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Submitter : Mr. Michael Yount **Date:** 07/23/2007

Organization : Rite Aid

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-4124-P-7-Attach-1.PDF

RITE AID Corporation

LEGAL DEPARTMENT

MICHAEL C. YOUNT, R.Ph., J.D.
Vice President, Regulatory Law
Compliance Officer
Privacy Officer

• MAILING ADDRESS
P.O. Box 3165
Harrisburg, PA 17105

• GENERAL OFFICE
30 Hunter Lane
Camp Hill, PA 17011

• Telephone (717) 761-2633

July 23, 2007

Alissa deBoy
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4124-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: Proposed Regulations: 42 CFR Parts 422 and 423: Medicare Program (CMS-4130-P), 72 *Federal Register* 29403 through 29423, May 25, 2007

Dear Ms. deBoy,

Rite Aid Corporation has reviewed the above-referenced regulations and we have several concerns relating to the potential imposition of new fraud and abuse training requirements on retail pharmacies, as well as potential new expanded abilities of Part D plans and the Medicare program to have access to proprietary retail pharmacy cost and pricing data.

Rite Aid Corporation is one of the nation's leading drug store chains, operating approximately 5,100 pharmacies in 31 states and the District of Columbia. We are major providers of pharmacy services to Medicare Part D beneficiaries.

Expansion of Parameters for Agency Record Searches

While the revised rules do not require that providers offer their records for inspection by the Part D sponsor or MA-PD organization, the preamble states that the contracting parties are to assign responsibilities for submitting required information to CMS during contract negotiations. This appears to permit access by Part D plan sponsors and MA-PD organizations to all kinds of provider information, including proprietary information regarding price concessions by manufacturers or wholesalers to pharmacy providers and agreements with providers of on-site clinical and medical services.

Specifically, regulations governing contract provisions (42 CFR 422.504 and 423.505) are revised to clarify that contracts with providers must specify their obligations to make records available to inspection. The revised regulations specify that HHS and the Comptroller General *or their designees* may audit, evaluate, or inspect *any* books, contracts, medical records, patient care documentation, and other records of the sponsor or organization, or its first tier, downstream, or related entities that pertain to *any* aspect of services performed, reconciliation of benefit liabilities, and determination of reimbursement payable that the Secretary of HHS deems necessary to enforce the contract.

CMS states in the preamble that it is taking the opportunity "*to clarify, without specific regulatory change in* [the] *rule* that HHS, the Comptroller General, or their designees have the authority to request records relating to Part D rebate *and any other price concessions information* from Part D sponsors or their first tier, *downstream,* or related entities. CMS lists the following examples of records that could be sought: rebate agreements between PBMs and manufacturers; records reflecting discounts; price concessions; chargebacks; rebates; cash discounts; free goods contingent on a purchase agreement; up-front payments; coupons; goods in kind; free or reduced price services; grants; or price concessions or similar benefits offered to some or all purchasers. It also leaves the list open to further informal and apparently unlimited expansion by stating it will not commit the list to formal, specific, regulatory language (72 Fed Reg 29374, column 3).

We do not believe that CMS can seek information on discounts, chargebacks, or in-kind goods granted to pharmacy providers by manufacturers or wholesalers for drugs dispensed under Medicare without a more formal regulatory notice and comment period. If the agency's recordkeeping and inspection authority is to be expanded to cover this type of information, this expansion should be expressly stated in formal regulation adopted through the formal regulatory adoption process.

Moreover, Rite Aid urges that the final version of these regulations strictly limit the ability of a Part D sponsor or MA-PD organization expressly prohibit Part D plans from physically inspecting any records submitted for delivery to CMS. With respect to the "records" that CMS should have the authority to obtain, pharmacy providers should be required to provide the same information that would be provided upon submission of a claim to the Part D Sponsor or MA Organization.

Any further information required by HHS to complete an investigation should be provided directly by the pharmacy to CMS. It is critical, in light of direct pharmacy competitor ownership of PBMs or plan sponsors, that confidential and proprietary information not be made available to pharmacy competitors. Therefore, downstream entities such as pharmacies must be protected from sharing information with PBMs or plan sponsors to which they would not otherwise have access. A clarification that "HHS or the Comptroller General" only would have access to such records beyond the claims data is a necessary protection.

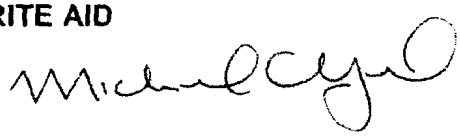
Fraud Waste and Abuse Programs

The proposed regulations that require Part D sponsors and MA organizations to apply their training and education and effective lines of communication requirements to their first tier, downstream, and related entities lacks clarity. Would this amendment require that pharmacy providers, such as Rite Aid, accept the training and/or education courses of each Part D sponsor or MA organization and be required to implement it as its own? If so, this is an unreasonable requirement. In addition to the operational burden that would be created if each plan were to require pharmacies to complete the plan's individual training course, this training would also lack the specificity of the pharmacy provider's own training and educational courses.

A training course imposed by a plan could not adequately address a pharmacy provider's policies and procedures for detecting and preventing fraud and the specific training requirements that the pharmacy provider might find necessary to implement. Pharmacies must be provided the ability to certify to the Part D sponsor/MA organization that the pharmacy has a FWA training/educational program and should not be required to implement a third party's training program.

Thank you for the opportunity to comment on these regulations.

Sincerely,
RITE AID



Michael C. Yount, R.Ph., J.D.
Vice President, Regulatory Law
Compliance Officer/Privacy Officer