill
Executive Director

Enclosure

American Medical Association

Physicians dedicated to the health of America



Jesse S. Hixson, PhD 515 North State Street 312-464-5427
Principal Economist Chicago, Illinois 60610 312-464-5849 Fax
Center for
Health Policy Research

December 30, 1996

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

My Dear General:

Your report, "Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies," which you sent to John Seward, MD, Executive Vice President of the American Medical Association (AMA) for review and comment, was referred to me for review.

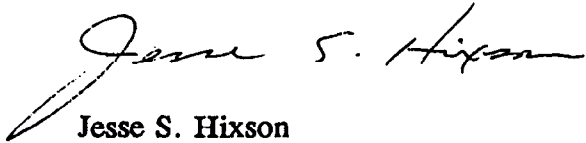
The report is indeed timely and examines a facet -- HMO contracting with Pharmacy benefit management companies (PBMs) -- of the managed care industry which deserves further scrutiny. The AMA shares the concern expressed by many of the HMOs about the potential for bias resulting from the PBM's alliances with drug manufacturers.

The AMA has a clear position regarding potential conflicts of interest inherent in managed care cost containment involving prescription drugs. Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives and other approaches are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Managed care plans must adhere to the requirement of informed consent that patients be given full disclosure of material information. This requires that managed care plans inform potential subscribers of incentives or pressures to lower prescription drug costs.

Patients must be informed of the methods used by their managed care plans to limit prescription drug costs such as the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary, and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition plans should disclose any relationships with PBMs or pharmaceutical companies that could influence availability of prescription drugs to patients.

Thank you for the opportunity to review the report. We agree with your recommendations for the Medicare and Medicaid programs and the practice of pharmacy. We encourage you to continue your scrutiny of this and other practices that could place the financial interests of health care providers above the welfare of their patients.

Sincerely,

A handwritten signature in cursive script that reads "Jesse S. Hixson". The signature is written in black ink and is positioned above the printed name.

Jesse S. Hixson

cc: Kirk B. Johnson, JD



American
Pharmaceutical
Association

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*The National Professional
Society of Pharmacists*

January 23, 1997

The Honorable June Gibbs Brown
Inspector General
U.S. Department of Health & Human Services
Room 5250 Cohen Building
Washington, DC 20201

Re: OEI-01-95-00110

Dear Ms. Brown:

On behalf of the American Pharmaceutical Association (APhA), the national professional society of pharmacists, I would like to express my appreciation for this opportunity to comment on the draft report, "Experience of Health Maintenance Organizations with Pharmacy Benefit Management Companies."

This report is a timely and concise examination of an important aspect of health care delivery: the management of prescription drug benefits by pharmacy benefits managers (PBMs). Your staff deserve credit for adopting the market-savvy approach of interviewing customers of PBMs, and for having gone to some lengths to solicit input from a variety of organizations in preparing this study. We are proud that your report references the *APhA Principles of Practice for Pharmaceutical Care* and the *Guidelines for Medication Incentive Programs*, two important consensus documents speaking to the appropriate management of drug benefits in today's health care system. In sum, your staff has done an excellent job capturing key elements of drug therapy management despite the modest amount of information for evaluation which is available from the PBMs themselves.

The Pivotal Role of the Pharmacist. While the study examines the experience of health maintenance organizations with pharmacy benefits managers, it is important for the report's audience to understand that PBM performance depends to a great extent on the performance of the pharmacists serving the PBM's enrollees. When it comes to patient care, the functional unit of the PBM is the pharmacist. Nowhere is this more evident than in the area of quality measurement and assurance.

Pharmacists at the patient interface, loosely organized in networks created and administered by the benefits managers, are key to the delivery of cost effective, high quality pharmacy services. Unfortunately, certain features of these networks not only fail to support high quality pharmacy practice, but tend instead to undermine quality.

Ms. June Gibbs Brown
January 23, 1997

Consider, for example, that most pharmacists work for a number of PBM networks. Each of these PBMs depends on the pharmacist to perform at a high level, and each PBM attempts to impose its own administrative and other requirements to achieve this end. Yet neither the pharmacist, nor any one of the individual PBMs with which the pharmacist is under contract, can reconcile the many conflicting requirements of the competing PBMs. In fact, one of the dominant realities of contemporary pharmacy practice is that the practitioner must divert time and attention from patient care to contend with the conflicting demands of different PBMs. It is unlikely that individual action by any PBM can resolve this fundamental problem. A solution may depend on action to eliminate these inefficiencies by standard-setting organizations such as the National Council of Prescription Drug Programs (NCPDP).

Inasmuch as PBMs repackage, sell, and may someday be held accountable for pharmacists' pharmaceutical care services, it is imperative for those reading your report to understand the need for the PBM to support quality pharmacy practice by the pharmacists they employ and with whom they contract. In particular, PBMs must be challenged to integrate their network of community-based pharmacists (who tend to have strong personal relationships with patients) into the best practices of their clinical pharmacy centers, which are capable of providing valuable information to patients and their physicians.

Economic Disincentives for Quality Pharmaceutical Care. It is critical for your examination of the services and impact of PBMs (and managed pharmaceutical benefits in general) to include reference to economic issues related to drug benefits. Your study mirrors the reality that virtually all HMOs and their PBMs have used cost control measures, including restricted networks and discounted fee structures, as the most common mechanism to manage the drug benefit. While we certainly respect the role these strategies play in achieving one of the aims of drug benefit management --drug product cost containment-- it will be hazardous to the health of elderly and low income Americans if this limited objective remains the primary preoccupation of PBMs.

PBMs have aggressively undertaken drug product cost containment for many years without a rigorous analysis of its impact on patient care. Medicare and Medicaid officials would be wise to insist on measures to guard against the very real threat that short-term measures to control drug product prices and consumer access to pharmaceuticals may inadvertently increase morbidity, mortality, and total health costs.

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It is especially important that those responsible for managing drug benefits utilized by vulnerable populations, such as the elderly and poor, provide appropriate incentives for providers to offer pharmaceutical care services. Previous reports issued by the HHS Office of Inspector General (OIG) have called for expanding the clinical role of community pharmacists to optimize patient outcomes and total health care costs. One OIG report issued in 1991 spoke directly to the need to change the payment strategies within pharmacy benefits to more appropriately align economic incentives with the imperative of quality care. This practical recommendation has now been echoed in the *Action Plan for the Provision of Useful Prescription Medicine Information*, which was formally endorsed by the HHS Secretary on January 13, 1997.

While some progress has been achieved toward this end, payment for pharmaceutical care lags far behind PBMs' standard strategy of deeply discounting drug product reimbursement. It is an inescapable business reality that these steady reductions in product-related payments must force pharmacies to become volume distributors, speeding up the dispensing of low- or no-margin drug products to the point where there simply is no time to educate patients about compliance or other aspects of their drug therapy. Pharmacists are extremely concerned that this trend is rapidly eroding their capacity to deliver needed caregiving services to the growing number of older and low income Americans enrolled in private and public plans administered by PBMs.

Poor Quality Oversight of Managed Pharmaceutical Benefits. The report on pages 13-14 speaks to the lack of review or oversight activities, by either HCFA or State Medicaid officials, of PBMs and the quality of their services. APhA commends OIG for raising this issue, and urges that the report assign a higher priority to improved quality oversight of pharmacy services, both within Federal programs and in all quality review and accreditation organizations. In fact, there are troubling signs that quality oversight of Medicaid prescription drug benefits is actually weaker today than it was four years ago.

The first problem is structural: maintaining separate fee for service and managed care Medicaid drug benefits programs fragments encounter data and impedes quality oversight of drug benefits. Retrospective drug use review (DUR) programs examine prescribing and utilization data to identify potential quality problems (e.g., identifying prescribers or dispensers associated with potentially hazardous practices). The best of these programs venture outside the confines of the drug benefit by merging drug utilization data with other health care utilization data to investigate potential causes and costs of drug-related morbidity and mortality. When a large share of Medicaid prescription utilization data is captured and maintained by managed care entities, Medicaid quality officials cannot access the information, and quality oversight is undermined.

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Another problem is HCFA's practice in recent years to routinely waive the only existing quality requirements for Medicaid drug benefits --the Drug Use Review (DUR) program that just took effect in 1993-- when approving State requests to provide Medicaid benefits to low income individuals through managed care organizations. It remains unclear whether the managed care organizations operating under these waivers are accountable to public officials to provide an equivalent quality oversight mechanism in lieu of the Federal DUR safeguards. This area deserves further attention by the OIG.

With respect to prospective DUR (one element of the Federal DUR statute), PBMs generally have grafted these features on to the online systems originally developed for claims adjudication (please see page eight of the report). Much more thought needs to go into such systems before they can be valid and reliable as a quality improvement tool for pharmacists. For example, the text of the OIG report should note the lack of uniformity of criteria used to generate warning messages pertinent to individual patients' therapies. The result of such inconsistencies is a barrage of conflicting messages sent to the pharmacist. It is fair to say that the content of these warnings depends to a great extent on the identity of the company managing the patient's drug benefit, rather than on established scientific knowledge of drug interactions, dosage problems, and the like.

Recent research (accepted for publication in a peer reviewed medical journal) has confirmed the existence of conflicts between the DUR programs serving public health programs. More troubling still is the revelation in this article that such programs all too often alert the pharmacist to clinical dangers which are not supported by the scientific literature. This phenomenon of "false positive" messages --messages alerting the pharmacist to a danger which either does not exist, or is clinically unimportant -- remains a problem which is at once well-known but much neglected by software vendors, PBMs and others. When commercial software programs repeatedly cry "wolf" on dozens of occasions daily many pharmacists become inured to these warnings, and are more likely to miss meaningful "alerts" generated by the computer.

Equally worrisome is the tendency for some of these software packages to fail to generate "alerts" which are well-substantiated. To the extent that warnings, and the absence of appropriate warnings, are taken seriously by pharmacy practitioners (who may then contact the prescriber), such inconsistencies simply promote prescribing and dispensing behavior which is scientifically unfounded. These defects in commonly used prospective DUR programs explain much of the limited impact of these software programs in preventing adverse drug events, and deserve a serious mention in the report.

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In sum, to avoid further diminution of what OIG has correctly identified as inadequate quality oversight of drug benefit programs, managed care contractors should be accountable to precisely document the quality oversight efforts they offer in lieu of the statutory DUR program. Another improvement would be an obligation for such contractors to cooperate with State Medicaid officials by sharing data on drug utilization in a mutually agreeable format. Finally, OIG could usefully inquire into the substance and documented accomplishments of these parallel programs --both in Medicaid's fee for service and managed care drug benefit programs-- and recommend enhancements.

Measures of Quality of Pharmacy Practice. Existing tools for quality oversight in managed care, particularly pharmacy performance measures, remain primitive. These must be improved to extend beyond simple analyses of parameters, such as "per member per month" prescription drug charges, that offer no true insight into the quality of prescribing or patient care. APhA concurs with your recommendations, and particularly recommendation #3, which calls on Federal agencies to actively engage the private sector to expand existing efforts to define and utilize quality measures for pharmacy services.

It is true that these efforts lag behind the progress being made to define relevant and valid measures of quality for hospitals, health plans, and physicians. However, APhA and other pharmacy organizations have been working both individually and collectively for some time to define a framework for quality measurement and to communicate to quality assurance and accreditation organizations the need to improve their performance measures of pharmacy and drug therapy. We enthusiastically encourage the Health Care Financing Administration (HCFA), the Health Resources and Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC) and other Federal agencies to join us in this important effort.

In this regard, please note the Association will be expanding its quality initiatives considerably in 1997. Within the context of a new center of activity, APhA will offer a clearinghouse for information pertinent to the quality of pharmacy practice, and will initiate research to identify and validate proposed measures of quality. APhA intends to develop programs which recognize and reward excellence in services provided by pharmacists in all practice settings. We believe that this effort, coordinated with the work of other organizations in pharmacy and the health professional community, will help build understanding of the importance of quality measurement and improvement and stimulate the delivery of health-promoting pharmaceutical care.

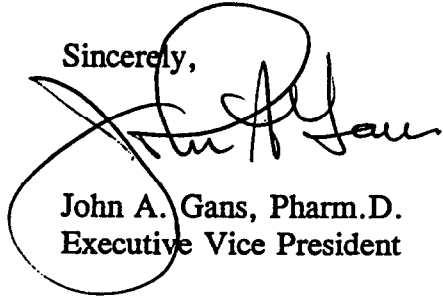
Confidentiality. The issues raised in the report pertaining to patient confidentiality are also extremely important. Appropriate protection against unauthorized disclosure of sensitive personal information must be guaranteed, while at the same time permitting practitioners the opportunity to exchange information about prescribing, patient compliance, and other patient care concerns. Establishing different criteria for access

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and sharing of data by and among health care professionals, as distinguished from PBMs and other administrative entities, would be a fruitful approach to resolution of this problem. APhA has developed recommendations in the context of implementation of the Health Insurance Portability and Accountability Act, available upon request, which address this issue more fully.

Again, please accept my congratulations for producing such a substantive contribution to the emerging literature on this important subject. APhA is committed to assisting OIG and others challenged by the report's recommendations. Please don't hesitate to contact me or my staff for additional information, or for clarification of any element of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Gans". The signature is written in a cursive style with a large, looping initial "J".

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

**AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS***Pharmacists in health systems helping people make the best use of medications*

January 6, 1997

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, "Experience of Health Maintenance Organizations with Pharmacy Benefit Management Companies."

Dear Ms. Brown:

The American Society of Health-System Pharmacists appreciates the opportunity to comment on the draft report referenced above. 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, and other components of health care networks. Because the HMO environment represents one of the fastest growing segments of our membership, we have a particular interest in the subject matter of the draft report.

ASHP is in general agreement with the recommendations contained in the draft report. Quality of care and patient outcomes are the primary consideration of our membership, and we share the Department's concern that cost containment not become the driver of health care delivery, as opposed to the natural and inevitable result of prudent health care practices. We also share the concern expressed in the draft report that there exists a very real potential for bias stemming from the relationship of a pharmacy benefit management company (PBM) to a specific pharmaceutical manufacturer. Where we have suggestions in addition to the recommendations arrived at in the draft report is in the proposal for federal and state agencies to develop a yardstick for the accountability of Medicare and Medicaid HMOs for the quality of the services rendered by PBMs to beneficiaries. While this is a totally legitimate objective overall, and one that ASHP can support, we strongly encourage the Department to collaborate with existing credentialing and standards writing bodies that already possess the most in-depth experience and data on the subject of health care quality.

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The National Committee for Quality Assurance (NCQA) is an accreditation body considerably knowledgeable of and responsible for standardized quality of care in HMOs. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the national accrediting body for hospitals and other health care organizations, also has considerable involvement in this area. ASHP has been a voluntary advisor to both NCQA and JCAHO on standards pertinent to pharmaceutical care and pharmacy services. These organizations are the logical starting places for addressing the concerns raised in the draft report, and will be invaluable sources of information for the Health Care Financing Administration (HCFA) in assessing the quality of services afforded to Medicare and Medicaid beneficiaries by PBMs.

The input of health professionals such as pharmacists who are directly responsible for drug management in HMOs, whether or not affiliated with PBMs, is also essential to safeguard against slippage in the quality of the services rendered in these environments. For example, ASHP has been active in the development of specific standards as well as general guidance on the development of formulary systems and their management, which have formed the basis for current standards of acceptable practice in HMOs. The formulary system, as a means of local, informed, interdisciplinary decision-making about the best therapeutic agents (drugs) to have available, was pioneered in hospitals. ASHP has a long history of fostering that sort of formulary system, and we stand ready to advise the Department and others on standards to ensure the operation of such good formulary systems. Our published standards (which generally are not hospital-specific) are aimed at the primary goal of appropriate therapy, with cost being an important but secondary concern. It appears to ASHP that PBMs have, to date, focused on the cost-minimization aspects of formularies and less on the goal of optimizing therapy. We welcome the opportunity to share our expertise with practitioner groups and other interested organizations with the objective of developing guidelines to assess and assure the quality of pharmacy services provided by PBMs. Considerable valuable material already exists on the subject, and as a starting point, a list of ASHP's relevant guidance documents is enclosed. Reference to and reliance upon these documents, and those published by other credible standards writing bodies, will render the task of developing reasonable guidelines for PBMs used by HMOs less onerous than it may currently appear.

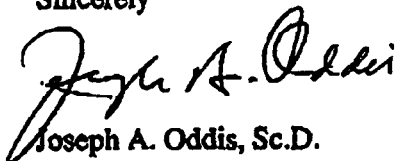
From a more practical business viewpoint, HMOs must learn to be better negotiators with PBMs for quality services, realizing that, ultimately, they will be competing for patients on the basis of quality just as they now compete for customers (i.e., employers) on a cost basis. An underlying problem that must be addressed is that, because of their short-term focus on low reimbursement rates for prescription medicines, PBMs have generally not provided incentives for ambulatory care pharmacists to provide various cognitive services that help HMO beneficiaries make the best use of medications. Thus, while money may be saved in drug expenditures, overall health care

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costs are being increased because of subsequent interventions to deal with adverse events that a pharmacist could have prevented had the PBM payment system offered the proper encouragement. This is a serious issue for Medicare and Medicaid beneficiaries served by HMOs, and we urge you to strengthen this point in the report. To summarize, there is a definite role for education here. ASHP would support efforts to foster the education of consumers (patients and employers) regarding the nature and benefit of pharmaceutical care services that they should expect from their HMO.

ASHP looks forward to working with the Department, HCFA, NCQA, JCAHO, and private sector pharmacy organizations to address the concerns raised in the draft report. Please call us for additional comments, and advise us of a role that we may play in the upcoming process.

Sincerely



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

Enclosure

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RELEVANT ASHP GUIDANCE DOCUMENTS

- ASHP Statement on the Pharmacy and Therapeutics Committee. (1992)
- ASHP Statement on the Formulary System. (1983)
- ASHP Statement on Third-Party Compensation for Clinical Services by Pharmacists. (1985)
- ASHP Statement on the Pharmacist's Role in Clinical Pharmacokinetic Services. (1989)
- ASHP Statement on the Pharmacist's Responsibility for Distribution and Control of Drug Products. (1996).
- ASHP Statement on the Use of Medications for Unlabeled Uses. (1992)
- ASHP Statement on Pharmaceutical Care. (1993)
- ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems. (1993)
- ASHP Statement on the Role of the Pharmacist in Patient-Focused Care. (1995)
- ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Suppliers. (1991)
- ASHP Guidelines for Obtaining Authorization for Documenting Pharmaceutical Care in Patient Medical Records. (1989)
- ASHP Guidelines on Medication-use Evaluation. (1996)
- ASHP Guidelines on Pharmaceutical Services for Ambulatory Patients. (1991)
- ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting. (1995)
- ASHP Guidelines on Pharmacists' Relationships with Industry. (1992)
- ASHP Guidelines on Formulary System Management. (1992)
- ASHP Guidelines on the Pharmacist's Role in Home Care. (1993)
- ASHP Guidelines for Pharmacists on the Activities of Vendors' Representatives in Organized Health Care Systems. (1994)
- ASHP Guidelines on a Standardized Method for Pharmaceutical Care. (1996)
- ASHP Guidelines on the Provision of Medication Information by Pharmacists. (1996)
- ASHP Guidelines on the Pharmacist's Role in the Development of Clinical Care Plans. (In Press, 2/97)
- ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling. (In Press, 2/97).
- ASHP Technical Assistance Bulletin on Drug Formularies. (1991)
- ASHP Technical Assistance Bulletin on the Evaluation of Drugs for Formularies. (1988)
- ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. (1990)
- ASHP Technical Assistance Bulletin on Assessing Cost-Containment Strategies for Pharmacies in Organized Health-Care Settings. (1992)
- ASHP Technical Assistance Bulletin on Quality Assurance for Pharmacy-Prepared Sterile Products. (1993)
- ASHP Technical Assistance Bulletin on the Recruitment, Selection, and Retention of Pharmacy Personnel. (1994)
- ASHP Therapeutic Position Statement on Strict Glycemic Control in Selected Patients with Insulin-Dependent Diabetes Mellitus. (1995)



December 30, 1996

June Gibbs Brown
Inspector General
Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Washington DC, 20201

Dear Inspector General Brown:

The Consumer Coalition for Quality Health Care appreciates the opportunity to comment on your draft report, "Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies." The Consumer Coalition represents national consumer groups with an interest in advancing policies and programs that protect and improve the quality health care for all Americans. During the holiday season we did not have adequate time to solicit the views of our membership but we are confident that the following comments on the draft report reflect current member thinking.

The Consumer Coalition enthusiastically endorses the report's recommendations. The importance of outpatient prescription drugs, particularly for the elderly population, and the extensive use of pharmacy benefit management companies (PBMs) by HMOs argue for expanded government oversight of the services these companies provide within HMO delivery systems. Government and private payer contracts with HMOs should include language that require HMOs to evaluate the performance of PBMs. Public and private payers should conduct independent evaluations of HMOs to ensure that systems of quality accountability have been established between the HMO and PBM subcontractors. In principle, the Consumer Coalition believes that HMOs should be held responsible for the performance of all its subcontractors, including PBMs.

The Consumer Coalition recommends that the evaluation of HMO arrangements with PBMs highlight issues of direct relevance to the consumer. Chief among these are formulary development, marketing of drug benefits, the appeals system for reduction or denial of prescription drugs, and patient confidentiality.

The oversight of HMO arrangements with PBMs should start with the appropriateness of drug formularies, particularly in light of the ownership of PBMs by drug manufacturers. Next, HMO marketing and benefit coverage materials should be required to include a clear description of a plan's drug benefit, the specific contents of any drug formulary, the drug

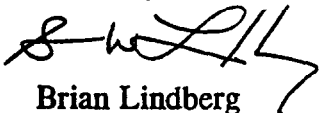
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utilization review process, and complete information on an enrollee's right to appeal a drug benefit decision. PBMs should also be evaluated for maintaining systems that safeguard patient confidentiality.

Finally, the Consumer Coalition is in agreement with the report's recommendation that explicit quality measures be developed for pharmacy practice. Current HMO licensing/accreditation standards and Medicare/Medicaid conditions of participation do not include quality measures for pharmacy practice, leaving an important component of medical practice within HMO delivery systems unregulated. The development of explicit quality standards for pharmacy practice should become a priority for government regulators, private accrediting bodies, payers, and consumer groups with appropriate input from the pharmacy profession.

Once again, the Consumer Coalition appreciates the opportunity to comment on the draft report.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian Lindberg", written over a horizontal line.

Brian Lindberg
Executive Director



TERRY E. BRANSTAD, GOVERNOR

DEPARTMENT OF HUMAN SERVICES

CHARLES M. PALMER, DIRECTOR

February 5, 1997

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

Dear Ms. Brown:

This is in reply to your letter of December 2, 1996 requesting review and comment on the draft inspection report, "Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies." You submitted the report to me in my capacity as Chair of the Medicaid Pharmacy Technical Advisory Group (P-TAG).

With respect to Medicaid the draft report recommends that "State Medicaid agencies should take steps to ensure that its Medicaid HMO's are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries". The report has been reviewed by the P-TAG. We agree on the importance of ensuring accountability when using a PBM and have the following specific observations:

- The definition of quality can be quite variable and needs to be analyzed from multiple viewpoints, i.e., beneficiary, payer, provider and health outcomes.
- Caution is urged that the quality measures developed for use by Medicare may or may not be applicable (in total or in part) to Medicaid. Experiences with HEDIS reveal that. The report language seems to imply that Medicaid should follow the Medicare lead. Perhaps it could be stated that Medicaid can learn from Medicare but states also need to address quality issues that are unique to the Medicaid population.
- OIG recommends that HCFA, FDA, and the Health Resources and Services Administration build on existing efforts to develop quality measures for pharmacy practice in managed care settings. The P-TAG suggests that states be involved in this effort. Perhaps, the P-TAG could also be a contributor.

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- The report focuses on HMO industry use of PBMs. However, other entities have had experience with PBMs. For example, some of the PHS Ryan White funded AIDS Drug Assistance Programs use PBMs. It would be of interest to see if the perspective of enhanced access to care, coordination of services, home delivery, etc. are viewed by these consumers as advantages to PBM use vs. the depicted cost savings focus of HMO industry use of PBMs.
- Caution is also urged about automatically assuming that PBMs owned by pharmaceutical manufacturers are inherently bad and subject to suspicion. This should be put into the perspective of an existing business relationship which can be safeguarded by contractual performance measures which specify the outcomes to be achieved.

Overall, I believe the report accurately reflects the current status of the relationship between HMOs and PBMs.

Thank you for the opportunity to comment on the draft report.

Sincerely,



Donald W. Herman
Administrator
DIVISION OF MEDICAL SERVICES and
Chair, Pharmacy Technical Advisory Group

DH:JM:vh

APPENDIX E

NOTES

1. Nationally, enrollment in HMOs grew from approximately 36 million to 58 million between 1990 and 1995. (See American Association of Health Plans, *1995 AAHP HMO PPO Trends Report*, Washington, D.C.)

2. By mid-1996, the number of risk plans contracting with HCFA had grown to nearly 220. Medicare's risk contracts have become more attractive to HMOs, which operate in a highly competitive marketplaces and face continuing pressures to hold down costs and generate revenues. The HCFA's average payments to its risk contractors, per enrollee, have continued to increase (10.1 percent in 1996 and 5.9 percent in 1997).

For recent discussion of Medicare-risk contracts, see:

"Medicare Risk Payments Rise 5.9%...", *News and Strategies for Managed Medicare & Medicaid*, 2 (September 9, 1996) 19: 1.

"New Ideas for Medicare Risk," *Perspectives, Medicine and Health*, July 1, 1996.

Louise J. Sargent et al., "Overview of Medicare for Managed Care Professionals," *Journal of Managed Care Pharmacy*, 2 (March/April 1996) 2: 165-172.

Health Care Financing Administration, *Medicare Managed Care Monthly Report*, July 1996.

Value Line, July 5, 1996, Medical Services Industry, 656.

3. U.S. General Accounting Office, *Medicare and Medicaid: Opportunities to Save Program Dollars by Reducing Fraud and Abuse*, Testimony of Sarah F. Jaggar, Director, Health Financing and Policy Issues, Health, Education, and Human Services Division, before the Subcommittee on Human Resources and Intergovernmental Relations of the Committee on Government Reform and Oversight, U.S. House of Representatives, March 22, 1995.

Jane E. Sisk, PhD. et al., "Evaluation of Medicaid Managed Care," *Journal of the American Medical Association*, 276 (July 3, 1996) 1: 50-55.

See also comments on the draft report (appendix D) from the Health Care Financing Administration.

4. James S. Genuardi et al., "Changing Prescription Drug Sector: New Expenditure Methodologies," *Health Care Financing Review*, 17 (Spring 1996) 3: 192.
5. U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, "Medicaid Vendor Payments by Type of Service, 1993-1995."
6. With few exceptions, Medicare has not generally paid for outpatient prescription drugs under Part B. Coverage for drugs is allowed by some Medigap policies, which can be purchased separately by beneficiaries. But because many beneficiaries have no drug coverage, risk HMOs that offer prescription drug benefits are very appealing to beneficiaries. Nearly two-thirds of these risk plans now offer prescription coverage. Although HCFA does not pay for this benefit directly, it does pay for it indirectly: the prescription drug benefit is considered an additional benefit, one that is supported with excess Medicare profits to the HMOs, which they would otherwise return to HCFA.

For additional information on drugs and Medicare, see:

HCFA, *Medicare Managed Care Monthly Report*, July 1996.

_____, *1995 Guide to Health Insurance for People with Medicare*, Publication No. HCFA-02110, revised January 1995.

Stephen H. Long, "Prescription Drugs and the Elderly: Issues and Options," 158 *Health Affairs*, Spring (II) 1994.

Lynn Etheredge, Consultant, *Pharmacy Benefit Management: The Right Rx?*, Research Agenda Brief sponsored by the Health Insurance Reform Project at George Washington University, Washington, DC, 1995.

7. For fuller description of issues associated with misedication, noncompliance, and drug use among the elderly, see:

Adverse Drug Reactions in the Elderly: Hearing before the Special Committee on Aging, United States Senate, 104th Cong., 2nd Sess., March 28, 1996.

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), 1949-1956.

Stephen H. Long, "Prescription Drugs and the Elderly: Issues and Options," *Health Affairs* 158 Spring (II) 1994.

Robert McCarthy, "Patient Compliance: Strategies to Overcome a Costly Problem," *Medical Utilization Management* 24 (July 11, 1996) 14: 5-8.

Stephen C. Montamat, M.D. et al., "Management of Drug Therapy in the Elderly," *The New England Journal of Medicine*, 321 (August 3, 1989) 5, 303-309.

Sharon M. Willcox et al., "Inappropriate Drug Prescribing for the Community-Dwelling Elderly," *Journal of the American Medical Association*, 272 (July 27, 1994) 4: 292-296.

8. U.S. General Accounting Office, *Pharmacy Benefit Managers: Early Results on Ventures, with Drug Manufacturers*, HEHS-96-45, November 1995. Our analysis reflects GAO's estimates of the five largest PBMs at the time of its report: Medco Containment Services, Inc.; Diversified Pharmaceutical Services (DPS); PCS Health Systems, Inc.; Caremark International, Inc.; Value Health/Value Rx.

It is important to note, however, that estimates of the size of PBMs vary and are subject to change in this rapidly evolving marketplace.

9. Benefit structure includes such items as co-payments and deductibles, breadth and depth of the formulary, and prior authorization requirements. Approaches to managing the benefit include those such as generic and therapeutic interchange programs; developing and applying criteria and standards guiding utilization reviews, drug therapy protocols, educational interventions, and cost-effectiveness studies.

10. The three PBMs owned by drug companies are **Medco Containment Services, Inc.**, purchased by Merck & Co. for \$6.6 billion in 1993; **Diversified Pharmaceutical Services (DPS)**, purchased by SmithKline Beecham Corporation for \$2.3 billion in 1994; and **PCS Health Systems, Inc. (PCS)**, purchased by Eli Lilly and Company for \$4 billion in 1994.

The other two largest PBMs, **Caremark International, Inc.** and **Value Health/Value Rx**, are not owned by drug companies, but have strategic alliances and partnerships with them.

For fuller descriptions of these relationships, see:

U.S. General Accounting Office, *Pharmacy Benefit Managers*.

Lynn Etheredge, *Pharmacy Benefit Management: The Right Rx?*

Weekly Pharmacy Reports--"The Green Sheet," 45 (January 22, 1996) 4.

11. The Federal Trade Commission reviewed the Lilly-PCS merger of 1994 for its anti-competitive implications. The Commissioners, in a 3-1 vote with one recusal, subsequently approved a consent agreement with Lilly that requires the company to maintain an "open formulary" that includes any drug approved by an independent Pharmacy and Therapeutics (P & T) Committee and requires that PCS accept discounts, etc. offered by Lilly competitors for drugs on the open formulary and to reflect these discounts in the formulary rankings. Finally, the agreement prohibits PCS from sharing proprietary information with Lilly. This requirement has become known as the "firewall" provision. The Commission stated its intentions to continue to monitor this and other mergers. (See Federal Trade Commission, "FTC Gives Final Approval to Lilly Order; Pledges Continued Monitoring for Anticompetitive Practices," *FTC News*, July 31, 1995.)

The consent agreement has been widely criticized. One Commissioner dissented at the time of the agreement, and numerous consumer and pharmacy organizations complained. In July 1996, the Commission was again petitioned on this issue by a pharmacy trade organization, charging that drug manufacturer ownership of PBMs continues to be anti-competitive and harmful to consumers. It urges the FTC to modify and strengthen the 1995 consent agreement.

12. In 1994, the Food and Drug Administration met with representatives from several PBMs and drug manufacturers to discuss information that is disseminated about drug products by the PBMS. It also convened a public hearing in October 1995 on the topic of "Pharmaceutical Marketing and Information Exchange in the Managed Care Environment" to help inform its deliberations about regulating drug marketing and promotion by drug manufacturers and PBMs. (See FDA, Transcript 95N.0228, October 19, 1995.)

13. For a general overview of PBMs, see:

U.S. Department of Health and Human Services, Health Care Financing Administration, "Assessment of the Impact of Pharmacy Benefit Managers," Contract No. HCFA-95-023/PK, September 30, 1996.

U.S. General Accounting Office, *Pharmacy Benefit Managers*.

Lynn Etheredge, *Pharmacy Benefit Management: The Right Rx?*

Anita M. McGahan, "Industry Structure and Competitive Advantage, *Harvard Business Review*, November-December 1994, 115-124.

13. Most (87 percent) HMOs that serve Medicare and Medicaid beneficiaries use their PBM to manage the beneficiaries' prescription drug benefits.

15. The for-profit plans are statistically more likely to use PBMs than the non-profit plans (Chi-square=6.709, DF=1, significant at the .01 level). There is also a statistically significant difference between the number of for-profit and non-profit HMOs responding to our survey (Chi-square=6.453, DF=1, significant at the .01 level). (See appendix B.) When we estimated the effect of the nonresponse bias on this question of whether or not there was an association between an HMO's tax status and whether or not it contracts with an external PBM, we found that taking into account the tax status of the nonrespondents affected the percentages less than one percent.

16. Of the 263 HMOs responding to our survey, 199 report they use PBMs (75 percent). These 199 HMOs represent 303 local plans. Some of these local plans (185) are unaffiliated with any national or regional managed care organizations. The rest (118) are local plans affiliated with national or regional managed care organizations (see appendix A).

17. Thirty-one (31) of the 368 HMOs did not report data on the number of covered lives for the AMCRA data base.

Twenty-seven percent (53/199) of the HMOs, covering 8 million lives, suggest they may manage their pharmacy benefits in-house over the next few years. Twenty-two percent (14/63) of the HMOs not using PBMs, covering nearly 1 million lives, suggest they may contract with PBMs in the next couple of years.

18. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) exempts HMOs from having to conduct prospective and retrospective drug use reviews under the federally mandated Drug Use Review Program for Medicaid.

19. Formularies (which are lists of drugs approved for reimbursement by payers) can be extremely important tools for managing the costs of prescription drug benefits. They also can have significant impact on the quality of pharmacy programs and their consequences for patients' health outcomes.

The consequences of formularies for cost and quality are controversial. They are the focus of significant interest by payers, regulators, consumer and industry groups, and researchers.

For some recent discussion of these issues, see:

Naomi Freundlich, "Formularies: Friend or Foe?," *Harvard Health Letter*, July 1995.

Susan D. Horn, PhD. et al., "Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project," and "Managed Care Outcomes Project: Study Design, Baseline Patient Characteristics, and Outcome Measures," *The American Journal of Managed Care*, II (March 1996) 3: 253-264 and 237-247.

Bryan L. Walser et al., "Do Open Formularies Increase Access To Clinically Useful Drugs?," *Health Affairs*, 15 (Fall 1996) 3: 95-107.

20. Drug manufacturers are relying less on price increases for improving their profits and more on increasing market share through their arrangements with PBMs, which develop and/or control the formularies used by large purchasers such as HMOs.

For their part, PBMs are interested in getting the best price for the products on their formularies, so they can compete more successfully for contracts with purchasers such as HMOs.

For a historical overview of the pharmaceutical industry and changes resulting from PBMs, see Anita M. McGahan, "Industry Structure and Competitive Advantage."

21. Some argue that PBMs' practices can be anti-competitive and, in fact, encourage higher costs to consumers. As we have noted above, these issues were central to the review of the Lilly-PCS merger by the Federal Trade Commission.

22. For a discussion of the cost-effectiveness of DUR programs, see Stephen B. Soumerai, Sc.D. and Helene L. Lipton, Ph.D., "Computer-Based Drug-Utilization Review--Risk, Benefit, or Boondoggle?," *The New England Journal of Medicine*, 332 (June 15, 1995) 24: 1641-1645.

A recent GAO report documented savings attributable to drug use review programs in five State Medicaid programs. See U.S. General Accounting Office, *Prescription Drugs and Medicaid: Automated Review Systems Can Help Promote Safety, Save Money*, GAO/AIMD-96-72, June 1996.

23. Health Care Financing Administration, *Assessment of the Impact of Pharmacy Benefit Managers*, Contract HCFA-95-023/PK.

Another recent, independent study of one large purchaser's experiences documents the significant savings that it achieved by using its two PBMs to implement a benefit change. See U.S. General Accounting Office, *Blue Cross FEHBP Pharmacy Benefits*, GAO/HEHS-96-182R, July 1996.

24. Disease management programs are being developed by drug manufacturers, health plans, and specialty care organizations as well as by PBMs. These programs are widely discussed: what they are, what they do, what will be their value and consequences in terms of cost and quality of health care. For recent discussion of these issues, see:

Robert McCarthy, "Disease Management: A Critical Look," *Medical Utilization Management*, December 21, 1995.

Kenneth Moss, "DSM: A Concept Coming Into Focus," *Perspectives, Medicine & Health*, 50 (August 12, 1996) 32.

George Anders, "Drug Makers Help Manage Patient Care," *The Wall Street Journal*, May 17, 1995.

25. In using PBMs, HMOs "carve out" the management of the benefit, thereby making it more difficult and less likely for plans and payers to assess the impact of pharmacy costs on overall health care costs. With a "carved out" benefit, pharmacy costs are treated separately from other health care costs, and pharmacy data and medical data are often not linked together.

It is important to recognize that reducing overall health care costs may require increased expenditures on prescription drugs, as, for instance, may be true for the emerging disease management programs.

26. A few PBMs are now developing computer connectivity with physicians' offices. This capability will enable on-line discussion between the PBM and the physician about the appropriate drug therapy for a patient before s/he leaves the physician's office with a prescription.

27. For a fuller description of PBMs and their influence on costs and market share, see:

Charles Beever, "Why PBMs Work--And Why They Don't," *In Vivo*, 12 (November 1994) 10: 8-13.

Health Care Financing Administration, *Assessment of the Impact of Pharmacy Benefit Managers*, Contract HCFA-95-023/PK.

28. Examining concerns about bias on the part of HMOs who deal directly with drug manufacturers was beyond the scope of this inquiry.

29. The GAO, reporting in 1995 on its examination of PBMs, found that changes in Medco's formularies favored Merck products between 1993 and 1995. Because of the proprietary nature of the financial negotiations between Medco and other drug companies, GAO could not confirm these changes resulted without Medco having considered other competitors' products. See GAO, *Pharmacy Benefit Managers*.

The motivation behind the acquisition of PBMs by drug manufacturers has been described by senior executives from the companies involved:

"Merck products are Medco's house brand. Part of the secret to success will be to develop Merck medicines for categories in which we are not now represented...Consider what happens if instead of having 20 products on the formulary we have 40. The more Merck products on the formulary, the greater our power on the market and the more plan sponsors will save." (See Nancy A. Nichols, "Medicine, Management, and Mergers: An Interview with Merck's P. Roy Vagelos," *Harvard Business Review*, November-December 1994, 113.)

[The senior executive from another drug company owning a PBM] "said there has been some progress [in boosting market share of the company's products through the PBM]. These capabilities [to switch market share] are what we're building, and we want to give that a fair shot." The article summarized another executive from the same company as saying "Lilly also hopes to shift patients to Lilly drugs by hooking up doctors' offices to pharmacies via computer. Then when the doctor orders a certain drug, the pharmacist will be able to urge an alternative..." (See E.S. Browning and Thomas M. Burton, "PCS Gets Rx for Write-Down After Its Weak Performance," *The Wall Street Journal*, July 30, 1996.)

30. Concern about these practices has been widespread among professional organizations and government agencies concerned with consumer protection, fraud and abuse, and with drug product information. For examples:

- (1) **The American Medical Association** has recently adopted several policies and recommendations focussed on acceptable professional practice for drug formulary systems, responsibilities of Pharmacy & Therapeutics Committees, therapeutic interchange, and prescription switching. See Resolution 501, *Opposition to Payment for Prescription Switching*, June 1995; AMA Policy A-95, *Managed Care Cost Containment Involving Prescription Drugs*, AMA Policy 165.896, *Drug Issues in Health System Reform, 1994*, and AMA Policy 125.991, *Drug Formularies and Therapeutic Interchange*, 1993.

- (2) **The American Pharmaceutical Association** adopted in 1995 its *Guidelines for Medication Incentive Programs* to provide guidance to pharmacists when dealing with incentive programs sponsored by drug companies, PBMs, and other third-parties to influence choice of drug product dispensed. Programs may include coupon programs, therapeutic switch programs, academic detailing, and the like.
- (3) **The Attorneys General of several States** have joined together in negotiating consent agreements with several drug manufacturers in recent years.

Disclosure issues, particularly with respect to PBMs and drug manufacturers, were addressed in the 1995 17-State consumer protection settlement negotiated with Merck & Co., Inc. and Medco Containment Services, Inc. While not admitting to any legal wrong doing, the companies agreed to several provisions including (1) full disclosure of the company relationships and drug product manufacturer when pharmacists telephone physicians about switching prescriptions, (2) substantiation of claims of cost-savings resulting from the switch, (3) written notification of consumers about the switch programs, the ownership of the PBM, and their rights to refuse the switch, and (4) extent to which Medco will keep confidential the patient information in their files and that it might make this information available to employers. (See *In the Matter of Merck & Co., Inc. and Medco Containment Services, Inc.*, No. C6-95-10614, Ramsey Co. Dist. Ct., Agreement (Assurance of Discontinuance) and Order Approving Assurance of Discontinuance (October 25, 1995), State of Minnesota, Office of the Attorney General.)

- (4) **The Office of Inspector General**, in the U.S. Department of Health and Human Services, raised questions about prescription drug marketing practices, including switch programs, in a 1994 Special Fraud Alert, *Prescription Drug Marketing Schemes*.
- (5) **The Food and Drug Administration**, as noted above, is considering its regulatory responsibilities vis a vis drug product information disseminated by PBMs and standards to guide cost-effectiveness research. See also David A. Kessler, M.D., et al., "Therapeutic-Class Wars--Drug Promotion in A Competitive Marketplace," *The New England Journal of Medicine*, 331 (November 17, 1994) 10: 1350-1353.

See also: Milt Freudenheim, "Not Quite What Doctor Ordered," *The New York Times*, October 8, 1996, D-1.

31. The American Medical Association, the American Pharmaceutical Association, and Pharmaceutical Research and Manufacturers of America (then known as the Pharmaceutical Manufacturers Association) emphasized the importance of using DUR programs to enhance the quality of patient care in their *Principles of Drug Use Review (DUR)* issued in 1991.

Moreover, the Federal Omnibus Budget Reconciliation Act of 1990 (OBRA 90) mandates DUR programs for Medicaid. It states the purpose of these DUR programs is "to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and that they are not likely to result in adverse medical results." (See *Federal Register*, 59 (September 23, 1994) 184: 48811.) Further, in an effort to ensure the credibility of the reviews, the law requires that standards for review be consistent with three authoritative compendia and with peer-reviewed medical literature. Finally, the statute requires these predetermined standards be available to the public and to pharmacists and physicians. (It is important to note that OBRA 90 specifically exempts HMOs from the Federal requirements for prospective and retrospective reviews for Medicaid outpatient drugs. It does not, however, preclude States from imposing their own DUR requirements on HMOs.)

For views on the potential conflict of interest in the DUR programs of PBMs and the importance of disclosure principles, see Stephen B. Soumerai, Sc.D. et al., "Computer-Based Drug-Utilization Review--Risk, Benefit, or Boondoggle?," *The New England Journal of Medicine*.

32. These efforts include one-on-one interventions by PBMs with providers or patients, including disease state management programs, as well as more broadly based education programs directed to groups of providers or patients.

33. See Note 12.

34. Gina Kolata, "New Frontier In Research: Mining Patient Records," *The New York Times*, August 9, 1994, A21.

Questions arise about the credibility and validity of this research, whether conducted by PBMs, drug manufacturers, or others, because there is no consensus on standards for conducting these studies to ensure the validity and objectivity of the results. The FDA addressed this issue in its public hearing on "Pharmaceutical Marketing and Information Exchange in Managed Care Environments" in October 1995.

35. Having access to these databases figured prominently in the manufacturers' decisions to purchase the PBMs in 1993 and 1994.

A former drug company executive, who oversaw his company's acquisition of a large PBM, commented in an interview:

We saw a tremendous opportunity to create a new model for the pharmaceutical industry that would simultaneously improve the quality of health care, help contain costs, and increase Merck's market share. Expanding our information base is critical to these goals. (See Nancy A. Nichols, "Medicine, Management, and Mergers: An Interview with Merck's P. Roy Vagelos," *Harvard Business Review*, 106.

Another news report summarizes comments of a drug manufacturer executive about his company's programs with its PBM:

[He] listed several steps Lilly plans to take to "ensure the continued growth of Prozac in the U.S." during 1995, including tie-ins with Lilly's pharmacy benefit management subsidiary PCS... "Analysis of patient pharmaceutical care data can help identify people who are being treated for what appear to be unrelated ailments but are in fact symptoms of depression. As a result, information can help us develop depression management programs for our managed care customers that include Prozac...In one PCS database, we also found that half of the 50,000 people taking an antidepressant remained on their medication for less than 90 days...PCS information can help ensure that patients continue Prozac for as long as they need it."...PCS is also "pursuing a number of other relationships, including the development of capabilities involving mail order and other delivery systems and new interventions that encourage physicians to switch" prescriptions, Taurel said. "We believe that PCS will be most successful in changing prescriptions in the retail sector that still comprises the overwhelming majority of scripts in the U.S."

The article further mentions Lilly's physician education program for antidepressant therapy, its development of a clinical labs network, and the introduction of its electronic prescription network linking pharmacies with physicians' offices (which will transmit prescription data including information on the physician, the patient, and the ICD-9 code). (See *F-D-C Reports*--"The Pink Sheet," May 22, 1995, 11-13.)

See also: "Who's Reading your Medical Records?," *Consumer Reports*, October 1994, 628-632.

36. Examples of the PBMs with integrated databases include DPS, PCS, Caremark, and Express Scripts.

Diversified Pharmaceutical Services (DPS) had its beginnings in an HMO before it was sold to SmithKline Beecham. It maintains integrated databases of patients' pharmacy and medical information. And **PCS Health Systems** bought an interest in a company that coordinates patient information among hospitals, physicians, and other providers. (See Greg Muirhead, "The ABCs of PBMs," *Drug Topics*, September 5, 1994, 68, 78.)

The same pharmacy publication reports on a recently established link between medical and pharmacy data for another PBM as follows:

Caremark and [Blue Cross] Idaho are forming a new PBM as a joint venture, to target markets within Idaho. The PBM will begin with 282,000 members enrolled in BC Idaho's health plans. As part of the deal, Caremark will gain access to "medical and prescription drug patient data that will facilitate the company's outcomes research initiatives and on-going development of disease management programs." (See Greg Muirhead, "Network Notes," *Drug Topics*, September 4, 1995, 40.)

Finally, according to *Weekly Pharmacy Reports--"The Green Sheet," Express Scripts* "will integrate what is happening on the pharmacy side with the medical data from the patient side through its Practice Patterns Science subsidiary." (May 27, 1996, 3.)

37. Some, but not all, States have legislation governing medical record confidentiality and patient consent. These requirements vary widely and are increasingly inadequate in an era of computerized medical records, interstate electronic transfers of information, and changes in health services delivery systems. These deficiencies concern a growing number of consumer groups, professional organizations, and State and Federal regulators. Among efforts to seek a Federal remedy is a recent legislative mandate to HHS, contained in the recent health insurance reform legislation, to study ways to protect confidentiality. Other legislative proposals addressing medical records confidentiality have been under consideration in the Congress.

For further elaboration on the issue and recent Federal activity, see:

Beverly Woodward, PhD, "Sounding Board: The Computer-Based Patient Record and Confidentiality," *The New England Journal of Medicine*, 333 (November 23, 1995) 21: 1419-1422.

Leigh Page, "All sides want confidentiality, but dispute the "how to"," *American Medical News*, January 1, 1996, 1,7.

"Insurance Bill Forces Privacy Issue," *Medicine & Health*, 50 (August 12, 1996) 32: 1.

38. The legislatures in many States and the Congress have been inundated recently with legislative proposals for regulating managed care plans in ways intended to inform and protect consumers. For a summary of recent activity, see "Backlash: How Worried Should Health Plans Be?," Perspectives, *Medicine & Health*, June 3, 1996.

See also Note 30 for comment about recent activity of States' Attorneys General.

Finally, several professional, consumer, and research organizations have articulated guidelines and principles addressing patients' rights and responsibilities in managed health care settings. While they address health care generally, most are applicable to pharmacy services in particular. Among these publications are:

- (1) National Health Council, *Putting Patients First - Patients' Rights & Responsibilities*, Washington, D.C.
- (2) National Consumers League, *Questions To Ask - Taking Charge of Your Health*, Washington, D.C. The section entitled "Questions to Ask About Your Health Plan" includes several questions about health plans' pharmacy benefits, in particular.
- (3) American Pharmaceutical Association, *Guidelines for Medication Incentive Programs*, Washington, D.C., 1995. See also Apha's *Principles of Practice for Pharmaceutical Care*, 1995.
- (4) Council on Ethical and Judicial Affairs, American Medical Association, "Ethical Issues in Managed Care," *Journal of the American Medical Association*, 273 (January 25, 1995) 4: 330-335. This document includes guidelines addressing principles for disclosure of plans' benefits packages and financial incentives for physicians. See also AMA's Policy A-95, "Managed Care Cost Containment Involving Prescription Drugs."
- (5) Institute of Medicine, *Improving the Medicare Market - Adding Choice and Protections*, National Academy Press, Washington, D.C., 1996. This report makes recommendations specific to the Medicare managed care program. Among them are recommendations that specify the types of information that should be made available to beneficiaries about the health plan benefits, including pharmacy, and that call for the prohibition of "anti-criticism clauses or gag rules."

39. This analysis excludes those HMOs that purchase only claims processing services and those who have contracted with a PBM for less than one year.

40. The recently issued HCFA report on PBMs states:

Quality. As in other sectors of the health care arena, competition among PBMs for clients centers on price, not quality. Purchasers (i.e., plan sponsors) are not insisting on sophisticated quality measurements and reporting requirements from PBMs because their attention is riveted on containing drug costs. (See Contract HCFA-95-023/PK, September 30, 1996, 124-125.)

41. States do not license PBMs, although, of course, they all license managed care organizations. Several State legislatures have standing committees or special task forces focussed on managed care.

The National Association of Insurance Commissioners (NAIC) is developing a series of model acts and regulations for State insurance agencies to use with health plans. These models do not address pharmacy or PBMs directly, although they could apply indirectly. These model acts focus on the adequacy of managed care plan networks, professional credentialing verification, grievance procedures, confidentiality of health information, utilization review, and quality assessment and improvement.

42. The JCAHO does review pharmacy programs based in hospitals and home care organizations and free-standing pharmacies that serve long-term care facilities.

43. Among the organizations developing guidelines and standards are:

Academy of Managed Care Pharmacy: *Guidelines for Good Managed Care Pharmacy Practices*, 1995.

American Pharmaceutical Association: *Principles of Practice for Pharmaceutical Care*, 1995; *Guidelines for Medication Incentive Programs*, 1995.

American Society of Health-System Pharmacists: *Practice Standards of ASHP*, 1995-96.

44. A recent study focussed on the practices of several large, private employer groups who use PBMs. The researchers report a striking lack of familiarity among these private sector payers with their PBMs' policies and practices. Only half discussed closed or open formulary choices with their PBMs; none reported having input into the formulary development or knowledge of the criteria used by the PBMs in developing their formularies. The researchers conclude by urging greater accountability for PBMs and identify approaches for achieving it. (See Kevin A. Schulman, MD et al., "The Effect of Pharmaceutical Benefits Managers: Is It Being Evaluated?," *Annals of Internal Medicine*, 124 (May 1996) 10: 906-913.)