



IMPORTANT ADVOCACY ALERT about Medicare Part D Off-Label Prescription Parity Act H.R. 5732

On 7-15-10, U.S. Representatives Mary Jo Kilroy (OH-15) and Mac Thornberry (TX-13) announced introduction of the bipartisan Part D Off-Label Prescription Parity Act (H.R. 5732) to allow Medicare coverage of medications when use is supported by experts.

Currently, many Medicare consumers with serious and sometimes life-threatening conditions are unable to access safe and effective medications because their use is off-label*. Off-label prescribing is common. The bill would give Part D plans the same flexibility allowed under other parts of the Medicare program and in the commercial insurance market. H.R. 5732 expands treatment options for Medicare consumers, and brings Part D rules in line with other parts of the Medicare program, including Part B** and the Part D coverage standard for drugs used to treat cancer. (<http://kilroy.house.gov>)

Doctors and patients should be able to decide the best safe and effective medications for their treatments," said Rep. Kilroy. "We must fight for the right to be treated with the best, safest medicine in consultation with our physicians, not a government bureaucrat." (<http://kilroy.house.gov>)

Contact your U.S. Representative if you wish him/her to advocate for the Part D Off-Label Prescription Parity Act (H.R. 5732)

You may view the press release at:

http://www.medicarerights.org/newsroom/pressreleases/2010_39.html



***Definition of "Off-Label" use of Medication**


<http://bpd.about.com/od/glossary/g/offlabel.htm>

Sometimes a medication will be approved for use by the Food and Drug Administration (FDA) for a particular condition or patient group, but will also show success in treating another condition or group. Until the medication is approved by the FDA for treatment of this additional condition or group, this new use is called an "off-label use."

Once the FDA has approved a medication, a physician can legally prescribe that medication for off-label use. It is the physician's responsibility to be well-informed about medication, to only prescribe a medication for an off-label use if there is a good scientific or medical reason for doing so, and to track the patient's response to the medication. Medicare currently allows the off-label use of medication to treat cancer when its use is supported by peer-reviewed medical literature.

**Medicare Part B covers drugs that aren't usually self-administered and are given as part of a doctor's service. Coverage is usually limited to drugs that are given by injection or infusion. Medicare Part B also covers some Vaccinations.

Under Medicare Part B**, CMS allows carriers to consider "the major drug compendia, authoritative medical literature and/or accepted standards of medical practice" in determining whether an off-label use is medically accepted. In 2008, through the Medicare Improvements for Patients and Providers Act (MIPPA), Congress required the Centers for Medicare & Medicaid Services to apply the Part B standard to Part D cancer drugs used off-label.



Why Medicare Part D should Cover “Off-Label” use of Prescription Medications

Article from the Medicare Rights Center (November 20, 2008)

Part D Plans Must Cover Medically Necessary Off-Label Use Of Prescription Drugs Based On Evidence Published In Peer-Reviewed Medical Literature

www.medicarerights.org/issuesactions/Obama_Administration_Transition_Memo.pdf

The exclusion from Medicare Part D coverage of *off-label* uses that are not listed in the compendia* hurts the most vulnerable beneficiaries, including those for whom alternative medications are neither safe nor effective. For the following reasons, CMS should require coverage of off-label use of medications based on supportive clinical evidence in peer-reviewed medical literature. [emphasis added]

[*Off-label prescriptions may only be covered by Part D if they are supported in one of the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopoeia Drug Information, DRUGDEX Information System. (www.medicarerights.org/pdf/partd_appeals_manual.pdf)]

First, the statutory definition of a covered Part D drug neither prohibits coverage of off-label uses nor imposes a compendia requirement. To support a compendia requirement, CMS has interpreted the statute’s use of the term “includes” as implicitly excluding any drug uses that are not explicitly mentioned. However, section 1101(b) of the Act provides that the term “includes’ . . . when used in a definition contained in this Act shall not be deemed to exclude other things otherwise within the meaning of the term defined”^{vii} As a result, the term “includes” cannot be read as a limiting term, but must be interpreted as an illustrative term. In other words, a compendia-listed drug use is merely illustrative of a kind of drug that is a “covered Part D drug,” but is not an essential prerequisite for covered drug status. Moreover, none of the exclusions enumerated within the definition of “covered Part D drug,” and none of the exclusions to which the definition explicitly refers, support the compendia requirement that the regulation adopts.^{viii}

Second, the intent of Congress is clearly expressed by the plain language of the statute; the Act’s legislative history also indicates that Congress intended the definition to be read expansively. The Conference Report accompanying the law provides that “[t]he definition would include any use of a covered outpatient drug for a medically accepted indication. . . . A plan could exclude from coverage, subject to reconsideration and appeals provisions, any drug which would not meet *Medicare’s definition of medically necessary* or was not prescribed in accordance with the plan or Part D”^{ix} (Emphasis added) The broad definition of medical necessity in the Medicare statute includes no compendia or other similar requirement.^x

ⁱ The Medicare Rights Center is currently challenging this regulation in the Southern District of New York on the grounds that it is inconsistent with the Social Security Act. *Layzer et al. v. Leavitt* (No. 07-CV-11339 (GEL)).

ⁱⁱ Centers for Medicare & Medicaid Services, Medicare Benefit Policy Manual, September, 2008. This standard for off label coverage applies to all drugs except anticancer chemotherapy drugs. With the passage of the Medicare Improvements for Patients and Providers Act, the Part B and Part D standards for off-label coverage of anticancer chemotherapy drugs are aligned.

ⁱⁱⁱ 42 U.S.C. § 1395w-102(e) (incorporating § 1396r-8(k)(2)(A)(i)-(iii)). These provisions also permit coverage of drugs commercially used or sold in the United States before 1962 or a drug for which the Secretary has determined there is compelling justification for its medical need.

^{iv} 42 U.S.C. § 1396r-8(k)(6)

^v 42 U.S.C. § 1396r-8(g)(1)(B)(i).

^{vi} 42 C.F.R. § 423.100.

^{vii} 42 U.S.C. § 1301(b).

^{viii} See 42 U.S.C. §§ 1396r-8(d)(2) and 1396r-8(d)(3).

^{ix} See H.R. Rep. No. 108-391, at 442 (2003) (Conference Report)

^x The Medicare statute requires coverage for services or treatments that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).