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Part D Drug Benefit

Part D Fraud, Waste, Abuse Guidance Similar to Integrity Pacts, Attorney Says

The fraud, waste, and abuse (FWA) requirements in the draft guidance to Part D drug benefit plans are ''unprecedented'' and exceed everyone's expectations, attorney Kenneth M. Bruntel said Feb. 23 at a teleconference sponsored by his law firm, Crowell & Moring LLP, in Washington, D.C.

''If any plan operated under a corporate integrity agreement, there would be a great sense of deja vu and I don't think that it's a coincidence that the draft guidance'' is similar to a CIA, Bruntel, the moderator of the teleconference, said. CIAs often are imposed as a result of a government investigation of alleged wrongdoing by a health care entity.

Attorneys at the conference also raised the possibility that False Claims Act litigation could be filed by the employees of certain government contractors in the new drug program.

Bruntel joined other Crowell & Moring attorneys to discuss initiatives in implementing compliance programs and avoiding the pitfalls of the updated draft of the FWA section (Chapter 9) of the *Prescription Drug Benefit Manual* issued by the Centers for Medicare & Medicaid Services on Feb. 8 (10 HFRA 134, 2/15/06). The other participating Crowell & Moring attorneys included Shauna E. Alonge, Benjamin T. Butler, Arthur N. Lerner, Christine C. Rinn, and Robert L. Roth.

The February CMS guidance for Part D drug benefit plan sponsors to implement a comprehensive program to detect, correct, and prevent FWA expands on a summary document issued in June 2005.

Integrated Provisions. Bruntel noted that CMS expects FWA provisions to be integrated into each of the plan sponsor's existing compliance plan, a departure from the past. The draft guidance is couched in terms of ''recommendations'' and ''guidelines,'' but uses ''must'' and ''should'' a number of times, he said.

CMS is banking on the Medicare Drug Integrity Contractors (MEDICs) to do the monitoring and auditing of the compliance programs, and every ''must'' and ''should'' will be on the MEDICs' checklist, according to Bruntel. Comments are due by March 1, and the final Part D compliance program will be issued by the end of April, with implementation by plans expected within the next three months, CMS said.

Compliance costs will be incurred at every level of the Part D contracting chain, including pharmacy benefit managers, other subcontractors, and pharmacies, Bruntel said. He added that the costs of the compliance program, which will increase in 2007, could not have been anticipated in the bids submitted in June 2005.

Onerous Requirements. Requirements under the Part D compliance program offer little choice, have highly detailed minimum requirements, are onerous and costly, and once the plan is committed to writing, it must be followed, Alonge said.

Although many organizations have compliance officers, the requirement relating to compliance officers under Part D is so different, and responsibilities are so much larger, that a sponsor is encouraged to take a hard look at the person filling the compliance officer's role due to the new duties, she added.

In addition to the requirement that a compliance officer cannot hold other responsibilities that could lead to self-policing, neither the duties of the compliance office nor the compliance committee can be delegated or subcontracted. Compliance officers must be highly experienced in compliance fraud and abuse issues, Alonge said, and CMS has ruled out any on-the-job training.

The role of MEDICs contracting with CMS includes ''preliminary'' fraud investigations, Alonge said. The draft guidance reflects the tension between law enforcement agencies and CMS.

MEDICs are to receive reports of potential violations of law as an alternative to law enforcement. Alonge said. Even though CMS has said reporting to MEDICs

might be discretionary, ''when they come knocking at your door, you must comply,'' she said.

FCA Cases Coming. The draft guidance explicitly provides that plans cannot require MEDICs, which are acting on behalf of the federal government, to execute confidentiality or nondisclosure agreements. Bruntel considered that a ''recipe for disaster,'' and questioned how CMS would enforce confidentiality.

The case law under the False Claims Act that tends to knock out actions by government employees might not extend to MEDIC employees, Bruntel said, adding, ''It is only a matter of time before an employee files an FCA case.''

The draft guidance also says the training ''should'' be ''informative, interesting, and even enjoyable,'' Bruntel said. The ''should'' in this case is not a ''shall,'' he said, because it would be impossible to meet these conditions.

Bruntel also saw problems with the small amount of time that CMS allows for compliance training of workers at drug plan sponsors; for example, general compliance training is just a minimum of two hours. Specialized training, which includes any areas previously deemed noncompliant or implicated in past misconduct, has a minimum of four hours.

Training Times. CMS suggested 10 topics under specialized training, but the list is not exhaustive. ''The importance gets lost if too much is covered—and, hopefully, comments to CMS will persuade the agency to rethink the training times,'' Bruntel said.

Alonge said that reporting fraud, waste, or abuse by a sponsor to a MEDIC is encouraged, but appears not to be mandatory. However, reporting sponsor fraud to the Centers for Medicare & Medicaid Services, the Health and Human Services Office of Inspector General, the Department of Justice, and other government offices is mandatory under 42 C.F.R. § 423.504(b)(4)(vi)(H).

The nature of reporting to the MEDICs may change for 2007, the second year of the Part D drug benefit, Alonge noted.

Lerner noted that the old rules on avoiding fraud and abuse dangers by doing it right, honestly, and accurately are probably inadequate. Government agencies are looking for programs that go beyond that—they are looking for active compliance activity, prevention, monitoring, and control.

Lerner said that on complex transactions, drug plans should follow the money by:

- making sure that administrative costs of PBMs do not show up as claims costs, given the need for those costs to be separately identified;
- matching payments to actual services provided, to avoid misreporting of costs;
- paying extremely close attention to accuracy of rate submissions, and
- fulfilling coordination-of-benefits obligations to avoid dodging payment responsibility.

The guidance does not specifically address issues surrounding rebates paid to long-term care pharmacies by manufacturers, Lerner said.

Although earlier statements by CMS indicate rebates should be reported to the plan and treated as reduction in claims cost, that seems in conflict with other statements that only a portion of the rebate to independent pharmacy benefit managers (PBMs) that is paid over to the plan should be treated as offset to cost, he added.

Speculative Buying. According to CMS, speculative buying is an example of wholesaler fraud, waste, and abuse by stockpiling drugs in anticipation of manufacturer price increases to improperly influence market share, Lerner said. Speculative buying could be viewed as a camouflaged discount by a manufacturer to a wholesaler, intended to drive market share, but CMS gave no clear explanation why it is fraudulent or abusive, he said.

In addition to stockpiling concerns, Lerner suggested additional public comments seeking clarification of CMS guidance may be worthwhile. Questions about PBM ''drug switching'' activities and the need to report rebates not actually received especially where existence of the rebate to a pharmacy could have been taken into account already in the price paid for drugs.

Crowley & Moring's Butler said the draft FWA guidance only devotes four pages to subcontractor liability, but there are more than 120 references to subcontractors throughout the guidance. Compliance initiatives must extend downstream from the Part D plan sponsor in several respects, but it is a difficult task to determine what the requirements are and how they affect subcontractors, he said.

There is a lot of overlap and the burden is on subcontractors, Butler said. The question is whether sponsors will ''pile on'' subcontractors their responsibilities, including monitoring and auditing, training, internal exclusion list checks, data certifications, and others.

Section 40 of the draft compliance guidance maintains the compliance officer's function by preventing any delegation of the program, and also states that contracts with subcontractors must enable revocation at CMS's request.

Certify Data. Butler said that requirement was somewhat inconsistent with the regulations. However, Butler did not find surprising the requirement that subcontractors must certify accuracy of data and acknowledge that data will be used to obtain federal reimbursement.

Robert L. Roth, addressing situations where drugs that may be covered under Part D are also covered under Part A or Part B, said that the definition of a Part D drug is broad and includes Food and Drug Adminstration-approved drugs and biologicals, insulin and vaccines.

However, Roth said, the latest statement from CMS, said that if coverage is available under Part A or Part B; however, it is excluded from the definition of a Part D drug and cannot be included in Part D basic coverage.

Roth said that Medicare Part B drugs contain specific drugs covered under both Part B and Part D, creating a greater likelihood of a crossover between Part B and Part D. CMS requires sponsors to have mechanisms in place to ensure drugs are adjudicated correctly to either Part B or Part D. Part A drugs prescribed within an institutional setting are exceptions, and the potential for crossover between Part A and Part D is unlikely, he added.

Because home infusion is paid fees for delivery and dispensing and is part of both Part B and Part D networks, CMS has identified it as a potential billing scheme where a claim for coverage could be submitted inappropriately, Roth said. Other potential billing schemes implicated by a crossover between Part B and

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Part D include duplicate billing, crossover drugs, and differential co-pays, he added.

Reversing Errors. Plan sponsors are responsible for instituting controls such as prior authorization to ensure pharmacies are billing the correct program, Roth said. He also noted that CMS requires sponsors to have procedures in place to reverse claims paid in error under Part D for Part B covered products.

Discussing data analysis and claims processing systems, Christine C. Rinn said the internal monitoring and auditing program is a required element of a comprehensive program to detect, prevent, and control Part D fraud, waste, and abuse. She found the guidance overwhelming in what is expected of a monitoring and auditing program, including testing for compliance with Part D regulations, CMS guidance, contracts, all applicable state and federal laws, and internal policies and procedures.

''The program better work to address all elements,'' Rinn said. ''There is no room for error.''

According to the draft guidance, data analysis, which is an effective auditing and monitoring program, may or may not indicate potential problems. The guidance lacks specificity regarding CMS's expectations for sponsor's data analysis system, Rinn said.

It is not clear whether CMS appreciates that indicators are to be developed over time, Rinn added. Although the draft guidance provides a nonexhaustive list of recommended edits to verify various elements of a claim and provider status, Rinn said that only a few are aimed at targeting fraud, waste, and abuse—edits for excessive claims for controlled substances, deceased, excluded or suspended physicians or other providers, and deceased or disenrolled beneficiaries.