

105TH CONGRESS
1ST SESSION

H. R. 405

To amend title XVIII of the Social Security Act to provide for coverage of expanded nursing facility and in-home services for dependent individuals under the Medicare program, to provide for coverage of outpatient prescription drugs under part B of such program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 9, 1997

Mr. ENGEL introduced the following bill; which was referred to the Committee on 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 expanded nursing facility and in-home services for dependent individuals under the Medicare program, to provide for coverage of outpatient prescription drugs under part B of such 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 “Comprehensive Long-
5 Term Care Act of 1997”.

1 **SEC. 2. EXPANDED LONG-TERM CARE SERVICES UNDER**
2 **MEDICARE PROGRAM FOR DEPENDENT INDIVIDUALS.**
3

4 (a) IN GENERAL.—

5 (1) PART A.—Section 1812 of the Social Security Act (42 U.S.C. 1395d) is amended—

7 (A) in subsection (a)—

8 (i) in paragraph (2)(B), by striking
9 “subsection (f),” and inserting “subsection
10 (f) and section 1889,”

11 (ii) by striking “and” at the end of
12 paragraph (3),

13 (iii) by striking the period at the end
14 of paragraph (4) and inserting “; and”,
15 and

16 (iv) by adding at the end the following
17 new paragraph:

18 “(5) long-term care services consisting of extended care services (in accordance with section
19 1889).”; and
20

21 (B) in subsection (b)(2), by striking “post-hospital” and inserting “except as provided in
22 section 1889, post-hospital”.
23

24 (2) PART B.—Section 1861(s)(2) of such Act
25 (42 U.S.C. 1395x(s)(2)) is amended—

1 (A) in subparagraph (N), by striking
2 “and” at the end;

3 (B) in subparagraph (O), by striking
4 “and” at the end; and

5 (C) by inserting after subparagraph (O)
6 the following new subparagraph:

7 “(P) long-term care services consisting of in-
8 home care (in accordance with section 1889); and”.

9 (b) DESCRIPTION OF SERVICES; ELIGIBILITY.—Title
10 XVIII of the Social Security Act is amended by inserting
11 after section 1888 the following new section:

12 “LONG-TERM CARE SERVICES FOR DEPENDENT
13 INDIVIDUALS

14 “SEC. 1889. (a) IN GENERAL.—An individual enti-
15 tled to benefits under this part shall be entitled to have
16 payments made on the individual’s behalf for long-term
17 care services if—

18 “(1) the individual is a dependent individual;
19 and

20 “(2) such services are provided in accordance
21 with a case management plan developed by a case
22 management agency.

23 “(b) SERVICES PROVIDED.—In this section, the term
24 ‘long-term care services’ means—

25 “(1) in-home care (as defined in subsection (e));
26 and

1 “(2) extended care services (as defined in sec-
2 tion 1861(h)), but only with respect to a chronically
3 dependent individual.

4 “(c) PAYMENT FOR SERVICES.—

5 “(1) IN GENERAL.—Subject to paragraph (2),
6 the amount payable for long-term care services
7 under this section shall be determined in accordance
8 with a fee schedule for such services established by
9 the Secretary.

10 “(2) IMPOSITION OF DEDUCTIBLE.—The
11 amount otherwise payable for long-term care services
12 under this section furnished during a calendar year
13 shall be reduced by an amount equal to the deduct-
14 ible imposed for inpatient hospital services for the
15 year under section 1813(a)(1).

16 “(d) DEPENDENT INDIVIDUAL DEFINED.—

17 “(1) IN GENERAL.—In this section, the term
18 ‘dependent individual’ means an individual who—

19 “(A) is unable to perform (without sub-
20 stantial assistance from another individual) be-
21 cause of physical or cognitive impairment at
22 least 2 of the following activities of daily living:
23 bathing, dressing, toileting, transferring, and
24 eating; or

1 “(B) has a similar level of disability due to
2 cognitive impairment that requires substantial
3 direction, instruction, or supervision of another
4 individual in order—

5 “(i) to perform 2 or more of the ac-
6 tivities of daily living described in subpara-
7 graph (A), or

8 “(ii) to remain in the community
9 without causing harm to self or others be-
10 cause of inappropriate behavioral patterns.

11 “(2) CHRONICALLY DEPENDENT INDIVIDUAL.—

12 In this section, the term ‘chronically dependent indi-
13 vidual’ means an individual described in paragraph
14 (1) who—

15 “(A) for purposes of subparagraph (A) of
16 such paragraph, is unable to perform at least 3
17 of the activities of daily living described in such
18 subparagraph; or

19 “(B) for purposes of subparagraph (B)(i)
20 of such paragraph, has a level of disability that
21 requires direction, instruction, or supervision of
22 another individual to perform 3 or more of such
23 activities of daily living.

1 “(3) ACTIVITIES OF DAILY LIVING DEFINED.—

2 The ‘activities of daily living’ referred to in this sub-
3 section are as follows:

4 “(A) Eating.

5 “(B) Bathing.

6 “(C) Dressing.

7 “(D) Toileting.

8 “(E) Transferring in and out of a bed or
9 in and out of a chair.

10 “(e) IN-HOME CARE.—

11 “(1) IN GENERAL.—For purposes of this sec-
12 tion, the term ‘in-home care’ means the items and
13 services described in paragraph (2) furnished to an
14 individual by a home care agency (as defined in sec-
15 tion 1861(oo)) or by others under arrangements
16 with them made by the agency provided in a place
17 of residence used as such individual’s home (other
18 than services described in paragraph (2)(H)).

19 “(2) SERVICES DESCRIBED.—The items and
20 services described in this paragraph are as follows:

21 “(A) Nursing care provided by or under
22 the supervision of a registered professional
23 nurse.

24 “(B) Services of a homemaker/home health
25 aide who has successfully completed a training

1 and competency evaluation program approved
2 by the Secretary.

3 “(C) Personal care services.

4 “(D) Medical social services.

5 “(E) Physical, occupational, or respiratory
6 therapy or speech-language pathology.

7 “(F) Medical supplies (other than drugs
8 and biologicals) and durable medical equipment,
9 while under such a plan.

10 “(G) Patient and caregiver (including fam-
11 ily caregiver) education and training to develop
12 skills necessary to permit the individual to re-
13 main in the home setting.

14 “(H) Community care services furnished
15 outside of the place of residence.

16 “(I) Such other home-based items and
17 services (other than room and board) as the
18 Secretary may approve.

19 “(f) CASE MANAGEMENT REQUIREMENTS.—

20 “(1) REQUESTS FOR ASSESSMENT.—Each indi-
21 vidual entitled to benefits under this title (or an-
22 other person on such individual’s behalf) may re-
23 quest a case management agency to conduct an as-
24 sessment under this section to determine whether

1 the individual is a dependent individual or a chron-
2 ically dependent individual.

3 “(2) DESCRIPTION OF PLANS.—For purposes of
4 this section, a ‘case management plan’ means, with
5 respect to an individual, a written plan of care
6 which—

7 “(A) is established and periodically re-
8 viewed and revised by a case management agen-
9 cy; and

10 “(B) reflects the individual’s needs identi-
11 fied in the assessment under paragraph (1).

12 “(3) CASE MANAGEMENT AGENCY DEFINED.—
13 In this section, the term ‘case management agency’
14 means a nonprofit or public agency or organization
15 (or a nonprofit or public subdivision of such an
16 agency or organization) certified by the Secretary to
17 conduct assessments and establish case management
18 plans under this subsection which—

19 “(A) is experienced in conducting assess-
20 ments, in establishing and periodically reviewing
21 and revising case management plans for nurs-
22 ing facility services and in-home care, and in
23 coordinating and reviewing the quality of the
24 provision of such services and care;

1 “(B) is capable of efficiently and effectively
 2 performing directly or through contracts under
 3 paragraph (4) such duties; and

4 “(C) does not provide nursing facility serv-
 5 ices or in-home care and does not have a direct
 6 or indirect ownership or control interest in, or
 7 direct or indirect affiliation or relationship with,
 8 an entity that provides, such services or care.

9 “(4) CONTRACTING OUT CERTAIN FUNC-
 10 TIONS.—The Secretary shall permit a case manage-
 11 ment agency, to the extent necessary to carry out
 12 functions under this section, to provide for assess-
 13 ments and case management plans through con-
 14 tracts with nonprofit or public organizations which
 15 do not provide nursing facility services or in-home
 16 care and do not have a direct or indirect ownership
 17 or control interest in, or direct or indirect affiliation
 18 or relationship with, an entity that provides, such
 19 services or care.”.

20 (c) CONFORMING AMENDMENTS.—(1) Section
 21 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)) is amend-
 22 ed—

23 (A) by striking “and (P)” and inserting “(P)”;
 24 and

1 (B) by striking the semicolon at the end and in-
2 serting the following: “, and (Q) with respect to ex-
3 penses incurred for services described in section
4 1861(s)(2)(P), the amounts paid shall be the
5 amounts determined under section 1889(e);”.

6 (2) Section 1861 of such Act (42 U.S.C. 1395x) is
7 amended by adding at the end the following new sub-
8 section:

9 “HOME CARE AGENCY

10 “(oo) The term ‘home care agency’ means a public
11 agency or private organization, or a subdivision of such
12 an agency or organization, which is a home health agency
13 (as defined in subsection (o)) or—

14 “(1) is primarily engaged in providing services
15 of homemaker/home health aides and personal care
16 aides;

17 “(2) maintains clinical records on all patients;

18 “(3) in the case of an agency or organization in
19 any State in which State or applicable local law pro-
20 vides for the licensing of agencies or organizations of
21 this nature, (A) is licensed pursuant to such law, or
22 (B) is approved, by the agency of such State or lo-
23 cality, responsible for licensing agencies or organiza-
24 tions of this nature, as meeting the standards estab-
25 lished for such licensing; and

1 “(4) meets such other requirements as the Sec-
 2 retary may find necessary in the interest of the
 3 health and safety of individuals who are furnished
 4 services by such agency or organization and for the
 5 effective and efficient operation of the program.”.

6 (d) EFFECTIVE DATE.—The amendments made by
 7 this section shall apply to items and services furnished on
 8 or after January 1, 1998.

9 **SEC. 3. MEDICARE COVERAGE OF OUTPATIENT PRESCRIP-**
 10 **TION DRUGS.**

11 (a) DESCRIPTION OF COVERED OUTPATIENT
 12 DRUGS.—

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

16 “(J) covered outpatient drugs;”.

17 (2) DRUGS DESCRIBED.—Section 1861(t) of
 18 such Act (42 U.S.C. 1395x(t)) is amended—

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

21 (B) in paragraph (1)—

22 (i) by striking “paragraph (2)” and
 23 inserting “the succeeding paragraphs of
 24 this subsection”, and

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

5 (3) by striking paragraph (2) and inserting the
6 following:

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

9 “(A) a drug which may be dispensed only upon
10 prescription and—

11 “(i) which is approved for safety and effec-
12 tiveness as a prescription drug under section
13 505 or 507 of the Federal Food, Drug, and
14 Cosmetic Act or which is approved under sec-
15 tion 505(j) of such Act;

16 “(ii)(I) which was commercially used or
17 sold in the United States before the date of the
18 enactment of the Drug Amendments of 1962 or
19 which is identical, similar, or related (within the
20 meaning of section 310.6(b)(1) of title 21 of the
21 Code of Federal Regulations) to such a drug,
22 and (II) which has not been the subject of a
23 final determination by the Secretary that it is
24 a ‘new drug’ (within the meaning of section

201(p) of the Federal Food, Drug, and Cos-
metic Act) or an action brought by the Sec-
retary under section 301, 302(a), or 304(a) of
such Act to enforce section 502(f) or 505(a) of
such Act; or

“(iii)(I) which is described in section
107(c)(3) of the Drug Amendments of 1962
and for which the Secretary has determined
there is a compelling justification for its medi-
cal need, or is identical, similar, or related
(within the meaning of section 310.6(b)(1) of
title 21 of the Code of Federal Regulations) to
such a drug, and (II) for which the Secretary
has not issued a notice of an opportunity for a
hearing under section 505(e) of the Federal
Food, Drug, and Cosmetic Act on a proposed
order of the Secretary to withdraw approval of
an application for such drug under such section
because the Secretary has determined that the
drug is less than effective for all conditions of
use prescribed, recommended, or suggested in
its labeling;

“(B) a biological product which—

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

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

3 “(iii) is produced at an establishment li-
4 censed under such section to produce such
5 product; and

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

8 “(3)(A) The term ‘covered outpatient drug’ does not
9 include any drug, biological product, or insulin provided
10 as, as part of, or as incident to, any of the following (and
11 for which payment may be included under this title):

12 “(i) Inpatient hospital services (described in
13 subsection (b)(2)).

14 “(ii) Extended care services (described in sub-
15 section (h)(5)).

16 “(iii) Physicians’ services under subparagraph
17 (A) or (B) of subsection (s)(2).

18 “(iv) Dialysis supplies under subsection
19 (s)(2)(F).

20 “(v) Antigens under subsection (s)(2)(G).

21 “(vi) Blood clotting factors for hemophiliacs
22 under subsection (s)(2)(I).

23 “(vii) Services of a physician assistant, nurse
24 practitioner, or clinical nurse specialist under sub-
25 section (s)(2)(K).

1 “(viii) Pneumococcal, hepatitis B, or influenza
2 vaccines under subsection (s)(10).

3 “(ix) Rural health clinic services (under sub-
4 section (aa)(1)).

5 “(x) Comprehensive outpatient rehabilitation fa-
6 cility services (under subsection (cc)(1)).

7 “(xi) Hospice care (as defined in subsection
8 (dd)(1)).

9 “(xii) Certified nurse-midwife services (as de-
10 fined in subsection (gg)(1)).

11 “(xiii) Inpatient or outpatient rural primary
12 care hospital services (as defined in subsection
13 (mm)).

14 “(xiv) A covered surgical procedure in an ambu-
15 latory surgical center (under section
16 1832(a)(2)(F)(i)).

17 “(B) The term ‘covered outpatient drug’ does not in-
18 clude any drug that is intravenously administered in a
19 home setting.

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

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

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

4 (b) DEDUCTIBLE AND PAYMENT AMOUNTS.—(1)
 5 Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)),
 6 as amended by section 2(c)(1), is amended—

7 (A) by striking “and (Q)” and inserting “(Q)”;
 8 and

9 (B) by striking the semicolon at the end and in-
 10 serting the following “, and (R) with respect to ex-
 11 penses incurred for covered outpatient drugs, the
 12 amounts paid shall be the amounts determined
 13 under section 1834(d)(2);”.

14 (2) Section 1833(a)(2) of such Act (42 U.S.C.
 15 1395l(a)(2)) is amended by inserting “(other than covered
 16 outpatient drugs)” after “(2) in the case of services”.

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 inserting “or with respect
 22 to covered outpatient drugs” after “1861(kk)”.

23 (4) Section 1834 of such Act (42 U.S.C. 1395m) is
 24 amended by inserting after subsection (c) the following
 25 new subsection:

1 “(d) PAYMENT FOR COVERED OUTPATIENT
2 DRUGS.—

3 “(1) DEDUCTIBLE.—

4 “(A) APPLICATION.—

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

19 “(ii) DEDUCTIBLE NOT APPLIED TO
20 1ST YEAR IMMUNOSUPPRESSIVES.—The
21 prescription drug deductible established
22 under this paragraph shall not apply to
23 drugs described in section 1861(t)(2)(A)
24 used in immunosuppressive therapy and
25 furnished, to an individual who receives an

1 organ transplant for which payment is
2 made under this title, within 1 year after
3 the date of the transplant.

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

14 “(C) PRESCRIPTION DRUG DEDUCTIBLE
15 AMOUNT.—The prescription drug deductible
16 specified in this subparagraph for—

17 “(i) 1999 is \$250, and

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

25 “(2) PAYMENT AMOUNT.—

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

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

“(ii) the applicable payment limit established under paragraph (3).

“(B) TREATMENT OF CERTAIN COST-BASED PREPAID ORGANIZATIONS.—In applying subparagraph (A) in the case of an organization under a reasonable cost reimbursement contract under section 1876 and in the case of an organization receiving payment under section 1833(a)(1)(A) and providing coverage of covered outpatient drugs, the Secretary shall provide for an appropriate adjustment in the payment amounts otherwise made to reflect the aggregate increase in payments that would otherwise be made with respect to enrollees in such an organization if payments were made other than under such clause or such a contract on an individual-by-individual basis.

“(3) PAYMENT LIMITS.—

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

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

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

23 “(I) the number of tablets (or
24 other dosage units) dispensed, and

1 “(II) the per tablet or unit aver-
2 age wholesale price for such drug (as
3 determined under subparagraph (C)
4 for the period for purposes of this
5 subparagraph).

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

15 “(i) the number of tablets (or other
16 dosage units) dispensed, and

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

22 “(C) DETERMINATION OF UNIT PRICE.—

23 “(i) IN GENERAL.—For purposes of
24 this paragraph, the Secretary shall deter-
25 mine, with respect to the dispensing of a

1 covered outpatient drug in a payment cal-
2 culation period (beginning on or after Jan-
3 uary 1, 1999), the per tablet or unit aver-
4 age wholesale price for the drug.

5 “(ii) BASIS FOR DETERMINATIONS.—

6 “(I) DETERMINATION FOR NON-
7 MULTIPLE-SOURCE DRUGS.—For pur-
8 poses of subparagraph (A), such de-
9 termination shall be based on a bian-
10 nual survey conducted by the Sec-
11 retary of a representative sample of
12 direct sellers, wholesalers, or phar-
13 macies (as appropriate) of wholesale
14 (or comparable direct) prices (exclud-
15 ing discounts to pharmacies); except
16 that if, because of low volume of sales
17 for the drug or other appropriate rea-
18 sons or in the case of covered out-
19 patient drugs during 1999, the Sec-
20 retary determines that such a survey
21 is not appropriate with respect to a
22 specific drug, such determination shall
23 be based on published average whole-
24 sale (or comparable direct) prices for
25 the drug.

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

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

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

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

18 “(iv) GEOGRAPHIC BASIS.—The Sec-
19 retary shall make such determination, and
20 calculate the payment limits under this
21 paragraph, on a national basis; except that
22 the Secretary may make such determina-
23 tion, and calculate such payment limits, on
24 a regional basis to take account of limita-
25 tions on the availability of drug products

1 and variations among regions in the aver-
2 age wholesale prices for a drug product.

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

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

7 “(i) 1999, the administrative allow-
8 ance under this paragraph is—

9 “(I) \$5.00 for drugs dispensed by
10 a participating pharmacy, or

11 “(II) \$3.00 for drugs dispensed
12 by another pharmacy; or

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

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

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

12 “(5) ASSURING APPROPRIATE PRESCRIBING
13 AND DISPENSING PRACTICES.—

14 “(A) IN GENERAL.—The Secretary shall
15 establish a program to identify (and to educate
16 physicians and pharmacists concerning)—

17 “(i) instances or patterns of unneces-
18 sary or inappropriate prescribing or dis-
19 pensing practices for covered outpatient
20 drugs;

21 “(ii) instances or patterns of sub-
22 standard care with respect to such drugs;
23 and

24 “(iii) potential adverse reactions.

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

14 “(C) PROHIBITION OF FORMULARY.—
15 Nothing in this title (other than section
16 1862(c)) shall be construed as authorizing the
17 Secretary to exclude from coverage or to deny
18 payment—

19 “(i) for any specific covered out-
20 patient drug, or specific class of covered
21 outpatient drug; or

22 “(ii) for any specific use of such a
23 drug for a specific indication unless such
24 exclusion is pursuant to section 1862(a)(1)

1 based on a finding by the Secretary that
2 such use is not safe or is not effective.

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

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

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

21 “(i) expenses incurred by the bene-
22 ficiary for covered outpatient drugs reim-
23 bursed under the plan shall not be counted
24 toward the prescription drug deductible,
25 but

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

12 “(C) TREATMENT OF EXPENSES FOR COV-
13 ERED OUTPATIENT DRUGS INCURRED WHILE
14 ENROLLED IN A PREPAID PLAN OTHER THAN A
15 DRUG BUY-OUT PLAN.—The Secretary may not
16 enter into a contract with an organization
17 under section 1876, or provide for payment
18 under section 1833(a)(1)(A) with respect to an
19 organization which provides reimbursement for
20 covered outpatient drugs, with respect to a plan
21 that is not a drug buy-out plan, unless the or-
22 ganization provides assurances, satisfactory to
23 the Secretary, that—

24 “(i) the organization will maintain
25 and make available, for its enrollees and in

1 coordination with the appropriate carriers
2 under this part, an accounting of expenses
3 incurred by (or on behalf of) enrollees
4 under the plan for covered outpatient
5 drugs; and

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

15 “(D) DRUG BUY-OUT PLAN DEFINED.—In
16 this paragraph, the term ‘drug buy-out plan’
17 means a plan under section 1833(a)(1)(A) or
18 offered by an organization under section 1876
19 and with respect to which—

20 “(i) the amount of any deductible
21 under the plan with respect to covered out-
22 patient drugs under this title,
23 is less than 50 percent of—

24 “(ii) the prescription drug deductible
25 specified in paragraph (1)(C).

“(E) MEDICARE BENEFICIARY DEFINED.—

In this subsection, the term ‘medicare beneficiary’ means, with respect to a month, an individual covered for benefits under this part for the month.

“(F) TREATMENT OF PLAN CHARGES.—In

the case of covered outpatient drugs furnished by an eligible organization under section 1876(b) or an organization described in section 1833(a)(1)(A) which does not impose charges on covered outpatient drugs dispensed to its members, for purposes of this subsection the actual charges of the organization shall be the organization’s standard charges to members, and other individuals, not entitled to benefits with respect to such drugs.

“(7) PHYSICIAN GUIDE.—

“(A) IN GENERAL.—The Secretary shall

develop, and update annually, an information guide for physicians concerning the comparative average wholesale prices of at least 500 of the most commonly prescribed covered outpatient drugs. Such guide shall, to the extent practicable, group covered outpatient drugs (including multiple source drugs) in a manner useful

1 to physicians by therapeutic category or with
2 respect to the conditions for which they are pre-
3 scribed. Such guide shall specify the average
4 wholesale prices on the basis of the amount of
5 the drug required for a typical daily therapeutic
6 regimen.

7 “(B) MAILING GUIDE.—The Secretary
8 shall provide for mailing, in January of each
9 year (beginning with 1999), a copy of the guide
10 developed and updated under subparagraph
11 (A)—

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

14 “(ii) to each physician (as defined in
15 section 1861(r)(1)) who routinely provides
16 services under this part; and

17 “(iii) to Social Security offices, senior
18 citizen centers, and other appropriate
19 places.

20 “(8) REPORTS ON UTILIZATION AND EFFECTS
21 ON PRICES.—

22 “(A) COMPILATION OF INFORMATION.—
23 The Secretary shall compile information on—

1 “(i) manufacturers’ prices for covered
2 outpatient drugs, and on charges of phar-
3 macists for covered outpatient drugs, and
4 “(ii) the use of covered outpatient
5 drugs by individuals entitled to benefits
6 under this part.

7 The information compiled under clause (i) shall
8 include a comparison of the increases in prices
9 and charges for covered outpatient drugs dur-
10 ing each 6 month period (beginning with Janu-
11 ary 1997) with the semiannual average increase
12 in such prices and charges during the 5 years
13 beginning with 1991.

14 “(B) REPORTS.—The Secretary shall sub-
15 mit to the Committees on Ways and Means and
16 Commerce of the House of Representatives and
17 the Committee on Finance of the Senate a re-
18 port, in May and November of 1998 and 1999
19 and in May of each succeeding year, providing
20 the information compiled under subparagraph
21 (A). For each such report submitted after
22 2000, the report shall include an explanation of
23 the extent to which the increases in outlays for
24 covered outpatient drugs under this part are

1 due to the factors described in subparagraphs
 2 (A)(i) and (A)(ii).

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

4 “(A) MULTIPLE SOURCE DRUG.—

5 “(i) IN GENERAL.—The term ‘mul-
 6 tiple source drug’ means, with respect to a
 7 payment calculation period, a covered out-
 8 patient drug for which there are 2 or more
 9 drug products which—

10 “(I) are rated as therapeutically
 11 equivalent (under the Food and Drug
 12 Administration’s most recent publica-
 13 tion of ‘Approved Drug Products with
 14 Therapeutic Equivalence Evalua-
 15 tions’);

16 “(II) except as provided in clause
 17 (ii), are pharmaceutically equivalent
 18 and bioequivalent, as defined in clause
 19 (iii) and as determined by the Food
 20 and Drug Administration; and

21 “(III) are sold or marketed dur-
 22 ing the period.

23 “(ii) EXCEPTION.—Subclause (II) of
 24 clause (i) shall not apply if the Food and
 25 Drug Administration changes by regulation

1 (after an opportunity for public comment
2 of 90 days) the requirement that, for pur-
3 poses of the publication described in clause
4 (i)(I), in order for drug products to be
5 rated as therapeutically equivalent, they
6 must be pharmaceutically equivalent and
7 bioequivalent, as defined in clause (iii).

8 “(iii) DEFINITIONS.—For purposes of
9 this subparagraph:

10 “(I) PHARMACEUTICALLY EQUIV-
11 ALENT.—Drug products are pharma-
12 ceutically equivalent if the products
13 contain identical amounts of the same
14 active drug ingredient in the same
15 dosage form and meet compendial or
16 other applicable standards of strength,
17 quality, purity, and identity.

18 “(II) BIOEQUIVALENT.—Drugs
19 are bioequivalent if they do not
20 present a known or potential bio-
21 equivalence problem or, if they do
22 present such a problem, are shown to
23 meet an appropriate standard of bio-
24 equivalence.

1 “(III) SOLD OR MARKETED.—A
2 drug is considered to be sold or mar-
3 keted during a period if it is listed in
4 the publications referred to in clause
5 (i)(I), unless the Secretary determines
6 that such sale or marketing is not ac-
7 tually taking place.

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

10 “(i) in the case of a written prescrip-
11 tion, the prescription for the drug indi-
12 cates, in the handwriting of the physician
13 or other person prescribing the drug and
14 with an appropriate phrase (such as ‘brand
15 medically necessary’) recognized by the
16 Secretary, that the particular drug must be
17 dispensed; or

18 “(ii) in the case of a prescription is-
19 sued by telephone—

20 “(I) the physician or other per-
21 son prescribing the drug (through use
22 of such an appropriate phrase) states
23 that the particular drug must be dis-
24 pensed, and

1 “(II) the physician or other per-
 2 son submits to the pharmacy involved,
 3 within 30 days after the date of the
 4 telephone prescription, a written con-
 5 firmation which is in the handwriting
 6 of the physician or other person pre-
 7 scribing the drug and which indicates
 8 with such appropriate phrase that the
 9 particular drug was required to have
 10 been dispensed.

11 “(C) PAYMENT CALCULATION PERIOD.—
 12 The term ‘payment calculation period’ means
 13 the 6-month period beginning with January of
 14 each year and the 6-month period beginning
 15 with July of each year.”.

16 (c) PARTICIPATING PHARMACIES; CIVIL MONEY
 17 PENALTIES.—

18 (1) PARTICIPATING PHARMACIES.—Section
 19 1842 of such Act (42 U.S.C. 1395t) is amended—

20 (A) in subsection (h)(1), by inserting be-
 21 fore the period at the end of the second sen-
 22 tence the following: “, except that, with respect
 23 to a supplier of covered outpatient drugs, the

1 term ‘participating supplier’ means a participat-
2 ing pharmacy (as defined in subsection
3 (o)(1))”;

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

9 (C) by inserting after subsection (n) the
10 following new subsection:

11 “(o)(1) For purposes of this section, the term ‘par-
12 ticipating pharmacy’ means, with respect to covered out-
13 patient drugs dispensed on or after January 1, 1999, an
14 entity which is authorized under a State law to dispense
15 covered outpatient drugs and which has entered into an
16 agreement with the Secretary, providing at least the fol-
17 lowing:

18 “(A) The entity agrees to accept payment under
19 this part on an assignment-related basis for all cov-
20 ered outpatient drugs dispensed to an individual en-
21 titled to benefits under this part (in this subsection
22 referred to as a ‘medicare beneficiary’) during a year
23 after—

1 “(i) the Secretary has notified the entity,
2 through the electronic system described in para-
3 graph (4); or

4 “(ii) in the absence of such a system, the
5 entity is otherwise notified that the Secretary
6 has determined,
7 that the individual has met the prescription drug de-
8 ductible with respect to such drugs under section
9 1834(d)(1) for the year.

10 “(B) The entity agrees—

11 “(i) not to refuse to dispense covered out-
12 patient drugs stocked by the entity to any medi-
13 care beneficiary; and

14 “(ii) not to charge medicare beneficiaries
15 (regardless of whether or not the beneficiaries
16 are enrolled under a prepaid health plan or with
17 eligible organization under section 1876) more
18 for such drugs than the amount it charges to
19 the general public (as determined by the Sec-
20 retary in regulations).

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

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

6 “(E) The entity agrees—

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

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

18 “(F) The entity agrees to provide the informa-
19 tion requested by the Secretary in surveys under sec-
20 tion 1834(d)(3)(C)(ii).

21 Nothing in this paragraph shall be construed as requiring
22 a pharmacy operated by an eligible organization (described
23 in section 1876(b)) or an organization described in section
24 1833(a)(1)(A) for the exclusive benefit of its members to

1 dispense covered outpatient drugs to individuals who are
2 not members of the organization.

3 “(2) The Secretary shall provide to each participating
4 pharmacy—

5 “(A) a distinctive emblem (suitable for display
6 to the public) indicating that the pharmacy is a par-
7 ticipating pharmacy; and

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

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

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

18 “(B) the accuracy of information submitted by
19 the pharmacies under this title.

20 “(4) The Secretary shall establish, by not later than
21 January 1, 1999, a point-of-sale electronic system for use
22 by carriers and participating pharmacies in the submission
23 of information respecting covered outpatient drugs dis-
24 pensed to medicare beneficiaries under this part.

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

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

11 (A) by striking “or” at the end of para-
 12 graph (1);

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

16 (C) by striking “, or” at the end of para-
 17 graph (2) and inserting a semicolon;

18 (D) by adding “or” at the end of para-
 19 graph (3); and

20 (E) by inserting after paragraph (3) the
 21 following new paragraph:

22 “(4) 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(d)(3)(C)(ii);”.

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

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

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

19 (3) by redesignating subparagraphs (A) and
 20 (B) of paragraph (2) as clauses (i) and (ii);

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

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

24 (6) by adding at the end the following new
 25 paragraph:

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

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

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

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

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

16 (C) by adding at the end the following new
 17 paragraph:

18 “(3) with respect to implementation and oper-
 19 ation (and related functions) of the electronic system
 20 established under subsection (o)(4), a voluntary as-
 21 sociation, corporation, partnership, or other non-
 22 governmental organization, which the Secretary de-
 23 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 (o)(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(d)(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 (o)(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 follow-
 14 ing 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 (o)(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 section 1153(e)(2) and paragraphs
7 (1) and (2) of section 1153(h) of such Act shall
8 apply to such activities in the same manner as
9 they apply to contracts with peer review organi-
10 zations, instead of the requirements of the sec-
11 ond and third sentences of section
12 1842(b)(2)(A) of such Act.

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

23 (4) DELAY IN APPLICATION OF COORDINATED
24 BENEFITS WITH MEDIGAP.—The provisions of sub-
25 paragraph (B) of section 1842(h)(3) of the Social

1 Security Act shall not apply to covered outpatient
2 drugs (other than drugs described in section
3 1861(s)(2)(J) of such Act as of the date of the en-
4 actment of this Act) dispensed before January 1,
5 2000.

6 (5) BATCH PROMPT PROCESSING OF CLAIMS.—
7 Section 1842(c) of such Act (42 U.S.C. 1395u(c)),
8 as amended by section 202(b)(2) of the Health In-
9 surance Portability and Accountability Act of 1996,
10 is amended—

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

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

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

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

1 recent date on which such a payment was made with re-
 2 spect to the participating pharmacy or individual submit-
 3 ting the claim.

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

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

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

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

24 (g) CONFORMING AMENDMENTS.—

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

3 (A) by inserting “1834(d),” after
 4 “1833(b),”; and

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

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

15 (h) PRESCRIPTION DRUG PAYMENT REVIEW COM-
 16 MISSION.—Part B is amended by inserting after section
 17 1846 the following new section:

18 “PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION
 19 “SEC. 1847. (a)(1) The Director of the Congressional
 20 Office of Technology Assessment (in this section referred
 21 to as the ‘Director’ and the ‘Office’, respectively) shall
 22 provide for the appointment of a Prescription Drug Pay-
 23 ment Review Commission (in this section referred to as
 24 the ‘Commission’), to be composed of individuals with ex-
 25 pertise in the provision and financing of covered out-
 26 patient drugs appointed by the Director (without regard

1 to the provisions of title 5, United States Code, governing
2 appointments in the competitive service).

3 “(2) The Commission shall consist of 11 individuals.
4 Members of the Commission shall first be appointed by
5 no later than January 1, 1998, for a term of 3 years, ex-
6 cept that the Director may provide initially for such short-
7 er terms as will ensure that (on a continuing basis) the
8 terms of no more than 4 members expire in any one year.

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

14 “(b)(1) The Commission shall submit to Congress an
15 annual report no later than May 1 of each year, beginning
16 with 1999, concerning methods of determining payment
17 for covered outpatient drugs under this part.

18 “(2) Such report, in 2000 and thereafter, shall in-
19 clude, with respect to the previous year, information on—

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

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

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

3 “(c) Section 1845(c)(1) shall apply to the Commis-
4 sion in the same manner as it applies to the Physician
5 Payment Review Commission.

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

10 (i) DEVELOPMENT OF STANDARD MEDICARE CLAIMS
11 FORM.—

12 (1) The Secretary shall develop, in consultation
13 with representatives of pharmacies and other inter-
14 ested individuals, a standard claims form (and a
15 standard electronic claims format) to be used in re-
16 quests for payment for covered outpatient drugs
17 under the medicare program and other third-party
18 payors.

19 (2) Not later than October 1, 1998, the Sec-
20 retary shall distribute official sample copies of the
21 format developed under paragraph (1) to pharmacies
22 and other interested parties and by not later than
23 October 1, 1998, shall distribute official sample cop-
24 ies of the form developed under paragraph (1) to
25 pharmacies and other interested parties.

1 (j) EFFECTIVE DATES.—

2 (1) IN GENERAL.—Except as otherwise pro-
3 vided in this subsection, the amendments made by
4 this section shall apply to items dispensed on or
5 after January 1, 1999.

6 (2) CARRIERS.—The amendments made by sub-
7 section (e) shall take effect on the date of the enact-
8 ment of this Act; except that the amendments made
9 by subsection (e)(5) shall take effect on January 1,
10 2000, but shall not be construed as requiring pay-
11 ment before February 1, 2000.

12 (3) HMO/CMP ENROLLMENTS.—The amend-
13 ment made by subsection (f) shall apply to enroll-
14 ments effected on or after January 1, 1999.

○