The View From Managed Care Pharmacy

Where managed care pharmacy directors stand on the use of cost-effectiveness information, disease management programs, and regulation of pharmacoeconomic claims.

by Bryan R. Luce, C. Alan Lyles, and Anne M. Rentz

ABSTRACT: This stratified, national telephone survey of fifty-one managed care organizations concerns the perspectives of managed care pharmacy directors on pharmacoeconomics, disease management, and the roles of the pharmaceutical industry and the Food and Drug Administration (FDA). Respondents rated clinical effectiveness assessments as most useful, cost-effectiveness assessments second, and quality-of-life assessments as least useful. Peer-reviewed and industry literature were rated as equally important for decision making. Most plans would consider establishing a partnership with a drug company for disease management, if they have not already done so. Most plans (76 percent) support some form of FDA regulation of pharmacoeconomic claims. Conversely, 69 percent favor either no regulation (24 percent) or less stringent regulation (45 percent) than exists today.

The consolidation of purchasing power in larger managed care organizations and employer benefit plans is changing the traditional relationships pharmaceutical firms have had with providers and beneficiaries. Managed care plans are increasingly using restrictive formularies, which control access to many drugs, and the pharmaceutical industry is funding pharmacoeconomic and other outcomes studies at a steadily increasing rate, in large part to influence decisions regarding managed care formularies. In addition, the pharmaceutical industry has been offering disease management programs to managed care organizations as a way of demonstrating the potential value of their drugs. Meanwhile, the Food and Drug Administration (FDA) has issued draft guidelines for regulating all pharmacoeconomic and other promotional claims of prescription drugs, which limit the flow of information from drug manufacturers to managed care pharmacy.

The above issues take on added significance when coupled with...
the consolidation of purchasing power, the phenomenal growth of both managed care and pharmacy benefit plans, and the fact that virtually all managed care plans offer some sort of prescription benefit, commonly with no deductible. Possibly in response to these concerns, the FDA is reconsidering its criteria for regulating pharmacoeconomic claims.

In this study we report findings from a representative national survey of managed care pharmacy directors. The survey was conducted to elucidate the role of pharmacoeconomic information in managed care formulary decisions, managed care pharmacy’s use of disease management programs, its perspective on the pharmaceutical industry’s role in these activities, and its views on the FDA’s role in regulating pharmacoeconomic claims. A more complete description of the sampling process and survey findings concerning managed care formulary structure, how managed care is organized for and makes use of pharmacoeconomic information for formulary decision making, how it rates the credibility and usefulness of all drug assessment literature, and its views about the future of pharmacoeconomic assessment are reported elsewhere.

Methods

The main organizational attributes upon which we based our sample were health maintenance organization (HMO) plan type (staff, group, network, and individual practice association [IPA]) and tax status. Using the Group Health Association of America’s 1995 National Directory of HMOs, we developed a quota sampling process stratified by plan type and tax status to achieve a representative national sample of fifty-one medium-to-large managed care plans. Exhibit 1 describes our sample, which encompasses 22 percent of all managed care plans with more than 50,000 enrollees and includes 12.7 million enrollees. Of these plans, 65 percent were for-profit and 35 percent were not-for-profit. Although our sample is similar to the mix of plans in the universe of medium-to-large plans, it includes larger not-for-profit group plans based on enrollment figures.

Eleven plans (18 percent) declined to participate in this survey. Nine were IPA-model plans—evenly divided between for-profit and not-for-profit plans. To minimize the potential for selection bias we continued to the next randomly chosen plan in the same sampling stratum until we met our sample quota; however, it is possible that plans that chose not to participate differed in some unknown but important respects from those that did participate.

Of the fifty-one participating plans, four contracted their drug assessment functions to a pharmaceutical benefit management company. These plans were more likely to be for-profit and network or
IPA models. We assumed that these management companies represented the practice of the plan with which they contracted; accordingly, we interviewed each company and included those responses in the analyses. Finally, although one plan was corporately owned, we treated it as independent. For the following analyses, we report p values only when they are less than or equal to 0.10.

**Results**

All plans in our sample had formularies. Forty-one percent were reported as being open, 35 percent as closed, and 24 percent as partially closed. The terms open, closed, and partially closed refer to the degree of access to drugs, with open formularies exercising the least control. No quantification of coverage of pharmaceuticals was used to define open or closed; rather, we relied on the respondent pharmacy director(s) to know these categories as they are generally understood. Our sample is comparable to the results reported by Ciba-Geneva in its annual survey, in which 35 percent of respondents reported closed formularies in 1994 and 47 percent in 1995.6

**Use and usefulness of economic assessments.** Respondents consistently endorsed the use of economic considerations regarding
new drugs. Ninety-four percent of the respondents said that cost management was one type of decision that affected the addition of new drugs to their formulary.

The proportion of new drugs that undergo assessment varies, although more than half of the plans reported assessments for at least half of all new drugs. Although we were primarily interested in the use of pharmacoeconomic assessment, for completeness we defined the term assessment to include clinical and safety issues. Virtually all respondents reported using clinical effectiveness, safety, cost-of-treatment and cost-effectiveness assessments, but only two-thirds indicated that quality-of-life assessments were used. The quality-of-life response differed somewhat by plan type, in that 70 percent of IPA/network plans reported using quality-of-life assessments, while only 57 percent of group/staff plans reported their use.

The usefulness of these types of assessments was rated by respondents on a scale of “most useful” (1) to “least useful” (6) (Exhibit 2). The highest rating was for clinical effectiveness (1.6), and the second-highest was for cost-effectiveness (2.6). The lowest ratings were for cost of treatment (4.0) and quality of life (4.1).

**Ratings of assessment sources.** Pharmacoeconomic assessments of drugs can be done by managed care organizations themselves or by one of a number of external sources, including peer-reviewed journal articles and industry-sponsored reports, government reports, pharmaceutical benefit managers, and other literature that was not peer-reviewed. Here we report how respondents view in-

---

**EXHIBIT 2**

Usefulness Of Various Types Of Drug Assessments, By Type Of Plan And Tax Status, 1995

<table>
<thead>
<tr>
<th>Type of plan</th>
<th>Group/ staff</th>
<th>IPA/ network</th>
<th>Tax status</th>
<th>For profit</th>
<th>Not for profit</th>
<th>Weighted mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical effectiveness</td>
<td>1.5 (0.76)</td>
<td>1.7 (0.92)</td>
<td>1.7 (0.83)</td>
<td>1.6 (0.96)</td>
<td>1.6</td>
<td></td>
</tr>
<tr>
<td>Safety</td>
<td>2.2 (1.12)</td>
<td>2.9 (1.02)*</td>
<td>2.8 (0.98)</td>
<td>2.6 (1.26)</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Cost of treatment</td>
<td>4.2 (0.89)</td>
<td>3.9 (1.16)</td>
<td>4.0 (1.22)</td>
<td>4.1 (0.85)</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td>3.0 (1.04)</td>
<td>2.4 (1.27)</td>
<td>2.4 (1.15)</td>
<td>2.9 (1.33)</td>
<td>2.6</td>
<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td>4.1 (1.07)</td>
<td>4.1 (1.15)</td>
<td>4.2 (1.13)</td>
<td>3.9 (1.10)</td>
<td>4.1</td>
<td></td>
</tr>
<tr>
<td>Total plans</td>
<td>14</td>
<td>36</td>
<td>32</td>
<td>18</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SOURCE:** Authors’ survey results.

**NOTES:** IPA is Individual practice association. Respondents were told to check all that apply. Scores are based on a scale of 1 (most useful) to 6 (least useful). Standard deviations are in parentheses. A total of fifty plans (96 percent of the Sample) responded.

* p < 0.05.
dustry reports compared with peer-reviewed literature with regard to quality, validity, timeliness, comprehensiveness, and overall importance. Few statistically significant differences in ratings were detected by plan type or tax status.

Peer-reviewed literature scored relatively high on quality, validity, and, to a lesser extent, comprehensiveness, whereas industry reports scored higher on availability and timeliness. Interestingly, both peer-reviewed and industry literature scored similarly (about average) on overall importance. There were some differences relative to subgroups. Not-for-profit plans rated industry reports lower on validity ($p = 0.03$) than did for-profit plans, whereas for-profits and IPA/network models ranked peer-reviewed literature lower in overall importance than their counterparts did.

Most respondents (83-100 percent) reported familiarity with clinical trials and retrospective analyses, whereas only 65 percent were familiar with modeling as an assessment technique. Clinical trials were rated as having slightly higher credibility than retrospective reviews; models were rated lowest in credibility (Exhibit 3).

If available, externally conducted drug assessments would “always” or “sometimes” be used by 92 percent of the plans. Reasons for not using external drug assessments were led by concern about the study sponsor, potential for bias, and concern about applicability of results to a plan’s population. Thirty-eight percent of respondents reported difficulties in adapting external assessments to their plans, with IPA/network and for-profit plans reporting less difficulty ($p < 0.05$). The main reasons given for adaptation problems were applicability and differences in goals or viewpoints of the external assessment. This finding is in contrast to respondents’ reporting that internal assessments have high acceptability.

Disease management and partnerships with industry. All respondents were familiar with the term disease management, believing

### Exhibit 3
Rating Types Of Drug Assessments On Credibility, By Type Of Plan And Tax Status

<table>
<thead>
<tr>
<th>Type of plan</th>
<th>Tax status</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Weighted mean</td>
</tr>
<tr>
<td>Group/staff</td>
<td>IPA/network</td>
<td>For profit</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>1.5 (0.53)</td>
<td>1.9 (0.73)</td>
</tr>
<tr>
<td>Retrospective reviews</td>
<td>2.2 (0.45)</td>
<td>2.0 (0.67)</td>
</tr>
<tr>
<td>Models</td>
<td>2.7 (0.76)</td>
<td>2.5 (0.73)</td>
</tr>
</tbody>
</table>

**Source:** Authors’ survey results.

**Notes:** IPA is individual practice association. Respondents were told to check all that apply. Scores are based on a scale of 1 (excellent) to 4 (poor). Standard deviations are in parentheses.
that it is broader than drug treatment and encompasses written treatment protocols and measuring outcomes. Fifty-nine percent viewed disease management as sharing financial risks for patient care, although more IPA/network plans (65 percent) than group/staff plans (43 percent) viewed it this way. When asked whether they would accept a disease management program offered by a drug company, thirteen respondents (25 percent) reported that they already had (twelve were with IPA/network plans). Seventy-six percent of those who had not accepted such an offer indicated that they would consider doing so. Also, 73 percent of plans said that partnerships with drug companies were important or very important, with 84 percent of for-profit plans and only 53 percent of nonprofit plans rating them in these categories (p < 0.05).

Future plans. A majority (75–100 percent) of plans reported that they would use externally produced pharmacoeconomic assessments more if assessments were more standardized, more available, and better targeted to their organizations. Eighty-six percent of the plans saw a future role for the pharmaceutical industry in drug assessments. However, among the open-ended responses given by forty-four plans, about half (twenty-three) saw the appropriate role for industry as providing more objective, timely assessments and sponsoring comparative drug assessments. More than 20 percent of plans believed that the role of industry is to support education and/or independent researchers, while some indicated an interest in partnerships with industry for internal trials. A small number of respondents (five) believed that the role of the drug industry will be limited because of the potential for bias or for exclusive promotion of a company's own products.

Although one plan reported that the pharmaceutical industry already sponsored "very credible" research, other plans suggested ways in which the credibility of industry-sponsored research could be enhanced: independence of the research/researcher (50 percent), partnerships with managed care plans (44 percent), direct comparative drug trials (20 percent), methodological standardization (14 percent), and full disclosure of all information (12 percent).

Most plans (88 percent) were receptive to training in evaluation methods, and a slightly smaller number (76 percent) were interested in training to conduct drug assessments. Respondents indicated that training should be tailored to specific needs of the organization or individual, convenient (time and location), cost-effective, and unbiased. Also, respondents suggested that resources be provided in addition to financial or service incentives.

The FDA in pharmacoeconomics. Most respondents (76 percent) believed that the FDA should regulate pharmacoeconomic
### EXHIBIT 4
Views On Whether The U.S. Food And Drug Administration (FDA) Should Have A Role In Regulations Of Pharmacoeconomic Claims, By Type Of Plan And Tax Status, 1995

<table>
<thead>
<tr>
<th>Type of plan</th>
<th>Tax status</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group/staff</td>
<td>IPA/network</td>
</tr>
<tr>
<td>Regulate</td>
<td>79%</td>
<td>76%</td>
</tr>
<tr>
<td>Do not regulate</td>
<td>21</td>
<td>24</td>
</tr>
</tbody>
</table>

Number of plans answering 14 37 32 19 100 51

If yes, how should the FDA regulate?

<table>
<thead>
<tr>
<th>Independent peer review and ratings of all pharmacoeconomic claims, whether based on randomized trials, decision models, or retrospective claims analysis</th>
<th>45%</th>
<th>64%</th>
<th>68%</th>
<th>47%</th>
<th>59%</th>
<th>23%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using same standards as now required for safety and efficacy, which would generally permit the use of randomized trials only</td>
<td>45</td>
<td>29</td>
<td>27</td>
<td>41</td>
<td>33</td>
<td>13</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td>7</td>
<td>5</td>
<td>12</td>
<td>8</td>
<td>3</td>
</tr>
</tbody>
</table>

Number of plans answering 11 28 22 17 100 39

**Source:** Authors’ survey results.

**Notes:** IPA is individual practice association. Respondents were told to check only one.

claims in some form, with more not-for-profit plans (89 percent) agreeing than for-profit plans (69 percent) (Exhibit 4). Of those respondents supporting regulation, 59 percent agreed that the FDA should regulate claims using independent peer review and ratings of all pharmacoeconomic claims, whether based on randomized trials, decision models, or retrospective claims analysis, while 33 percent agreed that the FDA should regulate claims using the same standards as are now required for safety and efficacy, which generally would permit the use of randomized trials only. Thus, 69 percent of the plans in our sample favor either no regulation of pharmacoeconomic claims or a form of regulation that is less restrictive than the current standards for clinical claims.

**Discussion**

Our findings suggest that managed care pharmacy directors have some appreciation for the trade-off between quality/validity and timeliness/availability. Even though they are consumers of industry-generated assessments, they are skeptical about the drug industry’s
motives and the potential for bias. By rating industry reports low in quality and validity but equal in overall importance to peer-reviewed articles, these decisionmakers have shown that they discount the credibility of industry literature but still find it useful. Managed care pharmacy’s near-universal adoption of disease management programs, with an emphasis on outcomes measurement, further contributes to the need for pharmacoeconomic information.

The FDA now regulates pharmacoeconomic claims using standards similar to those applied to safety and efficacy claims: two randomized, controlled clinical studies. However, our survey results suggest that this practice may not be the model preferred by the industry. Rather, the majority of our respondents, while supporting some form of FDA regulation of claims, prefer independent peer review and rating of claims. This is consistent with the need these plans have for timely information, since coverage decisions must be made with or without information. This idea also was demonstrated by Claudia Steiner and colleagues, who wrote: “The largest barrier to decision-making for all types of insurers is the paucity of reliable information on the effectiveness, safety and cost-effectiveness of new technologies at the time coverage decisions have to be made.”

Our respondents also are receptive to the idea of partnerships with industry for pharmacoeconomic assessments, training, and disease management activities, subject to safeguards against bias.

Study limitations. Our study has several strengths: size, representative national sample, and comprehensiveness of the survey itself, however, some weaknesses exist as well. Most important, we have no independent way of validating the accuracy of responses. For instance, 92 percent of the respondents said that they use cost-effectiveness in assessing drugs, yet it is well known that the concept of cost-effectiveness is not widely understood.

Ensuring informed decision making. Our findings suggest several courses of action to help meet managed care pharmacy’s needs for timely, informed, and efficient decision making about drugs. First, the credibility, quality, and timeliness of externally sponsored assessments must be improved. This could be done via a combination of partnering with industry, using independent researchers, and reducing the time for publishing pharmacoeconomic research findings. Electronic peer review and publication also could be helpful. In addition, the FDA needs to revise its evidence requirements for pharmacoeconomic claims, at least to the level of independent peer review and claims rating, for sophisticated consumers. Present standards likely restrict timely availability and use of pharmacoeconomic studies for decision making in managed care pharmacy. A peer-review process would help to ensure that claims are evaluated
for validity and potential for bias so that decisionmakers would be better able to distinguish high- from low-quality studies.

As federal research funds plateau or decrease and private industry is increasingly viewed as a source of funds, creative ways must be pursued and industrywide standards adopted to address managed care pharmacy’s concerns about bias and limited disclosure.

The authors acknowledge the assistance of Christopher Lyu, Linda Morris, and Frances Patterson of Battelle SRA, who did the bulk of the interviewing; Letitia Howland, who contacted the original sample of plans to be interviewed and provided support throughout the project; Viviane Cooney, Leola Farmer, and Amanda North, who supported the administrative effort; and, most of all, the respondents in all fifty-one of the managed care plans, without whom there would be no study. Financial support from Rhone-Poulenc Rorer and professional support from Bernard Genesté are most appreciated. The paper also benefited from the careful review and constructive comments of two anonymous reviewers. The results of this survey were presented at the Association for Pharmacoeconomics and Outcomes Research Annual Meeting, Philadelphia, Pennsylvania, May 1996.

NOTES
4. FDA, “Principles for the Review of Pharmacoeconomics Promotions.”