

108TH CONGRESS
1ST SESSION

H. R. 1045

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

MARCH 3, 2003

Mr. ENGEL 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 2003”.

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

15 (II) which has not been the subject of a
16 final determination by the Secretary that it is
17 a ‘new drug’ (within the meaning of section
18 201(p) of the Federal Food, Drug, and Cos-
19 metic Act) or an action brought by the Sec-
20 retary under section 301, 302(a), or 304(a) of
21 such Act to enforce section 502(f) or 505(a) of
22 such Act; or

23 “(iii)(I) which is described in section
24 107(c)(3) of the Drug Amendments of 1962
25 and for which the Secretary has determined

1 there is a compelling justification for its med-
2 ical need, or is identical, similar, or related
3 (within the meaning of section 310.6(b)(1) of
4 title 21 of the Code of Federal Regulations) to
5 such a drug, and

6 (II) for which the Secretary has not issued
7 a notice of an opportunity for a hearing under
8 section 505(e) of the Federal Food, Drug, and
9 Cosmetic Act on a proposed order of the Sec-
10 retary to withdraw approval of an application
11 for such drug under such section because the
12 Secretary has determined that the drug is less
13 than effective for all conditions of use pre-
14 scribed, recommended, or suggested in its label-
15 ing;

16 “(B) a biological product which—

17 “(i) may only be dispensed upon prescrip-
18 tion,

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

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

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

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

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

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

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

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

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

19 (3) CONFORMING AMENDMENTS REPEALING
20 SEPARATE COVERAGE OF CERTAIN DRUGS AND
21 PRODUCTS.—(A) Effective January 1, 2005, section
22 1861(s)(2) of such Act (42 U.S.C. 1395x(s)(2)) is
23 amended—

1 (i) in each of subparagraphs (A) and (B),
2 by striking “(including drugs” and all that fol-
3 lows through “patient”); and

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

6 (B) Effective January 1, 2005, section 1861 of
7 such Act (42 U.S.C. 1395x) is amended by striking
8 the subsection (kk).

9 (C) Effective January 1, 2005, 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 is amended—

24 (A) by striking “and (U)” and inserting “(U)”;

25 and

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

6 (2) Section 1833(a)(2) of such Act (42 U.S.C.
7 1395l(a)(2)) is amended—

8 (A) by inserting “(other than covered out-
9 patient drugs)” after “(2) in the case of services”;
10 and

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

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

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

17 (B) in clause (2), by striking “ (other than a
18 covered osteoporosis drug (as defined in section
19 1861(kk)))”.

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

23 “(e) PAYMENT FOR COVERED OUTPATIENT
24 DRUGS.—

25 “(1) DEDUCTIBLE.—

1 “(A) APPLICATION.—

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

16 “(ii) DEDUCTIBLE NOT APPLIED TO
17 1ST YEAR IMMUNOSUPPRESSIVES.—The
18 prescription drug deductible established
19 under this paragraph shall not apply to
20 drugs described in section 1861(t)(2)(A)
21 used in immunosuppressive therapy and
22 furnished, to an individual who receives an
23 organ transplant for which payment is
24 made under this title, within 1 year after
25 the date of the transplant.

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

11 “(C) PRESCRIPTION DRUG DEDUCTIBLE
12 AMOUNT.—The prescription drug deductible
13 specified in this subparagraph for—

14 “(i) 2005 is \$250, and

15 “(ii) any succeeding year, is the pre-
16 scription drug deductible for the preceding
17 year, increased by the percentage by which
18 the monthly premium under section 1839
19 for months during the year exceeds the
20 monthly premium under such section for
21 months during the preceding year.

22 “(2) PAYMENT AMOUNT.—

23 “(A) IN GENERAL.—Subject to the pre-
24 scription drug deductible established under
25 paragraph (1)(A) and except as provided in

1 subparagraph (B), the amounts payable under
2 this part with respect to a covered outpatient
3 drug is equal to 80 percent of the lesser of—

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

5 “(ii) the applicable payment limit es-
6 tablished under paragraph (3).

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

23 “(3) PAYMENT LIMITS.—

24 “(A) PAYMENT LIMIT FOR NON-MULTIPLE
25 SOURCE DRUGS AND MULTIPLE-SOURCE DRUGS

1 WITH RESTRICTIVE PRESCRIPTIONS.—In the
2 case of a drug that either is not a multiple
3 source drug (as defined in paragraph (9)(A)) or
4 is a multiple source drug and has a restrictive
5 prescription (as defined in paragraph (9)(B)),
6 the payment limit for the drug under this para-
7 graph for a payment calculation period is equal
8 to the lesser of—

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

18 “(ii) the amount of the administrative
19 allowance (established under paragraph
20 (4)) plus the product of—

21 “(I) the number of tablets (or
22 other dosage units) dispensed, and

23 “(II) the per tablet or unit aver-
24 age wholesale price for such drug (as
25 determined under subparagraph (C))

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

3 “(B) PAYMENT LIMIT FOR MULTIPLE
4 SOURCE DRUGS WITHOUT RESTRICTIVE PRE-
5 SCRIPTIONS.—In the case of a drug that is a
6 multiple source drug but does not have a re-
7 strictive prescription, the payment limit for the
8 drug under this paragraph for a payment cal-
9 culation period is equal to the amount of the
10 administrative allowance (established under
11 paragraph (4)) plus the product of—

12 “(i) the number of tablets (or other
13 dosage units) dispensed, and

14 “(ii) the unweighted median of the
15 per tablet or unit average wholesale prices
16 (determined under subparagraph (C) for
17 purposes of this subparagraph) for such
18 drug for the period.

19 “(C) DETERMINATION OF UNIT PRICE.—

20 “(i) IN GENERAL.—For purposes of
21 this paragraph, the Secretary shall deter-
22 mine, with respect to the dispensing of a
23 covered outpatient drug in a payment cal-
24 culation period (beginning on or after Jan-

1 uary 1, 2005), the per tablet or unit aver-
2 age wholesale price for the drug.

3 “(ii) BASIS FOR DETERMINATIONS.—

4 “(I) DETERMINATION FOR NON-
5 MULTIPLE-SOURCE DRUGS.—For pur-
6 poses of subparagraph (A), such de-
7 termination shall be based on a bian-
8 nual survey conducted by the Sec-
9 retary of a representative sample of
10 direct sellers, wholesalers, or phar-
11 macies (as appropriate) of wholesale
12 (or comparable direct) prices (exclud-
13 ing discounts to pharmacies); except
14 that if, because of low volume of sales
15 for the drug or other appropriate rea-
16 sons or in the case of covered out-
17 patient drugs during 2005, the Sec-
18 retary determines that such a survey
19 is not appropriate with respect to a
20 specific drug, such determination shall
21 be based on published average whole-
22 sale (or comparable direct) prices for
23 the drug.

24 “(II) DETERMINATION FOR MUL-
25 TIPLE-SOURCE DRUGS.—For purposes

1 of subparagraph (B), the Secretary
2 may base the determination under
3 this subparagraph on the published
4 average wholesale (or comparable di-
5 rect) prices for the drug or on a bian-
6 nual survey conducted by the Sec-
7 retary of a representative sample of
8 direct sellers, wholesalers, or phar-
9 macists (as appropriate) of wholesale
10 (or comparable direct) prices (exclud-
11 ing discounts to pharmacies).

12 “(III) COMPLIANCE WITH SUR-
13 VEY REQUIRED.—If a wholesaler or
14 direct seller of a covered outpatient
15 drug refuses, after being requested by
16 the Secretary, to provide the informa-
17 tion required in a survey under this
18 clause, or deliberately provides infor-
19 mation that is false, the Secretary
20 may impose a civil money penalty of
21 not to exceed \$10,000 for each such
22 refusal or provision of false informa-
23 tion. The provisions of section 1128A
24 (other than subsections (a) and (b))
25 shall apply to civil money penalties

1 under the previous sentence in the
2 same manner as such provisions apply
3 to a penalty or proceeding under sec-
4 tion 1128A(a). Information gathered
5 pursuant to the survey shall not be
6 disclosed except as the Secretary de-
7 termines to be necessary to carry out
8 the purposes of this part.

9 “(iii) QUANTITY AND TIMING.—Such
10 determination shall be based on the price
11 or prices for purchases in reasonable quan-
12 tities and shall be made for a payment cal-
13 culation period based on prices for the first
14 day of the first month of the previous pay-
15 ment calculation period.

16 “(iv) GEOGRAPHIC BASIS.—The Sec-
17 retary shall make such determination, and
18 calculate the payment limits under this
19 paragraph, on a national basis.

20 “(v) ADJUSTMENT FOR GEOGRAPHIC
21 VARIATIONS IN COSTS.—The Secretary
22 shall adjust the payment limits under this
23 paragraph to take account of limitations
24 on the availability of drug products and
25 variations among regions in the average

1 wholesale prices for a drug product, using
2 an appropriate index as determined by the
3 Secretary.

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

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

8 “(i) 2005, the administrative allow-
9 ance under this paragraph is—

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

12 “(II) \$3 for drugs dispensed by
13 another pharmacy; or

14 “(ii) a subsequent year, the adminis-
15 trative allowance under this paragraph is
16 the administrative allowance under this
17 paragraph for the preceding year increased
18 by the percentage increase (if any) in the
19 implicit price deflator for gross national
20 product (as published by the Department
21 of Commerce in its ‘Survey of Current
22 Business’) over the 12-month period end-
23 ing with August of such preceding year.

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

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

15 “(5) ASSURING APPROPRIATE PRESCRIBING
16 AND DISPENSING PRACTICES.—

17 “(A) IN GENERAL.—The Secretary shall
18 establish a program to identify (and to educate
19 physicians and pharmacists concerning)—

20 “(i) instances or patterns of unneces-
21 sary or inappropriate prescribing or dis-
22 pensing practices for covered outpatient
23 drugs;

1 “(ii) instances or patterns of sub-
2 standard care with respect to such drugs;
3 and

4 “(iii) potential adverse reactions.

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

18 “(C) PROHIBITION OF FORMULARY.—
19 Nothing in this title (other than section
20 1862(c)) shall be construed as authorizing the
21 Secretary to exclude from coverage or to deny
22 payment—

23 “(i) for any specific covered out-
24 patient drug, or specific class of covered
25 outpatient drug; or

1 “(ii) for any specific use of such a
2 drug for a specific indication unless such
3 exclusion is pursuant to section 1862(a)(1)
4 based on a finding by the Secretary that
5 such use is not safe or is not effective.

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

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

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

1 “(i) expenses incurred by the bene-
2 ficiary for covered outpatient drugs reim-
3 bursed under the plan shall not be counted
4 toward the prescription drug deductible,
5 but

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

17 “(C) TREATMENT OF EXPENSES FOR COV-
18 ERED OUTPATIENT DRUGS INCURRED WHILE
19 ENROLLED IN A PREPAID PLAN OTHER THAN A
20 DRUG BUY-OUT PLAN.—The Secretary may not
21 enter into a contract with a Medicare+Choice
22 organization under part C, an organization
23 under section 1876, or provide for payment
24 under section 1833(a)(1)(A) with respect to an
25 organization which provides reimbursement for

1 covered outpatient drugs, with respect to a plan
2 that is not a drug buy-out plan, unless the or-
3 ganization provides assurances, satisfactory to
4 the Secretary, that—

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

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

21 “(D) DRUG BUY-OUT PLAN DEFINED.—In
22 this paragraph, the term ‘drug buy-out plan’
23 means a plan under section 1833(a)(1)(A) or
24 offered by a Medicare+Choice organization

1 under part C, or an organization under section
2 1876 and with respect to which—

3 “(i) the amount of any deductible
4 under the plan with respect to covered out-
5 patient drugs under this title,
6 is less than 50 percent of—

7 “(ii) the prescription drug deductible
8 specified in paragraph (1)(C).

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

14 “(F) TREATMENT OF PLAN CHARGES.—In
15 the case of covered outpatient drugs furnished
16 by a Medicare+Choice organization under part
17 C, an eligible organization under section
18 1876(b) or an organization described in section
19 1833(a)(1)(A) which does not impose charges
20 on covered outpatient drugs dispensed to its
21 members, for purposes of this subsection the
22 actual charges of the organization shall be the
23 organization’s standard charges to members,
24 and other individuals, not entitled to benefits
25 with respect to such drugs.

1 “(7) PHYSICIAN GUIDE.—

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

16 “(B) MAILING GUIDE.—The Secretary
17 shall provide for mailing, in January of each
18 year (beginning with 2005), a copy of the guide
19 developed and updated under subparagraph
20 (A)—

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

23 “(ii) to each physician (as defined in
24 section 1861(r)(1)) who routinely provides
25 services under this part; and

1 “(iii) to Social Security offices, senior
2 citizen centers, and other appropriate
3 places.

4 “(8) REPORTS ON UTILIZATION AND EFFECTS
5 ON PRICES.—

6 “(A) COMPILATION OF INFORMATION.—

7 The Secretary shall compile information on—

8 “(i) manufacturers’ prices for covered
9 outpatient drugs, and on charges of phar-
10 macists for covered outpatient drugs, and

11 “(ii) the use of covered outpatient
12 drugs by individuals entitled to benefits
13 under this part.

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

21 “(B) REPORTS.—The Secretary shall sub-
22 mit to the Committees on Ways and Means and
23 Commerce of the House of Representatives and
24 the Committee on Finance of the Senate a re-
25 port, in May and November of 2004 and 2005

1 and in May of each succeeding year, providing
2 the information compiled under subparagraph
3 (A). For each such report submitted after
4 2006, the report shall include an explanation of
5 the extent to which the increases in outlays for
6 covered outpatient drugs under this part are
7 due to the factors described in subparagraphs
8 (A)(i) and (A)(ii).

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

10 “(A) MULTIPLE SOURCE DRUG.—

11 “(i) IN GENERAL.—The term ‘mul-
12 tiple source drug’ means, with respect to a
13 payment calculation period, a covered out-
14 patient drug for which there are 2 or more
15 drug products which—

16 “(I) are rated as therapeutically
17 equivalent (under the Food and Drug
18 Administration’s most recent publica-
19 tion of ‘Approved Drug Products with
20 Therapeutic Equivalence Evalua-
21 tions’);

22 “(II) except as provided in clause
23 (ii), are pharmaceutically equivalent
24 and bioequivalent, as defined in clause

1 (iii) and as determined by the Food
2 and Drug Administration; and

3 “(III) are sold or marketed dur-
4 ing the period.

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

15 “(iii) DEFINITIONS.—For purposes of
16 this subparagraph:

17 “(I) PHARMACEUTICALLY EQUIV-
18 ALENT.—Drug products are pharma-
19 ceutically equivalent if the products
20 contain identical amounts of the same
21 active drug ingredient in the same
22 dosage form and meet compendial or
23 other applicable standards of strength,
24 quality, purity, and identity.

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

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

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

17 “(i) in the case of a written prescrip-
18 tion, the prescription for the drug indi-
19 cates, in the handwriting of the physician
20 or other person prescribing the drug and
21 with an appropriate phrase (such as ‘brand
22 medically necessary’) recognized by the
23 Secretary, that the particular drug must be
24 dispensed; or

1 “(ii) in the case of a prescription
2 issued by telephone—

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

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

18 “(C) PAYMENT CALCULATION PERIOD.—
19 The term ‘payment calculation period’ means
20 the 6-month period beginning with January of
21 each year and the 6-month period beginning
22 with July of each year.”.

23 (c) PARTICIPATING PHARMACIES; CIVIL MONEY
24 PENALTIES.—

1 (1) PARTICIPATING PHARMACIES.—Section
2 1842 of such Act (42 U.S.C. 1395t) is amended—

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

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

15 (C) by inserting after subsection (t) the
16 following new subsection:

17 “(u)(1) For purposes of this section, the term ‘par-
18 ticipating pharmacy’ means, with respect to covered out-
19 patient drugs dispensed on or after January 1, 2005, an
20 entity which is authorized under a State law to dispense
21 covered outpatient drugs and which has entered into an
22 agreement with the Secretary, providing at least the fol-
23 lowing:

24 “(A) The entity agrees to accept payment under
25 this part on an assignment-related basis for all cov-

1 ered outpatient drugs dispensed to an individual en-
2 titled to benefits under this part (in this subsection
3 referred to as a ‘Medicare beneficiary’) during a
4 year after—

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

8 “(ii) in the absence of such a system, the
9 entity is otherwise notified that the Secretary
10 has determined,

11 that the individual has met the prescription drug de-
12 ductible with respect to such drugs under section
13 1834(e)(1) for the year.

14 “(B) The entity agrees—

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

18 “(ii) not to charge Medicare beneficiaries
19 (regardless of whether or not the beneficiaries
20 are enrolled under a prepaid health plan, a
21 Medicare+Choice organization under part C, or
22 with eligible organization under section 1876)
23 more for such drugs than the amount it charges
24 to the general public (as determined by the Sec-
25 retary in regulations).

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

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

9 “(E) The entity agrees—

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

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

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

24 Nothing in this paragraph shall be construed as requiring
25 a pharmacy operated by a Medicare+Choice organization

1 under part C, an eligible organization (described in section
2 1876(b)) or an organization described in section
3 1833(a)(1)(A) for the exclusive benefit of its members to
4 dispense covered outpatient drugs to individuals who are
5 not members of the organization.

6 “(2) The Secretary shall provide to each participating
7 pharmacy—

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

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

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

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

21 “(B) the accuracy of information submitted by
22 the pharmacies under this title.

23 “(4) The Secretary shall establish, by not later than
24 January 1, 2005, a point-of-sale electronic system for use
25 by carriers and participating pharmacies in the submission

1 of information respecting covered outpatient drugs dis-
2 pensed to medicare beneficiaries under this part.

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

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

13 (A) in paragraph (2)(C), by inserting “or
14 to be a participating pharmacy under section
15 1842(u)” after “1842(h)(1)”;

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

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

20 (D) by inserting after paragraph (7) the
21 following new paragraph:

22 “(8) in the case of a participating or non-
23 participating pharmacy (as defined for purposes of
24 part B of title XVIII)—

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

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

12 (d) LIMITATION ON LENGTH OF PRESCRIPTION.—
13 Section 1862(c) of such Act (42 U.S.C. 1395y(e)) is
14 amended—

15 (1) by redesignating subparagraphs (A) through
16 (D) of paragraph (1) as clauses (i) through (iv) re-
17 spectively;

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

20 (3) by redesignating subparagraphs (A) and
21 (B) of paragraph (2) as clauses (i) and (ii) respec-
22 tively;

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

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

1 (6) by adding at the end the following new
2 paragraph:

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

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

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

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

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

18 (C) by adding at the end the following new
19 paragraph:

20 “(3) with respect to implementation and oper-
21 ation (and related functions) of the electronic system
22 established under subsection (u)(4), a voluntary as-
23 sociation, corporation, partnership, or other non-
24 governmental organization, which the Secretary de-
25 termines to be qualified to conduct such activities.”.

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

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

6 (B) by redesignating subparagraph (L) as
7 subparagraph (J); and

8 (C) by inserting after subparagraph (J)
9 (as so redesignated) the following new subpara-
10 graphs:

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

13 “(i) receive information transmitted under
14 the electronic system established under sub-
15 section (u)(4), and

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

22 “(L) will enter into such contracts with organi-
23 zations described in subsection (f)(3) as the Sec-
24 retary determines may be necessary to implement
25 and operate (and for related functions with respect

1 to) the electronic system established under sub-
2 section (u)(4) for covered outpatient drugs under
3 this part.”.

4 (3) SPECIAL CONTRACT PROVISIONS FOR ELEC-
5 TRONIC CLAIMS SYSTEM.—

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

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

10 (ii) in the first sentence, by inserting
11 “, except as provided in subparagraph
12 (B),” after “under this part, and”; and

13 (iii) by adding at the end the fol-
14 lowing new subparagraph:

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

22 (B) APPLICATION OF DIFFERENT PER-
23 FORMANCE STANDARDS.—The Secretary of
24 Health and Human Services, before entering
25 into contracts under section 1842 of the Social

1 Security Act with respect to the implementation
2 and operation (and related functions) of the
3 electronic system for covered outpatient drugs,
4 shall establish standards with respect to per-
5 formance with respect to such activities. The
6 provisions of subsections (e)(2), (h)(1), and
7 (h)(2) of section 1153 of such Act (42 U.S.C.
8 1320c-2) shall apply to such activities in the
9 same manner as they apply to contracts with
10 peer review organizations, instead of the re-
11 quirements of the second and third sentences of
12 section 1842(b)(2)(A) of such Act (42 U.S.C.
13 1395u(b)(2)(A)).

14 (C) USE OF REGIONAL CARRIERS.—Section
15 1842(b)(2)(A) of such Act (42 U.S.C.
16 1395u(b)(2)(A)) is amended by adding at the
17 end the following new sentence: “With respect
18 to activities relating to implementation and op-
19 eration (and related functions) of the electronic
20 system established under subsection (u)(4), the
21 Secretary may enter into contracts with carriers
22 under this section to perform such activities on
23 a regional basis.”.

24 (4) DELAY IN APPLICATION OF COORDINATED
25 BENEFITS WITH MEDIGAP.—The provisions of sub-

1 paragraph (B) of section 1842(h)(3) of the Social
2 Security Act (42 U.S.C. 1395u(h)(3)) shall not
3 apply to covered outpatient drugs (other than drugs
4 described in section 1861(s)(2)(J) of such Act (42
5 U.S.C. 1395x(s)(2)(J)) as of the date of the enact-
6 ment of this Act) dispensed before January 1, 2006.

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

10 (A) by redesignating paragraph (6) as
11 paragraph (7);

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

15 (C) by inserting after paragraph (5) the
16 following new paragraph:

17 “(6)(A) Each contract under this section which pro-
18 vides for the disbursement of funds, as described in sub-
19 section (a)(1)(B), with respect to claims for payment for
20 covered outpatient drugs shall provide for a payment cycle
21 under which each carrier will, on a monthly basis, make
22 a payment with respect to all claims which were received
23 and approved for payment in the period since the most
24 recent date on which such a payment was made with re-

1 spect to the participating pharmacy or individual submit-
2 ting the claim.

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

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

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

19 (2) ADDITIONAL OPTIONAL BENEFITS.—Section
20 1876(g)(3)(A) of such Act (42 U.S.C.
21 1395mm(g)(3)(A)) is amended by striking “rate”
22 and inserting “rates”.

23 (g) CONFORMING AMENDMENTS.—

24 (1) The first sentence of section 1866(a)(2)(A)
25 (42 U.S.C. 1395cc(a)(2)(A)) is amended—

1 (A) by inserting “1834(e),” after
2 “1833(b),”; and

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

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

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

16 “PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION
17 “SEC. 1849. (a)(1) The Director of the Congressional
18 Office of Technology Assessment (in this section referred
19 to as the ‘Director’ and the ‘Office’, respectively) shall
20 provide for the appointment of a Prescription Drug Pay-
21 ment Review Commission (in this section referred to as
22 the ‘Commission’), to be composed of individuals with ex-
23 pertise in the provision and financing of covered out-
24 patient drugs appointed by the Director (without regard
25 to the provisions of title 5, United States Code, governing
26 appointments in the competitive service).

1 “(2) The Commission shall consist of 11 individuals.
2 Members of the Commission shall first be appointed by
3 no later than January 1, 2004, for a term of 3 years, ex-
4 cept that the Director may provide initially for such short-
5 er terms as will ensure that (on a continuing basis) the
6 terms of no more than 4 members expire in any one year.

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

12 “(b)(1) The Commission shall submit to Congress an
13 annual report no later than May 1 of each year, beginning
14 with 2005, concerning methods of determining payment
15 for covered outpatient drugs under this part.

16 “(2) Such report, in 2006 and thereafter, shall in-
17 clude, with respect to the previous year, information on—

18 “(A) increases in manufacturers’ prices for cov-
19 ered outpatient drugs and in charges of pharmacists
20 for covered outpatient drugs,

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

23 “(C) administrative costs relating to covered
24 outpatient drugs.

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

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

6 “(2) Subsection (d) (relating to staffing and ad-
7 ministration).

8 “(3) Subsection (e) (relating to powers of the
9 Commission generally).

10 “(4) Subsection (f)(1) (relating to requests for
11 appropriations).

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

16 (i) DEVELOPMENT OF STANDARD MEDICARE CLAIMS
17 FORM.—

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

1 (2) Not later than October 1, 2004, the Sec-
2 retary shall distribute official sample copies of the
3 format developed under paragraph (1) to pharmacies
4 and other interested parties and by not later than
5 October 1, 2004, shall distribute official sample cop-
6 ies of the form developed under paragraph (1) to
7 pharmacies and other interested parties.

8 (j) EFFECTIVE DATES.—

9 (1) IN GENERAL.—Except as otherwise pro-
10 vided in this subsection, the amendments made by
11 this section shall apply to items dispensed on or
12 after January 1, 2005.

13 (2) CARRIERS.—The amendments made by sub-
14 section (e) shall take effect on the date of the enact-
15 ment of this Act; except that the amendments made
16 by subsection (e)(5) shall take effect on January 1,
17 2006, but shall not be construed as requiring pay-
18 ment before February 1, 2006.

19 (3) HMO/CMP ENROLLMENTS.—The amend-
20 ment made by subsection (f) shall apply to enroll-
21 ments effected on or after January 1, 2005.

○