

1 upon request, a manufacturer with a hearing con-
2 cerning such a termination, but such hearing shall
3 not delay the effective date of the termination.
4 Failure of a State to provide any advance notice of
5 such a termination as required by regulation shall
6 not affect the State's right to terminate coverage of
7 the drugs affected by such termination as of the ef-
8 fective date of such termination.

9 “(ii) BY A MANUFACTURER.—A manufacturer
10 may terminate its participation in the master re-
11 bate agreement under this section for any reason.
12 Any such termination shall not be effective until
13 the calendar quarter beginning at least 60 days
14 after the date the manufacturer provides notice to
15 the Secretary.

16 “(iii) EFFECTIVENESS OF TERMINATION.—
17 Any termination under this subparagraph shall not
18 affect rebates due under the agreement before the
19 effective date of its termination.

20 “(iv) NOTICE TO STATES.—In the case of a
21 termination under this subparagraph, the Secretary
22 shall provide notice of such termination to the
23 States within not less than 30 days before the ef-
24 fective date of such termination.

25 “(v) APPLICATION TO TERMINATIONS OF
26 OTHER AGREEMENTS.—The provisions of this sub-
27 paragraph shall apply to the terminations of master
28 agreements described in section 8126(a) of title 38,
29 United States Code.

30 “(C) DELAY BEFORE REENTRY.—In the case of
31 any rebate agreement with a manufacturer under this
32 section which is terminated, another such agreement
33 with the manufacturer (or a successor manufacturer)
34 may not be entered into until a period of 1 calendar
35 quarter has elapsed since the date of the termination,

1 unless the Secretary finds good cause for an earlier re-
2 instatement of such an agreement.

3 “(5) SETTLEMENT OF DISPUTES.—

4 “(A) SECRETARY.—The Secretary shall have the
5 authority to resolve, settle, and compromise disputes
6 regarding the amounts of rebates owed under this sec-
7 tion and section 1927.

8 “(B) STATE.—Each State, with respect to covered
9 outpatient drugs paid for under the State’s State plan,
10 shall have authority, independent of the Secretary’s au-
11 thority under subparagraph (A), to resolve, settle, and
12 compromise disputes regarding the amounts of rebates
13 owed under this section. Any such action shall be
14 deemed to comply with the requirements of this title,
15 and such covered outpatient drugs shall be eligible for
16 payment under the State plan under this title.

17 “(C) AMOUNT OF REBATE.—The Secretary shall
18 limit the amount of the rebate payable in any case in
19 which the Secretary determines that, because of un-
20 usual circumstances or questionable data, the provi-
21 sions of subsection (c) result in a rebate amount that
22 is inequitable or otherwise inconsistent with the pur-
23 poses of this section.

24 “(c) DETERMINATION OF AMOUNT OF REBATE.—

25 “(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND
26 INNOVATOR MULTIPLE SOURCE DRUGS.—

27 “(A) IN GENERAL.—Except as provided in para-
28 graph (2), the amount of the rebate specified in this
29 subsection with respect to a State participating in the
30 master rebate agreement for a rebate period (as de-
31 fined in subsection (i)(7)) with respect to each dosage
32 form and strength of a single source drug or an innova-
33 tor multiple source drug shall be equal to the product
34 of—

1 “(i) the total number of units of each dosage
2 form and strength paid for under the State plan in
3 the rebate period (as reported by the State); and

4 “(ii) the greater of—

5 “(I) the difference between the average
6 manufacturer price and the best price (as de-
7 fined in subparagraph (C)) for the dosage form
8 and strength of the drug, or

9 “(II) the minimum rebate percentage
10 (specified in subparagraph (B)) of such average
11 manufacturer price,
12 for the rebate period.

13 “(B) MINIMUM REBATE PERCENTAGE.—For pur-
14 poses of subparagraph (A)(ii)(II), the ‘minimum rebate
15 percentage’ is 15 percent.

16 “(C) BEST PRICE DEFINED.—For purposes of this
17 section—

18 “(i) IN GENERAL.—The term ‘best price’
19 means, with respect to a single source drug or in-
20 novator multiple source drug of a manufacturer,
21 the lowest price available from the manufacturer
22 during the rebate period to any wholesaler, retailer,
23 provider, health maintenance organization, non-
24 profit entity, or governmental entity within the
25 United States, excluding—

26 “(I) any prices charged on or after Octo-
27 ber 1, 1992, to the Indian Health Service, the
28 Department of Veterans Affairs, a State home
29 receiving funds under section 1741 of title 38,
30 United States Code, the Department of De-
31 fense, the Public Health Service, or a covered
32 entity described in section 340B(a)(4) of the
33 Public Health Service Act.

34 “(II) any prices charged under the Fed-
35 eral Supply Schedule of the General Services
36 Administration.

1 “(III) any prices used under a State phar-
2 maceutical assistance program, and

3 “(IV) any depot prices and single award
4 contract prices, as defined by the Secretary, of
5 any agency of the Federal Government.

6 “(ii) SPECIAL RULES.—The term ‘best
7 price’—

8 “(I) shall be inclusive of cash discounts,
9 free goods that are contingent on any purchase
10 requirement, volume discounts, and rebates
11 (other than rebates under this section),

12 “(II) shall be determined without regard
13 to special packaging, labeling, or identifiers on
14 the dosage form or product or package,

15 “(III) shall not take into account prices
16 that are merely nominal in amount, and

17 “(IV) shall exclude rebates paid under this
18 section or any other rebates paid to a State
19 participating in the master rebate agreement.

20 “(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND
21 INNOVATOR MULTIPLE SOURCE DRUGS.—

22 “(A) IN GENERAL.—The amount of the rebate
23 specified in this subsection with respect to a State par-
24 ticipating in the master rebate agreement for a rebate
25 period, with respect to each dosage form and strength
26 of a single source drug or an innovator multiple source
27 drug, shall be increased by an amount equal to the
28 product of—

29 “(i) the total number of units of such dosage
30 form and strength dispensed after December 31,
31 1990, for which payment was made under the
32 State plan for the rebate period; and

33 “(ii) the amount (if any) by which—

34 “(I) the average manufacturer price for
35 the dosage form and strength of the drug for
36 the period, exceeds

1 “(II) the average manufacturer price for
2 such dosage form and strength for the calendar
3 quarter beginning July 1, 1990 (without regard
4 to whether or not the drug has been sold or
5 transferred to an entity, including a division or
6 subsidiary of the manufacturer, after the first
7 day of such quarter), increased by the percent-
8 age by which the Consumer Price Index for All
9 Urban Consumers (United States city average)
10 for the month before the month in which the
11 rebate period begins exceeds such index for
12 September 1990.

13 “(B) TREATMENT OF SUBSEQUENTLY APPROVED
14 DRUGS.—In the case of a covered outpatient drug ap-
15 proved by the Food and Drug Administration after Oc-
16 tober 1, 1990, clause (ii)(II) of subparagraph (A) shall
17 be applied by substituting ‘the first full calendar quar-
18 ter after the day on which the drug was first marketed’
19 for ‘the calendar quarter beginning July 1, 1990’ and
20 ‘the month prior to the first month of the first full cal-
21 endar quarter after the day on which the drug was first
22 marketed’ for ‘September 1990’.

23 “(3) REBATE FOR OTHER DRUGS.—

24 “(A) IN GENERAL.—The amount of the rebate
25 paid to a State participating in the master rebate
26 agreement for a rebate period with respect to each dos-
27 age form and strength of covered outpatient drugs
28 (other than single source drugs and innovator multiple
29 source drugs) shall be equal to the product of—

30 “(i) the applicable percentage (as described in
31 subparagraph (B)) of the average manufacturer
32 price for the dosage form and strength for the re-
33 bate period, and

34 “(ii) the total number of units of such dosage
35 form and strength dispensed after December 31,

1 1990, for which payment was made under the
2 State plan for the rebate period.

3 “(B) APPLICABLE PERCENTAGE DEFINED.—For
4 purposes of subparagraph (A)(i), the ‘applicable per-
5 centage’ is 11 percent.

6 “(4) LIMITATION ON AMOUNT OF REBATE TO
7 AMOUNTS PAID FOR CERTAIN DRUGS.—

8 “(A) IN GENERAL.—Upon request of the manufac-
9 turer of a covered outpatient drug, the Secretary shall
10 limit, in accordance with subparagraph (B), the
11 amount of the rebate under this subsection with respect
12 to a dosage form and strength of such drug if the ma-
13 jority of the estimated number of units of such dosage
14 form and strength that are subject to rebates under
15 this section were dispensed to inpatients of nursing fa-
16 cilities.

17 “(B) AMOUNT OF REBATE.—In the case of a cov-
18 ered outpatient drug subject to subparagraph (A), the
19 amount of the rebate specified in this subsection for a
20 rebate period, with respect to each dosage form and
21 strength of such drug, shall not exceed the amount
22 paid under the State plan with respect to such dosage
23 form and strength of the drug in the rebate period
24 (without consideration of any dispensing fees paid).

25 “(5) SUPPLEMENTAL REBATES PROHIBITED.—No re-
26 bates shall be required to be paid by manufacturers with
27 respect to covered outpatient drugs furnished to individuals
28 in any State that provides for the collection of such rebates
29 in excess of the rebate amount payable under this section.

30 “(d) LIMITATIONS ON COVERAGE OF DRUGS BY STATES
31 PARTICIPATING IN MASTER AGREEMENT.—

32 “(1) PERMISSIBLE RESTRICTIONS.—A State partici-
33 pating in the master rebate agreement under this section
34 may—

35 “(A) subject to prior authorization under its State
36 plan any covered outpatient drug so long as any such

1 prior authorization program complies with the require-
2 ments of paragraph (5); and

3 “(B) exclude or otherwise restrict coverage under
4 its plan of a covered outpatient drug if—

5 “(i) the drug is contained in the list referred
6 to in paragraph (2);

7 “(ii) the drug is subject to such restrictions
8 pursuant to the master rebate agreement or any
9 agreement described in subsection (a)(4); or

10 “(iii) the State has excluded coverage of the
11 drug from its formulary established in accordance
12 with paragraph (4).

13 “(2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The
14 following drugs or classes of drugs, or their medical uses,
15 may be excluded from coverage or otherwise restricted by
16 a State participating in the master rebate agreement:

17 “(A) Agents when used for anorexia, weight loss,
18 or weight gain.

19 “(B) Agents when used to promote fertility.

20 “(C) Agents when used for cosmetic purposes or
21 hair growth.

22 “(D) Agents when used for the symptomatic relief
23 of cough and colds.

24 “(E) Agents when used to promote smoking ces-
25 sation.

26 “(F) Prescription vitamins and mineral products,
27 except prenatal vitamins and fluoride preparations.

28 “(G) Nonprescription drugs.

29 “(H) Covered outpatient drugs which the manu-
30 facturer seeks to require as a condition of sale that as-
31 sociated tests or monitoring services be purchased ex-
32 clusively from the manufacturer or its designee.

33 “(I) Barbiturates.

34 “(J) Benzodiazepines.

35 “(3) ADDITIONS TO DRUG LISTINGS.—The Secretary
36 shall, by regulation, periodically update the list of drugs or

1 classes of drugs described in paragraph (2), or their medi-
2 cal uses, which the Secretary has determined to be subject
3 to clinical abuse or inappropriate use.

4 “(4) REQUIREMENTS FOR FORMULARIES.—A State
5 participating in the master rebate agreement may establish
6 a formulary if the formulary meets the following require-
7 ments:

8 “(A) The formulary is developed by a committee
9 consisting of physicians, pharmacists, and other appro-
10 priate individuals appointed by the Governor of the
11 State.

12 “(B) Except as provided in subparagraph (C), the
13 formulary includes the covered outpatient drugs of any
14 manufacturer which has entered into and complies with
15 the agreement under subsection (a) (other than any
16 drug excluded from coverage or otherwise restricted
17 under paragraph (2)).

18 “(C) A covered outpatient drug may be excluded
19 with respect to the treatment of a specific disease or
20 condition for an identified population (if any) only if,
21 based on the drug’s labeling (or, in the case of a drug
22 the prescribed use of which is not approved under the
23 Federal Food, Drug, and Cosmetic Act but is a medi-
24 cally accepted indication, based on information from
25 the appropriate compendia described in subsection
26 (i)(5)), the excluded drug does not have a significant,
27 clinically meaningful therapeutic advantage in terms of
28 safety, effectiveness, or clinical outcome of such treat-
29 ment for such population over other drugs included in
30 the formulary and there is a written explanation (avail-
31 able to the public) of the basis for the exclusion.

32 “(D) The State plan permits coverage of a drug
33 excluded from the formulary (other than any drug ex-
34 cluded from coverage or otherwise restricted under
35 paragraph (2)) pursuant to a prior authorization pro-
36 gram that is consistent with paragraph (5).

1 “(E) The formulary meets such other require-
2 ments as the Secretary may impose in order to achieve
3 program savings consistent with protecting the health
4 of program beneficiaries.

5 A prior authorization program established by a State under
6 paragraph (5) is not a formulary subject to the require-
7 ments of this paragraph.

8 “(5) REQUIREMENTS OF PRIOR AUTHORIZATION PRO-
9 GRAMS.—The State plan of a State participating in the
10 master rebate agreement may require, as a condition of
11 coverage or payment for a covered outpatient drug for
12 which Federal financial participation is available in accord-
13 ance with this section, the approval of the drug before its
14 dispensing for any medically accepted indication (as defined
15 in subsection (i)(5)) only if the system providing for such
16 approval—

17 “(A) provides response by telephone or other tele-
18 communication device within 24 hours of a request for
19 prior authorization, and

20 “(B) except with respect to the drugs on the list
21 referred to in paragraph (2), provides for the dispens-
22 ing of at least a 72-hour supply of a covered outpatient
23 prescription drug in an emergency situation (as defined
24 by the Secretary).

25 “(6) OTHER PERMISSIBLE RESTRICTIONS.—A State
26 participating in the master rebate agreement may impose
27 limitations, with respect to all such drugs in a therapeutic
28 class, on the minimum or maximum quantities per prescrip-
29 tion or on the number of refills, if such limitations are nec-
30 essary to discourage waste, and may address instances of
31 fraud or abuse by individuals in any manner authorized
32 under this Act.

33 “(e) DRUG USE REVIEW.—

34 “(1) IN GENERAL.—A State participating in the mas-
35 ter rebate agreement may provide for a drug use review
36 program to educate physicians and pharmacists to identify

1 and reduce the frequency of patterns of fraud, abuse, gross
2 overuse, or inappropriate or medically unnecessary care,
3 among physicians, pharmacists, and patients, or associated
4 with specific drugs or groups of drugs, as well as potential
5 and actual severe adverse reactions to drugs.

6 “(2) APPLICATION OF STATE STANDARDS.—A State
7 with a drug use review program under this subsection shall
8 establish and operate the program under such standards as
9 it may establish.

10 “(f) ELECTRONIC CLAIMS MANAGEMENT.—In accordance
11 with chapter 35 of title 44, United States Code (relating to co-
12 ordination of Federal information policy), the Secretary shall
13 encourage each State to establish, as its principal means of
14 processing claims for covered outpatient drugs under its State
15 plan, a point-of-sale electronic claims management system, for
16 the purpose of performing on-line, real time eligibility verifica-
17 tions, claims data capture, adjudication of claims, and assisting
18 pharmacists (and other authorized persons) in applying for and
19 receiving payment.

20 “(g) ANNUAL REPORT.—

21 “(1) IN GENERAL.—Not later than May 1 of each
22 year, the Secretary shall transmit to the Committee on Fi-
23 nance of the Senate, and the Committee on Commerce of
24 the House of Representatives, a report on the operation of
25 this section in the preceding fiscal year.

26 “(2) DETAILS.—Each report shall include information
27 on—

28 “(A) ingredient costs paid under this title for sin-
29 gle source drugs, multiple source drugs, and
30 nonprescription covered outpatient drugs,

31 “(B) the total value of rebates received and num-
32 ber of manufacturers providing such rebates,

33 “(C) the effect of inflation on the value of rebates
34 required under this section,

35 “(D) trends in prices paid under this title for cov-
36 ered outpatient drugs, and

1 “(E) Federal and State administrative costs asso-
2 ciated with compliance with the provisions of this title.

3 “(h) EXEMPTION FOR CAPITATED HEALTH CARE ORGANI-
4 ZATIONS, HOSPITALS, AND CERTAIN NURSING FACILITIES.—

5 “(1) IN GENERAL.—Except as provided in paragraph
6 (2), the requirements of the master rebate agreement under
7 this section shall not apply with respect to covered out-
8 patient drugs dispensed by or through—

9 “(A) a capitated health care organization (as de-
10 fined in section 1504(c)(1)),

11 “(B) a hospital that dispenses covered outpatient
12 drugs using a drug formulary system and bills the
13 State no more than the hospital’s purchasing costs for
14 covered outpatient drugs, or

15 “(C) a nursing facility which receives payment
16 under this title for health care services, including pre-
17 scription drugs, on a capitated basis and which dis-
18 penses covered outpatient drugs using a drug formulary
19 system.

20 “(2) CONSTRUCTION IN DETERMINING BEST PRICE.—
21 Nothing in paragraph (1) shall be construed as excluding
22 amounts paid by the entities described in such paragraph
23 for covered outpatient drugs from the determination of the
24 best price (as defined in subsection (c)(1)(C)) for such
25 drugs.

26 “(i) DEFINITIONS.—In the section—

27 “(1) AVERAGE MANUFACTURER PRICE.—The term ‘av-
28 erage manufacturer price’ means, with respect to a covered
29 outpatient drug of a manufacturer for a rebate period, the
30 average price paid to the manufacturer for the drug in the
31 United States by wholesalers for drugs distributed to the
32 retail pharmacy class of trade, after deducting customary
33 prompt pay discounts.

34 “(2) COVERED OUTPATIENT DRUG.—Subject to the
35 exceptions in paragraph (3), the term ‘covered outpatient
36 drug’ means—

1 “(A) of those drugs which are treated as pre-
2 scribed drugs for purposes of section 1571(a)(8), a
3 drug which may be dispensed only upon prescription
4 (except as provided in subparagraph (D)), and—

5 “(i) which is approved as a prescription drug
6 under section 505 or 507 of the Federal Food,
7 Drug, and Cosmetic Act;

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

21 “(iii)(I) which is described in section 107(c)(3)
22 of the Drug Amendments of 1962 and for which
23 the Secretary has determined there is a compelling
24 justification for its medical need, or is identical,
25 similar, or related (within the meaning of section
26 310.6(b)(1) of title 21 of the Code of Federal Reg-
27 ulations) to such a drug, and (II) for which the
28 Secretary has not issued a notice of an opportunity
29 for a hearing under section 505(e) of the Federal
30 Food, Drug, and Cosmetic Act on a proposed order
31 of the Secretary to withdraw approval of an appli-
32 cation for such drug under such section because
33 the Secretary has determined that the drug is less
34 than effective for some or all conditions of use pre-
35 scribed, recommended, or suggested in its labeling;

1 “(B) a biological product, other than a vaccine
2 which—

3 “(i) may only be dispensed upon prescription,

4 “(ii) is licensed under section 351 of the Pub-
5 lic Health Service Act, and

6 “(iii) is produced at an establishment licensed
7 under such section to produce such product;

8 “(C) insulin certified under section 506 of the
9 Federal Food, Drug, and Cosmetic Act; and

10 “(D) a drug which may be sold without a prescrip-
11 tion (commonly referred to as an ‘over-the-counter
12 drug’), if the drug is prescribed by a physician (or
13 other person authorized to prescribe under State law).

14 “(3) LIMITING DEFINITION.—The term ‘covered out-
15 patient drug’ does not include any drug, biological product,
16 or insulin provided as part of, or as incident to and in the
17 same setting as, any of the following (and for which pay-
18 ment may be made under a State plan as part of payment
19 for the following and not as direct reimbursement for the
20 drug):

21 “(A) Inpatient hospital services.

22 “(B) Hospice services.

23 “(C) Dental services, except that drugs for which
24 the State plan authorizes direct reimbursement to the
25 dispensing dentist are covered outpatient drugs.

26 “(D) Physicians’ services.

27 “(E) Outpatient hospital services.

28 “(F) Nursing facility services and services pro-
29 vided by an intermediate care facility for the mentally
30 retarded.

31 “(G) Other laboratory and x-ray services.

32 “(H) Renal dialysis services.

33 Such term also does not include any such drug or product
34 for which a National Drug Code number is not required by
35 the Food and Drug Administration or a drug or biological
36 product used for a medical indication which is not a medi-

1 cally accepted indication. Any drug, biological product, or
2 insulin excluded from the definition of such term as a re-
3 sult of this paragraph shall be treated as a covered out-
4 patient drug for purposes of determining the best price (as
5 defined in subsection (e)(1)(C)) for such drug, biological
6 product, or insulin.

7 “(4) MANUFACTURER.—The term ‘manufacturer’
8 means, with respect to a covered outpatient drug, the entity
9 holding legal title to or possession of the National Drug
10 Code number for such drug.

11 “(5) MEDICALLY ACCEPTED INDICATION.—The term
12 ‘medically accepted indication’ means any use for a covered
13 outpatient drug which is approved under the Federal Food,
14 Drug, and Cosmetic Act, or the use of which is supported
15 by one or more citations included or approved for inclusion
16 in any of the following compendia:

17 “(A) American Hospital Formulary Service Drug
18 Information.

19 “(B) United States Pharmacopeia-Drug Informa-
20 tion.

21 “(C) American Medical Association Drug Evalua-
22 tions.

23 “(D) The DRUGDEX Information System.

24 “(E) The peer-reviewed medical literature.

25 “(6) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE
26 SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG;
27 SINGLE SOURCE DRUG.—

28 “(A) DEFINED.—

29 “(i) MULTIPLE SOURCE DRUG.—The term
30 ‘multiple source drug’ means, with respect to a re-
31 bate period, a covered outpatient drug (not includ-
32 ing any drug described in paragraph (2)(D)) for
33 which there are 2 or more drug products which—

34 “(I) are rated as therapeutically equivalent
35 (under the Food and Drug Administration’s
36 most recent publication of ‘Approved Drug

1 Products with Therapeutic Equivalence Evalua-
2 tions'),

3 “(II) except as provided in subparagraph
4 (B), are pharmaceutically equivalent and
5 bioequivalent, as defined in subparagraph (C)
6 and as determined by the Food and Drug Ad-
7 ministration, and

8 “(III) are sold or marketed in the State
9 during the period.

10 “(ii) INNOVATOR MULTIPLE SOURCE DRUG.—
11 The term ‘innovator multiple source drug’ means a
12 multiple source drug that was originally marketed
13 under an original new drug application or product
14 licensing application approved by the Food and
15 Drug Administration.

16 “(iii) NONINNOVATOR MULTIPLE SOURCE
17 DRUG.—The term ‘noninnovator multiple source
18 drug’ means a multiple source drug that is not an
19 innovator multiple source drug.

20 “(iv) SINGLE SOURCE DRUG.—The term ‘sin-
21 gle source drug’ means a covered outpatient drug
22 (other than a drug described in subparagraph (C)
23 or (D) of paragraph (2)) which is produced or dis-
24 tributed under an original new drug application ap-
25 proved by the Food and Drug Administration, in-
26 cluding a drug product marketed by any cross-li-
27 censed producers or distributors operating under
28 the new drug application or product licensing appli-
29 cation.

30 “(B) EXCEPTION.—Subparagraph (A)(i)(II) shall
31 not apply if the Food and Drug Administration
32 changes by regulation the requirement that, for pur-
33 poses of the publication described in subparagraph
34 (A)(i)(I), in order for drug products to be rated as
35 therapeutically equivalent, they must be pharmaceuti-

1 cally equivalent and bioequivalent, as defined in sub-
2 paragraph (C).

3 “(C) DEFINITIONS.—For purposes of this para-
4 graph—

5 “(i) drug products are pharmaceutically equiv-
6 alent if the products contain identical amounts of
7 the same active drug ingredient in the same dosage
8 form and meet compendial or other applicable
9 standards of strength, quality, purity, and identity,

10 “(ii) drugs are bioequivalent if they do not
11 present a known or potential bioequivalence prob-
12 lem, or, if they do present such a problem, they are
13 shown to meet an appropriate standard of
14 bioequivalence, and

15 “(iii) a drug product is considered to be sold
16 or marketed in a State if it appears in a published
17 national listing of average wholesale prices selected
18 by the Secretary, if the listed product is generally
19 available to the public through retail pharmacies in
20 that State.

21 “(7) REBATE PERIOD.—The term ‘rebate period’
22 means, with respect to an agreement under subsection (a),
23 a calendar quarter or other period specified by the Sec-
24 retary with respect to the payment of rebates under such
25 agreement.”.

26 **SEC. 2004. STATE ELECTION; TERMINATION OF CUR-**
27 **RENT PROGRAM; AND TRANSITION.**

28 (a) **TERMINATION OF CURRENT PROGRAM; LIMITATION**
29 **ON MEDICAID PAYMENTS IN FISCAL YEAR 1997.—**

30 (1) **REPEAL OF TITLE.**—Title XIX of the Social Secu-
31 rity Act is repealed effective October 1, 1997, except that
32 the repeal of section 1928 of such Act is effective on the
33 date of the enactment of this Act and the succeeding two
34 sections of such title shall be effective during fiscal year
35 1996 in the same manner and to the same extent as such
36 sections were effective during fiscal year 1995.

1 (2) LIMITATION ON OBLIGATION AUTHORITY.—Not-
2 withstanding any other provision of such title—

3 (A) FISCAL YEAR 1997.—Subject to subparagraph
4 (B), the Secretary of Health and Human Services (in
5 this section referred to as the “Secretary”) may enter
6 into obligations under such title with any State (as de-
7 fined for purposes of such title) for expenses incurred
8 during fiscal year 1997, but not in excess of the sum
9 determined under clauses (i), (ii) and (iv) of section
10 1511(a)(2)(A) of the Social Security Act (as added by
11 section 2) for that State for fiscal year 1997.

12 (B) NONE AFTER EFFECTIVE DATE.—The Sec-
13 retary is not authorized to enter into any obligation
14 with any State under title XIX of such Act for ex-
15 penses incurred on or after the earlier of—

16 (i) October 1, 1997, or

17 (ii) the first day of the first quarter on which
18 the State plan under title XV of such Act (as
19 added by section 2) is first effective.

20 (C) AGREEMENT.—A State’s submission of claims
21 for payment under section 1903 of such Act on or after
22 October 1, 1996, is deemed to constitute the State’s ac-
23 ceptance of the obligation limitation under subpara-
24 graph (A) (including the formula for computing the
25 amount of such obligation limitation).

26 (D) EFFECT ON MEDICAL ASSISTANCE.—Effective
27 October 1, 1996—

28 (i) except as provided in this paragraph, the
29 Federal Government has no obligation to provide
30 payment with respect to items and services pro-
31 vided under title XIX of the Social Security Act,
32 and

33 (ii) such title and title XV of such Act shall
34 not be construed as providing for an entitlement.
35 under Federal law in relation to the Federal Gov-
36 ernment, in an individual or person (including any

1 provider) at the time of provision or receipt of serv-
2 ices.

3 (3) REQUIREMENT FOR TIMELY SUBMITTAL OF
4 CLAIMS.—No payment shall be made to a State under title
5 XIX of such Act with respect to an obligation incurred be-
6 fore October 1, 1996, unless the State has submitted to the
7 Secretary, by not later than April 1, 1997, a claim for Fed-
8 eral financial participation for expenses paid by the State
9 with respect to such obligations. Nothing in paragraph (2)
10 shall be construed as affecting the obligation of the Federal
11 Government to pay claims described in the previous sen-
12 tence.

13 (b) TRANSITION PROVISIONS.—

14 (1) Notwithstanding any other provision of law, in the
15 case where payment has been made under section 1903(a)
16 of the Social Security Act to a State before March 1, 1996,
17 and for which a disallowance has not been taken as of such
18 date (or, if so taken, has not been completed, including ju-
19 dicial review, by such date), the Secretary of Health and
20 Human Services shall discontinue the disallowance proceed-
21 ing and, if such disallowance has been taken as of the date
22 of the enactment of this Act, any payment reductions ef-
23 fected shall be rescinded and the payments returned to the
24 State.

25 (2) The repeal under subsection (a)(1) of section 1928
26 of the Social Security Act shall not affect the distribution
27 of vaccines purchased and delivered to the States before the
28 date of the enactment of this Act. No vaccine may be pur-
29 chased after such date by the Federal Government or any
30 State under any contract under section 1928(d) of the So-
31 cial Security Act.

32 (3) No judicial or administrative decision rendered re-
33 garding requirements imposed under title XIX of the Social
34 Security Act with respect to a State shall have any applica-
35 tion to the State plan of the State under title XV of such
36 Act. A State may, pursuant to the previous sentence, seek

1 the abrogation or modification of any such decision after
2 the date of termination of the State medicaid plan under
3 title XIX of such Act.

4 (4) No cause of action under title XIX of the Social
5 Security Act which seeks to require a State to establish or
6 maintain minimum payment rates under such title or claim
7 which seeks reimbursement for any period before the date
8 of the enactment of this Act based on the alleged failure
9 of the State to comply with such title and which has not
10 become final as of such date shall be brought or continued.

11 (5) Section 6408(a)(3) of the Omnibus Budget Rec-
12 onciliation Act of 1989 (as amended by section 13642 of
13 the Omnibus Budget Reconciliation Act of 1993) and sec-
14 tion 2 of Public Law 102-276 (as amended by section
15 13644 of the Omnibus Budget Reconciliation Act of 1993)
16 are each amended by striking "December 31, 1995" and
17 inserting "October 1, 1997".

18 (c) ANTI-FRAUD PROVISIONS.—Section 1128(h)(1) of the
19 Social Security Act (42 U.S.C. 1320a-7(h)(1)) is amended by
20 inserting "or a State plan under title XV" after "title XIX".

21 (d) TECHNICAL AND CONFORMING AMENDMENTS.—

22 (1) SECRETARIAL SUBMISSION OF LEGISLATIVE PRO-
23 POSAL.—Not later than 90 days after the date of the en-
24 actment of this Act, the Secretary of Health and Human
25 Services, in consultation, as appropriate, with heads of
26 other Federal agencies and the States (as defined in section
27 1101(a)(8) of the Social Security Act for purposes of title
28 XIX of such Act), shall submit to the appropriate commit-
29 tees of Congress a legislative proposal providing for such
30 technical and conforming amendments in the law as are re-
31 quired by the provisions of, and amendments made by, this
32 title.

33 (2) TRANSITIONAL RULE.—Any reference in any provi-
34 sion of law to title XIX of the Social Security Act or any
35 provision thereof shall be deemed to be a reference to such

1 title or provision as in effect on the day before the date of
2 the enactment of this Act.

3 **SEC. 2005. INTEGRATION DEMONSTRATION PROJECT.**

4 (a) DESCRIPTION OF PROJECTS.—

5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services (in this section referred to as the “Sec-
7 retary”) may waive such requirements of titles XVIII and
8 XV of the Social Security Act as may be necessary for
9 States to conduct demonstration projects under this sec-
10 tion. Such projects shall demonstrate the manner in which
11 States may use funds from the programs under such titles
12 to develop and implement innovative programs for individ-
13 uals dually eligible for benefits under both titles, including
14 such individuals who are chronically ill. The Secretary shall
15 grant waivers in a manner that permits States flexibility in
16 contracting with medicare risk providers and other provid-
17 ers for services, oversight of contract administration and
18 quality management, and administration of a single enroll-
19 ment process. Such a waiver may restrict time period dur-
20 ing which project participants may disenroll without cause
21 from capitated health plans under the medicare program.

22 (2) VOLUNTARY PARTICIPATION.—A State may not re-
23 quire an individual eligible to receive items and services
24 under the medicare and title XV programs to participate
25 in a demonstration project under this section.

26 (b) BUDGET NEUTRALITY AND REINVESTMENT OF SAV-
27 INGS.—

28 (1) BUDGET NEUTRALITY.—The Secretary shall not
29 approve a demonstration project under this section for a
30 State unless the State demonstrates that the amount of the
31 Federal expenditures under the program will not exceed the
32 amount of the Federal expenditures that would have been
33 made if the project had not been approve.

34 (2) USE OF SAVINGS.—The Secretary shall permit a
35 State to retain any savings achieved under a project and
36 to use such savings for—

1 (A) expanding eligibility for low income medicare
2 beneficiaries who are risk of institutionalization and
3 who, if institutionalized, are likely to qualify for benefits
4 under title XV of the Social Security Act, and

5 (B) providing a scope of services under the project
6 that exceeds the scope of services normally covered
7 under such title.

8 (c) LIMITATION ON NUMBER OF PROJECTS.—Not more
9 than 10 demonstration projects shall be conducted under this
10 section.

11 (d) DURATION.—

12 (1) IN GENERAL.—Subject to paragraph (2), a dem-
13 onstration project conducted under this section shall be
14 conducted for an initial period of 5 years and, upon the re-
15 quest of a State and a finding by the Secretary that the
16 project has been successful, shall be extended indefinitely.

17 (2) TERMINATION.—The Secretary may, with 90 days'
18 notice, terminate any demonstration project conducted
19 under this section that is not in substantial compliance
20 with the terms of the application approved by the Secretary
21 under this section.

22 (e) APPLICATIONS.—Each State, or a coalition of States,
23 desiring to conduct a demonstration project under this section
24 shall prepare and submit to the Secretary an application at
25 such time, in such manner, and containing such information as
26 the Secretary may require, including an explanation of a plan
27 for evaluating the project. The Secretary shall approve or deny
28 an application not later than 90 days after the receipt of such
29 application.

30 (f) PAYMENTS.—For each calendar quarter occurring dur-
31 ing a demonstration project conducted under this section, the
32 Secretary shall provide for payments to the State in a manner
33 consistent with subsection (b)(1).

34 (g) OVERSIGHT.—The Secretary shall establish quality
35 standards for evaluating and monitoring the demonstration
36 projects conducted under this section. Such quality standards

1 shall include reporting requirements which contain the follow-
2 ing:

3 (1) A description of the demonstration project.

4 (2) An analysis of beneficiary satisfaction under such
5 project.

6 (3) An analysis of the quality of the services delivered
7 under the project.

8 (4) A description of the savings to the medicare and
9 title XV programs as a result of the demonstration project.