United States Senate
WASHINGTON, DC 20510

May 22, 2008

The Honorable Max Baucus
Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Charles Grassley
Ranking Member
Senate Finance Committee
135 Hart Senate Office Building
Washington, D.C. 20510

Dear Colleague:

As Co-Chairs of the Senate Cancer Coalition, we write to ask for your help in ensuring that the best evidence-based treatments are available to patients enrolled in Medicare Part D plans. Currently, certain barriers exist that may prevent coverage of treatments prescribed by a physician on the basis of the patient's case history and the most current medical research.

Treating physicians look to research published in peer-reviewed journals and to the compendia which review and compile this research to determine the potential risks and benefits of using drugs to treat indications not approved by the Food and Drug Administration. Such "off-label" prescribing is an accepted medical practice and is particularly prevalent in the treatment of cancers, HIV/AIDS and rare disorders.

The Part D statute, however, restricts the compendia that prescription drug plans can consider when plans are determining whether an off-label use is medically accepted and, therefore, covered under Part D. This standard is more restrictive than the coverage criteria applied under Medicare Part B.

For anticancer treatments, this means that the journals specifically identified by the Centers for Medicare & Medicaid Services (CMS) for guiding off-label coverage under Part B cannot be consulted by Part D plans in determining coverage. In addition, the compendia that Part D plans can consider is fixed by statute and, absent congressional action, will not include any compendia that CMS decides, under a review process now underway, are most appropriate to guide Part B cancer coverage review.

Under Part B, off-label use of an anticancer treatment is considered to meet the definition of "medically accepted indication" if it is included in approved compendia (privately published reference guides), or if it has been shown to be effective in peer-reviewed literature identified by the Secretary of Health and Human Services. For noncancer treatments, CMS advises Part B carriers to take into "consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice" when determining whether Medicare should cover an off-label use of a drug.

Part D plans, on the other hand, are barred by statute from looking beyond the compendia even when they are presented with the results of peer-reviewed research in making individual, case-by-case, determinations.

We request that you include the enclosed language in the Medicare bill currently being drafted by your committee. This provision would allow prescription drug plans to consider the full range of evidence in making coverage decisions, and bring the coverage standards for Part D into line with coverage standards used under Medicare Part B and by commercial insurers.

We believe this language will improve the coverage available under the Medicare drug benefit to people diagnosed with cancer and other life-threatening diseases. Absent projections from the Congressional Budget Office that this change will result in prohibitive additional costs, this change should be welcomed by both supporters and critics of Part D. Thank you very much for your consideration of this request.

Best regards,

Dianne Feinstein

Sam Brownback

Enclosure

Use of Part B Definition of Medically Accepted Indication for Part D Drugs—

(1) In General.—Section 1860D-2(e)(1) of the Social Security Act (42 U.S.C. 1395w-102(e)(1)) is amended, by —

(A) striking "(as defined in section 1927(k)(6))" in subparagraph (B) and replacing it with "(as defined in paragraph (4))"; and

(B) by adding after paragraph (3) the following:

"(4) Medically Accepted Indication Defined.—For purposes of paragraph (1), the term 'medically accepted indication' has the meaning given that term—

(A) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1861(t)(2)(B), or as supported by one or more citations which are included (or approved for inclusion) in compendia identified in section 1927(g)(1)(B)(i)(III), except that in applying such sections, 'PDP sponsor or MA-PD sponsor' shall be substituted for 'carrier' each place it appears; and

(B) in the case of any other covered part D drug, in section 1927(k)(6)."

(C) Notwithstanding subparagraphs (B), nothing in shall preclude a PDP sponsor or MA-PD sponsor, upon the request for a coverage determination under section 1860-4(g)(1), from granting coverage after such determination, based upon guidance provided by the Secretary for determining accepted uses of drugs, that use of a drug or biological is medically accepted based on supportive clinical evidence in peer reviewed medical literature.

(2)Effective Date.—The amendments made by this subsection shall apply to plan years beginning on or after January 1, 2010.