THE DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

Date: June 11, 2007

To: All Stand-Alone Prescription Drug Plan Sponsors

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Subject: **Compliance Plan Best Practices Self-Assessment Tool**

More than a year has gone by since CMS published Chapter 9 of the Prescription Drug Benefit Manual – Part D Program to Control Fraud, Waste, and Abuse. Chapter 9 provides numerous interpretive rules and guidelines Part D sponsors can use to implement the regulatory requirements under 42 C.F.R. § 423.504(b)(4)(vi)(H) to have in place a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse. It also provides recommendations and guidelines for sponsors' Part D compliance plans overall.

As part of our routine activities for monitoring implementation of the Part D program, CMS is asking all PDPs to complete a Compliance Plan Best Practices Self-Assessment Tool by June 25, 2007. This tool will enable CMS to assess the degree to which many of the best practices and requirements identified in Chapter 9 have been implemented to date. A study conducted by the Office of Inspector General entitled, "Prescription Drug Plan Sponsors' Compliance Plans" (OEI-03-06-00100) indicated that many PDP sponsors were not fully satisfying CMS requirements for Compliance Plans. As that study was conducted prior to CMS' issuance of the Fraud, Waste, and Abuse manual chapter, we are eager to learn what progress the PDPs have made since then.

Simultaneous to the release of this memo, CMS is sending an email from DrugBenefitImpl@cms.hhs.gov to each PDP Compliance Officer with the link to the Compliance Plan Best Practices Self-Assessment Tool. Following instructions provided in the email, please click on the link in that email to complete and submit the tool electronically to CMS.

We are aware that some organizations will not receive the email due to firewall constraints (for more information to enable you to receive these communications in the future, please contact Natassja Manzanero at natassja.manzanero@cms.hhs.gov). If your organization's Compliance Officer did not receive the email notification, paste the following link into your web browser to access and complete the tool:

https://vovici.com/wsb.dll/s/11dc4g29e52

Please note that your organization's Unique ID for accessing the tool is your CMS contract number (e.g., S1234). Organizations with more than one PDP contract number may complete the tool once for each contract number, or alternatively, if responses are identical across PDP contract numbers, send an email to drugbenefitimpl@cms.hhs.gov stating the PDP contract number for which the tool was completed, and listing the other PDP contract number(s) to which the responses apply. At this time we are only asking that this tool be completed by stand-alone PDPs (S contracts). Responses need not be submitted at this time for H, R, or E contracts.

As a courtesy, CMS will email a copy of your complete set of responses to your organization's Compliance Officer within a few weeks.

Please complete the Compliance Plan Best Practices Self-Assessment Tool by June 25, 2007. Thank you in advance for taking the time to complete the tool. This information will help CMS continue to improve implementation of the Part D program and identify and disseminate best practices. If you have any questions about the Self-Assessment Tool, please contact Betty Burrier at Betty.Burrier@cms.hhs.gov or your Account Manager.

Thank you.

Attachment - Compliance Plan Best Practices Self-Assessment Tool

Note – The completed tool must be submitted electronically as described in the HPMS memo above.

Please complete the Compliance Plan Best Practices Self-Assessment Tool below by Monday, June 25. Thank you in advance for taking the time to complete the tool. This information will help CMS continue to improve implementation of the Part D program and identify and disseminate best practices.

As a courtesy, CMS will email a copy of your complete set of responses to your Compliance Officer within a few weeks.

Written Policies and Procedures

1) Does your organization have written Part D policies, procedures and standards of conduct that articulate your commitment to comply with all applicable Federal and State standards?

❍ Yes
❍ No

Additional comments (optional):
_____

2) Do your written standards include a code of conduct that has been approved by the Sponsor's governing body or a committee of the governing body?

❍ Yes
❍ No

Additional comments (optional):
_____

3) *[The tool will ask this question only if the prior response is yes, otherwise the tool will automatically skip to the next question.]* **Indicate the name of the governing body (i.e., Compliance Committee, Board of Directors, CEO, etc.)**

_____
_____
_____

4) Does the Code of Conduct articulate the organization's commitment to ethical behavior as related to Part D business?

❍ Yes
❍ No

5) Has your organization distributed your Code of Conduct to your employees?

❍ Yes
❍ No

Additional comments (optional):

_____

6) Does your organization distribute a Code of Conduct with first tier, downstream, and related entities?

❍ Yes
❍ No

Additional comments (optional):

_____

7) Are employees required to certify that they comply with all written standards of conduct as a condition of employment?

❍ Yes
❍ No

Additional comments (optional):

_____

8) How frequently does your organization conduct a thorough review of your written Part D compliance policies and procedures to determine if updates are necessary?

❍ Every 3 months
❍ Every 6 months
❍ Every 12 months
❍ Every 18 months
❍ Every 24 months
❍ Other (please specify)

If you selected other please specify:

_____

Additional comments (optional):

_____

9) How many times since January 1, 2006 have you made changes to your written Part D compliance policies and procedures?

_____

10) Do your Part D compliance policies and procedures include a comprehensive program to detect, prevent, and control fraud, waste, and abuse?

❍ Yes
❍ No

Additional comments (optional):

_____

11) Which of the following elements are included in your Part D policies and procedures for detecting, preventing, and controlling fraud, waste, and abuse? Check all that apply.

❑ Commitment to comply with applicable statutory, regulatory, and other requirements, subregulatory guidance, and contractual commitments related to the delivery of the Medicare Part D benefit.

❑ Procedures for the identification of potential fraud, waste, and abuse in your Plan D pharmacy network.

❑ Process to conduct a timely, reasonable inquiry into potential Part D violations of Federal and State criminal, civil, administrative laws, rules and regulations in a timely basis.

❑ Process to refer potential Part D violations of applicable Federal and state criminal, civil and administrative laws, rules, and regulations to the MEDIC and/or law enforcement for further investigation within a reasonable period (but not more than 60 days after a determination that a violation may have occurred).

❑ Process to ensure that you, your contractors, your subcontractors, agents, and brokers are marketing Part D in accordance with applicable federal and state laws, including state licensing laws, and CMS policy.

❑ Process to identify any claims that were submitted for Part D drugs that were prescribed by an excluded or deceased provider, and a process to report and properly repay any overpayments resulting from inaccurate payments in accordance with CMS policy.

❑ Process to ensure full disclosure to CMS upon request of all Sponsor pricing decisions for Part D items or services, related data and pricing records. This policy should ensure transparency in the pricing structure to include all rebate and negotiated price discounts applicable to Part D drugs and services and hold the Sponsors and first tier entities, downstream entities, and related entities accountable for accurately reporting pricing information.

❑ Policies that ensure and document the review of the DHHS Office of Inspector General (OIG) and General Services Administration (GSA) exclusion list for all new employees and at least once a year thereafter to ensure that its employees, board members, officers, and first tier entities, downstream entities, related entities that assist in the administration or delivery of Part D benefits are not included on such lists. If the Sponsor's employees, board members, officers, managers or first tier entities, downstream entities, or related entities are on such lists, the Sponsor's policies shall require the immediate removal of such employees, board members, or first tier entities, downstream entities, or related entities, from any work related directly or indirectly on all Federal health care programs and take appropriate corrective actions.

❑ A commitment to Pharmacy & Therapeutic (P&T) Committee decisions that are made in accordance with CMS regulations and guidance. In addition, the determination of clinical efficacy and the appropriateness of formulary drugs should precede and be paramount to cost considerations.

❑ Establish a process to ensure Sponsor's officers, directors, and managers sign a statement, attestation or certification related to conflict of interest at time of hire and annually thereafter. This certification should state (1) that the individual has reviewed the organization's conflict of interest policy; (2) that the individual has disclosed any potential conflict of interest; and (3) that the individual has obtained management approval to work despite any conflicts or has eliminated the conflict.

Additional comments (optional):

_____

<u>Compliance Officer and Committee</u>

12) Does your organization have an in-house Part D compliance officer who is accountable to senior management?

❍ Yes
❍ No

Additional comments (optional):

_____

13) Which of the following authorities are held by the Part D Compliance Officer? Check all that apply.

❑ Report directly to the Board of Directors.
❑ Interview or delegate the responsibility to interview the Sponsor's employees and other relevant individuals.
❑ Review and retain company contracts and other documents pertinent to the Part D program.
❑ Review or delegate the responsibility to review the submission of data to CMS to ensure that it is accurate and in compliance with CMS reporting requirements.
❑ Seek advice from legal counsel.
❑ Report misconduct to CMS, its designee and/or law enforcement.
❑ Conduct and direct internal audits and investigations of any first tier entities, downstream entities, or related entities.

Additional comments (optional):

_____

14) Does your organization have an in-house Part D compliance committee that is accountable to senior management?

❍ Yes
❍ No

Additional comments (optional):

_____

<u>Training and Education</u>

15) Does your organization provide training and education between the Part D Compliance Officer and organization employees, contractors, subcontractors, agents, and directors who are involved in the Part D benefit?

❍ Yes
❍ No

Additional comments (optional):

_____

16) Do employees of your organization who are responsible for the administration or delivery of Part D benefits receive compliance training?

❍ Yes

❍ No

Additional comments (optional):

_____

17) *[The tool will ask this question only if the prior response is yes, otherwise the tool will automatically skip to the next question.]* **Do they receive this training at least annually?**

❍ Yes
❍ No

Additional comments (optional):

_____

18) Does your organization require Part D compliance training for any first tier entities, downstream entities, and related entities?

❍ Yes
❍ No

Additional comments (optional):

_____

19) *[The tool will ask this question only if the prior response is yes, otherwise the tool will automatically skip to the next appropriate question.]* **Who provides the training? Check all that apply.**

❑ Your organization
❑ Subcontractor
❑ Other (please specify)

If you selected other please specify:

_____

Additional comments (optional):

_____

20) *[The tool will ask this question only if the response to #18 is yes, otherwise the tool will automatically skip to the next question.]* **How does your organization monitor the Part D compliance training? Please supply a short answer, such as, yearly quizzes, online updates, etc.**

_____
_____
_____

21) Do your organization's governing body, compliance committee members, officers, and senior management receive training on the structure and operation of the compliance program?

❍ Yes
❍ No

Additional comments (optional):
_____

22) Do employees of your organization who have specific responsibilities in Medicare Part D business area receive specialized training on issues posing compliance risks based on their job function?

❍ Yes
❍ No

Additional comments (optional):
_____

Effective Lines of Communication

23) Does your organization have a system that fosters communication between the Compliance Officer and the organization's employees, contractors, subcontractors, agents, directors, and members of the compliance committee regarding how to report compliance concerns and suspected or actual misconduct?

❍ Yes
❍ No

Additional comments (optional):
_____

24) Does your organization have a confidential or anonymous reporting mechanism for employees or contractors to report compliance concerns?

❍ Yes
❍ No

Additional comments (optional):
_____

25) Does your organization have a zero-tolerance policy for retaliation or retribution against any employee, contractor, or subcontractor who reports suspected misconduct?

❍ Yes
❍ No

Additional comments (optional):
_____

26) Does your organization have established investigation procedures for responding to Part D compliance inquiries and other complaints?

❍ Yes
❍ No

Additional comments (optional):
_____

27) Does your organization have procedures for timely hearing and resolving grievances between enrollees and your organization or any other entity or individual through whom your organization provides covered benefits under any Part D plan you offer?

❍ Yes
❍ No

Additional comments (optional):
_____

28) Does your organization educate Part D enrollees on prescription drug fraud, waste, and abuse?

❍ Yes
❍ No

Additional comments (optional):
_____

Enforcement of Standards

29) Does your organization have in place well publicized disciplinary guidelines used to enforce standards of conduct?

❍ Yes
❍ No

Additional comments (optional):
_____

30) *[The tool will ask this question only if the prior response is yes, otherwise the tool will automatically skip to the next question.]* **Do these guidelines provide the consequences of violating the organization's standards of conduct?**

❍ Yes
❍ No

Additional comments (optional):
_____

31) Which of the following methods have been used to publicize disciplinary guidelines to employees? Check all that apply.

- ❑ Newsletters which explain Part D compliance issues and methods
- ❑ Discussion at department staff meetings
- ❑ Communications with subcontractors
- ❑ Inclusion in the annual general compliance training
- ❑ Intranet site
- ❑ Posters or fliers
- ❑ Other (please specify)

If you selected other please specify:

_____

Additional comments (optional):

_____

32) Has your organization disseminated procedures to employees for asking compliance questions and making reports of potential fraud, waste or abuse to the Part D Compliance Officer or to the MEDIC?

- ❍ Yes
- ❍ No

Additional comments (optional):

_____

<u>Monitoring and Auditing</u>

33) Does your organization have in place documented procedures for internal monitoring and auditing of your Part D Compliance program?

- ❍ Yes
- ❍ No

Additional comments (optional):

_____

34) Who performs your organization's monitoring and auditing of the Part D compliance program? Check all that apply.

- ❑ Your organization
- ❑ Delegated to a third party contractor
- ❑ Other (please specify)

If you selected other please specify:

_____

Additional comments (optional):

_____

35) Does your organization maintain a schedule that lists all the Part D monitoring and auditing activities for the calendar year?

❍ Yes
❍ No

Additional comments (optional):

_____

36) Does your organization (or a third part on your behalf) produce an audit report with findings and recommendations after each Part D compliance audit?

❍ Yes
❍ No

Additional comments (optional):

_____

37) Does your organization have a documented process for responding to all Part D compliance monitoring and audit results?

❍ Yes
❍ No

Additional comments (optional):

_____

38) Does your organization have a documented strategy to monitor and audit first tier entities, downstream entities, and related entities involved in the administration or delivery of the Part D drug benefit?

❍ Yes
❍ No

Additional comments (optional):

_____

39) Does your organization use data analysis for Part D fraud, waste, and abuse prevention and detection?

❍ Yes
❍ No

Additional comments (optional):

_____

40) Does your Part D claims processing system have the capability to establish an edit on a given provider and use that edit to automatically deny a claim or suspend payment on a claim when appropriate?

❍ Yes
❍ No

Additional comments (optional):

_____

41) Does your organization maintain files on Part D pharmacy providers who have been the subject of complaints, investigations, violations, and prosecutions?

❍ Yes
❍ No

Additional comments (optional):
_____

42) Does your organization have a mechanism to ensure it is not paying for drugs prescribed or provided by a provider excluded by either the HHS OIG or GSA?

❍ Yes
❍ No

Additional comments (optional):
_____

43) Is your organization prepared to allow CMS or any auditor acting on behalf of the federal government to audit its financial records, including data related to Medicare utilization and costs?

❍ Yes
❍ No

Additional comments (optional):
_____

Prompt Responses to Detected Offenses and Corrective Action Plans

44) Does your organization have documented procedures for ensuring prompt responses to detected compliance and/or fraud, waste, and abuse offenses and the development of corrective action initiatives relating to the organization's contract as a Part D sponsor?

❍ Yes
❍ No

Additional comments (optional):
_____

45) Does your organization have an established Special Investigation Unit (SIU) that assists in identifying fraud, waste, and abuse committed by subcontractors involved in the delivery of the prescription drug benefit?

❍ Yes
❍ No

Additional comments (optional):
_____

Corrective Actions

46) Does your organization have a process in place to conduct appropriate corrective actions in response to potential Part D compliance and/or fraud, waste, and abuse violations?

- ❍ Yes
- ❍ No

Additional comments (optional):

_____

47) Does your organization have procedures in place to refer potential Part D fraud or misconduct related to the Part D program to the MEDIC?

- ❍ Yes
- ❍ No

Additional comments (optional):

_____

48) *[The tool will ask this question only if the prior response is yes, otherwise the tool will automatically skip to the next question.]* **Does the Part D referral occur within 60 days?**

- ❍ Always
- ❍ Usually
- ❍ Sometimes
- ❍ Never
- ❍ Have never needed to make a referral

Additional comments (optional):

_____

Program to Detect, Correct, and Prevent Fraud, Waste, and Abuse and Voluntarily Self-Report Potential Fraud or Misconduct

49) Does your organization have a documented, comprehensive fraud and abuse plan to detect, correct and prevent Part D fraud, waste, and abuse?

- ❍ Yes
- ❍ No

Additional comments (optional):

_____

50) Does your organization's fraud and abuse plan include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority?

❍ Yes
❍ No

Additional comments (optional):
_____

Thank you!