

107TH CONGRESS
1ST SESSION

H. R. 339

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs under part B of the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2001

Mr. ENGEL (for himself, Mr. FROST, Mr. HILLIARD, Mr. WEINER, Mr. NADLER, and Mr. McNULTY) 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 title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs under part B of the Medicare Program, and for other purposes.

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.**

4 This Act may be cited as the “Medicare Outpatient
5 Prescription Drug Coverage Act of 2001”.

1 **SEC. 2. MEDICARE COVERAGE OF OUTPATIENT PRESCRIP-**
2 **TION DRUGS.**

3 (a) DESCRIPTION OF COVERED OUTPATIENT
4 DRUGS.—

5 (1) COVERAGE.—Section 1861(s)(2)(J) of the
6 Social Security Act (42 U.S.C. 1395x(s)(2)(J)) is
7 amended to read as follows:

8 “(J) covered outpatient drugs (as defined in
9 subsection (t)(2));”.

10 (2) DRUGS DEFINED.—Section 1861(t) of such
11 Act (42 U.S.C. 1395x(t)) is amended—

12 (A) in the heading, by adding at the end
13 the following: “; Covered Outpatient Drugs”;

14 (B) in paragraph (1)—

15 (i) by striking “paragraph (2)” and
16 inserting “the succeeding paragraphs of
17 this subsection”, and

18 (ii) by striking the period at the end
19 and inserting “, but only if used for a
20 medically accepted indication (as described
21 in paragraph (4)).”; and

22 (C) by striking paragraph (2) and insert-
23 ing the following:

24 “(2) Subject to paragraph (3), the term ‘covered out-
25 patient drug’ means—

1 “(A) a drug which may be dispensed only upon
2 prescription and—

3 “(i) which is approved for safety and effec-
4 tiveness as a prescription drug under section
5 505 or 507 of the Federal Food, Drug, and
6 Cosmetic Act or which is approved under sec-
7 tion 505(j) of such Act;

8 “(ii)(I) which was commercially used or
9 sold in the United States before the date of the
10 enactment of the Drug Amendments of 1962 or
11 which is identical, similar, or related (within the
12 meaning of section 310.6(b)(1) of title 21 of the
13 Code of Federal Regulations) to such a drug,
14 and (II) which has not been the subject of a
15 final determination by the Secretary that it is
16 a ‘new drug’ (within the meaning of section
17 201(p) of the Federal Food, Drug, and Cos-
18 metic Act) or an action brought by the Sec-
19 retary under section 301, 302(a), or 304(a) of
20 such Act to enforce section 502(f) or 505(a) of
21 such Act; or

22 “(iii)(I) which is described in section
23 107(c)(3) of the Drug Amendments of 1962
24 and for which the Secretary has determined
25 there is a compelling justification for its med-

1 ical need, or is identical, similar, or related
2 (within the meaning of section 310.6(b)(1) of
3 title 21 of the Code of Federal Regulations) to
4 such a drug, and (II) for which the Secretary
5 has not issued a notice of an opportunity for a
6 hearing under section 505(e) of the Federal
7 Food, Drug, and Cosmetic Act on a proposed
8 order of the Secretary to withdraw approval of
9 an application for such drug under such section
10 because the Secretary has determined that the
11 drug is less than effective for all conditions of
12 use prescribed, recommended, or suggested in
13 its labeling;

14 “(B) a biological product which—

15 “(i) may only be dispensed upon prescrip-
16 tion,

17 “(ii) is licensed under section 351 of the
18 Public Health Service Act, and

19 “(iii) is produced at an establishment li-
20 censed under such section to produce such
21 product; and

22 “(C) insulin certified under section 506 of the
23 Federal Food, Drug, and Cosmetic Act.

24 “(3) The term ‘covered outpatient drug’ does not in-
25 clude—

1 “(A) any drug, biological product, or insulin
 2 when furnished as part of, or as incident to, a diag-
 3 nostic service or any other item or service for which
 4 payment may be made under this title (other than
 5 physicians’ services or services which would be physi-
 6 cians’ services if furnished by a physician); or

7 “(B) any drug that is intravenously adminis-
 8 tered in a home setting.

9 “(4) For purposes of paragraph (2), the term ‘medi-
 10 cally accepted indication’, with respect to the use of an
 11 outpatient drug, includes—

12 “(A) any use which has been approved by the
 13 Food and Drug Administration for the drug, and

14 “(B) any other use of the drug, unless the Sec-
 15 retary determines that such use is not medically ap-
 16 propriate.”.

17 (3) CONFORMING AMENDMENTS REPEALING
 18 SEPARATE COVERAGE OF CERTAIN DRUGS AND
 19 PRODUCTS.—(A) Effective January 1, 2003, section
 20 1861(s)(2) of such Act (42 U.S.C. 1395x(s)(2)) is
 21 amended—

22 (i) in each of subparagraphs (A) and (B)
 23 (as amended by section 112(a) of the Medicare,
 24 Medicaid, and SCHIP Benefits Improvement
 25 and Protection Act of 2000, as enacted into law

1 by section 1(a)(6) of Public Law 106–554), by
 2 striking “(including drugs” and all that follows
 3 through “patient)”; and

4 (ii) by striking subparagraphs (G), (I),
 5 (O), (Q), and (T).

6 (B) Effective January 1, 2003, section 1861 of
 7 such Act (42 U.S.C. 1395x) is amended by striking
 8 the subsection (kk).

9 (C) Effective January 1, 2003, section 1881(b)
 10 of such Act (42 U.S.C. 1395rr(b)) is amended—

11 (i) in the first sentence of paragraph (1)—

12 (I) by striking “, (B)” and inserting
 13 “and (B)”; and

14 (II) by striking “, and (C)” and all
 15 that follows and inserting a period; and

16 (ii) in paragraph (11)—

17 (I) by striking “(11)(A)” and insert-
 18 ing “(11)”; and

19 (II) by striking subparagraphs (B)
 20 and (C).

21 (b) DEDUCTIBLE AND PAYMENT AMOUNTS.—(1)
 22 Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)),
 23 as amended by sections 105(c) and 223(c) of the Medi-
 24 care, Medicaid, and SCHIP Benefits Improvement and

1 Protection Act of 2000, as enacted into law by section
2 1(a)(6) of Public Law 106–554, is amended—

3 (A) by striking “and (U)” and inserting “(U)”;
4 and

5 (B) by striking the semicolon at the end and in-
6 serting the following “, and (V) with respect to ex-
7 penses incurred for covered outpatient drugs, the
8 amounts paid shall be the amounts determined
9 under section 1834(e)(2);”.

10 (2) Section 1833(a)(2) of such Act (42 U.S.C.
11 1395l(a)(2)) is amended—

12 (A) by inserting “(other than covered out-
13 patient drugs)” after “(2) in the case of services”;
14 and

15 (B) by striking “(other than a covered
16 osteoporosis drug) (as defined in section 1861(kk))”.

17 (3) Section 1833(b) of such Act (42 U.S.C. 1395l(b))
18 is amended—

19 (A) in clause (1), by inserting “or for covered
20 outpatient drugs” after “1861(s)(10)(A)”, and

21 (B) in clause (2), by striking “ (other than a
22 covered osteoporosis drug (as defined in section
23 1861(kk)))”.

1 (4) Section 1834 of such Act (42 U.S.C. 1395m) is
2 amended by inserting after subsection (d) the following
3 new subsection:

4 “(e) PAYMENT FOR COVERED OUTPATIENT
5 DRUGS.—

6 “(1) DEDUCTIBLE.—

7 “(A) APPLICATION.—

8 “(i) IN GENERAL.—Except as pro-
9 vided in clauses (ii) and (iii), payment
10 shall be made under paragraph (2) only
11 with respect to expenses incurred by an in-
12 dividual for covered outpatient drugs dur-
13 ing a calendar year on or after such date
14 in the year as the Secretary determines
15 that the individual has incurred expenses
16 in the year for covered outpatient drugs
17 (during a period in which the individual is
18 entitled to benefits under this part) equal
19 to the amount of the prescription drug de-
20 ductible specified in subparagraph (C) for
21 that year.

22 “(ii) DEDUCTIBLE NOT APPLIED TO
23 1ST YEAR IMMUNOSUPPRESSIVES.—The
24 prescription drug deductible established
25 under this paragraph shall not apply to

1 drugs described in section 1861(t)(2)(A)
2 used in immunosuppressive therapy and
3 furnished, to an individual who receives an
4 organ transplant for which payment is
5 made under this title, within 1 year after
6 the date of the transplant.

7 “(B) RESPONSE TO APPLICATION.—If the
8 system described in section 1842(u)(4) has not
9 been established and an individual applies to
10 the Secretary to establish that the individual
11 has met the requirement of subparagraph (A),
12 the Secretary shall promptly notify the indi-
13 vidual (and, if the application was submitted by
14 or through a participating pharmacy, the phar-
15 macy) as to the date (if any) as of which the
16 individual has met such requirement.

17 “(C) PRESCRIPTION DRUG DEDUCTIBLE
18 AMOUNT.—The prescription drug deductible
19 specified in this subparagraph for—

20 “(i) 2003 is \$250, and

21 “(ii) any succeeding year, is the pre-
22 scription drug deductible for the preceding
23 year, increased by the percentage by which
24 the monthly premium under section 1839
25 for months during the year exceeds the

1 monthly premium under such section for
2 months during the preceding year.

3 “(2) PAYMENT AMOUNT.—

4 “(A) IN GENERAL.—Subject to the pre-
5 scription drug deductible established under
6 paragraph (1)(A) and except as provided in
7 subparagraph (B), the amounts payable under
8 this part with respect to a covered outpatient
9 drug is equal to 80 percent of the lesser of—

10 “(i) the actual charge for the drug, or

11 “(ii) the applicable payment limit es-
12 tablished under paragraph (3).

13 “(B) TREATMENT OF CERTAIN COST-
14 BASED PREPAID ORGANIZATIONS.—In applying
15 subparagraph (A) in the case of a
16 Medicare+Choice organization under part C, an
17 organization under a reasonable cost reimburse-
18 ment contract under section 1876, and in the
19 case of an organization receiving payment
20 under section 1833(a)(1)(A) and providing cov-
21 erage of covered outpatient drugs, the Secretary
22 shall provide for an appropriate adjustment in
23 the payment amounts otherwise made to reflect
24 the aggregate increase in payments that would
25 otherwise be made with respect to enrollees in

1 such an organization if payments were made
2 other than under such clause or such a contract
3 on an individual-by-individual basis.

4 “(3) PAYMENT LIMITS.—

5 “(A) PAYMENT LIMIT FOR NON-MULTIPLE
6 SOURCE DRUGS AND MULTIPLE-SOURCE DRUGS
7 WITH RESTRICTIVE PRESCRIPTIONS.—In the
8 case of a drug that either is not a multiple
9 source drug (as defined in paragraph (9)(A)) or
10 is a multiple source drug and has a restrictive
11 prescription (as defined in paragraph (9)(B)),
12 the payment limit for the drug under this para-
13 graph for a payment calculation period is equal
14 to the lesser of—

15 “(i) the 90th percentile of the actual
16 charges (computed on a statewide basis,
17 carrier-wide basis, or other appropriate ge-
18 ographic area basis, as specified by the
19 Secretary) for the drug for the second pre-
20 vious payment calculation period, adjusted
21 (as the Secretary determines to be appro-
22 priate) to reflect the number of tablets (or
23 other dosage units) dispensed; or

1 “(ii) the amount of the administrative
2 allowance (established under paragraph
3 (4)) plus the product of—

4 “(I) the number of tablets (or
5 other dosage units) dispensed, and

6 “(II) the per tablet or unit aver-
7 age wholesale price for such drug (as
8 determined under subparagraph (C)
9 for the period for purposes of this
10 subparagraph).

11 “(B) PAYMENT LIMIT FOR MULTIPLE
12 SOURCE DRUGS WITHOUT RESTRICTIVE PRE-
13 SCRIPTIONS.—In the case of a drug that is a
14 multiple source drug but does not have a re-
15 strictive prescription, the payment limit for the
16 drug under this paragraph for a payment cal-
17 culation period is equal to the amount of the
18 administrative allowance (established under
19 paragraph (4)) plus the product of—

20 “(i) the number of tablets (or other
21 dosage units) dispensed, and

22 “(ii) the unweighted median of the
23 per tablet or unit average wholesale prices
24 (determined under subparagraph (C) for

1 purposes of this subparagraph) for such
2 drug for the period.

3 “(C) DETERMINATION OF UNIT PRICE.—

4 “(i) IN GENERAL.—For purposes of
5 this paragraph, the Secretary shall deter-
6 mine, with respect to the dispensing of a
7 covered outpatient drug in a payment cal-
8 culation period (beginning on or after Jan-
9 uary 1, 2003), the per tablet or unit aver-
10 age wholesale price for the drug.

11 “(ii) BASIS FOR DETERMINATIONS.—

12 “(I) DETERMINATION FOR NON-
13 MULTIPLE-SOURCE DRUGS.—For pur-
14 poses of subparagraph (A), such de-
15 termination shall be based on a bian-
16 nual survey conducted by the Sec-
17 retary of a representative sample of
18 direct sellers, wholesalers, or phar-
19 macies (as appropriate) of wholesale
20 (or comparable direct) prices (exclud-
21 ing discounts to pharmacies); except
22 that if, because of low volume of sales
23 for the drug or other appropriate rea-
24 sons or in the case of covered out-
25 patient drugs during 2003, the Sec-

1 retary determines that such a survey
2 is not appropriate with respect to a
3 specific drug, such determination shall
4 be based on published average whole-
5 sale (or comparable direct) prices for
6 the drug.

7 “(II) DETERMINATION FOR MUL-
8 TIPLE-SOURCE DRUGS.—For purposes
9 of subparagraph (B), the Secretary
10 may base the determination under
11 this subparagraph on the published
12 average wholesale (or comparable di-
13 rect) prices for the drug or on a bian-
14 nual survey conducted by the Sec-
15 retary of a representative sample of
16 direct sellers, wholesalers, or phar-
17 macists (as appropriate) of wholesale
18 (or comparable direct) prices (exclud-
19 ing discounts to pharmacies).

20 “(III) COMPLIANCE WITH SUR-
21 VEY REQUIRED.—If a wholesaler or
22 direct seller of a covered outpatient
23 drug refuses, after being requested by
24 the Secretary, to provide the informa-
25 tion required in a survey under this

1 clause, or deliberately provides infor-
2 mation that is false, the Secretary
3 may impose a civil money penalty of
4 not to exceed \$10,000 for each such
5 refusal or provision of false informa-
6 tion. The provisions of section 1128A
7 (other than subsections (a) and (b))
8 shall apply to civil money penalties
9 under the previous sentence in the
10 same manner as such provisions apply
11 to a penalty or proceeding under sec-
12 tion 1128A(a). Information gathered
13 pursuant to the survey shall not be
14 disclosed except as the Secretary de-
15 termines to be necessary to carry out
16 the purposes of this part.

17 “(iii) QUANTITY AND TIMING.—Such
18 determination shall be based on the price
19 or prices for purchases in reasonable quan-
20 tities and shall be made for a payment cal-
21 culation period based on prices for the first
22 day of the first month of the previous pay-
23 ment calculation period.

24 “(iv) GEOGRAPHIC BASIS.—The Sec-
25 retary shall make such determination, and

1 calculate the payment limits under this
2 paragraph, on a national basis.

3 “(v) ADJUSTMENT FOR GEOGRAPHIC
4 VARIATIONS IN COSTS.—The Secretary
5 shall adjust the payment limits under this
6 paragraph to take account of limitations
7 on the availability of drug products and
8 variations among regions in the average
9 wholesale prices for a drug product, using
10 an appropriate index as determined by the
11 Secretary.

12 “(4) ADMINISTRATIVE ALLOWANCE FOR PUR-
13 POSES OF PAYMENT LIMITS.—

14 “(A) IN GENERAL.—Except as provided in
15 subparagraph (B), for drugs dispensed in—

16 “(i) 2003, the administrative allow-
17 ance under this paragraph is—

18 “(I) \$5 for drugs dispensed by a
19 participating pharmacy, or

20 “(II) \$3 for drugs dispensed by
21 another pharmacy; or

22 “(ii) a subsequent year, the adminis-
23 trative allowance under this paragraph is
24 the administrative allowance under this
25 paragraph for the preceding year increased

1 by the percentage increase (if any) in the
2 implicit price deflator for gross national
3 product (as published by the Department
4 of Commerce in its ‘Survey of Current
5 Business’) over the 12-month period end-
6 ing with August of such preceding year.

7 Any allowance determined under the clause (ii)
8 which is not a multiple of 1 cent shall be round-
9 ed to the nearest multiple of 1 cent.

10 “(B) ADJUSTMENT IN ALLOWANCE FOR
11 MAIL SERVICE PHARMACIES.—The Secretary
12 may, by regulation and after consultation with
13 pharmacists, elderly groups, and private insur-
14 ers, reduce the administrative allowances estab-
15 lished under subparagraph (A) for any drug
16 dispensed by a mail service pharmacy (as de-
17 fined by the Secretary) based on differences be-
18 tween such pharmacies and other pharmacies
19 with respect to operating costs and other econo-
20 mies.

21 “(5) ASSURING APPROPRIATE PRESCRIBING
22 AND DISPENSING PRACTICES.—

23 “(A) IN GENERAL.—The Secretary shall
24 establish a program to identify (and to educate
25 physicians and pharmacists concerning)—

1 “(i) instances or patterns of unneces-
2 sary or inappropriate prescribing or dis-
3 pensing practices for covered outpatient
4 drugs;

5 “(ii) instances or patterns of sub-
6 standard care with respect to such drugs;
7 and

8 “(iii) potential adverse reactions.

9 “(B) STANDARDS.—In carrying out the
10 program under subparagraph (A), the Secretary
11 shall establish for each covered outpatient drug
12 standards for the prescribing of the drug which
13 are based on accepted medical practice. In es-
14 tablishing such standards, the Secretary shall
15 incorporate standards from such current au-
16 thoritative compendia as the Secretary may se-
17 lect; except that the Secretary may modify such
18 a standard by regulation on the basis of sci-
19 entific and medical information that such
20 standard is not consistent with the safe and ef-
21 fective use of the drug.

22 “(C) PROHIBITION OF FORMULARY.—
23 Nothing in this title (other than section
24 1862(c)) shall be construed as authorizing the

1 Secretary to exclude from coverage or to deny
2 payment—

3 “(i) for any specific covered out-
4 patient drug, or specific class of covered
5 outpatient drug; or

6 “(ii) for any specific use of such a
7 drug for a specific indication unless such
8 exclusion is pursuant to section 1862(a)(1)
9 based on a finding by the Secretary that
10 such use is not safe or is not effective.

11 “(6) TREATMENT OF CERTAIN PREPAID ORGA-
12 NIZATIONS.—

13 “(A) GENERAL RULE COUNTING PREPAID
14 PLAN EXPENSES TOWARD THE PRESCRIPTION
15 DRUG DEDUCTIBLE.—Except as provided in
16 subparagraph (B), expenses incurred by (or on
17 behalf of) a medicare beneficiary for covered
18 outpatient drugs shall be counted (consistent
19 with subparagraph (C)) toward the prescription
20 drug deductible established under paragraph
21 (1) whether or not, at the time the expenses
22 were incurred, the beneficiary was enrolled in a
23 plan under section 1833(a)(1)(A), a
24 Medicare+Choice plan under part C, or under
25 section 1876.

1 “(B) TREATMENT OF DRUG BUY-OUT PLAN
2 EXPENSES.—In the case of a medicare bene-
3 ficiary enrolled in a month in a drug buy-out
4 plan (as defined in subparagraph (D))—

5 “(i) expenses incurred by the bene-
6 ficiary for covered outpatient drugs reim-
7 bursed under the plan shall not be counted
8 toward the prescription drug deductible,
9 but

10 “(ii) if the individual disenrolls from
11 the plan during the year, the beneficiary is
12 deemed to have incurred, for each month
13 of such enrollment, expenses for covered
14 outpatient drugs in an amount equal to the
15 actuarial value (with respect to such
16 month) of the deductible for covered out-
17 patient drugs (as computed by the Sec-
18 retary for purposes of section 1876(e)(1))
19 applicable on the average to individuals in
20 the United States.

21 “(C) TREATMENT OF EXPENSES FOR COV-
22 ERED OUTPATIENT DRUGS INCURRED WHILE
23 ENROLLED IN A PREPAID PLAN OTHER THAN A
24 DRUG BUY-OUT PLAN.—The Secretary may not
25 enter into a contract with a Medicare+Choice

1 organization under part C, an organization
2 under section 1876, or provide for payment
3 under section 1833(a)(1)(A) with respect to an
4 organization which provides reimbursement for
5 covered outpatient drugs, with respect to a plan
6 that is not a drug buy-out plan, unless the or-
7 ganization provides assurances, satisfactory to
8 the Secretary, that—

9 “(i) the organization will maintain
10 and make available, for its enrollees and in
11 coordination with the appropriate carriers
12 under this part, an accounting of expenses
13 incurred by (or on behalf of) enrollees
14 under the plan for covered outpatient
15 drugs; and

16 “(ii) the organization will take into
17 account, in any deductibles established
18 under the plan in a year with respect to
19 covered outpatient drugs under this part,
20 the amounts of expenses for covered out-
21 patient drugs incurred in the year by (or
22 on behalf of) the beneficiary and otherwise
23 counted toward the prescription drug de-
24 ductible in the year.

1 “(D) DRUG BUY-OUT PLAN DEFINED.—In
2 this paragraph, the term ‘drug buy-out plan’
3 means a plan under section 1833(a)(1)(A) or
4 offered by a Medicare+Choice organization
5 under part C, or an organization under section
6 1876 and with respect to which—

7 “(i) the amount of any deductible
8 under the plan with respect to covered out-
9 patient drugs under this title,
10 is less than 50 percent of—

11 “(ii) the prescription drug deductible
12 specified in paragraph (1)(C).

13 “(E) MEDICARE BENEFICIARY DEFINED.—
14 In this subsection, the term ‘Medicare bene-
15 ficiary’ means, with respect to a month, an in-
16 dividual covered for benefits under this part for
17 the month.

18 “(F) TREATMENT OF PLAN CHARGES.—In
19 the case of covered outpatient drugs furnished
20 by a Medicare+Choice organization under part
21 C, an eligible organization under section
22 1876(b) or an organization described in section
23 1833(a)(1)(A) which does not impose charges
24 on covered outpatient drugs dispensed to its
25 members, for purposes of this subsection the

1 actual charges of the organization shall be the
2 organization's standard charges to members,
3 and other individuals, not entitled to benefits
4 with respect to such drugs.

5 “(7) PHYSICIAN GUIDE.—

6 “(A) IN GENERAL.—The Secretary shall
7 develop, and update annually, an information
8 guide for physicians concerning the comparative
9 average wholesale prices of at least 500 of the
10 most commonly prescribed covered outpatient
11 drugs. Such guide shall, to the extent prac-
12 ticable, group covered outpatient drugs (includ-
13 ing multiple source drugs) in a manner useful
14 to physicians by therapeutic category or with
15 respect to the conditions for which they are pre-
16 scribed. Such guide shall specify the average
17 wholesale prices on the basis of the amount of
18 the drug required for a typical daily therapeutic
19 regimen.

20 “(B) MAILING GUIDE.—The Secretary
21 shall provide for mailing, in January of each
22 year (beginning with 2003), a copy of the guide
23 developed and updated under subparagraph
24 (A)—

1 “(i) to each hospital with an agree-
2 ment in effect under section 1866;

3 “(ii) to each physician (as defined in
4 section 1861(r)(1)) who routinely provides
5 services under this part; and

6 “(iii) to Social Security offices, senior
7 citizen centers, and other appropriate
8 places.

9 “(8) REPORTS ON UTILIZATION AND EFFECTS
10 ON PRICES.—

11 “(A) COMPILATION OF INFORMATION.—
12 The Secretary shall compile information on—

13 “(i) manufacturers’ prices for covered
14 outpatient drugs, and on charges of phar-
15 macists for covered outpatient drugs, and

16 “(ii) the use of covered outpatient
17 drugs by individuals entitled to benefits
18 under this part.

19 The information compiled under clause (i) shall
20 include a comparison of the increases in prices
21 and charges for covered outpatient drugs dur-
22 ing each 6 month period (beginning with Janu-
23 ary 1999) with the semiannual average increase
24 in such prices and charges during the 5 years
25 beginning with 1993.

1 “(B) REPORTS.—The Secretary shall sub-
2 mit to the Committees on Ways and Means and
3 Commerce of the House of Representatives and
4 the Committee on Finance of the Senate a re-
5 port, in May and November of 2002 and 2003
6 and in May of each succeeding year, providing
7 the information compiled under subparagraph
8 (A). For each such report submitted after
9 2004, the report shall include an explanation of
10 the extent to which the increases in outlays for
11 covered outpatient drugs under this part are
12 due to the factors described in subparagraphs
13 (A)(i) and (A)(ii).

14 “(9) DEFINITIONS.—In this subsection:

15 “(A) MULTIPLE SOURCE DRUG.—

16 “(i) IN GENERAL.—The term ‘mul-
17 tiple source drug’ means, with respect to a
18 payment calculation period, a covered out-
19 patient drug for which there are 2 or more
20 drug products which—

21 “(I) are rated as therapeutically
22 equivalent (under the Food and Drug
23 Administration’s most recent publica-
24 tion of ‘Approved Drug Products with

1 Therapeutic Equivalence Evalua-
2 tions’);

3 “(II) except as provided in clause
4 (ii), are pharmaceutically equivalent
5 and bioequivalent, as defined in clause
6 (iii) and as determined by the Food
7 and Drug Administration; and

8 “(III) are sold or marketed dur-
9 ing the period.

10 “(ii) EXCEPTION.—Subclause (II) of
11 clause (i) shall not apply if the Food and
12 Drug Administration changes by regulation
13 (after an opportunity for public comment
14 of 90 days) the requirement that, for pur-
15 poses of the publication described in clause
16 (i)(I), in order for drug products to be
17 rated as therapeutically equivalent, they
18 must be pharmaceutically equivalent and
19 bioequivalent, as defined in clause (iii).

20 “(iii) DEFINITIONS.—For purposes of
21 this subparagraph:

22 “(I) PHARMACEUTICALLY EQUIV-
23 ALENT.—Drug products are pharma-
24 ceutically equivalent if the products
25 contain identical amounts of the same

1 active drug ingredient in the same
2 dosage form and meet compendial or
3 other applicable standards of strength,
4 quality, purity, and identity.

5 “(II) BIOEQUIVALENT.—Drugs
6 are bioequivalent if they do not
7 present a known or potential bio-
8 equivalence problem or, if they do
9 present such a problem, are shown to
10 meet an appropriate standard of bio-
11 equivalence.

12 “(III) SOLD OR MARKETED.—A
13 drug is considered to be sold or mar-
14 keted during a period if it is listed in
15 the publications referred to in clause
16 (i)(I), unless the Secretary determines
17 that such sale or marketing is not ac-
18 tually taking place.

19 “(B) RESTRICTIVE PRESCRIPTION.—A
20 drug has a ‘restrictive prescription’ only if—

21 “(i) in the case of a written prescrip-
22 tion, the prescription for the drug indi-
23 cates, in the handwriting of the physician
24 or other person prescribing the drug and
25 with an appropriate phrase (such as ‘brand

1 medically necessary') recognized by the
2 Secretary, that the particular drug must be
3 dispensed; or

4 “(ii) in the case of a prescription
5 issued by telephone—

6 “(I) the physician or other per-
7 son prescribing the drug (through use
8 of such an appropriate phrase) states
9 that the particular drug must be dis-
10 pensed, and

11 “(II) the physician or other per-
12 son submits to the pharmacy involved,
13 within 30 days after the date of the
14 telephone prescription, a written con-
15 firmation which is in the handwriting
16 of the physician or other person pre-
17 scribing the drug and which indicates
18 with such appropriate phrase that the
19 particular drug was required to have
20 been dispensed.

21 “(C) PAYMENT CALCULATION PERIOD.—

22 The term ‘payment calculation period’ means
23 the 6-month period beginning with January of
24 each year and the 6-month period beginning
25 with July of each year.’’.

1 (c) PARTICIPATING PHARMACIES; CIVIL MONEY
2 PENALTIES.—

3 (1) PARTICIPATING PHARMACIES.—Section
4 1842 of such Act (42 U.S.C. 1395t) is amended—

5 (A) in subsection (h)(1), by inserting be-
6 fore the period at the end of the second sen-
7 tence the following: “, except that, with respect
8 to a supplier of covered outpatient drugs, the
9 term ‘participating supplier’ means a partici-
10 pating pharmacy (as defined in subsection
11 (u)(1))”;

12 (B) in subsection (h)(4), by adding at the
13 end the following: “In publishing directories
14 under this paragraph, the Secretary shall pro-
15 vide for separate directories (wherever appro-
16 priate) for participating pharmacies.”; and

17 (C) by inserting after subsection (t) the
18 following new subsection:

19 “(u)(1) For purposes of this section, the term ‘par-
20 ticipating pharmacy’ means, with respect to covered out-
21 patient drugs dispensed on or after January 1, 2003, an
22 entity which is authorized under a State law to dispense
23 covered outpatient drugs and which has entered into an
24 agreement with the Secretary, providing at least the fol-
25 lowing:

1 “(A) The entity agrees to accept payment under
2 this part on an assignment-related basis for all cov-
3 ered outpatient drugs dispensed to an individual en-
4 titled to benefits under this part (in this subsection
5 referred to as a ‘Medicare beneficiary’) during a
6 year after—

7 “(i) the Secretary has notified the entity,
8 through the electronic system described in para-
9 graph (4); or

10 “(ii) in the absence of such a system, the
11 entity is otherwise notified that the Secretary
12 has determined,
13 that the individual has met the prescription drug de-
14 ductible with respect to such drugs under section
15 1834(e)(1) for the year.

16 “(B) The entity agrees—

17 “(i) not to refuse to dispense covered out-
18 patient drugs stocked by the entity to any medi-
19 care beneficiary; and

20 “(ii) not to charge Medicare beneficiaries
21 (regardless of whether or not the beneficiaries
22 are enrolled under a prepaid health plan, a
23 Medicare+Choice organization under part C, or
24 with eligible organization under section 1876)
25 more for such drugs than the amount it charges

1 to the general public (as determined by the Sec-
2 retary in regulations).

3 “(C) The entity agrees to keep patient records
4 (including records on expenses) for all covered out-
5 patient drugs dispensed to all medicare beneficiaries.

6 “(D) The entity agrees to submit information
7 (in a manner specified by the Secretary to be nec-
8 essary to administer this title) on all purchases of
9 covered outpatient drugs dispensed to medicare
10 beneficiaries.

11 “(E) The entity agrees—

12 “(i) to offer to counsel, or to offer to pro-
13 vide information (consistent with State law re-
14 specting the provision of such information) to,
15 each Medicare beneficiary on the appropriate
16 use of a drug to be dispensed and whether there
17 are potential interactions between the drug and
18 other drugs dispensed to the beneficiary; and

19 “(ii) to advise the beneficiary on the avail-
20 ability (consistent with State laws respecting
21 substitution of drugs) of therapeutically equiva-
22 lent covered outpatient drugs.

23 “(F) The entity agrees to provide the informa-
24 tion requested by the Secretary in surveys under sec-
25 tion 1834(e)(3)(C)(ii).

1 Nothing in this paragraph shall be construed as requiring
2 a pharmacy operated by a Medicare+Choice organization
3 under part C, an eligible organization (described in section
4 1876(b)) or an organization described in section
5 1833(a)(1)(A) for the exclusive benefit of its members to
6 dispense covered outpatient drugs to individuals who are
7 not members of the organization.

8 “(2) The Secretary shall provide to each participating
9 pharmacy—

10 “(A) a distinctive emblem (suitable for display
11 to the public) indicating that the pharmacy is a par-
12 ticipating pharmacy; and

13 “(B) upon request, such electronic equipment
14 and technical assistance (other than the costs of ob-
15 taining, maintaining, or expanding telephone service)
16 as the Secretary determines may be necessary for
17 the pharmacy to submit claims using the electronic
18 system established under paragraph (4).

19 “(3) The Secretary shall provide for periodic audits
20 of participating pharmacies to assure—

21 “(A) compliance with the requirements for par-
22 ticipation under this title; and

23 “(B) the accuracy of information submitted by
24 the pharmacies under this title.

1 “(4) The Secretary shall establish, by not later than
 2 January 1, 2003, a point-of-sale electronic system for use
 3 by carriers and participating pharmacies in the submission
 4 of information respecting covered outpatient drugs dis-
 5 pensed to medicare beneficiaries under this part.

6 “(5) Notwithstanding subsection (b)(3)(B), payment
 7 for covered outpatient drugs may be made on the basis
 8 of an assignment described in clause (ii) of that subsection
 9 only to a participating pharmacy.”.

10 (2) CIVIL MONEY PENALTIES FOR VIOLATION
 11 OF PARTICIPATION AGREEMENT, FOR EXCESSIVE
 12 CHARGES FOR NONPARTICIPATING PHARMACIES AND
 13 FOR FAILURE TO PROVIDE SURVEY INFORMATION.—
 14 Section 1128A(a) of such Act (42 U.S.C. 1320a-
 15 7a(a)) is amended—

16 (A) in paragraph (2)(C), by inserting “or
 17 to be a participating pharmacy under section
 18 1842(u)” after “1842(h)(1)”;

19 (B) by striking “, or” at the end of para-
 20 graph (6);

21 (C) by adding “or” at the end of para-
 22 graph (7); and

23 (D) by inserting after paragraph (7) the
 24 following new paragraph:

1 “(8) in the case of a participating or non-
 2 participating pharmacy (as defined for purposes of
 3 part B of title XVIII)—

4 “(A) presents or causes to be presented to
 5 any person a request for payment for covered
 6 outpatient drugs dispensed to an individual en-
 7 titled to benefits under part B of title XVIII
 8 and for which the amount charged by the phar-
 9 macy is greater than the amount the pharmacy
 10 charges the general public (as determined by
 11 the Secretary in regulations), or

12 “(B) fails to provide the information re-
 13 quested by the Secretary in a survey under sec-
 14 tion 1834(e)(3)(C)(ii);”.

15 (d) LIMITATION ON LENGTH OF PRESCRIPTION.—
 16 Section 1862(c) of such Act (42 U.S.C. 1395y(c)) is
 17 amended—

18 (1) by redesignating subparagraphs (A) through
 19 (D) of paragraph (1) as clauses (i) through (iv) re-
 20 spectively;

21 (2) in paragraph (2)(A), by striking “paragraph
 22 (1)” and inserting “subparagraph (A)”;

23 (3) by redesignating subparagraphs (A) and
 24 (B) of paragraph (2) as clauses (i) and (ii) respec-
 25 tively;

1 (4) by redesignating paragraphs (1) and (2) as
2 subparagraphs (A) and (B) respectively;

3 (5) by inserting “(1)” after “(c)”; and

4 (6) by adding at the end the following new
5 paragraph:

6 “(2) No payment may be made under part B for any
7 expense incurred for a covered outpatient drug if the drug
8 is dispensed in a quantity exceeding a supply of 30 days
9 or such longer period of time (not to exceed 90 days, ex-
10 cept in exceptional circumstances) as the Secretary may
11 authorize.”.

12 (e) USE OF CARRIERS, FISCAL INTERMEDIARIES,
13 AND OTHER ENTITIES IN ADMINISTRATION.—

14 (1) AUTHORIZING USE OF OTHER ENTITIES IN
15 ELECTRONIC CLAIMS SYSTEM.—Section 1842(f) of
16 such Act (42 U.S.C. 1395u(f)) is amended—

17 (A) by striking “and” at the end of para-
18 graph (1);

19 (B) by striking the period at the end of
20 paragraph (2) and inserting “; and”; and

21 (C) by adding at the end the following new
22 paragraph:

23 “(3) with respect to implementation and oper-
24 ation (and related functions) of the electronic system
25 established under subsection (u)(4), a voluntary as-

1 society, corporation, partnership, or other non-
2 governmental organization, which the Secretary de-
3 termines to be qualified to conduct such activities.”.

4 (2) ADDITIONAL FUNCTIONS OF CARRIERS.—
5 Section 1842(b)(3) of such Act (42 U.S.C.
6 1395u(b)(3)) is amended—

7 (A) by striking “and” at the end of sub-
8 paragraph (I);

9 (B) by redesignating subparagraph (L) as
10 subparagraph (J); and

11 (C) by inserting after subparagraph (J)
12 (as so redesignated) the following new subpara-
13 graphs:

14 “(K) if it makes determinations or payments
15 with respect to covered outpatient drugs, will—

16 “(i) receive information transmitted under
17 the electronic system established under sub-
18 section (u)(4), and

19 “(ii) respond to requests by participating
20 pharmacies (and individuals entitled to benefits
21 under this part) as to whether or not such an
22 individual has met the prescription drug de-
23 ductible established under section
24 1834(e)(1)(A) for a year; and

1 “(L) will enter into such contracts with organi-
 2 zations described in subsection (f)(3) as the Sec-
 3 retary determines may be necessary to implement
 4 and operate (and for related functions with respect
 5 to) the electronic system established under sub-
 6 section (u)(4) for covered outpatient drugs under
 7 this part.”.

8 (3) SPECIAL CONTRACT PROVISIONS FOR ELEC-
 9 TRONIC CLAIMS SYSTEM.—

10 (A) PAYMENT ON OTHER THAN A COST
 11 BASIS.—Section 1842(c)(1) of such Act (42
 12 U.S.C. 1395u(c)(1)) is amended—

13 (i) by inserting “(A)” after “(c)(1)”;

14 (ii) in the first sentence, by inserting

15 “, except as provided in subparagraph

16 (B),” after “under this part, and”; and

17 (iii) by adding at the end the fol-

18 lowing new subparagraph:

19 “(B) To the extent that a contract under this section
 20 provides for implementation and operation (and related
 21 functions) of the electronic system established under sub-
 22 section (u)(4) for covered outpatient drugs, the Secretary
 23 may provide for payment for such activities based on any
 24 method of payment determined by the Secretary to be ap-
 25 propriate.”.

1 (B) APPLICATION OF DIFFERENT PER-
2 FORMANCE STANDARDS.—The Secretary of
3 Health and Human Services, before entering
4 into contracts under section 1842 of the Social
5 Security Act with respect to the implementation
6 and operation (and related functions) of the
7 electronic system for covered outpatient drugs,
8 shall establish standards with respect to per-
9 formance with respect to such activities. The
10 provisions of subsections (e)(2), (h)(1), and
11 (h)(2) of section 1153 of such Act (42 U.S.C.
12 1320c–2) shall apply to such activities in the
13 same manner as they apply to contracts with
14 peer review organizations, instead of the re-
15 quirements of the second and third sentences of
16 section 1842(b)(2)(A) of such Act (42 U.S.C.
17 1395u(b)(2)(A)).

18 (C) USE OF REGIONAL CARRIERS.—Section
19 1842(b)(2)(A) of such Act (42 U.S.C.
20 1395u(b)(2)(A)) is amended by adding at the
21 end the following new sentence: “With respect
22 to activities relating to implementation and op-
23 eration (and related functions) of the electronic
24 system established under subsection (u)(4), the
25 Secretary may enter into contracts with carriers

1 under this section to perform such activities on
 2 a regional basis.”.

3 (4) DELAY IN APPLICATION OF COORDINATED
 4 BENEFITS WITH MEDIGAP.—The provisions of sub-
 5 paragraph (B) of section 1842(h)(3) of the Social
 6 Security Act (42 U.S.C. 1395u(h)(3)) shall not
 7 apply to covered outpatient drugs (other than drugs
 8 described in section 1861(s)(2)(J) of such Act (42
 9 U.S.C. 1395x(s)(2)(J)) as of the date of the enact-
 10 ment of this Act) dispensed before January 1, 2004.

11 (5) BATCH PROMPT PROCESSING OF CLAIMS.—
 12 Section 1842(c) of such Act (42 U.S.C. 1395u(c)),
 13 is amended—

14 (A) by redesignating paragraph (6) as
 15 paragraph (7);

16 (B) in paragraphs (2)(A) and (3)(A), by
 17 striking “Each” and inserting “Except as pro-
 18 vided in paragraph (6), each”; and

19 (C) by inserting after paragraph (5) the
 20 following new paragraph:

21 “(6)(A) Each contract under this section which pro-
 22 vides for the disbursement of funds, as described in sub-
 23 section (a)(1)(B), with respect to claims for payment for
 24 covered outpatient drugs shall provide for a payment cycle
 25 under which each carrier will, on a monthly basis, make

1 a payment with respect to all claims which were received
 2 and approved for payment in the period since the most
 3 recent date on which such a payment was made with re-
 4 spect to the participating pharmacy or individual submit-
 5 ting the claim.

6 “(B) If payment is not issued, mailed, or otherwise
 7 transmitted within 5 days of when such a payment is re-
 8 quired to be made under subparagraph (A), interest shall
 9 be paid at the rate used for purposes of section 3902(a)
 10 of title 31, United States Code (relating to interest pen-
 11 alties for failure to make prompt payments) for the period
 12 beginning on the day after such 5-day period and ending
 13 on the date on which payment is made.”.

14 (f) MODIFICATION OF HMO/CMP CONTRACTS.—

15 (1) SEPARATE ACTUARIAL DETERMINATION
 16 FOR COVERED OUTPATIENT DRUG BENEFIT.—Sec-
 17 tion 1876(e)(1) of such Act (42 U.S.C.
 18 1395mm(e)(1)) is amended by adding at the end
 19 thereof the following new sentence: “The preceding
 20 sentence shall be applied separately with respect to
 21 covered outpatient drugs.”.

22 (2) ADDITIONAL OPTIONAL BENEFITS.—Section
 23 1876(g)(3)(A) of such Act (42 U.S.C.
 24 1395mm(g)(3)(A)) is amended by striking “rate”
 25 and inserting “rates”.

1 (g) CONFORMING AMENDMENTS.—

2 (1) The first sentence of section 1866(a)(2)(A)
3 (42 U.S.C. 1395cc(a)(2)(A)) is amended—

4 (A) by inserting “1834(e),” after
5 “1833(b),”; and

6 (B) by inserting “and in the case of cov-
7 ered outpatient drugs, applicable coinsurance
8 percent (specified in section 1834(e)(2)(C)) of
9 the lesser of the actual charges for the drugs or
10 the payment limit (established under section
11 1834(d)(3))” after “established by the Sec-
12 retary”).

13 (2) Section 1903(i)(5) (42 U.S.C. 1396b(i)(5))
14 is amended by striking “section 1862(c)” and insert-
15 ing “section 1862(c)(1)”.

16 (h) PRESCRIPTION DRUG PAYMENT REVIEW COM-
17 MISSION.—Part B is amended by adding at the end the
18 following new section:

19 “PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION
20 “SEC. 1849. (a)(1) The Director of the Congressional
21 Office of Technology Assessment (in this section referred
22 to as the ‘Director’ and the ‘Office’, respectively) shall
23 provide for the appointment of a Prescription Drug Pay-
24 ment Review Commission (in this section referred to as
25 the ‘Commission’), to be composed of individuals with ex-
26 pertise in the provision and financing of covered out-

1 patient drugs appointed by the Director (without regard
2 to the provisions of title 5, United States Code, governing
3 appointments in the competitive service).

4 “(2) The Commission shall consist of 11 individuals.
5 Members of the Commission shall first be appointed by
6 no later than January 1, 2002, for a term of 3 years, ex-
7 cept that the Director may provide initially for such short-
8 er terms as will ensure that (on a continuing basis) the
9 terms of no more than 4 members expire in any one year.

10 “(3) The membership of the Commission shall in-
11 clude recognized experts in the fields of health care eco-
12 nomics, medicine, pharmacology, pharmacy, and prescrip-
13 tion drug reimbursement, as well as at least one individual
14 who is a medicare beneficiary.

15 “(b)(1) The Commission shall submit to Congress an
16 annual report no later than May 1 of each year, beginning
17 with 2003, concerning methods of determining payment
18 for covered outpatient drugs under this part.

19 “(2) Such report, in 2004 and thereafter, shall in-
20 clude, with respect to the previous year, information on—

21 “(A) increases in manufacturers’ prices for cov-
22 ered outpatient drugs and in charges of pharmacists
23 for covered outpatient drugs,

24 “(B) the level of utilization of covered out-
25 patient drugs by medicare beneficiaries, and

1 “(C) administrative costs relating to covered
2 outpatient drugs.

3 “(c) The following provisions of section 1805 shall
4 apply to the Commission in the same manner as they
5 apply to the Medicare Payment Advisory Commission:

6 “(1) Subsection (c)(4) (relating to compensa-
7 tion of members).

8 “(2) Subsection (d) (relating to staffing and ad-
9 ministration).

10 “(3) Subsection (e) (relating to powers of the
11 Commission generally).

12 “(4) Subsection (f)(1) (relating to requests for
13 appropriations).

14 “(d) There are authorized to be appropriated such
15 sums as may be necessary to carry out the provisions of
16 this section. Such sums shall be payable from the Federal
17 Supplementary Medical Insurance Trust Fund.”.

18 (i) DEVELOPMENT OF STANDARD MEDICARE CLAIMS
19 FORM.—

20 (1) The Secretary shall develop, in consultation
21 with representatives of pharmacies and other inter-
22 ested individuals, a standard claims form (and a
23 standard electronic claims format) to be used in re-
24 quests for payment for covered outpatient drugs

1 under the medicare program and other third-party
2 payors.

3 (2) Not later than October 1, 2002, the Sec-
4 retary shall distribute official sample copies of the
5 format developed under paragraph (1) to pharmacies
6 and other interested parties and by not later than
7 October 1, 2002, shall distribute official sample cop-
8 ies of the form developed under paragraph (1) to
9 pharmacies and other interested parties.

10 (j) EFFECTIVE DATES.—

11 (1) IN GENERAL.—Except as otherwise pro-
12 vided in this subsection, the amendments made by
13 this section shall apply to items dispensed on or
14 after January 1, 2003.

15 (2) CARRIERS.—The amendments made by sub-
16 section (e) shall take effect on the date of the enact-
17 ment of this Act; except that the amendments made
18 by subsection (e)(5) shall take effect on January 1,
19 2004, but shall not be construed as requiring pay-
20 ment before February 1, 2004.

21 (3) HMO/CMP ENROLLMENTS.—The amend-
22 ment made by subsection (f) shall apply to enroll-
23 ments effected on or after January 1, 2003.

○