**LTC providers struggle to get correct medications to Part D patients**

*Pharma companies share frustration with system that channels long-term care residents into cheaper plans that discourage brand-name drugs*

Pharmaceutical companies’ access to long-term care (LTC) patients, especially the roughly 1.6 million dual eligibles in LTC facilities, will improve if LTC advocates are able to persuade Congress or CMS to change the Part D marketing rules to allow LTC facility staff and providers to help patients pick their own Part D plan.

“Physicians are finding themselves on the frontlines of managing the administrative burden created by Part D, particularly when plans do not cover or restrict access to the drugs physicians prescribe,” according to a new policy paper from the Long-term Care Pharmacy Alliance (LTCPA).

The LTCPA represents the five major specialized national long-term care pharmacies—Kindred Pharmacy Services, Omnicare, NCS Healthcare, NeighborCare, and PharMerica. The five LTCPA member companies serve more than 1.5 million people—over two-thirds of all nursing facility residents—through about 500 pharmacies nationwide.

Although responsibility for resolving the problems ultimately falls on the patients’ provider, drug companies are also struggling to sell brand-name drugs against intense downward price pressure from the plans.

“[The drug companies] are equally as frustrated as we are,” explains Jeff Kerr, DO, a physician who treats LTC patients in rural Missouri and a board member and past president of the Missouri Association of Long Term Care Physicians.

Providers in LTC facilities are becoming frustrated with the hurdles put up by Part D plans and CMS rules restricting their ability to help patients get into a plan that covers the drugs that the provider is prescribing, Kerr tells *Briefings on Part D Compliance*.

Therefore, the American Medical Directors Association (AMDA) and other professional societies are organizing support for reform of CMS’ regulations that prohibit LTC facility staff from helping patients chose their own Part D plan (see “LTCPA lobbies to allow LTC providers to counsel patients on Part D” on p. 3).

CMS’ *Part D Marketing Guidelines*, recently reinforced by a CMS directive to nursing home regulators, states that “Under no

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LTC providers

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circumstances should a nursing home require, request, coach, or steer any resident to select or change a [specific] plan for any reason.”

This restriction has made it difficult, if not impossible, for many nursing home Part D beneficiaries to enroll in or switch to a Part D plan that better covers their drugs.

Survey reflects LTC providers frustration with Part D

A survey of AMDA physicians in June 2006 reveals how Part D is making it difficult for physicians to prescribe brand-name drugs (see “LTC problems part of a larger trend against brand-name drugs” below).

For example, the survey found that 70% of respondents indicated that drug plan rules (e.g., prior authorization requirements, etc.) are frequently impeding their ability to obtain drugs for their patients, even though the drugs are on the formulary.

“These are drugs that are theoretically covered under the Medicare drug program, but in practice may not be available because of hurdles set up by drug plans,” according to AMDA. Some drugs are proving particularly hard to acquire.

For example, AMDA reports that over 23% of respondents to

LTC problems part of a larger trend against brand-name drugs

In addition to showing that physicians treating long-term care patients are frustrated with Part D, the 2006 American Medical Directors Association (AMDA) member survey illustrates the intense pressure that Part D puts on providers to use generic and less expensive substitutes to expensive brandname drugs.

The AMDA and the Long-Term Care Pharmacy Alliance’s recent efforts to lobby CMS and Congress to make it easier for providers to help patients choose their Part D plan suggests growing resistance among pharmacists and physicians to what they perceive as impediments put up by CMS and the Part D plans to the prescription of anything but the cheapest option for any given drug therapy.

However, some pharmaceutical manufacturers are signaling their expectation that the days of dominant blockbuster drug brands may be coming to an end, or at least, major pharma companies are hedging their bets by getting into the generics market, according to Sander Flaum, managing partner of Flaum Partners, a New York-based biotechnology and pharmaceutical industry consultancy.

Flaum points to Novartis’ 2003 launch of Sandoz, which consolidated its 14 generic brands under one name. Novartis also recently acquired NeuTec, a UK-based developer of genetically recombinant antibodies, or “grabs,” for the treatment of life-threatening infections.

Also recently, Merck dropped the price of its cholesterol drug Zocor below that of its generic competitors just as the drug was going off patent. “That shocked the hell out of everyone,” Flaum says.

“Brand-name companies have learned a lot about how to run a generics division and don’t be surprised if we see some other companies in that space, either beginning their own [generics business] or making some acquisition,” he says. There are three or four major firms for which that strategy makes sense, he adds.

According to Flaum, the United States as a whole must find a way to pay for the newer expensive drugs for cancer, epilepsy, and diabetes, and to do that, the government is going to make a concentrated effort to push down the costs of drugs for primary care illnesses like hypertension and heart failure, by pushing more and more patients toward cheaper alternatives to the major brand-name drugs.
its survey indicated problems obtaining drugs for Alzheimer’s disease such as Pfizer’s Aricept (donepezil HCl pills) usually because of the prior authorization requirement. This is a difficult problem in LTC facilities in which more than 40% of patients suffer from dementia.

Some drug plans also require certain examinations, which often are not practical, according to Kerr and other physicians.

Over half of the medical directors in the survey report significant problems in obtaining drugs that their patients need when those drugs are not on a patient’s plan formulary, and that often the substitutes that a plan offers are not suitable for frail elderly patients according to CMS’ own LTC facility guidelines.

Also, many dual-eligible patients were assigned to plans that are not suitable for patients with chronic conditions in LTC because they do not have representatives available day and night to quickly process requests.

In a recent OIG survey, 19% of formularies surveyed included all 178 of the most common Part D eligible drugs, and about the same percentage of randomly assigned dual eligibles are in these plans.

LTCPA lobbies to allow LTC providers to counsel patients on Part D

The Long Term Care Pharmacy Alliance (LTCPA) is seeking support in Washington to relax CMS rules that prevent long-term care providers and other facility staff from helping patients choose a Part D plan.

In a July 6 policy paper, the LTCPA writes, “The current restrictions on caregivers assisting beneficiaries are the creation of CMS, not Congress or federal law. They have been issued as sub-regulatory guidance, and have not even gone through a formal rule-making process. CMS created the guidelines at its own discretion, and it has the ability to change them at its own discretion at any time as well.”

However, although the Alliance maintains that CMS can change these rules on its own, it has found support in Congress, which is trying to persuade the agency to allow caregivers to help patients pick their Part D plans.

On the Senate side, Sen. Charles Schumer (D-NY) has introduced the Long-Term Care Resident Part D Assistance Act of 2006, which would amend the Medicare part of the Social Security Act to require that HHS establish procedures to provide residents of long-term care (LTC) facilities with assistance with respect to prescription drug coverage under Part D. The bill awaits action in the Finance committee.

In the House, Representatives Phil English (R-PA), Henry Waxman (D-CA), Jim Ramstad (R-MN), Michael Bilirakis (R-FL), and Ted Strickland (D-OH) sent a letter to CMS Administrator Mark McClellan urging CMS to change the Part D marketing guidelines to allow LTC health professionals to assist residents in selecting the best plan for their needs.

The movement for reforming CMS’ marketing guidelines is supported by legal precedent, according to the Washington, DC–based Washington Legal Foundation (WLF). “CMS restrictions are unconstitutional violations of the providers’ First Amendment commercial free speech guarantees,” WLF argues in a July 7 “Legal Backgrounder” by Ronald Rotunda, professor at George Mason School of Law.
LTC providers  

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However, an equal percentage includes 135 to 151 (76% to 85%) or less and about one-third of randomly assigned dual eligibles was assigned to these plans. By formulary, the average rate of inclusion is 92% of the commonly used drugs.

Dual eligibles who take drugs that are not included by their plan’s formulary can obtain a prescription for a different drug that treats the same condition, apply to their plan’s sponsor for an exception if the nonformulary drug is medically necessary, or switch to a plan that includes their drug.

Marketing rules restrict help with Part D decisions

A January 2006 report issued by the OIG found that Part D plan offerings for dual-eligible beneficiaries vary widely. Every region has at least one plan that offers all 178 drugs, so every dual eligible has an opportunity to enroll in a plan that includes all of the most commonly used drugs.

However, the Part D Marketing Guidelines released in the fall of 2005 state that LTC facility staff, including providers and pharmacists, should only provide limited assistance to patients in helping them choose a Part D plan.

The rules also state that the facility should not allow the pharmacy servicing the nursing home to coach or steer any resident to select or change a plan for any reason. The most that the facility can do is provide general information and education to residents about all available Part D plans or direct patients to contact Medicare for more information.

CMS reiterated its position on providers assisting patients with their Part D plan choice in a May 11 letter to survey agency directors, who regulate LTC facilities for the states. CMS justifies the strict rules against LTC staff helping patients with Part D decisions because of the indirect financial relationship that the LTC facility might have with the Part D plans through the specialized long-term pharmacies.

LTC pharmacists fill prescriptions as they are prescribed by the LTC attending physician and also help the LTC facility staff understand the drug utilization process and navigate Part D.

Plans will often refuse to grant coverage approval before the drug is dispensed, putting the LTC pharmacy at financial risk. Therefore, the LTC pharmacy must often choose either to risk not being covered for a drug that it has already dispensed or withhold the drug from a patient who needs it.

Therefore, according to CMS, the LTC pharmacy has a financial interest in having beneficiaries enrolled in plans that best cover their drugs. Under the CMS marketing guidelines, this financial interest means that the LTC pharmacists are prohibited from recommending such plans to nursing home beneficiaries.

Further, because of this relationship between the plans and the LTC pharmacy, anyone working for the LTC facility is considered to have a potential financial interest in one plan over another because of the LTC facility’s relationship with the LTC pharmacy.

Questions? Comments? Ideas?

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The state of Part D enrollment

Since the beginning of Part D, market observers have predicted that the number of players in the market will gradually shrink as some companies drop out of the program and others merge to achieve greater market share and leverage when negotiating prices with manufacturers. So far, however, the field remains fragmented with only UHC-PacifiCare and Humana commanding more than 10% of the total enrollment.

The following table shows the market share breakdown by enrollee as reported by CMS as the end of the first quarter of 2006.

<table>
<thead>
<tr>
<th>Parent organization</th>
<th># Enrolled</th>
<th>Percent of total</th>
<th>National contract</th>
<th>Marketed as</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC-PacifiCare</td>
<td>3,796,500</td>
<td>27%</td>
<td>yes</td>
<td>PacificCare Life and Health Insurance Company, United Healthcare</td>
</tr>
<tr>
<td>Humana, Inc.</td>
<td>2,437,300</td>
<td>18%</td>
<td></td>
<td>Humana Insurance Company, Humana Insurance Company of New York</td>
</tr>
<tr>
<td>Wellpoint, Inc.</td>
<td>1,012,400</td>
<td>7%</td>
<td>yes</td>
<td>BlueCross BlueShield New England Alliance, Blue MedicareRx, Unicare</td>
</tr>
<tr>
<td>Member Health, Inc.</td>
<td>924,100</td>
<td>7%</td>
<td>yes</td>
<td>MEMBERHEALTH</td>
</tr>
<tr>
<td>WellCare Health Plans, Inc.</td>
<td>849,700</td>
<td>6%</td>
<td>yes</td>
<td>WellCare</td>
</tr>
<tr>
<td>Coventry Health Care, Inc.</td>
<td>596,100</td>
<td>4%</td>
<td>yes</td>
<td>Coventry AdvantraRx, First Health Premier</td>
</tr>
<tr>
<td>Universal American Financial Corporation</td>
<td>442,000</td>
<td>3%</td>
<td></td>
<td>American Progressive Life &amp; Health Insurance Co of NY, Arkansas BlueCross and BlueShield, Marquette National Life Insurance Company, Pennsylvania Life Insurance Company</td>
</tr>
<tr>
<td>Caremark, Inc.</td>
<td>413,200</td>
<td>3%</td>
<td>yes</td>
<td>SilverScript</td>
</tr>
<tr>
<td>Medco Health Solutions, Inc.</td>
<td>410,400</td>
<td>3%</td>
<td>yes</td>
<td>Medco Health Solutions, Inc.</td>
</tr>
<tr>
<td>Aetna, Inc.</td>
<td>286,900</td>
<td>2%</td>
<td>yes</td>
<td>Aetna Medicare</td>
</tr>
<tr>
<td>Health Net, Inc.</td>
<td>279,400</td>
<td>2%</td>
<td></td>
<td>Health Net</td>
</tr>
<tr>
<td>Wellmark, Inc.</td>
<td>277,000</td>
<td>2%</td>
<td></td>
<td>BlueCross BlueShield Northern Plains Alliance</td>
</tr>
</tbody>
</table>

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## Part D enrollment

*continued from p. 5*

<table>
<thead>
<tr>
<th>Parent organization</th>
<th># Enrolled</th>
<th>Percent of total</th>
<th>National contract</th>
<th>Marketed as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Care Service Corporation</td>
<td>251,900</td>
<td>2%</td>
<td>BlueCross and BlueShield of Oklahoma, HISC–BlueCross BlueShield of Illinois, Texas, and New Mexico</td>
<td></td>
</tr>
<tr>
<td>Longs Drug Stores Corporation</td>
<td>214,400</td>
<td>2%</td>
<td>RxAmerica</td>
<td></td>
</tr>
<tr>
<td>QCC Insurance Company</td>
<td>186,100</td>
<td>1%</td>
<td>AmeriHealth Advantage, AmeriHealth Mercy Plan, AmeriHealth Rx, Select Option</td>
<td></td>
</tr>
<tr>
<td>Sierra Health Services, Inc.</td>
<td>184,400</td>
<td>1%</td>
<td>SierraRx</td>
<td></td>
</tr>
<tr>
<td>CIGNA</td>
<td>170,900</td>
<td>1%</td>
<td>yes</td>
<td>CIGNA HealthCare</td>
</tr>
<tr>
<td>Torchmark Corporation</td>
<td>153,600</td>
<td>1%</td>
<td>First United American Life Insurance Company, United American Insurance Company</td>
<td></td>
</tr>
<tr>
<td>BlueCross BlueShield of Michigan</td>
<td>150,400</td>
<td>1%</td>
<td>BlueCross BlueShield of Michigan</td>
<td></td>
</tr>
<tr>
<td>Total other</td>
<td>847,100</td>
<td>6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grand total</td>
<td>13,883,800</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Notes:
- Notation in the “National contract” column indicates that at least one marketed product offered by the parent organization covers all 50 States.
- Enrollment is aggregated at the parent organization level, meaning that enrollment across all plans with the same parent organization is summed and shown in one row. All names under which the aggregated plans are marketed are shown in the “Marketed as” column.
- Plans (at the parent organization level) with less than 1% of national enrollment are not displayed.
- Enrollment counts include beneficiaries with May 1 effective dates.
- Enrollment counts are rounded to the nearest 100.
- Excludes employer-sponsored prescription drug plans (PDP).

Overall prescription drug coverage enrollment figures as of June 11 areas as follows:
- Stand-alone PDPs: 10.4 million, including 2.2 million enrollees receiving the low income subsidy (LIS).
- Medicare Advantage with Prescription Drugs (MA-PD): 6 million, including 1.2 million new enrollees. Medicare Advantage includes 925,000 enrollees receiving the LIS. About 478,000 of these are full Medicare/Medicaid beneficiaries. About 1.1 million beneficiaries are currently enrolled in MA-only plans.
- Medicare/Medicaid: 6.1 million Medicare/Medicaid beneficiaries were automatically enrolled in prescription drug plans.
- Retiree coverage: 6.9 million retirees are enrolled in the Medicare retiree subsidy.
- Federal retiree coverage (TRICARE, FEHB): 3.5 million.
- Additional sources of prescription drug coverage for medicare beneficiaries: HHS estimates that approximately 5.4 million Medicare beneficiaries have alternative sources of "creditable" prescription drug coverage.

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Drugmakers’ 2007 Part D contracts will reflect recent CMS enforcement against plans

Drug manufacturers are watching how CMS’ effort to exclude a plan from Part D plays out and how it affects drug manufacturers and patients. In July, CMS announced a series of compliance enforcement actions against sponsors of Part D plans for various marketing and formulary access rules, including the agency’s intention to exclude America’s Health Choice of Florida (AHCF) from participating in Part D (see “CMS announces actions against Part D plans” on p. 8). AHCF is the first plan that CMS has tried to exclude from Part D due to compliance violations since the Medicare drug benefit began.

Will manufacturers pay for plans’ mistakes?
The short-term effect of a plans’ exclusion from Part D on pharmaceutical manufacturers depends on the formulary position of a company’s Part D products. Manufacturers with products in a preferred tier would lose that access, and CMS would likely move patients to alternate plans.

According to one pharma legal director, pharma companies should prepare for potential lost business due to a plan’s violations by negotiating protections with Part D plan sponsors when it contracts to have its drugs included on the plan’s formulary (see Briefings on Part D Compliance, May 2006, p. 6).

For example, a drug company could try to include a provision in its contract with a plan that states that the drug company will not be required to pay the contracted rebates if the plan is subject to certain sanctions from CMS.

Also, drug companies’ contracts with plans should clearly specify the plans’ obligations to notify drug companies if they know that CMS is about to sanction the plan.

“It’s going to come down to a [drug company’s] negotiating strength as to how much of that [protection] it can get, but it’s certainly not off of the table,” attorney Marci Handler of Epstein Becker & Green in Washington, DC, tells Briefings on Part D Compliance.

Therefore, in light of CMS’ recent enforcement actions, more of the provisions that protect drug companies in case of a plan’s compliance violations are likely to appear in 2007 Part D contracts. “Now that we see this kind of experience, these might be the kind of provisions that drug [companies] will want to beef up in their next round of contract negotiations with plans,” Handler predicts.

Will the Part D excluded list grow?
If Part D enforcement follows the pattern of the older Medicare programs, CMS will likely only move to bar participation in rare cases of persistent violations and may take into consideration how the exclusion will affect patient access.

When deciding whether to exclude or restrict a plan, the agency is not likely to give much consideration to any difficulties that the sanction will cause for drug companies, but will probably have to take into account the effect on beneficiaries, according to food, drug, and device lawyer Mark DuVal of DuVal & Associates, LLC, Minneapolis.

That is potentially good news for drug companies because it means that CMS would likely have a harder time excluding one of the larger plan sponsors from Part D. “Closing something down is going to be very difficult to do,” DuVal tells Briefings on Part D Compliance.

“In light of CMS’ recent enforcement actions more provisions protecting drug [companies] in case of a plan’s compliance violations will likely appear in 2007 Part D contracts.”

—Marci Handler, Epstein Becker & Green

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CMS announces enforcement actions against Part D plans

America’s Health Choice of Florida’s (AHCF) continued marketing violations and a recurrent pattern of noncompliance has prompted CMS to pursue expulsion of the plan from the Medicare Part D drug benefit.

On June 29, CMS announced that it was pursuing the termination of AHCF’s prescription drug plan and Medicare Advantage plan contracts for a persistent pattern of failure to comply with Medicare requirements beginning with violations by AHCF in its operation of a Medicare Advantage plan prior to the implementation of Part D.

AHCF is currently appealing CMS’ decision.

AHCF stands to be the first plan excluded from Part D for compliance violations, but CMS has imposed less severe sanctions on many other violators of Part D marketing and formulary rules.

CMS has imposed a corrective action plan (CAP) on one Medicare Advantage prescription drug plan to ensure access to “transitional” coverage of all current drugs for new enrollees.

On 75 occasions, the agency temporarily has removed information from its Personal Plan Finder Web site, because the information on drug prices and formularies submitted by the plan was incorrect.

The suppression of plans’ marketing has usually resulted in plans trying to correct the compliance problem, CMS says.

For example, some of the plans were failing to include required drugs in the plan formulary lists and restricting access to certain drugs in circumstances against utilization management rules, such as those in place for HIV/AIDS drugs.

Overall, the agency reports that, since the drug benefit began, it has issued 651 warning letters to plans on topics such as posting errors on the Medicare Personal Plan Finder and 152 notices of noncompliance for violations such as failing to meet call center performance requirements, particularly in the early months of the program.

The agency has also sent out 318 requests for specific business plans from plans that need to improve call center performance or more consistently submit correct information for the Medicare Personal Plan Finder.

Enforcement against plans is only first step

CMS announcement of its Part D enforcement actions represents just the first stage of Part D compliance enforcement.

Although the agency is currently focused on the implementation of Part D and trying to ensure that the plans are providing accurate information to beneficiaries, many industry observers believe that compliance enforcement against other entities involved in Part D, including pharmacy benefit managers, beneficiaries, pharmacies and manufacturers, is likely not far behind.

CMS listed the major types of anti-kickback violations that drug manufacturers might commit in Section 70.1.6 of its guidance on Part D fraud, waste, and abuse released in April (see Briefings on Part D Compliance, June 2006, p. 6).
Mandatory false claims training should balance *qui tam*, internal remedies
Five issues to keep in mind when developing compliance training

Employee training on the false claims act and legal *qui tam* (whistleblower) remedies available is about to become essentially mandatory for all pharmaceutical companies under the Federal Deficit Reduction Act (DRA) of 2005 (signed by President Bush in February 2006).

The act requires that any manufacturer that pays at least $5 million in Medicaid rebates annually must establish specific written policies and procedures to inform employees and others (e.g., contractors) about certain federal and state false claims and whistleblower laws beginning January 1, 2007 (see the sidebar on this page).

The low threshold of $5 million in annual Medicaid rebates means that nearly every manufacturer in the United States must train all of its employees, managers, and contractors about false claims acts (federal and state) and the options available to these individuals should they witness a violation of a false claims act, including starting a *qui tam* suit.

Even though this provision of the DRA is targeted at Medicaid, false claims and *qui tam* procedures could also apply to a drug company’s activities under Part D; and therefore, companies should keep in mind their exposure to false claims offenses under Part D when designing their training to meet the DRA requirement, according to attorney Wendy Schwartz, partner Reed Smith, LLP, Regulatory Litigation Group.

Many pharmaceutical firms have already incorporated this kind of employee and contractor training into their global compliance program, and others are working now to have it in place by the January 1 deadline. “A lot of companies are not all too focused on it yet, and they should be,” Schwartz says.

Following are five key concepts that Schwartz recommends pharmaceutical manufacturers keep in mind when designing training on false claims act and *qui tam* remedies:

Federal Deficit Reduction Act (DRA) employee training, compliance requirements

1. **Affected entities**—The new requirements apply to any entity that receives or makes annual payments of at least $5,000,000 under a state Medicaid plan.

2. **Written policies and procedures**—The DRA requires written policies and procedures. Training is not specifically required, but the provisions contemplate that entities dealing with state Medicaid programs will inform their employees of their policies.

3. **Whom to inform**—All employees, including management, and anyone who could be considered a contractor or agent of the entity must be informed.

4. **Content of the policies and procedures**—The policies and procedures must provide information on the following laws, including the role of such laws in preventing and detecting fraud, waste, and abuse in federal healthcare programs:
   - The federal False Claims Act
   - Federal administrative remedies for false claims, statements
   - State laws pertaining to civil or criminal penalties for false claims, statements
   - Whistleblower provisions under the federal and state laws

5. **Describe the entity’s policies and procedures**—The policies and procedures must also provide details regarding the entity’s policies and procedures for detecting and preventing fraud, waste, and abuse.

6. **Employee handbook**—The entity must include in its employee handbook the
   - Specific discussion of applicable fraud and abuse laws
   - Rights of employees who are whistleblowers to be protected from retaliation
   - Entity’s policies and procedures for detecting and preventing fraud, waste, and abuse


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1. Transparency and accuracy—Perhaps the easiest way for a drug company to run afoul of a false claims law is by reporting inaccurate or misleading price information. This is mainly a concern with Medicaid, in which drug companies report prices directly to the program, and many drug companies downplay the potential for similar violations under Medicare because the Part D program relies on the drug plan sponsors to report prices to CMS for reimbursement, Schwartz observes. “The sponsor is the one reporting the price and the sponsor is the one getting reimbursement—they’re the contractor with the government, so in an ideal world the pharmaceutical manufacturer wouldn’t have any liability, but the government casts a broad net and I think that the companies have to be careful and make sure that their reporting is accurate,” she says.

Training on false claims laws should emphasize the importance of allocating clear responsibility in all of the company’s contracts with Part D plans. “As with everything, accuracy and transparency is what matters,” Schwartz says (see Briefings on Drug Safety, May 2006, p. 6).

2. Fair and balanced—CMS will be monitoring companies’ training programs to ensure that they provide accurate and complete information on how employees or contractors can bring a qui tam action if they witness a false claims violation. However, the companies’ training on qui tam should be balanced with information on how the employee can work with the company’s compliance infrastructure to correct the problem internally. In a recent memo to clients, Schwartz wrote, “Companies must walk a fine line in terms of how they are communicating with their employees and agents about whistleblower activity. The statute requires providing detailed information to employees, yet companies will want to be careful not to encourage abuse of the whistleblower provisions.”

—Wendy Schwartz, Partner Reed Smith, LLP
Qui tam

continued from p. 10

statute requires providing detailed information to employees, yet companies will want to be careful not to encourage abuse of the whistleblower provisions.”

“[Although] there may be instances in which the False Claims Act is the appropriate approach, our experience has been that most of the time, employee use of internal compliance procedures will allow the company to better and more quickly address any issues . . . and that companies should encourage employees to make use of those procedures.”

Ideally, employees will be inclined to exhaust all possible internal remedies to a false claims violation that they have observed before filing a qui tam, because they want what is best for the company as a whole.

However, some employees may be lured into filing a qui tam by the prospect of the portion of damages that qui tam relaters are entitled to if the case is successful. However, qui tam suits rarely have such a positive outcome for the relater, says Schwartz.

“What you read about in the paper is the whistleblower who got the $25 million recovery, but for every one of those there are 50 whistleblowers whose cases never make it, who ostracizes themselves from their companies,” she observes.

“Even absent any kind of prohibited retaliatory activity, which we would never condone, that person is putting [him- or herself] in a very uncomfortable personal position where [he or she] could often more easily accomplish the same goals using the internally available compliance procedures,” Schwartz explains.

3. Internal communication—In order to encourage employees to use the company’s internal compliance procedures before trying the qui tam route, those internal procedures must function well, Schwartz acknowledges. Perhaps just as important is that employees must see that the company’s compliance system is working so they will have confidence that any problem that they report will be handled.

“Companies that don’t have standard operating procedures in place are just crazy.” says Minneapolis-based device and drug law attorney Mark DuVal of DuVal & Associates, LLC, in Minneapolis.

To make those procedures work, managers from different parts of the company, especially sales and marketing, must be regularly communicating with the compliance department and upper-management.

“Typically, the mistakes that are made are because the company doesn’t have processes and procedures that capture all that is going on in the organization, whereby you get the right people around a table to know, for example, what price you’re offering your accounts, what promotions you’re running, and what your consultation relations are with physicians,” DuVal says.

“What you read about in the paper is the whistleblower who got the $25 million recovery, but for every one of those there are 50 whistleblowers whose cases never make it, who ostracizes themselves from their companies.”

—Wendy Schwartz, Partner Reed Smith, LLP.

“Companies that don’t have standard operating procedures in place are just crazy.”

— Mark DuVal, DuVal and Associates

4. Cover both state and federal false claims—The DRA encourages states to establish their own laws that are as strong as federal law. DRA promises a state 10% of the amount that
the federal government collects under a state action brought under such a law.

Therefore, any false claims case will likely entail both state and federal action, so compliance training should incorporate the latest information on the relevant state laws.

“So now you have state attorney generals wanting to participate in these investigations and prosecutions. And they have their own statutes that they can use, and if the federal government [isn’t] handling the case in the way that state officials think it ought to be handled, they can go out on their own,” Schwartz says. Already, 25 states have a statute and five have a false claims law pending, he says.

5. Compliance problems often start as human resource problems—Qui tam relaters are often disgruntled employees or exemployees. Their false claims charges will be less credible to investigators if the company can document that the claimants have a history of problems with the company.

Therefore, compliance training, especially when directed at managers, should include a discussion of the importance of keeping careful records of problems with employees (see Briefings on Part D Compliance, May 2006, p. 10).

“You need to have strong internal compliance procedures that interact with human resources,” Schwartz says. “Those compliance procedures can’t just be ‘out there’ on their own.”

Upcoming Events

Audioconference

Tuesday, August 8, 2006, 1:00 p.m.–2:30 p.m. (EST)
CME vs. Promotion: Understanding MedEd Compliance

Just as CME budget and program planning for 2007 begin, legal and government surveillance of CME and traditional medical education are intensifying. So how do you keep MedEd strategic, effective, and creative, yet also compliant?

Find out on Tuesday, August 8, 2006 during “CME vs. Promotion: Understanding MedEd Compliance” beginning at 1 p.m. (EST). For more information or to register, visit our Web site at www.hcmarketplace.com or call our Customer Service Department at 877/437-4276. As a bonus, all registrants will receive a FREE 3-month subscription to Briefings on Part D Compliance.