

104TH CONGRESS
1ST SESSION

H. R. 507

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 13, 1995

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 1995”.

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

4 (a) IN GENERAL.—

5 (1) PART A.—Section 1812 of the Social Secu-
6 rity 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 1890,”

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 ex-
19 tended care services (in accordance with section
20 1890).”; and

21 (B) in subsection (b)(2), by striking “post-
22 hospital” and inserting “except as provided in
23 section 1890, post-hospital”.

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

1 147(f)(6)(B)(iii) of the Social Security Act Amend-
2 ments of 1994, is amended—

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

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

7 (C) by inserting after subparagraph (O)
8 the following new subparagraph:

9 “(P) long-term care services consisting of in-
10 home care (in accordance with section 1890); and”.

11 (b) DESCRIPTION OF SERVICES; ELIGIBILITY.—Title
12 XVIII of the Social Security Act is amended by inserting
13 after section 1889 the following new section:

14 “LONG-TERM CARE SERVICES FOR DEPENDENT
15 INDIVIDUALS

16 “SEC. 1890. (a) IN GENERAL.—An individual enti-
17 tled to benefits under this part shall be entitled to have
18 payments made on the individual’s behalf for long-term
19 care services if—

20 “(1) the individual is a dependent individual;
21 and

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

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

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

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

6 “(c) PAYMENT FOR SERVICES.—

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

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

18 “(d) DEPENDENT INDIVIDUAL DEFINED.—

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

21 “(A) is unable to perform (without sub-
22 stantial assistance from another individual) be-
23 cause of physical or cognitive impairment at
24 least 2 of the following activities of daily living:

1 bathing, dressing, toileting, transferring, and
2 eating; or

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

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

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

13 “(2) CHRONICALLY DEPENDENT INDIVIDUAL.—
14 In this section, the term ‘chronically dependent indi-
15 vidual’ means an individual described in paragraph
16 (1) who—

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

21 “(B) for purposes of subparagraph (B)(i)
22 of such paragraph, has a level of disability that
23 requires direction, instruction, or supervision of
24 another individual to perform 3 or more of such
25 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 1890(c);”.

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 (m)) 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 (B) by striking the period at the end and
2 inserting “, but only if used for a medically ac-
3 cepted indication (as described in paragraph
4 (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
25 201(p) of the Federal Food, Drug, and Cos-

1 metetic Act) or an action brought by the Sec-
2 retary under section 301, 302(a), or 304(a) of
3 such Act to enforce section 502(f) or 505(a) of
4 such Act; or

5 “(iii)(I) which is described in section
6 107(c)(3) of the Drug Amendments of 1962
7 and for which the Secretary has determined
8 there is a compelling justification for its medi-
9 cal need, or is identical, similar, or related
10 (within the meaning of section 310.6(b)(1) of
11 title 21 of the Code of Federal Regulations) to
12 such a drug, and (II) for which the Secretary
13 has not issued a notice of an opportunity for a
14 hearing under section 505(e) of the Federal
15 Food, Drug, and Cosmetic Act on a proposed
16 order of the Secretary to withdraw approval of
17 an application for such drug under such section
18 because the Secretary has determined that the
19 drug is less than effective for all conditions of
20 use prescribed, recommended, or suggested in
21 its labeling;

22 “(B) a biological product which—

23 “(i) may only be dispensed upon prescrip-
24 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) 1997 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.—

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

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

8 “(ii) the applicable payment limit es-
9 tablished under paragraph (3).

10 “(B) TREATMENT OF CERTAIN COST-
11 BASED PREPAID ORGANIZATIONS.—In applying
12 subparagraph (A) in the case of an organization
13 under a reasonable cost reimbursement contract
14 under section 1876 and in the case of an orga-
15 nization receiving payment under section
16 1833(a)(1)(A) and providing coverage of cov-
17 ered outpatient drugs, the Secretary shall pro-
18 vide for an appropriate adjustment in the pay-
19 ment amounts otherwise made to reflect the ag-
20 gregate increase in payments that would other-
21 wise be made with respect to enrollees in such
22 an organization if payments were made other
23 than under such clause or such a contract on
24 an individual-by-individual basis.

25 “(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, 1997), 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 1997, 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) 1997, 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 TOWARDS 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 towards 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 towards 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).

1 “(E) MEDICARE BENEFICIARY DEFINED.—
2 In this subsection, the term ‘medicare bene-
3 ficiary’ means, with respect to a month, an in-
4 dividual covered for benefits under this part for
5 the month.

6 “(F) TREATMENT OF PLAN CHARGES.—In
7 the case of covered outpatient drugs furnished
8 by an eligible organization under section
9 1876(b) or an organization described in section
10 1833(a)(1)(A) which does not impose charges
11 on covered outpatient drugs dispensed to its
12 members, for purposes of this subsection the
13 actual charges of the organization shall be the
14 organization’s standard charges to members,
15 and other individuals, not entitled to benefits
16 with respect to such drugs.

17 “(7) PHYSICIAN GUIDE.—

18 “(A) IN GENERAL.—The Secretary shall
19 develop, and update annually, an information
20 guide for physicians concerning the comparative
21 average wholesale prices of at least 500 of the
22 most commonly prescribed covered outpatient
23 drugs. Such guide shall, to the extent prac-
24 ticable, group covered outpatient drugs (includ-
25 ing 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 1997), 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 1995) with the semiannual average increase
12 in such prices and charges during the 5 years
13 beginning with 1989.

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 1996 and 1997
19 and in May of each succeeding year, providing
20 the information compiled under subparagraph
21 (A). For each such report submitted after
22 1998, 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
21 bioequivalence problem or, if they do
22 present such a problem, are shown to
23 meet an appropriate standard of
24 bioequivalence.

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
24 term ‘participating supplier’ means a participat-

1 ing pharmacy (as defined in subsection
2 (o)(1))”;

3 (B) in subsection (h)(4), is amended by
4 adding at the end the following: “In publishing
5 directories under this paragraph, the Secretary
6 shall provide for separate directories (wherever
7 appropriate) for participating pharmacies.”;
8 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, 1997, 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.

24 “(D) The entity agrees to submit information
25 (in a manner specified by the Secretary to be nec-

1 essary to administer this title) on all purchases of
2 covered outpatient drugs dispensed to medicare
3 beneficiaries.

4 “(E) The entity agrees—

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

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

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

19 Nothing in this paragraph shall be construed as requiring
20 a pharmacy operated by an eligible organization (described
21 in section 1876(b)) or an organization described in section
22 1833(a)(1)(A) for the exclusive benefit of its members to
23 dispense covered outpatient drugs to individuals who are
24 not members of the organization.

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

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

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

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

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

16 “(B) the accuracy of information submitted by
17 the pharmacies under this title.

18 “(4) The Secretary shall establish, by not later than
19 January 1, 1997, a point-of-sale electronic system for use
20 by carriers and participating pharmacies in the submission
21 of information respecting covered outpatient drugs dis-
22 pensed to medicare beneficiaries under this part.

23 “(5) Notwithstanding subsection (b)(3)(B), payment
24 for covered outpatient drugs may be made on the basis

1 of an assignment described in clause (ii) of that subsection
2 only to a participating pharmacy.”.

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

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

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

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

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

18 (E) by inserting after paragraph (3) the
19 following new paragraph:

20 “(4) in the case of a participating or
21 nonparticipating pharmacy (as defined for purposes
22 of part B of title XVIII)—

23 “(A) presents or causes to be presented to
24 any person a request for payment for covered
25 outpatient drugs dispensed to an individual en-

1 titled to benefits under part B of title XVIII
2 and for which the amount charged by the phar-
3 macy is greater than the amount the pharmacy
4 charges the general public (as determined by
5 the Secretary in regulations), or

6 “(B) fails to provide the information re-
7 quested by the Secretary in a survey under sec-
8 tion 1834(d)(3)(C)(ii);”.

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

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

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

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

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

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

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

23 “(2) No payment may be made under part B for any
24 expense incurred for a covered outpatient drug if the drug
25 is dispensed in a quantity exceeding a supply of 30 days

1 or such longer period of time (not to exceed 90 days, ex-
2 cept in exceptional circumstances) as the Secretary may
3 authorize.”.

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

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

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

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

13 (C) by adding at the end the following new
14 paragraph:

15 “(3) with respect to implementation and oper-
16 ation (and related functions) of the electronic system
17 established under subsection (o)(4), a voluntary as-
18 sociation, corporation, partnership, or other non-
19 governmental organization, which the Secretary de-
20 termines to be qualified to conduct such activities.”.

21 (2) ADDITIONAL FUNCTIONS OF CARRIERS.—
22 Section 1842(b)(3) of such Act (42 U.S.C.
23 1395u(b)(3)), as amended by section
24 151(b)(1)(B)(iii) of the Social Security Act Amend-
25 ments of 1994, is amended—

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

3 (B) by adding “and” at the end of sub-
4 paragraph (L);

5 (C) by redesignating subparagraph (L) as
6 subparagraph (J); and

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

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

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

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

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

1 section (o)(4) for covered outpatient drugs under
2 this part;”.

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

5 (A) PAYMENT ON OTHER THAN A COST
6 BASIS.—Section 1842(c)(1) of such Act (42
7 U.S.C. 1395u(c)(1)), as amended by section
8 126(h)(2) of the Social Security Act Amend-
9 ments of 1994, is amended—

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

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

14 (iii) by adding at the end the follow-
15 ing new subparagraph:

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

23 (B) APPLICATION OF DIFFERENT PER-
24 FORMANCE STANDARDS.—The Secretary of
25 Health and Human Services, before entering

1 into contracts under section 1842 of the Social
2 Security Act with respect to the implementation
3 and operation (and related functions) of the
4 electronic system for covered outpatient drugs,
5 shall establish standards with respect to per-
6 formance with respect to such activities. The
7 provisions of section 1153(e)(2) and paragraphs
8 (1) and (2) of section 1153(h) of such Act shall
9 apply to such activities in the same manner as
10 they apply to contracts with peer review organi-
11 zations, instead of the requirements of the sec-
12 ond and third sentences of section
13 1842(b)(2)(A) of such Act.

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 (o)(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 shall not apply to covered outpatient
3 drugs (other than drugs described in section
4 1861(s)(2)(J) of such Act as of the date of the en-
5 actment of this Act) dispensed before January 1,
6 1998.

7 (5) BATCH PROMPT PROCESSING OF CLAIMS.—
8 Section 1842(c) of such Act (42 U.S.C. 1395u(c)),
9 as amended by sections 125(a) and 135(b)(2) of the
10 Social Security Act Amendments of 1994, is
11 amended—

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

15 (B) by adding at the end the following new
16 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(d),” 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(d)(2)(C)) of
6 the lesser of the actual charges for the drugs or
7 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 inserting after section
15 1846 the following new section:

16 “PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION
17 “SEC. 1847. (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, 1996, for a term of 3 years, ex-
4 cept that the Director may provide initially for such short-
5 er terms as will insure 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 1997, concerning methods of determining payment
15 for covered outpatient drugs under this part.

16 “(2) Such report, in 1998 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) Section 1845(c)(1) shall apply to the Commis-
2 sion in the same manner as it applies to the Physician
3 Payment Review Commission.

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

8 (i) DEVELOPMENT OF STANDARD MEDICARE CLAIMS
9 FORM.—

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

17 (2) Not later than October 1, 1996, the Sec-
18 retary shall distribute official sample copies of the
19 format developed under paragraph (1) to pharmacies
20 and other interested parties and by not later than
21 October 1, 1996, shall distribute official sample cop-
22 ies of the form developed under paragraph (1) to
23 pharmacies and other interested parties.

24 (j) EFFECTIVE DATES.—

1 (1) IN GENERAL.—Except as otherwise pro-
2 vided in this subsection, the amendments made by
3 this section shall apply to items dispensed on or
4 after January 1, 1997.

5 (2) CARRIERS.—The amendments made by sub-
6 section (e) shall take effect on the date of the enact-
7 ment of this Act; except that the amendments made
8 by subsection (e)(5) shall take effect on January 1,
9 1998, but shall not be construed as requiring pay-
10 ment before February 1, 1998.

11 (3) HMO/CMP ENROLLMENTS.—The amend-
12 ment made by subsection (f) shall apply to enroll-
13 ments effected on or after January 1, 1997.

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