

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> 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.

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## 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

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## 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           metic 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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