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



CENTER FOR DRUG and HEALTH PLAN CHOICE

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Excluded Provider Guidance

DATE: March 29, 2010

The purpose of this memorandum is to provide additional guidance that addresses questions CMS has received since the issuance of the January 13, 2010 memorandum entitled, "Claims for Drugs Prescribed or Dispensed by Excluded Providers." As noted in the January 13 memorandum, the existing requirement, stated in §1862(e)(1)(B) of the Social Security Act and in 42 CFR 1001.1901, is that Medicare payment may not be made for items or services furnished by an excluded provider or entity or on the prescription of an excluded physician.

One question we have received relates to the continued need for sponsors to monitor the General Services Administration (GSA) excluded provider list as specified in the 2010 Call Letter. The List of Excluded Individuals and Entities (LEIE) maintained by the Department of Health and Human Services' Office of Inspector General (OIG) is a comprehensive listing of providers that are excluded from participation in Federal health care programs including Medicare. Sponsors, therefore, may rely upon the LEIE to identify claims involving excluded providers and need not continue to monitor the GSA list.

We have also received questions concerning our guidance on claims paid after the effective date of the exclusion. The guidance in the January 13 memorandum supersedes the 2010 Call Letter policy guidance on this issue. We require that any prescription drug event (PDE) data related to claims not rejected on/after the effective date of the exclusion must be deleted to ensure the dollars are not inadvertently included in reconciliation. Please note, since the OIG generally updates the LEIE on their Website 15 days prior to the exclusion effective date, if sponsors follow the guidance to subscribe to the OIG LISTSERV and update their systems timely, the affected claims will be denied at point-of sale and no PDEs will be submitted. With regard to the related question of who bears the payment responsibility for claims not rejected on/after the effective date of the exclusion, CMS believes that this is a matter of payment terms between the parties and should be resolved accordingly. CMS does not require that these claims be reversed. Sponsors, however, cannot include the costs of these claims in their Part D bids.

Finally, in the checklist associated with the model letter attached to the January 13 memorandum, we inadvertently included a reference to GSA exclusions. We have removed this

reference from the checklist and made several editorial changes to the model letter. These revised materials are attached. The model letter should be used when a sponsor is paying a claim for a Part D covered drug prescribed or dispensed by a provider on the LEIE with a future exclusion effective date and/or to alert the member that future medication fills will no longer be covered because the prescriber or pharmacy is being excluded from participation in the Medicare Program based on OIG findings

If you have any questions concerning this memorandum, please contact Deborah Larwood at 410-786-9500 or Deborah.Larwood@cms.hhs.gov.

[Instructions: This model should be used by Part D sponsors to alert their members that future medication fills prescribed or dispensed by their current provider (prescriber or pharmacy) will no longer be covered because the provider is being excluded from participating in the Medicare Program based upon an OIG exclusion. This letter should be sent to the plan member as soon as the Part D sponsor has knowledge that a provider has been posted to the exclusion lists and that a member has previously received a prescription or prescription medication from that provider.]

<DATE>

<MEMBER NAME>

<ADDRESS>

<CITY, STATE ZIP>

Dear < MEMBER NAME>:

This letter is to inform you that we can no longer cover prescription medications effective [Effective Date of OIG Exclusion] that are [*Insert one* cribed> < dispensed>] by [*Insert one* <NAME OF PRESCRIBER> <NAME OF PHARMACY>]. This includes new prescriptions, as well as any refills left on the prescription(s) you are currently taking.

<Plan name> cannot cover medications [*Insert one* prescribed> < dispensed>] by [*Insert one* <NAME OF PRESCRIBER> <NAME OF PHARMACY>] because he/she/it has been excluded from participation in all federal health care programs, including the Medicare program, by the U.S. Department of Health and Human Services' Office of Inspector General (OIG). Medicare plans are prohibited from making payment for prescriptions written or dispensed by excluded providers. For more information about excluded providers, you may visit the OIG's website at http://oig.hhs.gov/fraud/exclusions.asp.

[OPTIONAL: Please call <Customer/Member> Service at <phone number> (TTY/TDD users should call <TTY/TDD number>) if you need assistance finding another <pharmacy>.]
[OPTIONAL: Please call <Customer/Member> Service at <phone number> (TTY/TDD users should call <TTY/TDD number>) if you need assistance finding another provider] in your area who can prescribe your medications]. If you have further questions regarding the status of your prescription(s), we are available from <hours of operations>.

Sincerely,	
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<Plan Representative>

<Material ID> [<CMS Approval Date >]

Last Updated < Date >

Checklist for the 2010 Model Excluded Provider Letter

Instructions

- This model should be used by Part D sponsors to alert their members that future medication
 fills prescribed or dispensed by their current provider (prescriber or pharmacy) will no longer
 be covered because the provider is being excluded from participating in the Medicare
 Program based upon OIG findings.
- This letter should be sent to the plan member as soon as the Part D sponsor has knowledge that a provider has been posted to the exclusion lists and a member received a prescription or prescription medication from that provider.
- Complete the checklist and submit it with your Model letter which you will transmit via the HPMS PDP Marketing Module.
- This model is subject to the 10 day review unless the organization revises the model. Then it is subject to the 45 day review.

Requirements

All required and relevant information is included in the Model letter.
Marketing material ID is included.
Materials are in 12 point font.
Customer service number(s), TTY/TDD number, and days/hours of operation are identified.
OPTIONAL Language suggesting that members call the plan if they need assistance finding another prescriber (if this information is available to the plan) or pharmacy.
Based on my best knowledge, information, and belief, all information submitted to CMS in these documents are accurate, complete, and truthful. Our organization has performed a second quality review of the materials before submitting them to CMS for review and approval.
(Name & Title of preparer of materials/ Date)
(Name & Title of second Quality Reviewer/Date
On behalf of
(NAME OF ORGANIZATION)