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Off-label Prescription Drug Coverage Under Medicare Part D

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The July/August 2006 Legal Column addressed requirements of the newly created Medicare Part D prescription drug benefit, specifically those affecting off-label prescribing practices. One year later, oncologists continue to struggle with these requirements.

One of the most notable changes produced by the Part D program is a policy that limits coverage of drugs prescribed for a purpose that deviates from the drug labeling instructions, or "off-label" prescription drugs.[1] Specifically, Medicare Part D regulations issued in 2006 limit coverage for off-label prescription drugs by requiring all to be prescribed for a use supported in one of three medical compendia.[2] As a result of these new regulations, Part D plans are prohibited from covering a drug if it is not listed in one of the identified compendia even if the drug has been prescribed as an effective off-label treatment in the past.[3]

Until recently, physicians could rely on peer-reviewed medical journals and literature as well as medical compendia to evaluate the safety and potential efficacy of a drug for off-label use. If shown effective, off-label prescription drugs were incorporated into a patient's drug therapy regimen as part of the "reasonable and necessary" physician services provided, with few coverage restrictions. Medicare recipients who did not tolerate the prescription drugs specified for their conditions could use off-label drug therapy regimens without Medicare coverage concerns. Now, under the definition of a Covered Part D drug, these patients are forced to choose between paying out-of-pocket for potentially expensive off-label prescription drug regimens, or resorting to less desirable standard therapy regimens that are covered by Medicare Part D.

The text of the Medicare Part D statute requires drug plans to cover all drugs that are "reasonable and necessary" for the treatment of an illness, with particular exclusions listed for certain classes of drugs, such as weight loss products and fertility medications. This language mirrors the Medicare Part B statutory definition of a covered drug, which is defined to include drugs administered as part of reasonable and necessary treatment for illness or injury. When the Centers for Medicare & Medicaid Services (CMS) implemented the regulations to the Part D statute, however, it interpreted the statutory language to prohibit coverage for drugs that were not prescribed for a "medically accepted indication," a definition taken from the Medicaid statute that requires a drug to be referenced in a medical compendia for an off-label use in order to be covered. Notably, Congress never referenced the "medically accepted indication" requirement in the Medicare Part D statute and the statute's language indicates that Congress intended to provide coverage for all prescriptions deemed medically necessary for a patient unless a drug is explicitly excluded from coverage.[3]

This strict interpretation contradicts CMS's stated intent to limit restrictions on off-label prescribing practices, as outlined in the Medicare Part D Final Rule published in the Federal Register in January 2005. In the Final Rule, CMS acknowledged the value of off-label prescription drugs for certain medical conditions and assured recipients that the benefit plan designs would not discriminate against certain classes of Part D enrollees. However, the definition of a Covered Part D drug ultimately prohibits its coverage for those populations that do not respond to standard drug therapies or a drug treatment expressly outlined in one of the specified medical compendia. Further, this definition of a Covered Part D drug shows a disconnect between CMS's expressed intent to implement a prescription drug plan that provides extensive coverage to the variety of Medicare recipients and the current system of coverage under Part D: a prescription drug can only be covered under a Part D plan if there is a medically accepted indication for the drug's intended use even though many off-label drug therapy regimens that are acceptable medical practices are not specifically identified in one of the accepted compendia.

Members of the medical community and patients' rights advocacy groups are pressuring CMS to revise the current regulations defining a Covered Part D drug and adopt the covered drug language of the Medicare Part D statute. The restrictive nature of the current definition promulgated by the Part D regulations and the resulting limitations on available drugs under the benefit plan may ultimately disadvantage the health, well-being, and financial stability of Medicare populations most in need of prescription drug coverage.

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References

[1] Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 Fla. L. Rev. 181, 189 (1999) (defining "off-label use").
[2] 42 C.F.R. § 423.100 (2007) (defining "Covered Part D drug").
[3] Medicare Rights Center. *Off-Base: The Exclusion of Off-label Prescriptions from Medicare Part D Coverage*. August 2007; Available at *www.medicarerights.org/Off-label_PartD_Coverage.pdf*.