

109TH CONGRESS
2D SESSION

H. R. 5193

To amend titles XVIII and XIX of the Social Security Act to provide for continuity of Medicare prescription drug coverage for full-benefit dual eligible individuals, for Medicare prescription drug coverage of benzodiazepines and off-label uses of certain prescription drugs and biological products, for optional Medicaid coverage of Medicare prescription drug cost-sharing for full-benefit dual eligible individuals, for authorization to the Secretary of Health and Human Services to waive certain determinations denying Medicare prescription drug coverage, and for holding pharmacies harmless for certain costs incurred during implementation of Medicare part D.

IN THE HOUSE OF REPRESENTATIVES

APRIL 25, 2006

Mrs. WILSON of New Mexico introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for continuity of Medicare prescription drug coverage for full-benefit dual eligible individuals, for Medicare prescription drug coverage of benzodiazepines and off-label uses of certain prescription drugs and biological products, for optional Medicaid coverage of Medicare prescription drug cost-sharing for full-benefit dual eligible individuals, for authorization to the Secretary of Health and Human Services to waive certain deter-

minations denying Medicare prescription drug coverage, and for holding pharmacies harmless for certain costs incurred during implementation of Medicare part D.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. CONTINUITY OF MEDICARE PRESCRIPTION**
 4 **DRUG COVERAGE FOR FULL-BENEFIT DUAL**
 5 **ELIGIBLE INDIVIDUALS.**

6 (a) IN GENERAL.—Section 1860D–2(a) of the Social
 7 Security Act (42 U.S.C. 1395w–102(a)) is amended—

8 (1) in paragraph (1), by inserting “subject to
 9 paragraph (6),” after “part C”; and

10 (2) by adding at the end the following new
 11 paragraph:

12 “(6) CONTINUATION OF MEDICARE COVERAGE
 13 FOR CERTAIN PRESCRIPTIONS FOR FULL-BENEFIT
 14 DUAL ELIGIBLE INDIVIDUALS.—In the case of an in-
 15 dividual who, as of the date the individual is first
 16 enrolled under a prescription drug plan under this
 17 part (or an MA–PD plan under part D), is a full-
 18 benefit dual eligible individual and is being provided
 19 medical assistance for a covered part D drug under
 20 title XIX, qualified prescription drug coverage must
 21 include coverage for such drug unless a prescribing
 22 physician certifies that the coverage of such drug is
 23 not medically necessary, regardless of whether the

1 individual subsequently remains a full-benefit dual
2 eligible individual.”.

3 (b) EFFECTIVE DATE.—The amendments made by
4 subsection (a) shall be effective as if included in the enact-
5 ment of Medicare Prescription Drug, Improvement, and
6 Modernization Act of 2003 (Public Law 108–173).

7 **SEC. 2. MEDICARE PRESCRIPTION DRUG COVERAGE OF**
8 **BENZODIAZEPINES.**

9 (a) IN GENERAL.—Section 1860D–2(e)(2)(A) of the
10 Social Security Act (42 U.S.C. 1395w–112(e)(2)(A)) is
11 amended by inserting after “agents)” the following: “and
12 other than subparagraph (J) of such section (relating to
13 benzodiazepines)”.

14 (b) EFFECTIVE DATE.—The amendment made by
15 subsection (a) shall be effective as if included in the enact-
16 ment of Medicare Prescription Drug, Improvement, and
17 Modernization Act of 2003 (Public Law 108–173).

18 **SEC. 3. PERMITTING STATE MEDICAID PROGRAMS TO**
19 **COVER MEDICARE PRESCRIPTION DRUG CO-**
20 **PAYMENTS FOR FULL-BENEFIT DUAL ELIGI-**
21 **BLE INDIVIDUALS.**

22 (a) IN GENERAL.—Section 1935(d) of the Social Se-
23 curity Act (42 U.S.C. 1396u–5(d)) is amended by adding
24 at the end the following new paragraph:

1 “(3) OPTIONAL COVERAGE OF MEDICARE PRE-
 2 SCRIPTION DRUG COST-SHARING.—Notwithstanding
 3 paragraph (1), a State may, at its option, provide
 4 medical assistance under the plan under this title for
 5 the deductible and cost-sharing imposed under a
 6 prescription drug plan (or an MA–PD plan) for full-
 7 benefit dual eligible individuals and payment shall be
 8 available under section 1903(a) with respect to such
 9 assistance provided. ”.

10 (b) EFFECTIVE DATE.—The amendment made by
 11 subsection (a) shall be effective as if included in the enact-
 12 ment of Medicare Prescription Drug, Improvement, and
 13 Modernization Act of 2003 (Public Law 108–173).

14 **SEC. 4. MEDICARE COVERAGE OF OFF-LABEL USES OF PRE-**
 15 **SCRIPTION DRUGS AND BIOLOGICALS.**

16 (a) IN GENERAL.—Section 1860D—2(e) of the So-
 17 cial Security Act (42 U.S.C. 1395w–102(e)) is amended
 18 at the end by adding the following new paragraph:

19 “(4) RULE OF CONSTRUCTION.—Nothing in this sub-
 20 section shall be construed as excluding from the definition
 21 of the term ‘covered part D drug’—

22 “(A) a drug described in paragraph (1)(A) on
 23 the sole basis that such drug is prescribed by a phy-
 24 sician for a use other than a use included in the la-
 25 beling of such drug pursuant to the approval of the

1 safety and effectiveness of such drug as a prescrip-
 2 tion drug under section 505 or 507 of the Federal
 3 Food, Drug, and Cosmetic Act or approval of such
 4 drug under section 505(j) of such Act; or

5 “(B) a biological product described in para-
 6 graph (1)(B) on the sole basis that such product is
 7 prescribed by a physician for a use other than a use
 8 included in the labeling of such product pursuant to
 9 the licensure of such product under section 351 of
 10 the Public Health Service Act;

11 even if the unlabeled use of the drug or product is not
 12 included in a standard clinical reference compendia used
 13 by clinicians for purposes of providing guidance to such
 14 clinicians with respect to unlabeled uses of such a drug
 15 or product.”.

16 (b) EFFECTIVE DATE.—The amendment made by
 17 subsection (a) shall be effective as if included in the enact-
 18 ment of Medicare Prescription Drug, Improvement, and
 19 Modernization Act of 2003 (Public Law 108–173).

20 **SEC. 5. AUTHORIZATION FOR SECRETARY OF HEALTH AND**
 21 **HUMAN SERVICES TO WAIVE DENIAL OF PRE-**
 22 **SCRIPTION DRUG COVERAGE.**

23 (a) IN GENERAL.—Section 1860D–4(h) of the Social
 24 Security Act (42 U.S.C. 1395w–104(h)) is amended at the
 25 end by adding the following new paragraph:

1 “(4) AUTHORIZATION FOR SECRETARY TO WAIVE
2 DENIAL OF PRESCRIPTION DRUG COVERAGE.—After a
3 part D eligible individual has exhausted all rights of such
4 individual under this subsection and subsection (g), with
5 respect to a determination made under this subsection or
6 subsection (g) for a prescription drug plan not to provide
7 for coverage of a covered part D drug (or a determination
8 related to the application of tiered cost-sharing described
9 in subsection (g)(2)), the individual may apply to the Sec-
10 retary for a waiver that requires the prescription drug
11 plan to provide for such coverage (or provide for an excep-
12 tion to the structure of such tiered cost-sharing). Upon
13 receipt of such application, the Secretary may grant such
14 waiver if the prescribing physician certifies that the cov-
15 erage of such prescription drug is medically necessary with
16 respect to the individual.”.

17 (b) EFFECTIVE DATE.—The amendment made by
18 subsection (a) shall be effective as if included in the enact-
19 ment of Medicare Prescription Drug, Improvement, and
20 Modernization Act of 2003 (Public Law 108–173).

21 **SEC. 6. HOLDING PHARMACIES HARMLESS FOR CERTAIN**
22 **COSTS INCURRED DURING IMPLEMENTATION**
23 **OF MEDICARE PART D.**

24 (a) IN GENERAL.—The Secretary of Health and
25 Human Services shall provide for such payments to phar-

1 macies as may be necessary to reimburse pharmacies fully
2 for—

3 (1) transaction fees associated with any point-
4 of-sale facilitated identification and enrollment proc-
5 ess established by the Secretary to facilitate, at
6 point of sale, the identification of drug plan assign-
7 ment of full-benefit dual eligible individuals (as de-
8 fined in section 1935(c)(6) of the Social Security
9 Act (42 U.S.C. 1396u–5(c)(6)) or the enrollment of
10 previously unidentified or new full-benefit dual eligi-
11 ble individuals into Medicare prescription drug cov-
12 erage under part D of title XVIII of the Social Secu-
13 rity Act;

14 (2) costs associated with technology or software
15 upgrades necessary to make any identification and
16 enrollment inquiries as part of a process described in
17 paragraph (1); and

18 (3) costs of providing prescription drugs and bi-
19 ological products to part D eligible individuals (as
20 defined in section 1860D–1(a)(3)(A) of such Act (42
21 U.S.C. 1395w–101(a)(3)(A)) whose prescription
22 drug plans could not be identified, if the pharmacy
23 involved was not reimbursed for such costs upon
24 completion of plan reconciliation.

1 (b) TIME.—Payments under subsection (a) shall be
2 made with respect to fees and costs incurred during the
3 period beginning on December 1, 2005, and ending on
4 June 1, 2006.

5 (c) PAYMENTS FROM ACCOUNT.—Payments under
6 subsection (a) shall be made from the Medicare Prescrip-
7 tion Drug Account under section 1860D–16 of the Social
8 Security Act (42 U.S.C. 1395w–116) and shall be deemed
9 to be payments from such Account under subsection (b)
10 of such section.

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