

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2673

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

JULY 20, 1993

Mr. ENGEL introduced the following bill; which was referred jointly to the Committees on Ways and Means and Energy and Commerce

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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 1993”.

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 1821,”

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 1821, post-hospital”.

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

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

3 (B) in subparagraph (P), by adding “and”  
4 at the end and moving such subparagraph 2  
5 ems to the left; and

6 (C) by adding at the end the following new  
7 subparagraph:

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

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

13 “LONG-TERM CARE SERVICES FOR DEPENDENT  
14 INDIVIDUALS

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

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

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

24 “(b) SERVICES PROVIDED.—In this section, the term  
25 ‘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(mm)) 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  
22 another 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 “1834(h)(1), (M)” and inserting  
24 “1834(h)(1), (N)”;

1 (B) by striking “subsection (r)(2)) and (N)”  
2 and inserting “subsection (r)(2)), (O)”;

3 (C) by striking “1848(a)(1);” and inserting the  
4 following: “1848(a)(1), and (P) with respect to ex-  
5 penses incurred for services described in section  
6 1861(s)(2)(Q), the amounts paid shall be the  
7 amounts determined under section 1890(c);”.

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

11 “HOME CARE AGENCY

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

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

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

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

1 tions of this nature, as meeting the standards estab-  
2 lished for such licensing; and

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

8 (d) EFFECTIVE DATE.—The amendments made by  
9 this section shall apply to items and services furnished on  
10 or after January 1, 1994.

11 **SEC. 3. MEDICARE COVERAGE OF OUTPATIENT PRESCRIP-**  
12 **TION DRUGS.**

13 (a) DESCRIPTION OF COVERED OUTPATIENT  
14 DRUGS.—Section 1861 of the Social Security Act (42  
15 U.S.C. 1395x) is amended—

16 (1) in subsection (s)(2), by amending subpara-  
17 graph (J) to read as follows:

18 “(J) covered outpatient drugs (as defined in  
19 subsection (t)); and”;

20 (2) in subsection (t)—

21 (A) by inserting “and paragraph (2)” after  
22 “subsection (m)(5)”,

23 (B) by striking “(t)” and inserting  
24 “(t)(1)”, and

1 (C) by adding at the end the following new  
2 paragraphs:

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

5 “(A) a drug which may be dispensed only upon  
6 prescription and—

7 “(i) which is approved for safety and effec-  
8 tiveness as a prescription drug under section  
9 505 or 507 of the Federal Food, Drug, and  
10 Cosmetic Act or which is approved under sec-  
11 tion 505(j) of such Act;

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

1           “(iii)(I) which is described in section  
2           107(c)(3) of the Drug Amendments of 1962  
3           and for which the Secretary has determined  
4           there is a compelling justification for its medi-  
5           cal need, or is identical, similar, or related  
6           (within the meaning of section 310.6(b)(1) of  
7           title 21 of the Code of Federal Regulations) to  
8           such a drug, and (II) for which the Secretary  
9           has not issued a notice of an opportunity for a  
10          hearing under section 505(e) of the Federal  
11          Food, Drug, and Cosmetic Act on a proposed  
12          order of the Secretary to withdraw approval of  
13          an application for such drug under such section  
14          because the Secretary has determined that the  
15          drug is less than effective for all conditions of  
16          use prescribed, recommended, or suggested in  
17          its labeling;

18          “(B) a biological product which—

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

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

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

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

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

7           “(i) Inpatient hospital services (described in  
8           subsection (b)(2)).

9           “(ii) Extended care services (described in sub-  
10          section (h)(5)).

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

13          “(iv) Dialysis supplies under subsection  
14          (s)(2)(F).

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

16          “(vi) Blood clotting factors for hemophiliacs  
17          under subsection (s)(2)(I).

18          “(vii) Services of a physician assistant, nurse  
19          practitioner, or clinical nurse specialist under sub-  
20          section (s)(2)(K).

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

23          “(ix) Rural health clinic services (under sub-  
24          section (aa)(1)).

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

3           “(xi) Hospice care (as defined in subsection  
4           (dd)(1)).

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

7           “(xiii) Inpatient or outpatient rural primary  
8           care hospital services (as defined in subsection  
9           (mm)).

10           “(xiv) A covered surgical procedure in an ambu-  
11           latory surgical center (under section  
12           1832(a)(2)(F)(i)).

13           “(B) The term ‘covered outpatient drug’ does not in-  
14           clude any drug that is intravenously administered in a  
15           home setting.”.

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

19                   (A) by striking “and (P)” and inserting “(P)”;  
20           and

21                   (B) by striking the semicolon at the end and in-  
22           serting the following “, and (Q) with respect to ex-  
23           penses incurred for covered outpatient drugs, the  
24           amounts paid shall be the amounts determined  
25           under section 1834(d)(2);”.

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

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

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

8           (B) in clause (2), by inserting “or with respect  
9 to covered outpatient drugs” after “home health  
10 services”.

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

14       “(d) PAYMENT FOR COVERED OUTPATIENT  
15 DRUGS.—

16           “(1) DEDUCTIBLE.—

17               “(A) APPLICATION.—

18                   “(i) IN GENERAL.—Except as pro-  
19 vided in clauses (ii) and (iii), payment  
20 shall be made under paragraph (2) only  
21 with respect to expenses incurred by an in-  
22 dividual for covered outpatient drugs dur-  
23 ing a calendar year on or after such date  
24 in the year as the Secretary determines  
25 that the individual has incurred expenses

1 in the year for covered outpatient drugs  
2 (during a period in which the individual is  
3 entitled to benefits under this part) equal  
4 to the amount of the prescription drug de-  
5 ductible specified in subparagraph (C) for  
6 that year.

7 “(ii) DEDUCTIBLE NOT APPLIED TO  
8 1ST YEAR IMMUNOSUPPRESSIVES.—The  
9 prescription drug deductible established  
10 under this paragraph shall not apply to  
11 drugs described in section 1861(t)(2)(A)  
12 used in immunosuppressive therapy and  
13 furnished, to an individual who receives an  
14 organ transplant for which payment is  
15 made under this title, within 1 year after  
16 the date of the transplant.

17 “(B) RESPONSE TO APPLICATION.—If the  
18 system described in section 1842(o)(4) has not  
19 been established and an individual applies to  
20 the Secretary to establish that the individual  
21 has met the requirement of subparagraph (A),  
22 the Secretary shall promptly notify the individ-  
23 ual (and, if the application was submitted by or  
24 through a participating pharmacy, the phar-

1 macy) as to the date (if any) as of which the  
2 individual has met such requirement.

3 “(C) PRESCRIPTION DRUG DEDUCTIBLE  
4 AMOUNT.—The prescription drug deductible  
5 specified in this subparagraph for—

6 “(i) 1995 is \$250, and

7 “(ii) any succeeding year, is the pre-  
8 scription drug deductible for the preceding  
9 year, increased by the percentage by which  
10 the monthly premium under section 1839  
11 for months during the year exceeds the  
12 monthly premium under such section for  
13 months during the preceding year.

14 “(2) PAYMENT AMOUNT.—

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

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

22 “(ii) the applicable payment limit es-  
23 tablished under paragraph (3).

24 “(B) TREATMENT OF CERTAIN COST-  
25 BASED PREPAID ORGANIZATIONS.—In applying

1           subparagraph (A) in the case of an organization  
2           under a reasonable cost reimbursement contract  
3           under section 1876 and in the case of an orga-  
4           nization receiving payment under section  
5           1833(a)(1)(A) and providing coverage of cov-  
6           ered outpatient drugs, the Secretary shall pro-  
7           vide for an appropriate adjustment in the pay-  
8           ment amounts otherwise made to reflect the ag-  
9           gregate increase in payments that would other-  
10          wise be made with respect to enrollees in such  
11          an organization if payments were made other  
12          than under such clause or such a contract on  
13          an individual-by-individual basis.

14          “(3) PAYMENT LIMITS.—

15                 “(A) PAYMENT LIMIT FOR NON-MULTIPLE  
16                 SOURCE DRUGS AND MULTIPLE-SOURCE DRUGS  
17                 WITH RESTRICTIVE PRESCRIPTIONS.—In the  
18                 case of a drug that either is not a multiple  
19                 source drug (as defined in paragraph (9)(A)) or  
20                 is a multiple source drug and has a restrictive  
21                 prescription (as defined in paragraph (9)(B)),  
22                 the payment limit for the drug under this para-  
23                 graph for a payment calculation period is equal  
24                 to the lesser of—

1           “(i) the 90th percentile of the actual  
2 charges (computed on a statewide basis,  
3 carrier-wide basis, or other appropriate ge-  
4 ographic area basis, as specified by the  
5 Secretary) for the drug for the second pre-  
6 vious payment calculation period, adjusted  
7 (as the Secretary determines to be appro-  
8 priate) to reflect the number of tablets (or  
9 other dosage units) dispensed; or

10           “(ii) the amount of the administrative  
11 allowance (established under paragraph  
12 (4)) plus the product of—

13                   “(I) the number of tablets (or  
14 other dosage units) dispensed, and

15                   “(II) the per tablet or unit aver-  
16 age wholesale price for such drug (as  
17 determined under subparagraph (C)  
18 for the period for purposes of this  
19 subparagraph).

20           “(B) PAYMENT LIMIT FOR MULTIPLE  
21 SOURCE DRUGS WITHOUT RESTRICTIVE PRE-  
22 SCRIPTIONS.—In the case of a drug that is a  
23 multiple source drug but does not have a re-  
24 strictive prescription, the payment limit for the  
25 drug under this paragraph for a payment cal-

1            culation period is equal to the amount of the  
2            administrative allowance (established under  
3            paragraph (4)) plus the product of—

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

6            “(ii) the unweighted median of the  
7            per tablet or unit average wholesale prices  
8            (determined under subparagraph (C) for  
9            purposes of this subparagraph) for such  
10           drug for the period.

11           “(C) DETERMINATION OF UNIT PRICE.—

12           “(i) IN GENERAL.—For purposes of  
13           this paragraph, the Secretary shall deter-  
14           mine, with respect to the dispensing of a  
15           covered outpatient drug in a payment cal-  
16           culation period (beginning on or after Jan-  
17           uary 1, 1995), the per tablet or unit aver-  
18           age wholesale price for the drug.

19           “(ii) BASIS FOR DETERMINATIONS.—

20           “(I) DETERMINATION FOR NON-  
21           MULTIPLE-SOURCE DRUGS.—For pur-  
22           poses of subparagraph (A), such de-  
23           termination shall be based on a bian-  
24           nual survey conducted by the Sec-  
25           retary of a representative sample of

1 direct sellers, wholesalers, or phar-  
2 macies (as appropriate) of wholesale  
3 (or comparable direct) prices (exclud-  
4 ing discounts to pharmacies); except  
5 that if, because of low volume of sales  
6 for the drug or other appropriate rea-  
7 sons or in the case of covered out-  
8 patient drugs during 1995, the Sec-  
9 retary determines that such a survey  
10 is not appropriate with respect to a  
11 specific drug, such determination shall  
12 be based on published average whole-  
13 sale (or comparable direct) prices for  
14 the drug.

15 “(II) DETERMINATION FOR MUL-  
16 TIPLE-SOURCE DRUGS.—For purposes  
17 of subparagraph (B), the Secretary  
18 may base the determination under  
19 this subparagraph on the published  
20 average wholesale (or comparable di-  
21 rect) prices for the drug or on a bian-  
22 nual survey conducted by the Sec-  
23 retary of a representative sample of  
24 direct sellers, wholesalers, or phar-  
25 macists (as appropriate) of wholesale

1 (or comparable direct) prices (exclud-  
2 ing discounts to pharmacies).

3 “(III) COMPLIANCE WITH SUR-  
4 VEY REQUIRED.—If a wholesaler or  
5 direct seller of a covered outpatient  
6 drug refuses, after being requested by  
7 the Secretary, to provide the informa-  
8 tion required in a survey under this  
9 clause, or deliberately provides infor-  
10 mation that is false, the Secretary  
11 may impose a civil money penalty of  
12 not to exceed \$10,000 for each such  
13 refusal or provision of false informa-  
14 tion. The provisions of section 1128A  
15 (other than subsections (a) and (b))  
16 shall apply to civil money penalties  
17 under the previous sentence in the  
18 same manner as such provisions apply  
19 to a penalty or proceeding under sec-  
20 tion 1128A(a). Information gathered  
21 pursuant to the survey shall not be  
22 disclosed except as the Secretary de-  
23 termines to be necessary to carry out  
24 the purposes of this part.

1           “(iii) QUANTITY AND TIMING.—Such  
2           determination shall be based on the price  
3           or prices for purchases in reasonable quan-  
4           tities and shall be made for a payment cal-  
5           culation period based on prices for the first  
6           day of the first month of the previous pay-  
7           ment calculation period.

8           “(iv) GEOGRAPHIC BASIS.—The Sec-  
9           retary shall make such determination, and  
10          calculate the payment limits under this  
11          paragraph, on a national basis; except that  
12          the Secretary may make such determina-  
13          tion, and calculate such payment limits, on  
14          a regional basis to take account of limita-  
15          tions on the availability of drug products  
16          and variations among regions in the aver-  
17          age wholesale prices for a drug product.

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

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

22                         “(i) 1995, the administrative allow-  
23                         ance under this paragraph is—

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

1                   “(II) \$3.00 for drugs dispensed  
2                   by another pharmacy; or

3                   “(ii) a subsequent year, the adminis-  
4                   trative allowance under this paragraph is  
5                   the administrative allowance under this  
6                   paragraph for the preceding year increased  
7                   by the percentage increase (if any) in the  
8                   implicit price deflator for gross national  
9                   product (as published by the Department  
10                  of Commerce in its ‘Survey of Current  
11                  Business’) over the 12-month period end-  
12                  ing with August of such preceding year.

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

16                  “(B) ADJUSTMENT IN ALLOWANCE FOR  
17                  MAIL SERVICE PHARMACIES.—The Secretary  
18                  may, by regulation and after consultation with  
19                  pharmacists, elderly groups, and private insur-  
20                  ers, reduce the administrative allowances estab-  
21                  lished under subparagraph (A) for any drug  
22                  dispensed by a mail service pharmacy (as de-  
23                  fined by the Secretary) based on differences be-  
24                  tween such pharmacies and other pharmacies

1 with respect to operating costs and other econo-  
2 mies.

3 “(5) ASSURING APPROPRIATE PRESCRIBING  
4 AND DISPENSING PRACTICES.—

5 “(A) IN GENERAL.—The Secretary shall  
6 establish a program to identify (and to educate  
7 physicians and pharmacists concerning)—

8 “(i) instances or patterns of unneces-  
9 sary or inappropriate prescribing or dis-  
10 pensing practices for covered outpatient  
11 drugs;

12 “(ii) instances or patterns of sub-  
13 standard care with respect to such drugs;  
14 and

15 “(iii) potential adverse reactions.

16 “(B) STANDARDS.—In carrying out the  
17 program under subparagraph (A), the Secretary  
18 shall establish for each covered outpatient drug  
19 standards for the prescribing of the drug which  
20 are based on accepted medical practice. In es-  
21 tablishing such standards, the Secretary shall  
22 incorporate standards from such current au-  
23 thoritative compendia as the Secretary may se-  
24 lect; except that the Secretary may modify such  
25 a standard by regulation on the basis of sci-

1           entific and medical information that such  
2           standard is not consistent with the safe and ef-  
3           fective use of the drug.

4           “(C) PROHIBITION OF FORMULARY.—  
5           Nothing in this title (other than section  
6           1862(c)) shall be construed as authorizing the  
7           Secretary to exclude from coverage or to deny  
8           payment—

9                   “(i) for any specific covered out-  
10                   patient drug, or specific class of covered  
11                   outpatient drug; or

12                   “(ii) for any specific use of such a  
13                   drug for a specific indication unless such  
14                   exclusion is pursuant to section 1862(a)(1)  
15                   based on a finding by the Secretary that  
16                   such use is not safe or is not effective.

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

19                   “(A) GENERAL RULE COUNTING PREPAID  
20                   PLAN EXPENSES TOWARDS THE PRESCRIPTION  
21                   DRUG DEDUCTIBLE.—Except as provided in  
22                   subparagraph (B), expenses incurred by (or on  
23                   behalf of) a medicare beneficiary for covered  
24                   outpatient drugs shall be counted (consistent  
25                   with subparagraph (C)) toward the prescription

1 drug deductible established under paragraph  
2 (1) whether or not, at the time the expenses  
3 were incurred, the beneficiary was enrolled in a  
4 plan under section 1833(a)(1)(A) or under sec-  
5 tion 1876.

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

10 “(i) expenses incurred by the bene-  
11 ficiary for covered outpatient drugs reim-  
12 bursed under the plan shall not be counted  
13 towards the prescription drug deductible,  
14 but

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

1           “(C) TREATMENT OF EXPENSES FOR COV-  
2           ERED OUTPATIENT DRUGS INCURRED WHILE  
3           ENROLLED IN A PREPAID PLAN OTHER THAN A  
4           DRUG BUY-OUT PLAN.—The Secretary may not  
5           enter into a contract with an organization  
6           under section 1876, or provide for payment  
7           under section 1833(a)(1)(A) with respect to an  
8           organization which provides reimbursement for  
9           covered outpatient drugs, with respect to a plan  
10          that is not a drug buy-out plan, unless the or-  
11          ganization provides assurances, satisfactory to  
12          the Secretary, that—

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

20                 “(ii) the organization will take into  
21                 account, in any deductibles established  
22                 under the plan in a year with respect to  
23                 covered outpatient drugs under this part,  
24                 the amounts of expenses for covered out-  
25                 patient drugs incurred in the year by (or

1 on behalf of) the beneficiary and otherwise  
2 counted towards the prescription drug de-  
3 ductible in the year.

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

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

13 “(ii) the prescription drug deductible  
14 specified in paragraph (1)(C).

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

20 “(F) TREATMENT OF PLAN CHARGES.—In  
21 the case of covered outpatient drugs furnished  
22 by an eligible organization under section  
23 1876(b) or an organization described in section  
24 1833(a)(1)(A) which does not impose charges  
25 on covered outpatient drugs dispensed to its

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

6 “(7) PHYSICIAN GUIDE.—

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

21 “(B) MAILING GUIDE.—The Secretary  
22 shall provide for mailing, in January of each  
23 year (beginning with 1995), a copy of the guide  
24 developed and updated under subparagraph  
25 (A)—

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

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

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

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

11           “(A) COMPILATION OF INFORMATION.—

12          The Secretary shall compile information on—

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

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

19          The information compiled under clause (i) shall  
20          include a comparison of the increases in prices  
21          and charges for covered outpatient drugs dur-  
22          ing each 6 month period (beginning with Janu-  
23          ary 1993) with the semiannual average increase  
24          in such prices and charges during the 5 years  
25          beginning with 1987.

1           “(B) REPORTS.—The Secretary shall sub-  
2           mit to the Committees on Ways and Means and  
3           Energy and Commerce of the House of Rep-  
4           resentatives and the Committee on Finance of  
5           the Senate a report, in May and November of  
6           1994 and 1995 and in May of each succeeding  
7           year, providing the information compiled under  
8           subparagraph (A). For each such report sub-  
9           mitted after 1996, the report shall include an  
10          explanation of the extent to which the increases  
11          in outlays for covered outpatient drugs under  
12          this part are due to the factors described in  
13          subparagraphs (A)(i) and (A)(ii).

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

15                 “(A) MULTIPLE SOURCE DRUG.—

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

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

1 Therapeutic Equivalence Evalua-  
2 tions’);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(C) PAYMENT CALCULATION PERIOD.—

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

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

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

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

12 (B) in subsection (h)(4), is amended by  
13 adding at the end the following: “In publishing  
14 directories under this paragraph, the Secretary  
15 shall provide for separate directories (wherever  
16 appropriate) for participating pharmacies.”;  
17 and

18 (C) by inserting after subsection (n) the  
19 following new subsection:

20 “(o)(1) For purposes of this section, the term ‘par-  
21 ticipating pharmacy’ means, with respect to covered out-  
22 patient drugs dispensed on or after January 1, 1995, an  
23 entity which is authorized under a State law to dispense  
24 covered outpatient drugs and which has entered into an

1 agreement with the Secretary, providing at least the fol-  
2 lowing:

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

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

12                   “(ii) in the absence of such a system, the  
13 entity is otherwise notified that the Secretary  
14 has determined,  
15 that the individual has met the prescription drug de-  
16 ductible with respect to such drugs under section  
17 1834(d)(1) for the year.

18           “(B) The entity agrees—

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

22                   “(ii) not to charge medicare beneficiaries  
23 (regardless of whether or not the beneficiaries  
24 are enrolled under a prepaid health plan or with  
25 eligible organization under section 1876) more

1 for such drugs than the amount it charges to  
2 the general public (as determined by the Sec-  
3 retary in regulations).

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

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

12 “(E) The entity agrees—

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

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

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

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

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

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

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

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

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

1           “(B) the accuracy of information submitted by  
2           the pharmacies under this title.

3           “(4) The Secretary shall establish, by not later than  
4 January 1, 1995, a point-of-sale electronic system for use  
5 by carriers and participating pharmacies in the submission  
6 of information respecting covered outpatient drugs dis-  
7 pensed to medicare beneficiaries under this part.

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

12           (2) CIVIL MONEY PENALTIES FOR VIOLATION  
13 OF PARTICIPATION AGREEMENT, FOR EXCESSIVE  
14 CHARGES FOR NONPARTICIPATING PHARMACIES AND  
15 FOR FAILURE TO PROVIDE SURVEY INFORMATION.—  
16 Section 1128A(a) of such Act (42 U.S.C. 1320a-  
17 7a(a)) is amended—

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

20           (B) in paragraph (2)(C), by inserting “or  
21 to be a participating pharmacy under section  
22 1842(o)” after “1842(h)(1)”;

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

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

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

5 “(4) in the case of a participating or  
6 nonparticipating pharmacy (as defined for purposes  
7 of part B of title XVIII)—

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

16 (B) fails to provide the information re-  
17 quested by the Secretary in a survey under sec-  
18 tion 1834(d)(3)(C)(ii);”.

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

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

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

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

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

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

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

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

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

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

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

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

23                         (C) by adding at the end the following new  
24                         paragraph:

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

7           (2) ADDITIONAL FUNCTIONS OF CARRIERS.—  
8           Section 1842(b)(3) of such Act (42 U.S.C.  
9           1395u(b)(3)) is amended—

10           (A) by striking “and” at the end of sub-  
11           paragraph (H);

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

14           (C) by redesignating subparagraph (L) as  
15           subparagraph (I); and

16           (D) by inserting after subparagraph (I) (as  
17           so redesignated) the following new subpara-  
18           graphs:

19           “(J) if it makes determinations or payments  
20           with respect to covered outpatient drugs, will—

21           “(i) receive information transmitted under  
22           the electronic system established under sub-  
23           section (o)(4), and

24           “(ii) respond to requests by participating  
25           pharmacies (and individuals entitled to benefits

1 under this part) as to whether or not such an  
2 individual has met the prescription drug de-  
3 ductible established under section  
4 1834(d)(1)(A) for a year; and

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

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

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

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

19 (ii) in the first sentence, by inserting  
20 “, except as provided in clause (ii),” after  
21 “under this part, and”; and

22 (iii) by adding at the end the follow-  
23 ing new clause:

24 “(ii) To the extent that a contract under this section  
25 provides for implementation and operation (and related

1 functions) of the electronic system established under sub-  
2 section (o)(4) for covered outpatient drugs, the Secretary  
3 may provide for payment for such activities based on any  
4 method of payment determined by the Secretary to be ap-  
5 propriate.”.

6 (B) APPLICATION OF DIFFERENT PER-  
7 FORMANCE STANDARDS.—The Secretary of  
8 Health and Human Services, before entering  
9 into contracts under section 1842 of the Social  
10 Security Act with respect to the implementation  
11 and operation (and related functions) of the  
12 electronic system for covered outpatient drugs,  
13 shall establish standards with respect to per-  
14 formance with respect to such activities. The  
15 provisions of section 1153(e)(2) and paragraphs  
16 (1) and (2) of section 1153(h) of such Act shall  
17 apply to such activities in the same manner as  
18 they apply to contracts with peer review organi-  
19 zations, instead of the requirements of the last  
20 2 sentences of section 1842(b)(2) of such Act.

21 (C) USE OF REGIONAL CARRIERS.—Section  
22 1842(b)(2)(A) of such Act (42 U.S.C.  
23 1395u(b)(2)(A)) is amended by adding at the  
24 end the following new sentence: “With respect  
25 to activities relating to implementation and op-

1           eration (and related functions) of the electronic  
2           system established under subsection (o)(4), the  
3           Secretary may enter into contracts with carriers  
4           under this section to perform such activities on  
5           a regional basis.”.

6           (4) DELAY IN APPLICATION OF COORDINATED  
7           BENEFITS WITH MEDIGAP.—The provisions of sub-  
8           paragraph (B) of section 1842(h)(3) of the Social  
9           Security Act shall not apply to covered outpatient  
10          drugs (other than drugs described in section  
11          1861(s)(2)(J) of such Act as of the date of the en-  
12          actment of this Act) dispensed before January 1,  
13          1996.

14          (5) BATCH PROMPT PROCESSING OF CLAIMS.—  
15          Section 1842(c) (42 U.S.C. 1395u(c)) is amended—

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

19                 (B) by adding at the end the following new  
20                 paragraph:

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

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

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

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

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

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

1 (g) CONFORMING AMENDMENTS.—

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

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

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

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

16 (h) PRESCRIPTION DRUG PAYMENT REVIEW COM-  
17 MISSION.—Part B is amended by inserting after section  
18 1846 the following new section:

19 “PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION  
20 “SEC. 1847. (a)(1) The Director of the Congressional  
21 Office of Technology Assessment (in this section referred  
22 to as the ‘Director’ and the ‘Office’, respectively) shall  
23 provide for the appointment of a Prescription Drug Pay-  
24 ment Review Commission (in this section referred to as  
25 the ‘Commission’), to be composed of individuals with ex-  
26 pertise in the provision and financing of covered out-

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

4 “(2) The Commission shall consist of 11 individuals.  
5 Members of the Commission shall first be appointed by  
6 no later than January 1, 1994, for a term of 3 years, ex-  
7 cept that the Director may provide initially for such short-  
8 er terms as will insure that (on a continuing basis) the  
9 terms of no more than 4 members expire in any one year.

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

15 “(b)(1) The Commission shall submit to Congress an  
16 annual report no later than May 1 of each year, beginning  
17 with 1995, concerning methods of determining payment  
18 for covered outpatient drugs under this part.

19 “(2) Such report, in 1996 and thereafter, shall in-  
20 clude, with respect to the previous year, information on—

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

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

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

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

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

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

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

19                 (2) Not later than October 1, 1994, the Sec-  
20                 retary shall distribute official sample copies of the  
21                 format developed under paragraph (1) to pharmacies  
22                 and other interested parties and by not later than  
23                 October 1, 1994, shall distribute official sample cop-  
24                 ies of the form developed under paragraph (1) to  
25                 pharmacies and other interested parties.

1 (j) EFFECTIVE DATES.—

2 (1) IN GENERAL.—Except as otherwise pro-  
3 vided in this subsection, the amendments made by  
4 this section shall apply to items dispensed on or  
5 after January 1, 1995.

6 (2) CARRIERS.—The amendments made by sub-  
7 section (e) shall take effect on the date of the enact-  
8 ment of this Act; except that the amendments made  
9 by subsection (e)(5) shall take effect on January 1,  
10 1996, but shall not be construed as requiring pay-  
11 ment before February 1, 1996.

12 (3) HMO/CMP ENROLLMENTS.—The amend-  
13 ment made by subsection (f) shall apply to enroll-  
14 ments effected on or after January 1, 1995.

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