107TH CONGRESS 1ST SESSION H.R. 1387

To amend the Social Security Act to improve access to prescription drugs for low-income Medicare beneficiaries, the Internal Revenue Code and other Acts to improve access to health care coverage for seniors, the self-employed, and children, and to amend the Federal Food, Drug, and Cosmetic Act to improve meaningful access to reasonably priced prescription drugs.

IN THE HOUSE OF REPRESENTATIVES

April 4, 2001

Mr. GANSKE (for himself, Mrs. EMERSON, Mr. FRANK, Mr. WYNN, Mr. HORN, Mr. GILCHREST, Mr. TRAFICANT, Mr. LEACH, Mr. JONES of North Carolina, Mr. JOHNSON of Illinois, Mr. SANDERS, Mr. GUT-KNECHT, and Mr. TERRY) 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 the Social Security Act to improve access to prescription drugs for low-income Medicare beneficiaries, the Internal Revenue Code and other Acts to improve access to health care coverage for seniors, the self-employed, and children, and to amend the Federal Food, Drug, and Cosmetic Act to improve meaningful access to reasonably priced prescription drugs. 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. SHORT TITLE; TABLE OF CONTENTS.

- 4 (a) SHORT TITLE.—This Act may be cited as the
- 5 "Drug Availability and Health Care Access Improvement
- 6 Act of 2001".
- 7 (b) TABLE OF CONTENTS.—The table of contents of
- 8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—MEDICAID PRESCRIPTION DRUG COVERAGE FOR LOW-INCOME MEDICARE BENEFICIARIES

Sec. 101. Medicaid prescription drug coverage for low-income medicare beneficiaries.

TITLE II—IMPROVED ACCESS OF MEDICARE BENEFICIARIES TO MEDICARE+CHOICE PLANS

Sec. 201. Improved access to Medicare+Choice plans through an increase in the minimum Medicare+Choice capitation rate.

TITLE III—IMPROVED ACCESS TO REASONABLY PRICED PRESCRIPTION DRUGS

Sec. 301. Amendments to program for importation of certain prescription drugs by pharmacists and wholesalers.

9 TITLE I-MEDICAID PRESCRIP-

10 TION DRUG COVERAGE FOR

11 LOW-INCOME MEDICARE

12 **BENEFICIARIES**

13 SEC. 101. MEDICAID PRESCRIPTION DRUG COVERAGE FOR

14 LOW-INCOME MEDICARE BENEFICIARIES.

- 15 (a) IN GENERAL.—Section 1902(a)(10) of the Social
- 16 Security Act (42 U.S.C. 1396a(a)(10)) is amended—

1	(1) by striking "and" at the end of subpara-
2	graph (F);
3	(2) by adding "and" at the end of subpara-
4	graph (G); and
5	(3) by inserting after subparagraph (G) the fol-
6	lowing new subparagraph:
7	"(H) for making medical assistance avail-
8	able for prescribed drugs (in the same amount,
9	duration, and scope as for individuals described
10	in subparagraph (A)) for qualified medicare
11	beneficiaries described in section $1905(p)(1)$
12	and for individuals who would be such qualified
13	medicare beneficiaries but for the fact that
14	their income exceeds the income level estab-
15	lished by the State under section $1905(p)(2)$
16	but is less than 175 percent of the official pov-
17	erty line (referred to in such section) for a fam-
18	ily of the size involved;".
19	(b) 100 Percent Federal Financing of Addi-
20	TIONAL COSTS.—Section 1903(a) of such Act (42 U.S.C.
21	1396b(a)) is amended—
22	(1) by redesignating paragraph (7) as para-
23	graph (8) ; and
24	(2) by adding after paragraph (6) the following
25	new paragraph:

1	((7) an amount equal to 100 percent of
2	amounts as expended as medical assistance for pre-
3	scribed drugs described in section $1902(a)(10)(H)$ to
4	individuals who are eligible for such assistance only
5	on the basis of such section; and".
6	(c) Permitting Charging of Sliding Scale Pre-
7	MIUMS FOR QUALIFYING INDIVIDUALS WITH INCOMES
8	Above 135 Percent of Poverty Line.—Section 1916
9	of such Act Social Security Act is amended—
10	(1) in subsection (b), by striking "or (E)" and
11	inserting ", (E), or (H)"; and
12	(2) in subsection (d)—
13	(A) by inserting "(1)" after "(d)", and
14	(B) by adding at the end the following new
15	paragraph:
16	((2)(A) With respect to an individual described in
17	section $1902(a)(10)(H)$ whose income (as determined
18	under section $1905(p)(1)(B)$) exceeds 135 percent of the
19	official poverty line referred to in that section, the State
20	plan of a State shall provide for the charging of a premium
21	(expressed as a percentage of the average actuarial cost
22	of the benefits described in section $1902(a)(10)(H)$ pro-
23	vided with respect to individuals described in such section)
24	according to a sliding scale under which such percentage
25	increases from 0 percent to 100 percent, in reasonable in-

crements (as determined by the Secretary), as the individ ual's income increases from 135 percent of such poverty
 line to 175 percent of such poverty line.

4 "(B) A State shall not require prepayment of a pre-5 mium imposed pursuant to subparagraph (A) and shall not terminate eligibility of an individual for medical assist-6 7 ance under this title on the basis of failure to pay any 8 such premium until such failure continues for a period of 9 not less than 60 days. The State may waive payment of 10 any such premium in any case where the State determines that requiring such payment would create an undue hard-11 12 ship.

13 "(C) A State may permit State or local funds avail-14 able under other programs to be used for payment of a 15 premium imposed under subparagraph (A). Payment of 16 a premium with such funds shall not be counted as income 17 to the individual with respect to whom such payment is 18 made.".

(d) EFFECTIVE DATE.—The amendments made by
this section take effect on the first day of the first year
that begins more than 6 months after the date of the enactment of this Act.

1TITLE II—IMPROVED ACCESS OF2MEDICAREBENEFICIARIES3TOMEDICARE+CHOICE4PLANS

5 SEC. 201. IMPROVED ACCESS TO MEDICARE+CHOICE PLANS
6 THROUGH AN INCREASE IN THE MINIMUM
7 MEDICARE+CHOICE CAPITATION RATE.

8 (a) IN GENERAL.—Section 1853(c)(1)(B) of the So9 cial Security Act (42 U.S.C. 1395w-23(c)(1)(B)), as
10 amended by section 601(a) of Medicare, Medicaid, and
11 SCHIP Benefits Improvement and Protection Act of 2000
12 (as enacted into law by section 1(a)(6) of Public Law 10613 554), is amended—

14 (1) by redesignating clause (iv) as clause (v);
15 (2) by inserting after clause (iii) the following
16 new clause:

17 "(iv) For 2002—

18 "(I) for any area in the 50
19 States and the District of Columbia,
20 \$600; and

21 "(II) for any other area, the min22 imum amount specified in clause (iii)
23 for that area for 2001 increased by
24 the national per capita
25 Medicare+Choice growth percentage,

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1	described in paragraph (6)(A) for
2	2002."; and
3	(3) in clause (v), as so redesignated—
4	(A) by striking "2002" and inserting
5	"2003"; and
6	(B) by striking "or clause (iii)" and insert-
7	ing "or clause (iv)".
8	(b) EFFECTIVE DATE.—The amendments made by
9	subsection (a) apply to years beginning with 2002.
10	TITLE III—IMPROVED ACCESS
11	TO REASONABLY PRICED
12	PRESCRIPTION DRUGS
13	SEC. 301. AMENDMENTS TO PROGRAM FOR IMPORTATION
14	OF CERTAIN PRESCRIPTION DRUGS BY PHAR-
14 15	OF CERTAIN PRESCRIPTION DRUGS BY PHAR- MACISTS AND WHOLESALERS.
15 16	MACISTS AND WHOLESALERS.
15 16	MACISTS AND WHOLESALERS. Section 804 of the Federal Food, Drug, and Cosmetic
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15 16 17 18	MACISTS AND WHOLESALERS. Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(c)(2) of Public Law 106– 387) is amended—
15 16 17 18 19	MACISTS AND WHOLESALERS. Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(c)(2) of Public Law 106– 387) is amended— (1) by striking subsections (e) and (f) and in-
15 16 17 18 19 20	MACISTS AND WHOLESALERS. Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(e)(2) of Public Law 106– 387) is amended— (1) by striking subsections (e) and (f) and in- serting the following subsections:
15 16 17 18 19 20 21	MACISTS AND WHOLESALERS. Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(c)(2) of Public Law 106– 387) is amended— (1) by striking subsections (e) and (f) and in- serting the following subsections: "(e) TESTING; APPROVED LABELING.—
 15 16 17 18 19 20 21 22 	MACISTS AND WHOLESALERS. Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(c)(2) of Public Law 106– 387) is amended— (1) by striking subsections (e) and (f) and in- serting the following subsections: "(e) TESTING; APPROVED LABELING.— (1) TESTING.—Regulations under subsection
 15 16 17 18 19 20 21 22 23 	MACISTS AND WHOLESALERS. Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(c)(2) of Public Law 106– 387) is amended— (1) by striking subsections (e) and (f) and in- serting the following subsections: "(e) TESTING; APPROVED LABELING.— "(1) TESTING.—Regulations under subsection (a)—

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1	be conducted by the importer of the covered
2	product pursuant to subsection (a), or the man-
3	ufacturer of the product;
4	"(B) shall require that, if such tests are
5	conducted by the importer, information needed
6	to authenticate the product being tested be sup-
7	plied by the manufacturer of such product to
8	the importer; and
9	"(C) shall provide for the protection of any
10	information supplied by the manufacturer
11	under subparagraph (B) that is a trade secret
12	or commercial or financial information that is
13	privileged or confidential.
14	"(2) Approved labeling.—For purposes of
15	importing a covered product pursuant to subsection
16	(a), the importer involved may use the labeling ap-
17	proved for the product under section 505, notwith-
18	standing any other provision of law.
19	"(f) Discretion of Secretary Regarding Test-
20	ING.—The Secretary may waive or modify testing require-
21	ments described in subsection (d) if, with respect to spe-
22	cific countries or specific distribution chains, the Secretary
23	has entered into agreements or otherwise approved ar-
24	rangements that the Secretary determines ensure that the

covered products involved are not adulterated or in viola tion of section 505.";

3 (2) by striking subsections (h) and (i) and in4 serting the following subsections:

5 "(h) Prohibited Agreements; Nondiscrimina-6 tion.—

"(1) PROHIBITED AGREEMENTS.—No manufacturer of a covered product may enter into a contract
or agreement that includes a provision to prevent
the sale or distribution of covered products imported
pursuant to subsection (a).

12 "(2) NONDISCRIMINATION.—No manufacturer 13 of a covered product may take actions that discrimi-14 nate against, or cause other persons to discriminate 15 against, United States pharmacists, wholesalers, or 16 consumers regarding the sale or distribution of cov-17 ered products.

18 "(i) Study and Report.—

"(1) STUDY.—The Comptroller General of the
United States shall conduct a study on the imports
permitted under this section, taking into consideration the information received under subsection (a).
In conducting such study, the Comptroller General
shall—

1 "(A) evaluate importers' compliance with 2 regulations, determine the number of shipments, if any, permitted under this section that 3 4 have been determined to be counterfeit, mis-5 branded, or adulterated; and "(B) consult with the United States Trade 6 7 Representative and United States Patent and 8 Trademark Office to evaluate the effect of im-9 portations permitted under this section on trade 10 and patent rights under Federal law. 11 "(2) REPORT.—Not later than 5 years after the 12 effective date of final regulations issued pursuant to 13 this section, the Comptroller General of the United 14 States shall prepare and submit to Congress a re-15 port containing the study described in paragraph (1).";16 17 (3) in subsection (k)(2)— 18 (A) by redesignating subparagraphs (A) 19 through (E) as subparagraphs (B) through (F), 20 respectively; and 21 (B) by inserting before subparagraph (B) 22 (as so redesignated) the following subpara-23 graph: "(A) The term 'discrimination' includes a 24 25 contract provision, a limitation on supply, or

other measure which has the effect of providing 1 2 United States pharmacists, wholesalers, or con-3 sumers access to covered products on terms or conditions that are less favorable than the 4 5 terms or conditions provided to any foreign purchaser of such products."; 6 7 (4) by striking subsection (m); and (5) by inserting after subsection (1) the fol-8 9 lowing subsection:

"(m) FUNDING.—For the purpose of carrying out
this section, there are authorized to be appropriated such
sums as may be necessary for fiscal year 2002 and each
subsequent fiscal year.".

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