

105TH CONGRESS
2^D SESSION

H. R. 4753

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs and home infusion drug therapy under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 1998

Mr. STARK introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs and home infusion drug therapy under the Medicare Program.

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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Medicare Prescription Drug Coverage Act of 1998”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

- Sec. 2. Coverage of outpatient prescription drugs.
 Sec. 3. Payment rules and related requirements for covered outpatient drugs.
 Sec. 4. Medicare rebates for covered outpatient drugs.
 Sec. 5. Expansion of Medicare payment advisory commission.
 Sec. 6. Coverage of home infusion drug therapy services.
 Sec. 7. No mark-up for drugs, biologicals, or parenteral nutrients.
 Sec. 8. Treatment of part B premium increases resulting from enactment.
 Sec. 9. Effective date.

1 SEC. 2. COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS.

2 (a) COVERED OUTPATIENT DRUGS AS MEDICAL AND
 3 OTHER HEALTH SERVICES.—Section 1861(s)(2)(J) of the
 4 Social Security Act (42 U.S.C. 1395x(s)(2)(J)) is amend-
 5 ed to read as follows:

6 “(J) covered outpatient drugs;”.

7 (b) DEFINITION OF COVERED OUTPATIENT DRUG.—
 8 Section 1861(t) of such Act (42 U.S.C. 1395x(t)) is
 9 amended—

10 (1) in the heading, by adding at the end the fol-
 11 lowing: “; Covered Outpatient Drugs”;

12 (2) in paragraph (1)—

13 (A) by striking “paragraph (2)” and in-
 14 serting “the succeeding paragraphs of this sub-
 15 section”, and

16 (B) by striking the period at the end and
 17 inserting “, but only if used for a medically ac-
 18 cepted indication (as described in paragraph
 19 (4)).”; and

20 (3) by striking paragraph (2) and inserting the
 21 following:

1 “(2) Except as otherwise provided in paragraph (3),
2 the term ‘covered outpatient drug’ means any of the fol-
3 lowing products used for a medically accepted indication
4 (as described in paragraph (4)):

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.

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

3 “(D) Enteral nutrients (but only if provided as
4 a covered home infusion drug).

5 “(E) Medically-necessary foods for persons with
6 Phenylketonuria (PKU) and other inborn errors of
7 metabolism, in accordance with guidelines developed
8 by the Secretary.

9 “(3) The term ‘covered outpatient drug’ does not in-
10 clude any product—

11 “(A) which is administered through infusion in
12 a setting described in paragraph (5)(A)(ii) unless
13 the product is a covered home infusion drug (as de-
14 fined in paragraph (5));

15 “(B) when furnished as part of, or as incident
16 to, a diagnostic service or any other item or service
17 for which payment may be made under this title
18 (other than physicians’ services or services which
19 would be physicians’ services if furnished by a physi-
20 cian); or

21 “(C) which is listed under paragraph (2) of sec-
22 tion 1927(d) (other than subparagraph (B), (I), or
23 (J) of such subparagraph) as a drug which may be
24 excluded from coverage under a State plan under

1 title XIX and which the Secretary elects to exclude
2 from coverage under part B.

3 “(4) For purposes of paragraph (2), the term ‘medi-
4 cally accepted indication’, with respect to the use of an
5 outpatient drug, includes any use which has been approved
6 by the Food and Drug Administration for the drug, and
7 includes another use of the drug if—

8 “(A) the drug has been approved by the Food
9 and Drug Administration; and

10 “(B)(i) such use is supported by one or more
11 citations which are included (or approved for inclu-
12 sion) in one or more of the following compendia: the
13 American Hospital Formulary Service-Drug Infor-
14 mation, the American Medical Association Drug
15 Evaluations, the United States Pharmacopoeia-Drug
16 Information, and other authoritative compendia as
17 identified by the Secretary, unless the Secretary has
18 determined that the use is not medically appropriate
19 or the use is identified as not indicated in one or
20 more such compendia, or

21 “(ii) the carrier involved determines, based
22 upon guidance provided by the Secretary to carriers
23 for determining accepted uses of drugs, that such
24 use is medically accepted based on supportive clinical
25 evidence in peer reviewed medical literature appear-

1 ing in publications which have been identified for
2 purposes of this clause by the Secretary.

3 The Secretary may revise the list of compendia in sub-
4 paragraph (B)(i) designated as appropriate for identifying
5 medically accepted indications for drugs.

6 “(5)(A) For purposes of paragraph (3), the term
7 ‘covered home infusion drug’ means a covered outpatient
8 drug dispensed to an individual that—

9 “(i) is administered intravenously,
10 subcutaneously, or epidurally, using an access device
11 that is inserted into the body and an infusion device
12 to control the rate of flow of the drug (or through
13 other means of administration determined by the
14 Secretary);

15 “(ii) is administered—

16 “(I) in the individual’s home,

17 “(II) an institution used as the individual’s
18 home, but only if the drug is administered dur-
19 ing an inpatient day for which payment is not
20 made to the institution under part A for inpa-
21 tient or extended care services furnished to the
22 individual, or

23 “(III) in a facility other than the individ-
24 ual’s home if the administration of the drug at
25 the facility is determined by the Secretary to be

1 cost-effective (in accordance with such criteria
2 as the Secretary may establish); and

3 “(iii) with respect to a drug furnished in a
4 home setting—

5 “(I) is an antibiotic drug and the Sec-
6 retary has not determined, for the specific drug
7 or the indication to which the drug is applied,
8 that the drug cannot generally be administered
9 safely, effectively, and cost effectively in such a
10 setting, or

11 “(II) is not an antibiotic drug and the Sec-
12 retary has determined, for the specific drug or
13 the indication to which the drug is applied, that
14 the drug can generally be administered safely,
15 effectively, and cost effectively in such a setting.

16 “(B) Not later than January 1, 2002 (and periodi-
17 cally thereafter), the Secretary shall publish a list of the
18 drugs, and indications for such drugs, that are covered
19 home infusion drugs, with respect to which home infusion
20 drug therapy may be provided under this title.

21 “(C) In this paragraph, the term ‘cost effectively’
22 means, with respect to a home infusion drug, a determina-
23 tion by the Secretary that the coverage of the drug in a
24 non-hospital setting will, considering all expenses, result

1 in lower expenditures under this title than if the drug were
2 not so covered.”.

3 (c) CONFORMING AMENDMENTS REPEALING SEPA-
4 RATE COVERAGE OF CERTAIN DRUGS AND PRODUCTS.—
5 (1) Effective January 1, 2002, section 1861(s)(2) of such
6 Act (42 U.S.C. 1395x(s)(2)) is amended—

7 (A) in subparagraph (A), by striking “(includ-
8 ing drugs” and all that follows through “self-admin-
9 istered)”;

10 (B) by striking subparagraphs (G), (I), (O),
11 (Q), and (T);

12 (C) by adding “and” at the end of subpara-
13 graph (R); and

14 (D) by striking “; and” at the end of subpara-
15 graph (S) and inserting a period.

16 (2) Effective January 1, 2002, section 1861 of such
17 Act (42 U.S.C. 1395x) is amended by striking the sub-
18 section (kk).

19 (3) Effective January 1, 2002, section 1881(b) of
20 such Act (42 U.S.C. 1395rr(b)) is amended—

21 (A) in the first sentence of paragraph (1)—

22 (i) by striking “, (B)” and inserting “, and
23 (B)”, and

24 (ii) by striking “, and (C)” and all that
25 follows and inserting a period;

1 (B) in paragraph (11)—

2 (i) by striking “(11)(A)” and inserting
3 “(11)”, and

4 (ii) by striking subparagraphs (B) and (C).

5 **SEC. 3. PAYMENT RULES AND RELATED REQUIREMENTS**
6 **FOR COVERED OUTPATIENT DRUGS.**

7 (a) IN GENERAL.—Section 1834 of the Social Secu-
8 rity Act (42 U.S.C. 1395m) is amended by inserting after
9 subsection (d) the following new subsection:

10 “(e) PAYMENT FOR AND CERTAIN REQUIREMENTS
11 CONCERNING COVERED OUTPATIENT DRUGS.—

12 “(1) DEDUCTIBLE.—

13 “(A) IN GENERAL.—Payment shall be
14 made under paragraph (2) only for expenses in-
15 curred by an individual for a covered outpatient
16 drug during a calendar year after the individual
17 has incurred expenses in the year for such
18 drugs (during a period in which the individual
19 is entitled to benefits under this part) equal to
20 the deductible amount for that year.

21 “(B) DEDUCTIBLE AMOUNT.—

22 “(i) For purposes of subparagraph
23 (A), subject to clause (iii), the deductible
24 amount is—

1 “(I) for 2002, an amount equal
2 to \$____; and

3 “(II) for any succeeding year, the
4 amount applicable under this subpara-
5 graph for the previous year, increased
6 by the percentage increase in the con-
7 sumer price index for all urban con-
8 sumers (all items; U.S. city average)
9 for the 12-month period ending with
10 June of the previous year (or, if
11 lower, the percentage increase in the
12 pharmaceutical component of such
13 index for such period).

14 “(ii) The Secretary shall promulgate
15 the deductible amount for 2003 and each
16 succeeding year not later than October 1
17 of the previous year.

18 “(iii) If the deductible amount com-
19 puted under clause (i)(II) for a year is not
20 a multiple of \$10, the Secretary shall (for
21 that year only) round it to the nearest
22 multiple of \$10.

23 “(2) PAYMENT AMOUNT.—

24 “(A) IN GENERAL.—Subject to the deduct-
25 ible established under paragraph (1), the

1 amount payable under this part for a covered
2 outpatient drug furnished to an individual dur-
3 ing a calendar year shall be equal to—

4 “(i) 80 percent of the payment basis
5 described in paragraph (3), in the case of
6 an individual who has not incurred ex-
7 penses for covered outpatient drugs during
8 the year (including the deductible imposed
9 under paragraph (1)) in excess of the out-
10 of-pocket limit for the year under subpara-
11 graph (B); and

12 “(ii) 100 percent of the payment basis
13 described in paragraph (3), in the case of
14 any other individual.

15 “(B) OUT-OF-POCKET LIMIT DE-
16 SCRIBED.—

17 “(i) For purposes of subparagraph
18 (A), the out-of-pocket limit for a year is
19 equal to—

20 “(I) for 2002, \$____; and

21 “(II) for any succeeding year, the
22 amount applicable under this subpara-
23 graph for the previous year, increased
24 by the percentage increase described
25 in paragraph (1)(B)(i)(II).

1 “(ii) The Secretary shall promulgate
2 the out-of-pocket limit for 2003 and each
3 succeeding year not later than October 1
4 of the previous year.

5 “(iii) If the out-of-pocket limit com-
6 puted under clause (i)(II) for a year is not
7 a multiple of \$10, the Secretary shall (for
8 that year only) round it to the nearest
9 multiple of \$10.

10 “(3) PAYMENT BASIS.—For purposes of para-
11 graph (2), the payment basis is the lesser of—

12 “(A) the actual net payment for a covered
13 outpatient drug, or

14 “(B) the applicable payment limit estab-
15 lished under paragraph (4).

16 “(4) PAYMENT LIMITS.—

17 “(A) PAYMENT LIMIT FOR SINGLE SOURCE
18 DRUGS AND MULTIPLE SOURCE DRUGS WITH
19 RESTRICTIVE PRESCRIPTIONS.—In the case of a
20 covered outpatient drug that is a multiple
21 source drug which has a restrictive prescription,
22 or that is single source drug, the payment limit
23 for a payment calculation period is equal to the
24 amount of the administrative allowance (estab-
25 lished under paragraph (5)) plus the product of

1 the number of dosage units dispensed and the
2 per unit actual acquisition cost for the drug
3 product (determined under subparagraph (C))
4 for the period.

5 “(B) PAYMENT LIMIT FOR MULTIPLE
6 SOURCE DRUGS WITHOUT RESTRICTIVE PRE-
7 SCRIPTIONS.—In the case of a drug that is a
8 multiple source drug which does not have a re-
9 strictive prescription, the payment limit for a
10 payment calculation period is equal to the
11 amount of the administrative allowance (estab-
12 lished under paragraph (5)) plus the product of
13 the number of dosage units dispensed and the
14 lowest actual acquisition cost (determined under
15 subparagraph (C)) of any of the multiple source
16 drugs in the category as determined by the Sec-
17 retary for the period.

18 “(C) DETERMINATION OF UNIT PRICE.—

19 “(i) INITIAL PAYMENT CALCULATION
20 PERIOD.—The Secretary shall determine,
21 for the dispensing of a covered outpatient
22 drug product in the payment calculation
23 period beginning January 1, 2002, the ac-
24 tual acquisition cost for the drug product,
25 based upon—

1 “(I) in the case of a single source
2 drug or multiple source drug with a
3 restrictive prescription, based upon in-
4 formation from the period beginning
5 in 1998 updated (in a compound man-
6 ner) by the percentage change in the
7 consumer price index for all urban
8 consumers (U.S. city average) for the
9 4 12-month periods ending with June
10 2001; or

11 “(II) in the case of a multiple
12 source drug without a restrictive pre-
13 scription, based upon information
14 from the most recent year for which
15 data is available.

16 “(ii) SUBSEQUENT PERIODS.—The ac-
17 tual acquisition cost for a covered out-
18 patient drug product applicable under this
19 subparagraph for the dispensing of a drug
20 product in a payment calculation period
21 beginning in January of each year (begin-
22 ning with 2003) shall be equal to the ac-
23 tual acquisition cost for the product deter-
24 mined under this subparagraph for the pe-
25 riod ending in January of the previous

1 year, increased by the percentage increase
2 described in paragraph (1)(B)(i)(II).

3 “(iii) SIMPLIFICATION IN DETERMINA-
4 TION OF ACTUAL ACQUISITION COST.—The
5 Secretary shall consult with the provider
6 community to simplify the accounting and
7 reporting requirements used in calculating
8 actual acquisition cost and may accept var-
9 ious averaging procedures, tax documents,
10 and tax accounting procedures (such as
11 last-in-first-out (LIFO) and first-in-first-
12 out (FIFO)) instead of new reporting re-
13 quirements.

14 “(iv) COMPLIANCE WITH REQUEST
15 FOR INFORMATION.—If a wholesaler or di-
16 rect seller of a covered outpatient drug re-
17 fuses, after being requested by the Sec-
18 retary, to provide price information re-
19 quested to carry out clauses (i) or (ii), or
20 deliberately provides information that is
21 false, the Secretary may impose a civil
22 money penalty of not to exceed \$10,000
23 for each such refusal or provision of false
24 information. The provisions of section
25 1128A (other than subsections (a) and (b))

1 shall apply to civil money penalties under
2 the previous sentence in the same manner
3 as they apply to a penalty or proceeding
4 under section 1128A(a). Information gath-
5 ered pursuant to clause (i) or (ii) shall not
6 be disclosed except as the Secretary deter-
7 mines to be necessary to carry out the pur-
8 poses of this part and to permit the Comp-
9 troller General and the Director of the
10 Congressional Budget Office to review the
11 information provided.

12 “(D) DEMONSTRATION OF ALTERNATIVE
13 PURCHASING ARRANGEMENTS.—The Secretary
14 may conduct demonstrations with different
15 forms of purchasing, such as competitive bid-
16 ding, preferred provider organizations, bundling
17 of medical and pharmaceutical costs, and other
18 devices to obtain the lowest possible price for
19 quality pharmaceutical products under this
20 part. If the Secretary determines that a dem-
21 onstration results in lower costs to the program
22 and beneficiaries under this title while main-
23 taining the quality and access to needed prod-
24 ucts, the Secretary may implement the dem-
25 onstration regionally or nationally. The Sec-

1 retary shall from time to time report to Con-
2 gress on demonstrations conducted under this
3 subparagraph.

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

6 “(A) IN GENERAL.—Except as provided in
7 subparagraphs (B) through (D), the adminis-
8 trative allowance established under this para-
9 graph is—

10 “(i) for 2002, an amount equal to
11 \$____; and

12 “(ii) for each succeeding year, the
13 amount for the previous year, adjusted by
14 the percentage increase described in para-
15 graph (1)(B)(i)(II).

16 “(B) SPECIAL RULE.—The Secretary shall
17 establish a higher administrative allowance
18 under subparagraph (A) in the case of
19 compounding, consultation, and to ensure ac-
20 cess to covered drugs and antigens that entail
21 extra or unusual expense.

22 “(C) REDUCTION FOR MAIL ORDER PHAR-
23 MACIES.—The Secretary may, after consulting
24 with representatives of pharmacists, individuals
25 enrolled under this part, and of private insur-

1 ers, reduce the administrative allowances estab-
2 lished under subparagraph (A) for any covered
3 outpatient drug dispensed by a mail order phar-
4 macy, based on differences between such phar-
5 macies and other pharmacies with respect to
6 operating costs and other economies.

7 “(D) NO DISPENSING FEE FOR CERTAIN
8 DRUGS AND PRODUCTS.—No administrative al-
9 lowance may be provided under this paragraph
10 with respect to any of the following covered out-
11 patient drugs, unless the Secretary determines
12 that an administrative allowance is necessary to
13 assure access:

14 “(i) Erythropoietin provided to dialy-
15 sis patients.

16 “(ii) Drugs and biologicals provided
17 as an incident to a physician’s service or to
18 a service which would be a physician’s
19 service if furnished by a physician.

20 “(iii) Covered home infusion drugs.

21 “(6) ASSURING APPROPRIATE PRESCRIBING
22 AND DISPENSING PRACTICES.—

23 “(A) IN GENERAL.—The Secretary shall
24 develop a program to—

1 “(i) provide on-line prospective review
2 of prescriptions on a 24-hour basis (in ac-
3 cordance with subparagraph (B)) and ret-
4 rospective review of claims;

5 “(ii) establish standards for counsel-
6 ing individuals to whom covered outpatient
7 drugs are prescribed; and

8 “(iii) identify (and to educate physi-
9 cians, patients, and pharmacists concern-
10 ing)—

11 “(I) instances or patterns of un-
12 necessary or inappropriate prescribing
13 or dispensing practices for covered
14 outpatient drugs,

15 “(II) instances or patterns of
16 substandard care with respect to such
17 drugs,

18 “(III) potential adverse reactions,
19 and

20 “(IV) appropriate use of generic
21 products.

22 “(B) PROSPECTIVE REVIEW.—

23 “(i) IN GENERAL.—The program
24 under this paragraph shall provide for on-
25 line prospective review of each covered out-

1 patient drug prescribed for a patient be-
2 fore the prescription is filled or the drug is
3 furnished, including screening for potential
4 drug therapy problems due to therapeutic
5 duplication, drug-to-drug interactions, and
6 incorrect drug dosage or duration of drug
7 treatment, including inadequate pain man-
8 agement therapy.

9 “(ii) DISCUSSION OF APPROPRIATE
10 USE.—In conducting prospective review
11 under this subparagraph, any individual or
12 entity that dispenses a covered outpatient
13 drug shall offer to discuss with the patient
14 to whom the drug is furnished or the pa-
15 tient’s caregiver (in person if practicable,
16 or through access to a toll-free telephone
17 service) information regarding the appro-
18 priate use of the drug, potential inter-
19 actions between the drug and other drugs
20 dispensed to the individual, the need for
21 adequate pain management, and such
22 other matters as the Secretary may re-
23 quire.

1 “(iii) ADDITIONAL DUTIES.—In carry-
2 ing out this subparagraph, the Secretary
3 shall—

4 “(I) develop public domain soft-
5 ware which could be used by carriers
6 and pharmacies to provide the on-line
7 prospective review; and

8 “(II) study the feasibility and de-
9 sirability of requiring confidential, en-
10 coded patient diagnosis codes on pre-
11 scriptions and the feasibility of ex-
12 panding the prospective review pro-
13 gram to include the identification of
14 drug-disease contraindications, inter-
15 actions with over-the-counter drugs,
16 and drug-allergy interactions.

17 “(C) PRIOR AUTHORIZATION.—

18 “(i) DEVELOPMENT OF LIST OF MIS-
19 USED DRUGS.—The Secretary shall develop
20 (and periodically) update a list of covered
21 outpatient drugs which the Secretary has
22 determined, based on data collected, may
23 be subject to misuse or inappropriate use.
24 The Secretary shall provide a means for

1 manufacturers to appeal an initial decision
2 to include a drug on the list.

3 “(ii) PRIOR AUTHORIZATION FOR
4 DRUGS ON LIST.—The Secretary shall es-
5 tablish a process under which (subject to
6 clause (iii)) the Secretary may require ad-
7 vance approval for any covered outpatient
8 drug included on the list developed under
9 clause (i), and the Secretary shall develop
10 exceptions for oncologists, medical direc-
11 tors of hospice programs, and others who
12 are or should be regularly involved in ag-
13 gressive pain management.

14 “(iii) RESTRICTIONS ON DENIAL OF
15 APPROVAL.—The Secretary may not deny
16 the approval of a drug under the process
17 established under clause (ii) before its dis-
18 pensing unless the process—

19 “(I) provides responses by tele-
20 phone or other telecommunication de-
21 vice within 24 hours of a request for
22 prior authorization; and

23 “(II) provides for the dispensing
24 of at least a 72-hour supply of a cov-

1 ered outpatient prescription drug in
2 emergency situations.

3 “(D) DRUG USE REVIEW.—As part of the
4 program established under subparagraph (A),
5 the Secretary shall provide for a drug use re-
6 view program to provide for the ongoing peri-
7 odic examination of claims data and other
8 records on covered outpatient drugs furnished
9 to patients under this title in order to identify
10 patterns of fraud, abuse, gross overuse or
11 underuse, or inappropriate or medically unnec-
12 essary care among physicians, pharmacists, and
13 patients.

14 “(E) EXCEPTION FOR MANAGED CARE
15 PROGRAMS.—The Secretary may waive the ap-
16 plication of any provision of this paragraph to
17 the dispensing of covered outpatient drugs by
18 an organization described in section
19 1833(a)(1)(A) or a Medicare+Choice organiza-
20 tion under part C to the extent the Secretary
21 finds that the organization has in effect a pro-
22 gram that meets the objectives of such provi-
23 sion.

24 “(F) ADOPTION OF MEDICAID PRO-
25 GRAMS.—To the extent considered appropriate

1 by the Secretary, the program developed under
2 this paragraph with respect to drugs furnished
3 in a State may include elements applicable to
4 the furnishing of covered outpatient drugs
5 under the State Medicaid program under sec-
6 tion 1927.

7 “(7) ADMINISTRATIVE AND REPORTING REQUIRE-
8 MENTS.—

9 “(A) REQUIREMENTS RELATING TO CON-
10 TROLLED SUBSTANCES AND ILLEGAL USES.—
11 The Secretary shall require an entity furnishing
12 covered outpatient drugs under this part to re-
13 port electronically to the appropriate State
14 agency on any covered outpatient drugs dis-
15 pensed to individuals enrolled under this part
16 that are controlled substances under schedules
17 II through V of the Controlled Substance Act,
18 and on the illegal use or diversion of any such
19 drugs furnished by the entity.

20 “(B) PRIVACY PROTECTION.—The Sec-
21 retary shall establish standards to protect from
22 public disclosure the identity of any individual
23 (whether a patient or an individual involved in
24 the prescribing, dispensing, or administration of

1 the drug) who is the subject of information
2 under this section. Under such standards—

3 “(i) no information on the use of a
4 pharmaceutical by an identifiable individ-
5 ual shall be shared with anyone other than
6 the individual, the individual’s legal guard-
7 ian or custodian, or the individual’s physi-
8 cian;

9 “(ii) no information shall be shared
10 with the individual’s employer, or with a
11 pharmaceutical manufacturer or whole-
12 saler, or with any other individual for pur-
13 poses of contacting the individual to per-
14 suade, sell, or influence the individual’s
15 choice of pharmaceuticals; and

16 “(iii) no physician, pharmacist, or
17 other health care provider who receives any
18 form of compensation or thing of value
19 from a drug manufacturer or wholesaler
20 may contact a patient for purposes of in-
21 fluencing the patient to use the product of
22 that drug manufacturer or wholesaler.

23 “(C) STANDARD CLAIMS FORM.—The Sec-
24 retary shall develop, in consultation with rep-
25 resentatives of pharmacies and of other inter-

1 ested persons, a standard claims form for cov-
2 ered outpatient drugs in accordance with part C
3 of title IX.

4 “(8) BILLING REQUIREMENTS.—

5 “(A) MANDATORY ASSIGNMENT.—(i) Pay-
6 ment under this part for a covered outpatient
7 drug may only be made on an assignment-relat-
8 ed basis.

9 “(ii) Except for deductible, coinsurance, or
10 copayment amounts applicable under this part,
11 no person may bill or collect any amount from
12 an individual enrolled under this part or other
13 person for a covered outpatient drug for which
14 payment may be made under this part, and no
15 such individual or person is liable for payment
16 of any amounts billed in violation of this clause.
17 If a person knowingly and willfully bills or col-
18 lects an amount in violation of the previous sen-
19 tence, the Secretary may apply sanctions
20 against such person in accordance with section
21 1842(j)(2). Paragraph (4) of section 1842(j)
22 shall apply in this clause in the same manner
23 as such paragraph applies to such section.

24 “(B) USE OF ELECTRONIC SYSTEM.—The
25 Secretary shall establish, by not later than July

1 1, 2001, a point-of-sale electronic system for
2 use by carriers and pharmacies in the submis-
3 sion of information respecting covered out-
4 patient drugs dispensed to Medicare bene-
5 ficiaries under this part. Such system shall be
6 consistent with the standards established by the
7 National Council of Prescription Drug Pro-
8 grams, and to the maximum extent possible
9 shall be based on current industry best prac-
10 tices.

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

12 “(A) MULTIPLE AND SINGLE SOURCE
13 DRUGS.—The terms ‘multiple source drug’ and
14 ‘single source drug’ have the meanings of those
15 terms under section 1927(k)(7), except that the
16 reference in such section to a ‘covered out-
17 patient drug’ shall be considered a reference to
18 a covered outpatient drug under this title.

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 a particular drug product
3 must be dispensed, or

4 “(ii) in the case of a prescription
5 issued 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 a particular drug product must
10 be dispensed, 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 product was required
20 to have been dispensed.

21 The requirement of subclause (II) may be
22 satisfied in such alternative manner, in-
23 cluded electronic transmission of appro-
24 priate information, as the Secretary, after
25 consultation with physicians and providers,

1 finds will reduce paperwork and adminis-
2 trative costs while maintaining program in-
3 tegrity.

4 “(C) PAYMENT CALCULATION PERIOD.—
5 The term ‘payment calculation period’ means a
6 calendar year.”.

7 (b) REQUIRING PHARMACIES TO SUBMIT CLAIMS.—
8 Section 1848(g)(4) of such Act (42 U.S.C. 1395w-
9 4(g)(4)) is amended—

10 (1) in the heading—

11 (A) by striking “PHYSICIAN SUBMISSION”
12 and inserting “SUBMISSION”, and

13 (B) by inserting “BY PHYSICIANS AND
14 SUPPLIERS” after “CLAIMS”;

15 (2) in the matter in subparagraph (A) preced-
16 ing clause (i)—

17 (A) by striking “For services furnished on
18 or after September 1, 1990, within 1 year” and
19 inserting “Within 1 year (or 90 days in the
20 case of covered outpatient drugs)”;

21 (B) by striking “a service” and inserting
22 “an item or service”, and

23 (C) by inserting “or of providing a covered
24 outpatient drug,” after “basis,”; and

1 (3) in subparagraph (A)(i), by inserting “item
2 or” before “service”.

3 (c) SPECIAL RULES FOR CARRIERS.—

4 (1) USE OF CARRIERS.—Section 1842(b)(2) of
5 such Act (42 U.S.C. 1395u(b)(2)) is amended by
6 adding at the end the following:

7 “(F) With respect to activities related to covered out-
8 patient drugs, the Secretary may enter into contracts with
9 carriers under this section to perform the activities on a
10 regional or national basis.”.

11 (2) ADDITIONAL FUNCTIONS.—Section
12 1842(b)(3) of such Act (42 U.S.C. 1395u(b)(3)) is
13 amended—

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

16 (B) by inserting after subparagraph (H)
17 the following new subparagraphs:

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

20 “(i) receive information transmitted under
21 the electronic system established under section
22 1834(e)(8)(B), and

23 “(ii) respond to requests by pharmacies
24 (and individuals entitled to benefits under this
25 part) as to whether or not such an individual

1 has met the prescription drug deductible estab-
2 lished under section 1834(e)(1)(B) for a year;
3 “(J) will enter into such contracts with organi-
4 zations described in subsection (f)(3) as the Sec-
5 retary determines may be necessary to implement
6 and operate (and for related functions with respect
7 to) the electronic system established under section
8 1834(e)(8)(B) for covered outpatient drugs under
9 this part; and”.

10 (3) PAYMENT ON OTHER THAN A COST
11 BASIS.—Section 1842(c)(1) of such Act (42 U.S.C.
12 1395u(c)(1)) is amended—

13 (A) by inserting “(A)” after “(c)(1)”,
14 (B) in the first sentence, by inserting “,
15 except as otherwise provided in subparagraph
16 (B),” after “under this part, and”, and
17 (C) by adding at the end the following:

18 “(B) To the extent that a contract under this section
19 provides for activities related to covered outpatient drugs,
20 the Secretary may provide for payment for those activities
21 based on any method of payment determined by the Sec-
22 retary to be appropriate.”.

23 (4) BATCH PROMPT PROCESSING OF CLAIMS.—
24 Section 1842(c) of such Act (42 U.S.C. 1395u(c)) is
25 amended—

1 (A) in paragraphs (2)(A) and (3)(A), by
2 striking “Each” and inserting “Except as pro-
3 vided in paragraph (7), each”; and

4 (B) by adding at the end the following new
5 paragraph:

6 “(7)(A) Each contract under this section which pro-
7 vides for the disbursement of funds, as described in sub-
8 section (a)(1)(B), with respect to claims for payment for
9 covered outpatient drugs shall provide for a payment cycle
10 under which each carrier will, on a monthly basis, make
11 a payment with respect to all claims which were received
12 and approved for payment in the period since the most
13 recent date on which such a payment was made with re-
14 spect to the participating pharmacy or individual submit-
15 ting the claim.

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

1 (5) USE OF OTHER ENTITIES FOR COVERED
2 OUTPATIENT DRUGS.—Section 1842(f) of such Act
3 (42 U.S.C. 1395u(f)) is amended—

4 (A) by striking “and” at the end of para-
5 graph (1),

6 (B) by striking the period at the end of
7 paragraph (2) and inserting “; and”, and

8 (C) by adding at the end the following:

9 “(3) with respect to activities related to covered
10 outpatient drugs, any other private entity which the
11 Secretary determines is qualified to conduct such ac-
12 tivities.”.

13 (6) DESIGNATED CARRIERS TO PROCESS
14 CLAIMS OF RAILROAD RETIREES.—Section 1842(g)
15 of such Act (42 U.S.C. 1395u(g)) is amended by in-
16 serting “(other than functions related to covered
17 outpatient drugs)” after “functions”.

18 (d) CONFORMING AMENDMENTS.—

19 (1)(A) Section 1833(a)(1) of such Act (42
20 U.S.C. 1395l(a)(1)) is amended—

21 (i) by striking “and” at the end of clause

22 (R), and

23 (ii) by inserting before the semicolon at the
24 end the following: “, and (T) with respect to

1 covered outpatient drugs, the amounts paid
2 shall be as prescribed by section 1834(e)”.

3 (B) Section 1833(a)(2) of such Act (42 U.S.C.
4 1395l(a)(2)) is amended in the matter preceding
5 subparagraph (A) by inserting “, except for covered
6 outpatient drugs,” after “and (I) of such section”.

7 (2) Section 1833(b)(2) of such Act (42 U.S.C.
8 1395l(b)(2)) is amended by inserting “or with re-
9 spect to covered outpatient drugs” before the
10 comma.

11 (3) The first sentence of section 1842(h)(2) of
12 such Act (42 U.S.C. 1395u(h)(2)) is amended by in-
13 sserting “(other than a carrier described in sub-
14 section (f)(3))” after “Each carrier”.

15 (4) The first sentence of section 1866(a)(2)(A)
16 of such Act (42 U.S.C. 1395cc(a)(2)(A)) is amend-
17 ed—

18 (A) in clause (i), by inserting “section
19 1834(e),” after “section 1833(b),” and

20 (B) in clause (ii), by inserting “, other
21 than for covered outpatient drugs,” after “pro-
22 vider)”.

1 **SEC. 4. MEDICARE REBATES FOR COVERED OUTPATIENT**
2 **DRUGS.**

3 (a) IN GENERAL.—Part B of title XVIII of the Social
4 Security Act is amended by adding at the end the follow-
5 ing new section:

6 “REBATES FOR COVERED OUTPATIENT DRUGS

7 “Sec. 1849. (a) REQUIREMENT FOR REBATE AGREE-
8 MENT.—

9 “(1) IN GENERAL.—In order for payment to be
10 available under this part for covered outpatient
11 drugs of a manufacturer dispensed or provided on or
12 after January 1, 2002, subject to paragraph (2), the
13 manufacturer must have entered into and have in ef-
14 fect a rebate agreement with the Secretary meeting
15 the requirements of subsection (b) and an agreement
16 to give equal access to discounts in accordance with
17 subsection (e).

18 “(2) DEMONSTRATIONS.—The Secretary may
19 conduct demonstrations with different forms of pur-
20 chasing, such a competitive bidding, exclusive long-
21 term contracts resulting in lower prices, and other
22 devices to obtain the lowest possible price for quality
23 pharmaceutical products. If the Secretary deter-
24 mines that a demonstration results in lower costs to
25 the program and beneficiaries under this title than
26 the rebate program under paragraph (1) while main-

1 taining quality and access to needed products, the
2 Secretary may implement use of the demonstration
3 regionally or nationally as an alternative to the re-
4 bate program. The Secretary shall from time to time
5 report to Congress on such demonstrations.

6 “(b) TERMS, IMPLEMENTATION, AND ENFORCEMENT
7 OF REBATE AGREEMENT.—

8 “(1) PERIODIC REBATES.—

9 “(A) IN GENERAL.—A rebate agreement
10 under this section shall require the manufac-
11 turer to pay to the Secretary for each calendar
12 quarter, not later than 30 days after the date
13 of receipt of the information described in para-
14 graph (2) for such quarter, a rebate in an
15 amount determined under subsection (c) for all
16 covered outpatient drugs of the manufacturer
17 described in subparagraph (B).

18 “(B) DRUGS INCLUDED IN QUARTERLY
19 REBATE CALCULATION.—Drugs subject to a re-
20 bate with respect to a calendar quarter are cov-
21 ered outpatient drugs which are single source
22 and innovator multiple source drugs which are
23 dispensed or provided during such quarter to
24 individuals (other than individuals enrolled with
25 a Medicare+Choice organization under part C)

1 eligible for benefits under this part, as reported
2 to the Secretary.

3 “(2) INFORMATION FURNISHED TO MANUFAC-
4 TURERS.—The Secretary shall report to each manu-
5 facturer, not later than 60 days after the end of
6 each calendar quarter, information on the total num-
7 ber, for each covered outpatient drug described in
8 paragraph (1)(B), of units of each dosage form,
9 strength, and package size dispensed or provided
10 under the plan during the quarter, on the basis of
11 the data reported to the Secretary described in para-
12 graph (1)(B).

13 “(3) PROVISION OF PRICE INFORMATION BY
14 MANUFACTURER.—

15 “(A) QUARTERLY PRICING INFORMA-
16 TION.—Each manufacturer with an agreement
17 in effect under this section shall report to the
18 Secretary, not later than 30 days after the last
19 day of each calendar quarter, on the average
20 manufacturer retail price and the average man-
21 ufacturer non-retail price for each dosage form
22 and strength of each covered outpatient drug
23 described in paragraph (1)(B) for the quarter.

24 “(B) BASE QUARTER PRICES.—Each man-
25 ufacturer of a covered outpatient drug with an

1 agreement under this section shall report to the
2 Secretary, by not later than 30 days after the
3 effective date of such agreement (or, if later, 30
4 days after the end of the base quarter), the av-
5 erage manufacturer retail price, for such base
6 quarter, for each dosage form and strength of
7 each such covered drug.

8 “(C) VERIFICATION OF AVERAGE MANU-
9 FACTURER PRICE.—The Secretary may inspect
10 the records of manufacturers, and survey whole-
11 salers, pharmacies, and institutional purchasers
12 of drugs, as necessary to verify prices reported
13 under subparagraph (A).

14 “(D) PENALTIES.—

15 “(i) CIVIL MONEY PENALTIES.—The
16 Secretary may impose a civil money pen-
17 alty on a manufacturer with an agreement
18 under this section—

19 “(I) for failure to provide infor-
20 mation required under subparagraph
21 (A) on a timely basis, in an amount
22 up to \$10,000 per day of delay;

23 “(II) for refusal to provide infor-
24 mation about charges or prices re-
25 quested by the Secretary for purposes

1 of verification pursuant to subpara-
2 graph (C), in an amount up to
3 \$100,000; and

4 “(III) for provision, pursuant to
5 subparagraph (A) or (B), of informa-
6 tion that the manufacturer knows or
7 should know is false, in an amount up
8 to \$100,000 per item of information.

9 Such civil money penalties are in addition
10 to any other penalties prescribed by law.
11 The provisions of section 1128A (other
12 than subsections (a) (with respect to
13 amounts of penalties or additional assess-
14 ments) and (b)) shall apply to a civil
15 money penalty under this subparagraph in
16 the same manner as such provisions apply
17 to a penalty or proceeding under section
18 1128A(a).

19 “(ii) TERMINATION OF AGREE-
20 MENT.—If a manufacturer with an agree-
21 ment under this section has not provided
22 information required under subparagraph
23 (A) or (B) within 90 days of the deadline
24 imposed, the Secretary may suspend the
25 agreement with respect to covered out-

1 patient drugs dispensed after the end of
2 such 90-day period and until the date such
3 information is reported (but in no case
4 shall a suspension be for less than 30
5 days).

6 “(4) LENGTH OF AGREEMENT.—

7 “(A) IN GENERAL.—A rebate agreement
8 shall be effective for an initial period of not less
9 than one year and shall be automatically re-
10 newed for a period of not less than one year un-
11 less terminated under subparagraph (B).

12 “(B) TERMINATION.—

13 “(i) BY THE SECRETARY.—The Sec-
14 retary may provide for termination of a re-
15 bate agreement for violation of the require-
16 ments of the agreement or other good
17 cause shown. Such termination shall not be
18 effective earlier than 60 days after the
19 date of notice of such termination. The
20 Secretary shall afford a manufacturer an
21 opportunity for a hearing concerning such
22 termination, but such hearing shall not
23 delay the effective date of the termination.

24 “(ii) BY A MANUFACTURER.—A man-
25 ufacturer may terminate a rebate agree-

1 ment under this section for any reason.
2 Any such termination shall not be effective
3 until the calendar quarter beginning at
4 least 60 days after the date the manufac-
5 turer provides notice to the Secretary.

6 “(iii) EFFECTIVE DATE OF TERMI-
7 NATION.—Any termination under this sub-
8 paragraph shall not affect rebates due
9 under the agreement before the effective
10 date of its termination.

11 “(iv) NOTICE TO PHARMACIES.—In
12 the case of a termination under this sub-
13 paragraph, the Secretary shall notify phar-
14 macies and physician organizations not less
15 than 30 days before the effective date of
16 such termination.

17 “(c) AMOUNT OF REBATE.—

18 “(1) BASE REBATE.—Each manufacturer shall
19 remit a basic rebate to the Secretary for each cal-
20 endar quarter in an amount, with respect to each
21 dosage form and strength of a covered outpatient
22 drug equal to the product of—

23 “(A) the total number of units subject to
24 rebate for such quarter, as described in sub-
25 section (b)(1)(B); and

1 “(B)(i) in the case of a single-source drug
2 or an innovator-multiple source drug (other
3 than insulin furnished over-the-counter), 15
4 percent of the average manufacturer retail
5 price, or

6 “(ii) in the case of insulin furnished over-
7 the-counter, 10 percent of the average manufac-
8 turer retail price.

9 “(2) **ADDITIONAL REBATE.**—Each manufac-
10 turer shall remit to the Secretary, for each calendar
11 quarter, an additional rebate for each dosage form
12 and strength of a single-source drug or an innova-
13 tor-multiple source drug, in an amount equal to—

14 “(A) the total number of units subject to
15 rebate for such quarter, as described in sub-
16 section (b)(1)(B), multiplied by

17 “(B) the amount, if any, by which the av-
18 erage manufacturer retail price for such drugs
19 of the manufacturer exceeds the average manu-
20 facturer retail price for the base quarter, in-
21 creased by the percentage increase in the Con-
22 sumer Price Index for all urban consumers
23 (U.S. average) from the end of such base quar-
24 ter to the month before the beginning of such
25 calendar quarter.

1 “(3) DEPOSIT OF REBATES.—The Secretary
2 shall deposit rebates under this section in the Fed-
3 eral Supplementary Medical Insurance Trust Fund
4 established under section 1841.

5 “(d) CONFIDENTIALITY OF INFORMATION.—Notwith-
6 standing any other provision of law, information disclosed
7 by a manufacturer under this section is confidential and
8 shall not be disclosed by the Secretary (or a carrier), ex-
9 cept—

10 “(1) as the Secretary determines to be nec-
11 essary to carry out this section,

12 “(2) to permit the Comptroller General to re-
13 view the information provided, and

14 “(3) to permit the Director of the Congres-
15 sional Budget Office to review the information pro-
16 vided.

17 “(e) AGREEMENT TO GIVE EQUAL ACCESS TO DIS-
18 COUNTS.—An agreement under this subsection by a man-
19 ufacturer of covered outpatient drugs shall guarantee that
20 the manufacturer will offer, to each wholesaler or retailer
21 (or other purchaser representing a group of such whole-
22 salers or retailers) that purchases such drugs on substan-
23 tially the same terms (including such terms as prompt
24 payment, cash payment, volume purchase, single-site de-
25 livery, the use of formularies by purchasers, and any other

1 terms effectively reducing the manufacturer's costs) as
2 any other purchaser (including any institutional pur-
3 chaser) the same price for such drugs as is offered to such
4 other purchaser. In determining a manufacturer's compli-
5 ance with the previous sentence, there shall not be taken
6 into account prices that are merely nominal in amount or
7 prices excluded under section 1927(c)(1)(C)(i).

8 “(f) DEFINITIONS.—For purposes of this section—

9 “(1) AVERAGE MANUFACTURER RETAIL
10 PRICE.—The term ‘average manufacturer retail
11 price’ means, with respect to a covered outpatient
12 drug of a manufacturer for a calendar quarter, the
13 average price (inclusive of discounts for cash pay-
14 ment, prompt payment, volume purchases, and re-
15 bates (other than rebates under this section), but ex-
16 clusive of nominal prices) paid to the manufacturer
17 for the drug in the United States for drugs distrib-
18 uted to the retail pharmacy class of trade.

19 “(2) AVERAGE MANUFACTURER NON-RETAIL
20 PRICE.—The term ‘average manufacturer non-retail
21 price’ means, with respect to a covered outpatient
22 drug of a manufacturer for a calendar quarter, the
23 weighted average price (inclusive of discounts for
24 cash payment, prompt payment, volume purchases,
25 and rebates (other than rebates under this section),

1 but exclusive of nominal prices) paid to the manu-
2 facturer for the drug in the United States by hos-
3 pitals and other institutional purchasers that pur-
4 chase drugs for institutional use and not for resale.

5 “(3) BASE QUARTER.—The term ‘base quarter’
6 means, with respect to a covered outpatient drug of
7 a manufacturer, the calendar quarter beginning
8 April 1, 2002, or (if later) the first full calendar
9 quarter during which the drug was marketed in the
10 United States.

11 “(4) DRUG.—The terms ‘innovator multiple
12 source drug’, ‘noninnovator multiple source drug’,
13 and ‘single source drug’ have the meanings of those
14 terms under section 1927(k)(7), except that the ref-
15 erence in such section to a ‘covered outpatient drug’
16 shall be considered a reference to a covered out-
17 patient drug under this part.

18 “(5) MANUFACTURER.—The term ‘manufac-
19 turer’ means, with respect to a covered outpatient
20 drug—

21 “(A) the entity whose National Drug Code
22 number (as issued pursuant to section 510(e) of
23 the Federal Food, Drug, and Cosmetic Act) ap-
24 pears on the labeling of the drug; or

1 “(B) if the number described in subpara-
2 graph (A) does not appear on the labeling of
3 the drug, the person named as the applicant in
4 a human drug application (in the case of a new
5 drug) or the product license application (in the
6 case of a biological product) for such drug ap-
7 proved by the Food and Drug Administration.”.

8 (b) EXCLUSIONS FROM COVERAGE.—Section
9 1862(a) of such Act (42 U.S.C. 1395y(a)) is amended—

10 (1) by striking “and” at the end of paragraph
11 (20),

12 (2) by striking the period at the end of para-
13 graph (21) and inserting “; or”, and

14 (3) by inserting after paragraph (21) the fol-
15 lowing new paragraph:

16 “(22) consisting of a covered outpatient drug
17 (as described in section 1861(t)) furnished during a
18 year for which the drug’s manufacturer does not
19 have in effect a rebate agreement with the Secretary
20 that meets the requirements of section 1849 for the
21 year.”.

22 **SEC. 5. EXPANSION OF MEDICARE PAYMENT ADVISORY**
23 **COMMISSION.**

24 (a) IN GENERAL.—Effective January 1, 2000, the
25 membership of the Medicare Payment Advisory Commis-

1 sion (established under section 1805 of the Social Security
2 Act, (42 U.S.C. 1395b–6)) shall be expanded to include
3 2 additional members, appointed by the Comptroller Gen-
4 eral of the United States, with expertise in the area of
5 pharmacology and prescription drug benefit programs.

6 (b) APPLICATION OF PROVISIONS.—The provisions of
7 paragraphs (2)(D), (3), and (4) of subsection (c) of such
8 section (relating to ethical disclosure, terms, and com-
9 pensation) shall apply to the additional members ap-
10 pointed under subsection (a) in the same manner as they
11 apply to other members of the Commission.

12 **SEC. 6. COVERAGE OF HOME INFUSION DRUG THERAPY**
13 **SERVICES.**

14 (a) IN GENERAL.—Section 1832(a)(2)(A) of the So-
15 cial Security Act (42 U.S.C. 1395k(a)(2)(A)) is amended
16 by inserting “and home infusion drug therapy services”
17 before the semicolon.

18 (b) HOME INFUSION DRUG THERAPY SERVICES DE-
19 FINED.—Section 1861 of such Act (42 U.S.C. 1395x) is
20 amended by adding at the end the following new sub-
21 section:

22 “Home Infusion Drug Therapy Services

23 “(uu)(1) The term ‘home infusion drug therapy serv-
24 ices’ means the items and services described in paragraph

1 (2) furnished to an individual who is under the care of
2 a physician—

3 “(A) in a setting described in section
4 1861(t)(5)(A)(ii),

5 “(B) by a qualified home infusion drug therapy
6 provider (as defined in paragraph (3)) or by others
7 under arrangements with them made by that pro-
8 vider, and

9 “(C) under a plan established and periodically
10 reviewed by a physician.

11 “(2) The items and services described in this para-
12 graph are such nursing, pharmacy, and related services
13 (including medical supplies, intravenous fluids, delivery,
14 and equipment) as are necessary to conduct safely and ef-
15 fectively a drug regimen through use of a covered home
16 infusion drug (as defined in subsection (t)(5)), but do not
17 include such covered home infusion drugs.

18 “(3) The term ‘qualified home infusion drug therapy
19 provider’ means any entity that the Secretary determines
20 meets the following requirements (or, in the case of a
21 home health agency or an entity with respect to which the
22 only items and services described in paragraph (2) fur-
23 nished by the entity are enteral nutrition therapy services,
24 meets any of the following requirements which the Sec-
25 retary considers appropriate):

1 “(A) The entity is capable of providing or ar-
2 ranging for the items and services described in para-
3 graph (2) and covered home infusion drugs.

4 “(B) The entity maintains clinical records on
5 all patients.

6 “(C) The entity adheres to written protocols
7 and policies with respect to the provision of items
8 and services.

9 “(D) The entity makes services available (as
10 needed) seven days a week on a 24-hour basis.

11 “(E) The entity coordinates all service with the
12 patient’s physician.

13 “(F) The entity conducts a quality assessment
14 and assurance program, including drug regimen re-
15 view and coordination of patient care.

16 “(G) The entity assures that only trained per-
17 sonnel provide covered home infusion drugs (and any
18 other service for which training is required to pro-
19 vide the service safely).

20 “(H) The entity assumes responsibility for the
21 quality of services provided by others under arrange-
22 ments with the entity.

23 “(I) In the case of an entity in any State in
24 which State or applicable local law provides for the
25 licensing of entities of this nature, the entity (i) is

1 licensed pursuant to such law, or (ii) is approved, by
2 the agency of such State or locality responsible for
3 licensing entities of this nature, as meeting the
4 standards established for such licensing.

5 “(J) The entity meets such other requirements
6 as the Secretary may determine are necessary to as-
7 sure the safe and effective provision of home infu-
8 sion drug therapy services and the efficient adminis-
9 tration of the home infusion drug therapy benefit.”.

10 (c) PAYMENT.—

11 (1) IN GENERAL.—Section 1833 of such Act
12 (42 U.S.C. 1395l) is amended—

13 (A) in subsection (a)(2)(B), by striking “or
14 (E)” and inserting “(E), or (H)”,

15 (B) in subsection (a)(2)(F), by striking
16 “and” at the end,

17 (C) in subsection (a)(2)(G), by striking the
18 semicolon and inserting “; and”,

19 (D) by inserting after subsection (a)(2)(G)
20 the following new subparagraph:

21 “(H) with respect to home infusion drug
22 therapy services, the amounts described in sec-
23 tion 1834(m);”, and

1 (E) in the first sentence of subsection (b),
2 by inserting “and home infusion drug therapy
3 services” after “1861(kk))”.

4 (2) AMOUNT DESCRIBED.—Section 1834 of
5 such Act is amended by adding at the end the fol-
6 lowing new subsection:

7 “(m) HOME INFUSION DRUG THERAPY SERVICES.—

8 “(1) IN GENERAL.—With respect to home infu-
9 sion drug therapy services, payment under this part
10 shall be made in an amount equal to the lesser of
11 the actual charges for such services or the fee sched-
12 ule established under paragraph (2).

13 “(2) ESTABLISHMENT OF FEE SCHEDULE.—

14 “(A) IN GENERAL.—The Secretary shall
15 establish by regulation before the beginning of
16 2002 and each succeeding year a fee schedule
17 for home infusion drug therapy services for
18 which payment is made under this part. A fee
19 schedule established under this subsection shall
20 be on a per diem basis.

21 “(B) ADJUSTMENT FOR SERVICES FUR-
22 NISHED BY INSTITUTIONS.—The fee schedule
23 established by the Secretary under subpara-
24 graph (A) shall provide for adjustments in the
25 case of home infusion drug therapy services for

1 which payment is made under this part that are
2 furnished by a provider of services to avoid du-
3 plicative payments under this title for the serv-
4 ice costs associated with such services.”.

5 (d) CERTIFICATION.—Section 1835(a)(2) of such Act
6 (42 U.S.C. 1395n(a)(2)) is amended—

7 (1) by striking “and” at the end of subpara-
8 graph (E),

9 (2) by striking the period at the end of sub-
10 paragraph (F) and inserting “; and”, and

11 (3) by inserting after subparagraph (F) the fol-
12 lowing:

13 “(G) in the case of home infusion drug
14 therapy services, (i) such services are or were
15 required because the individual needed such
16 services for the administration of a covered
17 home infusion drug, (ii) a plan for furnishing
18 such services has been established and is re-
19 viewed periodically by a physician, and (iii)
20 such services are or were furnished while the in-
21 dividual is or was under the care of a physi-
22 cian.”.

23 (e) CERTIFICATION OF HOME INFUSION DRUG
24 THERAPY PROVIDERS; INTERMEDIATE SANCTIONS FOR
25 NONCOMPLIANCE.—

1 (1) TREATMENT AS PROVIDER OF SERVICES.—
2 Section 1861(u) of such Act (42 U.S.C. 1395x(u))
3 is amended by inserting “home infusion drug ther-
4 apy provider,” after “hospice program,”.

5 (2) CONSULTATION WITH STATE AGENCIES AND
6 OTHER ORGANIZATIONS.—Section 1863 of such Act
7 (42 U.S.C. 1395z) is amended by striking “and
8 (dd)(2)” and inserting “(dd)(2), and (uu)(3)”.

9 (3) USE OF STATE AGENCIES IN DETERMINING
10 COMPLIANCE.—Section 1864(a) of such Act (42
11 U.S.C. 1395aa(a)) is amended—

12 (A) in the first sentence, by striking “an
13 agency is a hospice program” and inserting “an
14 agency or entity is a hospice program or a
15 home infusion drug therapy provider,”; and

16 (B) in the second sentence—

17 (i) by striking “institution or agency”
18 and inserting “institution, agency, or en-
19 tity”, and

20 (ii) by striking “or hospice program”
21 and inserting “hospice program, or home
22 infusion drug therapy provider”.

23 (4) APPLICATION OF INTERMEDIATE SANC-
24 TIONS.—Section 1846 of such Act (42 U.S.C.
25 1395w-2) is amended—

1 (A) in the heading, by adding “AND FOR
2 QUALIFIED HOME INFUSION DRUG THERAPY
3 PROVIDERS” at the end,

4 (B) in subsection (a), by inserting “or that
5 a qualified home infusion drug therapy provider
6 that is certified for participation under this title
7 no longer substantially meets the requirements
8 of section 1861(uu)(3)” after “under this
9 part”, and

10 (C) in subsection (b)(2)(A)(iv), by insert-
11 ing “or home infusion drug therapy services”
12 after “clinical diagnostic laboratory tests”.

13 (f) USE OF INTERMEDIARIES IN ADMINISTRATION OF
14 BENEFIT.—Section 1816 of such Act (42 U.S.C. 1395h)
15 is amended by adding at the end the following new sub-
16 section:

17 “(l) With respect to carrying out functions relating
18 to payment for home infusion drug therapy services and
19 covered home infusion drugs, the Secretary may enter into
20 contracts with agencies or organizations under this section
21 to perform such functions on a regional or national
22 basis.”.

23 (g) CONFORMING AMENDMENTS.—(1) Section
24 1834(h)(4)(B) of such Act (42 U.S.C. 1395m(h)(4)(B))

1 is amended by striking “, except that” and all that follows
2 through “equipment”.

3 (2) Section 1861(n) of such Act (42 U.S.C.
4 1395x(n)) is amended by adding at the end the following:
5 “Such term does not include any home infusion drug ther-
6 apy services described in section 1861(uu) or any covered
7 outpatient drug used as a supply related to the furnishing
8 of an item of durable medical equipment.”.

9 (3) Section 1861(s)(8) of such Act (42 U.S.C.
10 1395x(s)(8)) is amended by inserting after “dental” the
11 following: “devices or enteral and parenteral nutrients,
12 supplies, and equipment”.

13 **SEC. 7. NO MARK-UP FOR DRUGS, BIOLOGICALS, OR PAREN-**
14 **TERAL NUTRIENTS.**

15 (a) IN GENERAL.—Section 1842(o) of the Social Se-
16 curity Act (42 U.S.C. 1395u(o)) is amended to read as
17 follows:

18 “(o)(1) If a physician’s, supplier’s, or any other per-
19 son’s bill or request for payment for services includes a
20 charge for a drug, biological, or parenteral nutrient for
21 which payment may be made under this part and the drug,
22 biological, or parenteral nutrient is not paid on a cost or
23 prospective payment basis as otherwise provided in this
24 part, the payment amount established in this subsection

1 for the drug, biological, or parenteral nutrient shall be the
2 lowest of the following:

3 “(A) The actual acquisition cost, as defined in
4 paragraph (2), to the person submitting the claim
5 for payment for the drug, biological, or parenteral
6 nutrient.

7 “(B) 95 percent of the average wholesale price
8 of such drug, biological, or parenteral nutrient, as
9 determined by the Secretary.

10 “(C) For payments for drugs, biologicals, or
11 parenteral nutrients furnished on or after January
12 1, 2000, the median actual acquisition cost of all
13 claims for payment for such drugs, biologicals, or
14 parenteral nutrients for the 12-month period begin-
15 ning July 1, 1998 (and adjusted, as the Secretary
16 determines appropriate, to reflect changes in the
17 cost of such drugs, biologicals, or parenteral nutri-
18 ents due to inflation, and such other factors as the
19 Secretary determines appropriate).

20 “(D) The amount otherwise determined under
21 this part.

22 “(2) For purposes of paragraph (1)(A), the term ‘ac-
23 tual acquisition cost’ means, with respect to such drugs,
24 biologicals, or parenteral nutrients the cost of the drugs,
25 biologicals, or parenteral nutrients based on the most eco-

1 nomical case size in inventory on the date of dispensing
2 or, if less, the most economical case size purchased within
3 six months of the date of dispensing whether or not that
4 specific drug, biological, or nutrient was furnished to an
5 individual whether or not enrolled under this part. Such
6 term includes appropriate adjustments, as determined by
7 the Secretary, for all discounts, rebates, or any other bene-
8 fit in cash or in kind (including travel, equipment, or free
9 products). The Secretary shall include an additional pay-
10 ment to cover costs reasonably incurred for administrative,
11 storage, and handling. The Secretary shall consult with
12 the provider community to simplify the accounting and re-
13 porting requirements used in calculating actual acquisition
14 cost and may accept various averaging procedures, tax
15 documents, and tax accounting procedures (such as last-
16 in-first-out (LIFO) and first-in-first-out (FIFO)) instead
17 of new reporting requirements.

18 “(3)(A) No payment shall be made under this part
19 for drugs, biologicals, or parenteral nutrients to a person
20 whose bill or request for payment for such drugs,
21 biologicals, or parenteral nutrients does not include a
22 statement of the person’s actual acquisition cost.

23 “(B) A person may not bill an individual enrolled
24 under this part—

1 “(i) any amount other than the payment
2 amount specified in paragraph (1), (4), or (5) (plus
3 any applicable deductible and coinsurance amounts),
4 or

5 “(ii) any amount for such drugs, biologicals, or
6 parenteral nutrients for which payment may not be
7 made pursuant to subparagraph (A).

8 “(C) If a person knowingly and willfully in repeated
9 cases bills one or more individuals in violation of subpara-
10 graph (B), the Secretary may apply sanctions against that
11 person in accordance with subsection (j)(2).

12 “(4) The Secretary may pay a reasonable dispensing
13 fee (less the applicable deductible and coinsurance
14 amounts) for drugs or biologicals to a licensed pharmacy
15 approved to dispense drugs or biologicals under this part,
16 if payment for such drugs or biologicals is made to the
17 pharmacy.

18 “(5) The Secretary shall pay a reasonable amount
19 (less the applicable deductible and coinsurance amounts)
20 for the services associated with the furnishing of paren-
21 teral nutrients for which payment is determined under this
22 subsection.”.

23 (b) EFFECTIVE DATE.—The amendments made by
24 subsection (a) apply to drugs, biologicals, and parenteral
25 nutrients furnished on or after January 1, 2001.

1 (c) ELIMINATION OF REPORT ON AVERAGE WHOLE-
2 SALE PRICE.—Section 4556 of the Balanced Budget Act
3 of 1997 is amended—

4 (1) by striking subsection (c); and

5 (2) by redesignating subsection (d) as sub-
6 section (c).

7 **SEC. 8. TREATMENT OF PART B PREMIUM INCREASES RE-**
8 **SULTING FROM ENACTMENT.**

9 (a) ADDITIONAL PART B PREMIUM COVERED UNDER
10 QMB AND SLMB PROGRAMS.—Any increase in the pre-
11 mium under part B of title XVIII of the Social Security
12 Act resulting from the amendments made by this Act is
13 covered for qualified Medicare beneficiaries and for special
14 low income Medicare beneficiaries under the medicaid pro-
15 gram under clauses (i) and (iii) of section 1902(a)(10)(A)
16 of such Act.

17 (b) SEPARATE LISTING OF PORTION OF PREMIUM
18 COVERING PRESCRIPTION DRUG BENEFIT.—The Sec-
19 retary of Health and Human Services shall provide, in any
20 statement of premiums established under section 1839 of
21 the Social Security Act, for a separate statement of the
22 portion of such premiums which is attributable to the
23 amendments made by this Act.

24 (c) WAIVER OF ADDITIONAL PORTION FOR MEDI-
25 CARE BENEFICIARIES HAVING ACTUARIALLY EQUIVA-

1 LENT COVERAGE.—The Secretary of Health and Human
2 Services shall establish a method under which the portion
3 of the premium described in subsection (b) is waived (and
4 not collected) for any individual enrolled under part B of
5 title XVIII of the Social Security Act who demonstrates
6 that the individual has coverage (through a group health
7 plan, Medicare supplemental policy, under the medicaid
8 program under title XIX of the Social Security Act,
9 through the Department of Veterans Affairs, or otherwise)
10 that is actuarially equivalent to the coverage provided
11 under such part.

12 **SEC. 9. EFFECTIVE DATE.**

13 Except as otherwise provided, the amendments made
14 by this Act apply to items and services furnished on or
15 after January 1, 2002.

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