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Medicaid Coverage for Drugs for Off-Label Uses

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Overview of Presentation

- Medicaid Coverage of "Medically Accepted Indications"
- Medicaid Coverage of Off-Label Uses Other than "Medically Accepted Indications"
- Implications for Manufacturers
- Questions?

Medicaid Coverage of "Medically Accepted" Indications

- The Medicaid rebate statute applies to "covered outpatient drugs." If a manufacturer enters into a rebate agreement, the States' ability to restrict coverage for the manufacturer's covered outpatient drugs is limited.
- BUT: States "may exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

Medicaid Coverage of "Medically Accepted" Indications (cont.)

- The Medicaid rebate statute defines "medically accepted indications" as FDA-approved ("on-label") uses and "off-label" uses supported by citations listed in one of four compendia (one of which is no longer published).
  - Drugdex Information System reportedly lists the greatest number of unapproved indications.
  - Some of the compendia listings include limitations or qualifications. Do such listings "support" an unapproved use?

Medicaid Coverage of "Medically Accepted" Indications (cont.)

- Because States may restrict coverage of covered outpatient drugs if the prescribed indication is not "medically accepted," the negative inference appears to be that States should cover off-label uses that are "medically accepted," subject to other generally applicable permissible restrictions (*e.g.*, prior authorization, formulary status, "lifestyle" drugs).

Medicaid Coverage of Off-Label Uses Other than "Medically Accepted Indications"

- Second negative inference is that States may cover covered outpatient drugs for indications that are not "medically accepted."
- *United States ex re. Franklin v. Parke-Davis*, 2003 WL 22048255 (D. Mass. Aug. 22, 2003)
  - Parke-Davis argued the negative inference above.
  - Relator cited other language in the statute to argue that States could not cover non-"medically accepted" indications: "Such term ["covered outpatient drug"] also does not include any such drug . . . used for a medical indication which is not a medically accepted indication."

Medicaid Coverage of Off-Label Uses Other than "Medically Accepted Indications" (cont.)

- *United States ex re. Franklin v. Parke-Davis*
  - Court observed that it was "not clear which side gets the better of the debate," declined to decide the issue, and invited the government to submit an *amicus* brief on the issue.
- Even if the relator's argument is accepted, not being a "covered outpatient drug" does not necessarily prohibit a State from providing coverage.
  - The category "covered outpatient drug" triggers *Medicaid rebates* and limits the States' ability to exclude or restrict coverage; it does not delimit the boundaries of Medicaid coverage.
  - CMS has said that States may cover investigational drugs, which are not "covered outpatient drugs."

Implications for Manufacturers

- If an off-label indication is "medically accepted," a manufacturer should be able to promote that indication (in accordance with FDA's rules) without the threat of False Claims Act liability.
- Even where a manufacturer abides by the FDA's rules for off-label promotion, it may still be vulnerable to False Claim Act liability for promoting any indications that are not "medically accepted."
- Before off-label materials are disseminated, a manufacturer should consider: (1) whether the indication(s) discussed in the materials are "medically accepted"; and (2) if not, whether all States cover the indication(s) or whether the dissemination will be geographically limited to those States that do.

Questions?

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