U.S. Department of Justice

Office of the Associate Attorney General

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DATE: 8-2-00

TO: DeVora Adler

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OF PAGES: _____ (INCLUDING COVER)

COMMENTS:

DeVora - Here's what we first sent HCFA via OMB. #4 is our big issue.

DEPARTMENT OF JUSTICE COMMENTS ON HHS PROPOSED PRESCRIPTION DRUG BENEFIT ACT OF 2000

The Department of Justice is very concerned that the proposed HHS bill lacks any anti-fraud controls. We believe that, at a minimum, the bill should include the following anti-fraud safeguards and address the following concerns:

1. A provision requiring each benefit manager to certify the truthfulness, completeness, and accuracy of its books and records, and also to certify the truthfulness, completeness and accuracy of any proposals made to the government. We would be willing to work with HHS to develop such language, which can be included on pages 18-19 of the proposed bill.

2. HHS is not explicitly given access to the pharmacies' records. Similarly, the scope of HHS' access to the records of the benefit managers is unclear. We would amend the language to give HHS access to all relevant records of the benefit manager, not just those that may relate to the Medicare line of business, as well as all relevant records of any subcontractors.

3. Each benefit manager should be required to develop an effective anti-fraud compliance program. We suggest the following language modeled after the Medicare+Choice program:

Each Benefit Manager shall have a compliance plan that consists of the following:

(A) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee that are accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Provision for internal monitoring and auditing.

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the benefit manager's contract, including the following steps:

(i) If the benefit manager discovers from any source evidence of misconduct related to payment or delivery of health care items or services under the contract, it must conduct a timely, reasonable inquiry into the misconduct.

(ii) If, and after reasonable inquiry, the benefit manager has determined that the misconduct resulted in an overpayment, the organization must report the overpayment to HCFA:

(iii) If, and after reasonable inquiry, the benefit manager has determined that the misconduct may violate federal criminal law, the civil False Claims Act, or the administrative authorities administered by the HHS Office of Inspector General (primarily sections 1128, 1128A and 1857 of the Social Security Act), the organization must report the existence of the misconduct promptly to the HHS Office of Inspector General within a reasonable period, but not more than 60 days after the determination that a violation may have occurred; and

(iv) The benefit manager must take appropriate corrective actions (e.g., repayment of overpayments, modifications to procedures to prevent the recurrence of the problem, disciplinary actions, etc.) in response to the potential violation(s) referenced above.

4. The bill does not require the benefit manager to give the government its best price (for the drugs themselves or for the administrative costs.) Once a benefit manager is in place for a given region, it is not clear what competitive mechanisms would provide downward cost pressures. No structural mechanism is created to ensure that Medicare beneficiaries and the program will continue to receive the lowest possible cost for prescription drugs. Without such explicit requirements for Medicare beneficiaries to receive "best prices," the government contract could end up being the most lucrative part of the benefit manager's business, which would enable the benefit manager to negotiate rock bottom deals for its private contracts. Coupled with such a "best price" requirement, the government must also be able to access all government and non-contract business records for each benefit manager to verify the accuracy and truthfulness of the benefit manager's pricing structure and billing data. In other arenas involving government contracting, cost data is a vital element in determining whether the government is receiving a fair deal and such information will be critical here.

5. Each benefit manager should be required to use electronic fraud detection (pre- and post-payment) methodologies. Furthermore, HHS should have explicit authorization to conduct program integrity functions similar to those performed under the Medicare Integrity Program for Part A and B programs. HCFA, through the Medicare Integrity Program, now operates supplemental program integrity contracts for Part A and B (called Program Safeguard Contractors or PSCs) which supplement the fraud control activities conducted by each Medicare fiscal intermediary (Part A) and carrier (Part B). For example, a Prescription Drug PSC could compile and review all the pricing and utilization data from all benefit managers and assist in fraud & abuse control as well as in evaluating whether to renew each benefit manager's contract non-competitively.

6. We recommend that civil money penalty provisions be included that would apply to the benefit managers, not just (as on p.24) the sponsors or health plans.

7. We would delete proposed subsection 1859G(i) on page 22. This provision is susceptible to various interpretations, some of which could seriously undermine the Secretary's and the Department of Justice's fraud control and fraud enforcement efforts.

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