



navigating the complex healthcare environment

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-2238-FC,
P.O. Box 8012,
Baltimore, MD 21244-8012

Comments in regard to the definition of physician administered drugs as covered outpatient drugs.

Centers for Medicare & Medicaid Services
42 CFR Part 447
[CMS-2238-FC]
RIN 0938- AO20
Medicaid Program; Prescription Drugs

FFP: Conditions Relating to Physician-Administered Drugs (§447.520)
Page 86

"We proposed, for the purpose of this section, that the term "physician-administered drugs" be defined as covered outpatient drugs under section 1927(k)(2) of the Act (many are also covered by Medicare Part B) that are typically furnished incident to a physician's service. These drugs are usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting."

Our comments relate to the definition distinction; "for the purpose of this section". We are concerned that this could be interpreted to mean that physician administered drugs are to be considered "covered outpatient drugs" **only** for the purposes of collecting utilization data and subsequent rebates.

This narrow interpretation currently, and in the future allows state Medicaid agencies to defer coverage and therefore accessibility of new physician administered drugs. In our opinion this is in conflict with CMS's own rules that state; "states must cover a manufacturer's drugs at the start of the Mandatory Effective Date (subject to the exceptions in section 1927 of the Social Security Act)" http://www.cms.hhs.gov/MedicaidDrugRebateProgram/14_NationalDrugRebateAgreement.asp. The rationale given by these states is that they have defined physician administered drugs as **not** covered outpatient drugs per Section 1927 of the Social Security Act⁽¹⁾

Specifically, many Medicaid agencies currently refer to the SSA drug definition in their state regulations that drugs dispensed **only by prescription** are deemed "covered outpatient drugs". Therefore, this delays physician administered drug coverage for extended periods of time; unlike their retail drug counterparts that must be covered on the mandatory effective date once the rebate agreement is in place. When physician administered drugs are deemed covered, rebates are collected per DRA stipulations but this can take six months to over a year pending agency deliberations such as prolonged medical review or the requirement of a permanent HCPCS code.

We therefore propose that CMS consider defining physician administered drugs as "covered outpatient drugs" more broadly, not just in terms of rebate collection purposes. We would further encourage CMS to specify that physician administered drugs qualify under the mandatory effective date regulations.

This would place new physician administered drugs in parity with new prescription drugs that must be covered per the stipulations in OBRA 90 and the national rebate agreement; eliminating unnecessary and lengthy waiting periods experienced by Medicaid recipients who need newly approved physician administered drugs.

Thank you for considering these comments.



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