/* Title II of the Health Security Act follows in two sections. */

Title II NEW BENEFITS

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(a) Covered Outpatient Drugs as Medical and Other Health Services. Section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)) is amended to read as follows:

"(J) covered outpatient drugs;".

(b) Definition of Covered Outpatient Drug. Section 1861(t) of such Act (42 U.S.C. 1395x(t)), as amended by section 13553(b) of the Omnibus Budget Reconciliation Act of 1993 (hereafter in this subtitle referred to as "OBRA091993"), is amended

(1) in the heading, by adding at the end the following: "; Covered Outpatient Drugs";

(2) in paragraph (1), by striking "paragraph (2)" and inserting "the succeeding paragraphs of this subsection"; and

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

"(2) Except as otherwise provided in paragraph (3), the term `covered outpatient drug' means any of the following products used for a medically accepted indication (as described in paragraph (4)):

"(A) A drug which may be dispensed only upon prescription and

"(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

"(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a `new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

"(B) A biological product which

"(i) may only be dispensed upon prescription,

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

"(iii) is produced at an establishment licensed under such section to produce such product.

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

"(3) The term `covered outpatient drug' does not include any product

"(A) which is administered through infusion in a home setting unless the product is a covered home infusion drug (as defined in paragraph (5));

"(B) when furnished as part of, or as incident to, any other item or service for which payment may be made under this title; or

"(C) which is listed under paragraph (2) of section 1927(d) (other than subparagraph (I) or (J) of such subparagraph) as a drug which may be excluded from coverage under a State plan under title XIX and which the Secretary elects to exclude from coverage under part B.

"(4) For purposes of paragraph (2), the term `medically accepted indication', with respect to the use of an outpatient drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if

"(A) the drug has been approved by the Food and Drug Administration; and

"(B)(i) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information, and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

"(ii) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this clause by the Secretary. The Secretary may revise the list of compendia in subparagraph (B)(i) designated as appropriate for identifying medically accepted indications for drugs.

"(5)(A) For purposes of paragraph (3), the term `covered home infusion drug' means a covered outpatient drug or an enteral or parenteral nutrient dispensed to an individual that

"(i) is administered intravenously, subcutaneously, epidurally, or through

other means determined by the Secretary, using an access device that is inserted in to the body and an infusion device to control the rate of flow of the drug,

"(ii) is administered in the individual's home (including an institution used as the individual's home, other than a hospital under subsection (e) or a skilled nursing facility that meets the requirements of section 1819(a)), and

"(iii)(I) is an antibiotic drug and the Secretary has not determined, for the specific drug or the indication to which the drug is applied, that the drug cannot generally be administered safely and effectively in a home setting, or

"(II) is not an antibiotic drug and the Secretary has determined, for the specific drug or the indication to which the drug is applied, that the drug can generally be administered safely and effectively in a home setting.

"(B) Not later than January 1, 1996, (and periodically thereafter), the Secretary shall publish a list of the drugs, and indications for such drugs, that are covered home infusion drugs, with respect to which home infusion drug therapy may be provided under this title.".

(c) Other Conforming Amendments.(1) Section 1861 of such Act (42 U.S.C. 1395x) is amended

(A) in subsection (s)(2), as amended by section 13553 of OBRA091993

(i) by striking subparagraphs (O) and (Q),

(ii) by adding "and" at the end of subparagraph (N),

(iii) by striking "; and" at the end of subparagraph (P) and inserting a period, and

(iv) by redesignating subparagraph (P) as subparagraph (O); and

(B) by striking the subsection (jj) added by section 4156(a)(2) of the Omnibus Budget Reconciliation Act of 1990.

(2) Section 1881(b)(1)(C) of such Act (42 U.S.C. 1395rr(b)(1)(C)), as amended by section 13566(a) of OBRA091993, is amended by striking "section 1861(s)(2)(P)" and inserting "section 1861(s)(2)(O)".

Section 2002 PAYMENT RULES AND RELATED REQUIREMENTS FOR COVERED OUTPATIENT DRUGS.

(a) In General. Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by inserting after subsection (c) the following new subsection:

"(d) Payment for and Certain Requirements Concerning Covered Outpatient Drugs.

"(1) Deductible.

"(A) In general. Payment shall be made under paragraph (2) only for expenses incurred by an individual for a covered outpatient drug during a calendar year after the individual has incurred expenses in the year for such drugs (during a period in which the individual is entitled to benefits under this part) equal to the deductible amount for that year.

"(B) Deductible amount.

"(i) For purposes of subparagraph (A), the deductible amount is

"(I) for 1996, $250, and

"(II) for any succeeding year, the amount (rounded to the nearest dollar) that the Secretary estimates will ensure that the percentage of the average number of individuals covered under this part (other than individuals enrolled with an eligible organization under section 1876 or an organization described in section 1833(a)(1)(A)) during the year who will incur expenses for covered outpatient drugs equal to or greater than such amount will be the same as the percentage for the previous year.

"(ii) The Secretary shall promulgate the deductible amount for 1997 and each succeeding year during September of the previous year.

"(C) Special rule for determination of expenses incurred.In determining the amount of expenses incurred by an individual for covered outpatient drugs during a year for purposes of subparagraph (A), there shall not be included any expenses incurred with respect to a drug to the extent such expenses exceed the payment basis for such drug under paragraph (3).

"(2) Payment amount.

"(A) In general. Subject to the deductible established under paragraph (1), the amount payable under this part for a covered outpatient drug furnished to an individual during a calendar year shall be equal to

"(i) 80 percent of the payment basis described in paragraph (3), in the case

of an individual who has not incurred expenses for covered outpatient drugs during the year (including the deductible imposed under paragraph (1)) in excess of the out-of-pocket limit for the year under subparagraph (B); and

"(ii) 100 percent of the payment basis described in paragraph (3), in the case of any other individual.

"(B) Out-of-pocket limit described.

"(i) For purposes of subparagraph (A), the out-of-pocket limit for a year is equal to

"(I) for 1996, $1000, and

"(II) for any succeeding year, the amount (rounded to the nearest dollar) that the Secretary estimates will ensure that the percentage of the average number of individuals covered under this part (other than individuals enrolled with an eligible organization under section 1876 or an organization described in section 1833(a)(1)(A)) during the year who will incur expenses for covered outpatient drugs equal to or greater than such amount will be the same as the percentage for the previous year.

"(ii) The Secretary shall promulgate the out-of-pocket limit for 1997 and each succeeding year during September of the previous year.

"(C) Special rule for determination of expenses incurred. In determining the amount of expenses incurred by an individual for covered outpatient drugs during a year for purposes of subparagraph (A), there shall not be included any expenses incurred with respect to a drug to the extent such expenses exceed the payment basis for such drug under paragraph (3).

"(3) Payment basis. For purposes of paragraph (2), the payment basis is the lesser of

"(A) the actual charge for a covered outpatient drug, or

"(B) the applicable payment limit established under paragraph (4).

"(4) Payment limits.

"(A) Payment limit for single source drugs and multiple source drugs with restrictive prescriptions. In the case of a covered outpatient drug that is a multiple source drug which has a restrictive prescription, or that is single source drug, the payment limit for a payment calculation period is equal to

"(i) the 90th percentile of the actual charges (computed on the geographic basis specified by the Secretary) for the drug product for the second previous payment calculation period, or

"(ii) the amount of the administrative allowance (established under paragraph (5)) plus the product of the number of dosage units dispensed and the per unit estimated acquisition cost for the drug product (determined under subparagraph (C)) for the period, whichever is less.

"(B) Payment limit for multiple source drugs without restrictive prescriptions. In the case of a drug that is a multiple source drug which does not have a restrictive prescription, the payment limit for a payment calculation period is equal to the amount of the administrative allowance (established under paragraph (5)) plus the product of the number of dosage units dispensed and the unweighted median of the unit estimated acquisition cost (determined under subparagraph (C)) for the drug products for the period.

"(C) Determination of unit price.

"(i) In general. The Secretary shall determine, for the dispensing of a covered outpatient drug product in a payment calculation period, the estimated acquisition cost for the drug product. With respect to any covered outpatient drug product, such cost may not exceed 93 percent of the published average wholesale price for the drug during the period.

"(ii) Compliance with request for information. If a wholesaler or direct seller of a covered outpatient drug refuses, after being requested by the Secretary, to provide price information requested to carry out clause (i), or deliberately provides information that is false, the Secretary may impose a civil money penalty of not to exceed $10,000 for each such refusal or provision of false information. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under the previous sentence in the same manner as they apply to a penalty or proceeding under section 1128A(a). Information gathered pursuant to clause (i) shall not be disclosed except as the Secretary determines to be necessary to carry out the purposes of this part.

"(5) Administrative allowance for purposes of payment limit.

"(A) In general. Except as provided in subparagraph (B), the administrative allowance established under this paragraph is

"(i) for 1996, $5, and

"(ii) for each succeeding year, the amount for the previous year adjusted by the percentage change in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of that previous year.

"(B) Reduction for mail order pharmacies. The Secretary may, after consulting with representatives of pharmacists, individuals enrolled under this part, and of private insurers, reduce the administrative allowances established under subparagraph (A) for any covered outpatient drug dispensed by a mail order pharmacy, based on differences between such pharmacies and other pharmacies with respect to operating costs and other economies.

"(6) Assuring appropriate prescribing and dispensing practices.

"(A) In general. The Secretary shall establish a program to identify (and to educate physicians and pharmacists concerning)

"(i) instances or patterns of unnecessary or inappropriate prescribing or dispensing practices for covered outpatient drugs,

"(ii) instances or patterns of substandard care with respect to such drugs,

"(iii) potential adverse reactions, and

"(iv) appropriate use of generic products.

"(B) Prior authorization. The Secretary may require advance approval for a covered outpatient drug which the Secretary finds is subject to misuse or inappropriate use, is not cost effective, which is a multiple source drug with a restrictive prescription, or is subject to negotiation under section 1850(c)(3). The Secretary may also establish maximum quantities per prescription and limits on the number of prescription refills. The Secretary
shall ensure that any advance approval requirements imposed under this subparagraph do not restrict the access of patients to medically necessary covered outpatient drugs on a timely basis, and assure prompt determinations of approval or disapproval and provide a means for providers and patients to appeal a decision to disapprove a drug.

"(C) Drug use review. The Secretary may provide for a drug use review program with respect to covered outpatient drugs dispensed to individuals eligible for benefits under this part. Such program may include such elements as the Secretary determines to be necessary to assure that prescriptions (i)
are appropriate, (ii) are medically necessary, and (iii) are not likely to result

in adverse medical results, including any elements of the State drug use review programs required under section 1927(g) that the Secretary determines to be appropriate.

"(7) Administrative improvements. The Secretary shall develop, in consultation with representatives of pharmacies and of other interested persons, a standard claims form for covered outpatient drugs in accordance with title V of the Health Security Act.

"(8) Counseling requirements for pharmacies. A pharmacy may not receive any payment under this part for a covered outpatient drug unless the pharmacy agrees to answer questions of individuals enrolled under this part who receive a covered outpatient drug from the pharmacy regarding the appropriate use of the drug, potential interactions between the drug and other drugs dispensed to the individual, and other matters relating to the dispensing of such drugs.

"(9) Definitions. In this subsection:

"(A) Multiple and single source drugs. The terms `multiple source drug' and `single source drug' have the meanings of those terms under section 1927(k)(7).

"(B) Restrictive prescription. A drug has a `restrictive prescription' only if

"(i) in the case of a written prescription, the prescription for the drug indicates, in the handwriting of the physician or other person prescribing the drug and with an appropriate phrase (such as `brand medically necessary') recognized by the Secretary, that a particular drug product must be dispensed,
or

"(ii) in the case of a prescription issued by telephone

"(I) the physician or other person prescribing the drug (through use of such an appropriate phrase) states that a particular drug product must be dispensed, and

"(II) the physician or other person submits to the pharmacy involved, within 30 days after the date of the telephone prescription, a written confirmation which is in the handwriting of the physician or other person prescribing the drug and which indicates with such appropriate phrase that the particular drug product was required to have been dispensed.

"(C) Payment calculation period. The term `payment calculation period' means the 6-month period beginning with January of each year and the 6-month period beginning with July of each year.".

(b) Submission of Claims by Pharmacies. Section 1848(g)(4) of such Act (42 U.S.C. 1395w0@4(g)(4)) is amended

(1) in the heading

(A) by striking "Physician", and

(B) by inserting "by physicians and suppliers" after "claims",

(2) in the matter in subparagraph (A) preceding clause (i)

(A) by striking "For services furnished on or after September 1, 1990, within 1 year" and inserting "Within 1 year (90 days in the case of covered outpatient drugs)",

(B) by striking "a service" and inserting "an item or service", and

(C) by inserting "or of providing a covered outpatient drug," after "basis," and

(3) in subparagraph (A)(i), by inserting "item or" before "service.

(c) Special Rules for Carriers.

(1) Use of regional carriers. Section 1842(b)(2) of such Act (42 U.S.C. 1395u(b)(2)) is amended by adding at the end the following:

"(D) With respect to activities related to covered outpatient drugs, the Secretary may enter into contracts with carriers under this section to perform the activities on a regional basis.".

(2) Payment on other than a cost basis. Section 1842(c)(1)(A) of such Act (42 U.S.C. 1395u(c)(1)(A)) is amended

(A) by inserting "(i)" after "(c)(1)(A)",

(B) in the first sentence, by inserting ", except as otherwise provided in clause (ii)," after "under this part, and", and

(C) by adding at the end the following:

"(ii) To the extent that a contract under this section provides for activities related to covered outpatient drugs, the Secretary may provide for payment for those activities based on any method of payment determined by the Secretary to be appropriate.".

(3) Use of other entities for covered outpatient drugs. Section 1842(f) of such Act (42 U.S.C. 1395u(f)) is amended

(A) by striking "and" at the end of paragraph (1),

(B) by striking the period at the end of paragraph (2) and inserting "; and", and

(C) by adding at the end the following:

"(3) with respect to activities related to covered outpatient drugs, any other private entity which the Secretary determines is qualified to conduct such activities.".

(4) Designated carriers to process claims of railroad retirees. Section 1842(g) of such Act (42 U.S.C. 1395u(g)) is amended by inserting "(other than functions related to covered outpatient drugs)" after "functions".

(d) Contracts for Automatic Data Processing Equipment. Actions taken before 1996 that affect contracts related to the processing of claims for covered outpatient drugs (as defined in section 1861(t) of the Social Security Act) shall not be subject to section 111 of the Federal Property and Administrative Services Act of 1949, and shall not be subject to administrative or judicial review.

(e) Conforming Amendments.

(1) (A) Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)), as amended by section 13544(b)(2) of OBRA091993, is amended

(i) by striking "and" at the end of clause (O), and

(ii) by inserting before the semicolon at the end the following: ", and (Q) with respect to covered outpatient drugs, the amounts paid shall be as prescribed by section 1834(d)".

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

(2) Section 1833(b)(2) of such Act (42 U.S.C. 1395l(b)(2)) is amended by inserting "or with respect to covered outpatient drugs" before the comma.

(3) The first sentence of section 1842(h)(2) of such Act (42 U.S.C. 1395u(h)(2)) is amended by inserting "(other than a carrier described in subsection (f)(3))" after "Each carrier".

(4) The first sentence of section 1866(a)(2)(A) of such Act (42 U.S.C. 1395cc(a)(2)(A)) is amended

(A) in clause (i), by inserting "section 1834(d)," after "section 1833(b),", and

(B) in clause (ii), by inserting ", other than for covered outpatient drugs," after "provider)".

Section 2003 MEDICARE REBATES FOR COVERED OUTPATIENT DRUGS.

(a) In General. Part B of title XVIII of the Social Security Act is amended by adding at the end the following new section:

"REBATES FOR COVERED OUTPATIENT DRUGS

"Sec. 1850. (a) Requirement for Rebate Agreement.In order for payment to be available under this part for covered outpatient drugs of a manufacturer dispensed on or after January 1, 1996, the manufacturer must have entered into and have in effect a rebate agreement with the Secretary meeting the requirements of subsection (b), and an agreement to give equal access to discounts in accordance with subsection (e).

"(b) Terms, Implementation, and Enforcement of Rebate Agreement.

"(1) Periodic rebates.

"(A) In general. A rebate agreement under this section shall require the to pay to the Secretary for each calendar quarter, not later than 30 days after the date of receipt of the information described in paragraph (2) for such quarter, a rebate in an amount determined under subsection (c) for all covered outpatient drugs of the manufacturer described in subparagraph (B).

"(B) Drugs included in quarterly rebate calculation. Drugs subject to rebate with respect to a calendar quarter are drugs which are dispensed by a pharmacy during such quarter to individuals (other than individuals enrolled with an eligible organization with a contract under section 1876) eligible for

benefits under this part, as reported by such pharmacies to the Secretary.

"(2) Information furnished to manufacturers.

"(A) In general. The Secretary shall report to each manufacturer, not later than 60 days after the end of each calendar quarter, information on the total number, for each covered outpatient drug, of units of each dosage form, strength, and package size dispensed under the plan during the quarter, on the basis of the data reported to the Secretary described in paragraph (1)(B).

"(B) Audit. The Comptroller General may audit the records of the Secretary to the extent necessary to determine the accuracy of reports by the Secretary pursuant to subparagraph (A). Adjustments to rebates shall be made to the extent determined necessary by the audit to reflect actual units of drugs
dispensed.

"(3) Provision of price information by manufacturer.

"(A) Quarterly pricing information. Each manufacturer with an agreement in effect under this section shall report to the Secretary, not later than 30 days after the last day of each calendar quarter, on the average manufacturer retail price and the average manufacturer non-retail price for each dosage form and strength of each covered outpatient drug for the quarter.

"(B) Base quarter prices. Each manufacturer of a covered outpatient drug with an agreement under this section shall report to the Secretary, by not later than 30 days after the effective date of such agreement (or, if later, 30 days after the end of the base quarter), the average manufacturer retail price, for such base quarter, for each dosage form and strength of each such covered drug.

"(C) Verification of average manufacturer price. The Secretary may inspect the records of manufacturers, and survey wholesalers, pharmacies, and institutional purchasers of drugs, as necessary to verify prices reported under subparagraph (A).

"(D) Penalties.

"(i) Civil money penalties.The Secretary may impose a civil money penalty on a manufacturer with an agreement under this section

"(I) for failure to provide information required under subparagraph (A) on a timely basis, in an amount up to $10,000 per day of delay;

"(II) for refusal to provide information about charges or prices requested by the Secretary for purposes of verification pursuant to subparagraph (C), in an amount up to $100,000; and

"(III) for provision, pursuant to subparagraph (A) or (B), of information that the manufacturer knows or should know is false, in an amount up to $100,000 per item of information. Such civil money penalties are in addition to any other penalties prescribed by law. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(ii) Termination of agreement. If a manufacturer with an agreement under this section has not provided information required under subparagraph (A) or (B) within 90 days of the deadline imposed, the Secretary may suspend the agreement with respect to covered outpatient drugs dispensed after the end of such 90-day period and until the date such information is reported (but in no case shall a suspension be for less than 30 days).

"(4) Length of agreement.

"(A) In general. A rebate agreement shall be effective for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

"(B) Termination.

"(i) By the secretary. The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall afford a manufacturer an opportunity for a hearing concerning such termination, but such hearing shall not delay the effective date of the termination.

"(ii) By a manufacturer. A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

"(iii) Effective date of termination. Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

"(iv) Notice to pharmacies. In the case of a termination under this

subparagraph, the Secretary shall notify pharmacies and physician organizations not less than 30 days before the effective date of such termination.

"(c) Amount of Rebate.

"(1) Basic rebate. Each manufacturer shall remit a basic rebate to the Secretary for each calendar quarter in an amount, with respect to each dosage form and strength of a covered drug (except as provided under paragraph (4)), equal to the product of

"(A) the total number of units subject to rebate for such quarter, as described in subsection (b)(1)(B); and

"(B) the greater of

"(i) the difference between the average manufacturer retail price and the average manufacturer non-retail price,

"(ii) 17 percent of the average manufacturer retail price, or

"(iii) the amount determined pursuant to paragraph (3).

"(2) Additional rebate. Each manufacturer shall remit to the Secretary, for each calendar quarter, an additional rebate for each dosage form and strength of a covered drug (except as provided under paragraph (4)), in an amount equal to

"(A) the total number of units subject to rebate for such quarter, as described in subsection (b)(1)(B), multiplied by

"(B) the amount, if any, by which the average manufacturer retail price for covered drugs of the manufacturer exceeds the average manufacturer retail price for the base quarter, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from the end of such base quarter to the month before the beginning of such calendar quarter.

"(3) Negotiated rebate amount for new drugs.

"(A) In general. The Secretary may negotiate with the manufacturer a per-unit rebate amount, in accordance with this paragraph, for any covered outpatient drug (except as provided under paragraph (4)) first marketed after June 30, 1993

"(i) which is not marketed in any country specified in section 802(b)(4)(A) of the Federal Food, Drug, and Cosmetic Act and for which the ssSecretary believes the average manufacturer's retail price may be excessive, or

"(ii) which is marketed in one or more of such countries, at prices significantly lower than the average manufacturer retail price.

"(B) Maximum rebate amount for drugs marketed in certain countries. The rebate negotiated pursuant to this paragraph for a drug described in subparagraph (A)(ii) may be an amount up to the difference between the average manufacturer retail price and any price at which the drug is available to wholesalers in a country specified in such section 802(b)(4)(A).

"(C) Factors to be considered. In making determinations with respect to the prices of a covered drug described in subparagraph (A) and in negotiating a rebate amount pursuant to this paragraph, the Secretary shall take into consideration, as applicable and appropriate, the prices of other drugs in the same therapeutic class, cost information requested by the Secretary and supplied by the manufacturer or estimated by the Secretary, prescription volumes, economies of scale, product stability, special manufacturing requirements, prices of the drug in countries specified in subparagraph (A)(i) (in the case of a drug described in such subparagraph), and other relevant factors.

"(D) Option to exclude coverage. If the Secretary is unable to negotiate with the manufacturer an acceptable rebate amount with respect to a covered outpatient drug pursuant to this paragraph, the Secretary may exclude such drug from coverage under this part.

"(E) Effective date of exclusion from coverage. An exclusion of a drug from coverage pursuant to subparagraph (D) shall be effective on and after

"(i) the date 6 months after the effective date of marketing approval of such drug by the Food and Drug Administration (but in no event earlier than July 1, 1996), or

"(ii) the date the manufacturer terminates negotiations with the Secretary concerning the rebate amount, whichever is earlier.

"(4) No rebate required for generic drugs. Paragraphs (1) through (3) shall not apply with respect to a covered outpatient drug that is not a single source drug or an innovator multiple source drug (as such terms are defined in section 1927(k)).

"(5) Deposit of rebates. The Secretary shall deposit rebates under this

section in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

"(d) Confidentiality of Information. Notwithstanding any other provision of law, information disclosed by a manufacturer under this section is confidential and shall not be disclosed by the Secretary, except

"(A) as the Secretary determines to be necessary to carry out this section,

"(B) to permit the Comptroller General to review the information provided, and

"(C) to permit the Director of the Congressional Budget Office to review the information provided.

"(e) Agreement to Give Equal Access to Discounts. An agreement under this subsection by a manufacturer of covered outpatient drugs shall guarantee that the manufacturer will offer, to each wholesaler or retailer (or other purchaser representing a group of such wholesalers or retailers) that purchases such drugs on substantially the same terms (including such terms as prompt payment, cash payment, volume purchase, single-site delivery, the use of formularies by purchasers, and any other terms effectively reducing the manufacturer's costs) as any other purchaser (including any institutional purchaser) the same price for such drugs as is offered to such other purchaser. In determining a manufacturer's compliance with the previous sentence, there shall not be taken into account terms offered to the Department of Veterans Affairs, the Department of Defense, or any public program.

"(f) Definitions. For purposes of this section

"(1) Average manufacturer retail price.The term `average manufacturer retail price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price (inclusive of discounts for cash payment, prompt payment, volume purchases, and rebates (other than rebates under this section), but exclusive of nominal prices) paid to the manufacturer for the drug in the United States for drugs distributed to the retail pharmacy class of trade.

"(2) Average manufacturer non-retail price. The term `average manufacturer non-retail price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the weighted average price (inclusive of discounts for cash payment, prompt payment, volume purchases, and rebates (other than rebates under this section), but exclusive of nominal prices) paid to the manufacturer for the drug in the United States

by hospitals and other institutional purchasers that purchase drugs for institutional use and not for resale.

"(3) Base quarter. The term `base quarter' means, with respect to a covered outpatient drug of a manufacturer, the calendar quarter beginning April 1, 1993, or (if later) the first full calendar quarter during which the drug was marketed in the United States.

"(4) Covered drug. The term `covered drug' includes each innovator multiple source drug and single source drug, as those terms are defined in section 1927(k)(7).

"(5) Manufacturer. The term `manufacturer' means, with respect to a covered outpatient drug

"(A) the entity whose National Drug Code number (as issued section 510(e) of the Federal Food, Drug, and Cosmetic Act) labeling of the drug; or

"(B) if the number described in subparagraph (A) does not appear on the labeling of the drug, the person named as the applicant in a human drug application (in the case of a new drug) or the product license application (in the case of a biological product) for such drug approved by the Food and Drug Administration.".

(b) Exclusions From Coverage. Section 1862(a) of such Act (42 U.S.C. 1395y(a)), as amended by sections 4034(b)(4) and 4118(b), is amended

(1) by striking "and" at the end of paragraph (15),

(2) by striking the period at the end of paragraph (16) and inserting "; or", and

(3) by inserting after paragraph (16) the following new paragraph:

"(17) A covered outpatient drug (as described in section 1861(t))

"(A) furnished during a year for which the drug's manufacturer does not have in effect a rebate agreement with the Secretary that meets the requirements of section 1850 for the year, or

"(B) excluded from coverage during the year by the Secretary pursuant to section 1850(c)(3)(D) (relating to negotiated rebate amounts for certain new drugs).".

Section 2004 EXTENSION OF 25 PERCENT RULE FOR PORTION OF

PREMIUM ATTRIBUTABLE TO COVERED OUTPATIENT DRUGS.

Section 1839(e) of the Social Security Act (42 U.S.C. 1395r(e)) is amended by adding at the end the following:

"(3) Notwithstanding the provisions of subsection (a), the portion of the monthly premium for each individual enrolled under this part for each month after December 1998 that is attributable to covered outpatient drugs shall be an amount equal to 50 percent of the portion of the monthly actuarial rate for enrollees age 65 and over, as determined under subsection (a)(1) and applicable to such month, that is attributable to covered outpatient drugs.".

Section 2005 COVERAGE OF HOME INFUSION DRUG THERAPY SERVICES.

(a) In General. Section 1832(a)(2)(A) of the Social Security Act (42 U.S.C. 1395k(a)(2)(A)) is amended by inserting "and home infusion drug therapy services" before the semicolon.

(b) Home Infusion Drug Therapy Services Defined. Section 1861 of such Act (42 U.S.C. 1395x) is amended

(1) by redesignating the subsection (jj) inserted by section 4156(a)(2) of the Omnibus Budget Reconciliation Act of 1990 as subsection (kk); and

(2) by inserting after such subsection the following new subsection:

"Home Infusion Drug Therapy Services

"(ll)(1) The term `home infusion drug therapy services' means the items and services described in paragraph (2) furnished to an individual who is under the care of a physician

"(A) in a place of residence used as the individual's home,

"(B) by a qualified home infusion drug therapy provider (as defined in paragraph (3)) or by others under arrangements with them made by that provider, and

"(C) under a plan established and periodically reviewed by a physician.

"(2) The items and services described in this paragraph are such nursing, pharmacy, and related services (including medical supplies, intravenous fluids, delivery, and equipment) as are necessary to conduct safely and effectively a drug regimen through use of a covered home infusion drug (as

defined in subsection (t)(5)), but do not include such covered home infusion drugs.

"(3) The term `qualified home infusion drug therapy provider' means any entity that the Secretary determines meets the following requirements:

"(A) The entity is capable of providing or arranging for the items and services described in paragraph (2) and covered home infusion drugs.

"(B) The entity maintains clinical records on all patients.

"(C) The entity adheres to written protocols and policies with respect to the provision of items and services.

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

"(E) The entity coordinates all service with the patient's physician.

"(F) The entity conducts a quality assessment and assurance program, including drug regimen review and coordination of patient care.

"(G) The entity assures that only trained personnel provide covered home infusion drugs (and any other service for which training is required to provide the service safely).

"(H) The entity assumes responsibility for the quality of services provided by others under arrangements with the entity.

"(I) In the case of an entity in any State in which State or applicable local law provides for the licensing of entities of this nature, the entity (i) is licensed pursuant to such law, or (ii) is approved, by the agency of such State or locality responsible for licensing entities of this nature, as meeting the standards established for such licensing.

"(J) The entity meets such other requirements as the Secretary may determine are necessary to assure the safe and effective provision of home infusion drug therapy services and the efficient administration of the home infusion drug therapy benefit.".

(c) Payment.

(1) In general. Section 1833 of such Act (42 U.S.C. 1395l) is amended

(A) in subsection (a)(2)(B), by striking "or (E)" and inserting "(E), or

(F)",

(B) in subsection (a)(2)(D), by striking "and" at the end,

(C) in subsection (a)(2)(E), by striking the semicolon and inserting "; and",

(D) by inserting after subsection (a)(2)(E) the following new subparagraph:

"(F) with respect to home infusion drug therapy services, the amounts described in section 1834(j);", and

(E) in the first sentence of subsection (b), by striking "services, (3)" and inserting "services and home infusion drug therapy services, (3)".

(2) Amount described. Section 1834 of such Act, as amended by section 13544(b)(i) of OBRA091993, is amended by adding at the end the following new subsection:

"(j) Home infusion Drug Therapy Services.

"(1) In general. With respect to home infusion drug therapy services, payment under this part shall be made in an amount equal to the lesser of the actual charges for such services or the fee schedule established under paragraph (2).

"(2) Establishment of fee schedule. The Secretary shall establish by regulation before the beginning of 1996 and each succeeding year a fee schedule for home infusion drug therapy services for which payment is made under this part. A fee schedule established under this subsection shall be on a per diem
basis.".

(3) Prohibition on certain referrals. Section 1877(h)(6) of such Act (42 U.S.C. 1395nn(h)(6)), as amended by section 13562(a) of OBRA091993, is amended by adding at the end the following:

"(L) Home infusion drug therapy services.".

(d) Certification. Section 1835(a)(2) of such Act (42 U.S.C. 1395n(a)(2)) is amended

(1) by striking "and" at the end of subparagraph (E),

(2) by striking the period at the end of subparagraph (F) and inserting "; and", and

(3) by inserting after subparagraph (F) the following:

"(G) in the case of home infusion drug therapy services, (i) such services are or were required because the individual needed such services for the administration of a covered home infusion drug, (ii) a plan for furnishing such services has been established and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.".

(e) Certification of Home infusion Drug Therapy Providers; Intermediate Sanctions for Noncompliance.

(1) Treatment as provider of services. Section 1861(u) of such Act (42 U.S.C. 1395x(u)) is amended by inserting "home infusion drug therapy provider," after "hospice program,".

(2) Consultation with state agencies and other organizations. Section 1863 of such Act (42 U.S.C. 1395z) is amended by striking "and (dd)(2)" and inserting "(dd)(2), and (ll)(3)".

(3) Use of state agencies in determining compliance. Section 1864(a) of such Act (42 U.S.C. 1395aa(a)) is amended

(A) in the first sentence, by striking "an agency is a hospice program" and inserting "an agency or entity is a hospice program or a home infusion drug therapy provider,"; and

(B) in the second sentence

(i) by striking "institution or agency" and inserting "institution, agency, or entity", and

(ii) by striking "or hospice program" and inserting "hospice program, or home infusion drug therapy provider".

(4) Application of intermediate sanctions. Section 1846 of such Act (42 U.S.C. 1395w0@2) is amended

(A) in the heading, by adding "and for qualified home infusion drug therapy providers" at the end,

(B) in subsection (a), by inserting "or that a qualified home infusion

drug therapy provider that is certified for participation under this title no longer substantially meets
the requirements of section 1861(ll)(3)" after "under this
part", and

(C) in subsection (b)(2)(A)(iv), by inserting "or home infusion drug therapy services" after "clinical diagnostic laboratory tests".

(f) Use of Regional Intermediaries in Administration of Benefit. Section 1816 of such Act (42 U.S.C. 1395h) is amended by adding at the end the following new subsection:

"(k) With respect to carrying out functions relating to payment for home infusion drug therapy services and covered home infusion drugs, the Secretary may enter into contracts with agencies or organizations under this section to perform such functions on a regional basis.".

(g) Conforming Amendments Relating to Coverage of Enteral and Parenteral Nutrients, Supplies, and Equipment. (1) Section 1834(h)(4)(B) of such Act (42 U.S.C. 1395m(h)(4)(B)) is amended by striking ", except that "and all that follows through "equipment".

(2) Section 1861(s)(8) of such Act (42 U.S.C. 1395x(s)(8)) is amended by inserting after "dental" the following: "devices or enteral and parenteral nutrients, supplies, and equipment".

Section 2006 CONFORMING AMENDMENTS TO MEDICAID PROGRAM.

(a) In General.

(1) Requiring medicare rebate as condition of coverage. The first sentence of section 1927(a)(1) of the Social Security Act (42 U.S.C. 1396r098(a)(1)) is amended

(A) in the first sentence of paragraph (1), by striking "and paragraph (6)" and inserting ", paragraph (6), and (for calendar quarters beginning on or after January 1, 1996)
paragraph (7)"; and

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

"(7) Requirement relating to rebate agreements for covered outpatient drugs under medicare program. A manufacturer meets the requirements of this paragraph for quarters in a year if the manufacturer has in effect an agreement with the Secretary under section 1850 for providing rebates for

covered outpatient drugs furnished to individuals under title XVIII during the year.".

(2) Non-duplication of rebates. Section 1927(b)(1) of such Act (42 U.S.C. 1396r098(b)(1)) is amended

(A) by redesignating subparagraph (B) as subparagraph (C), and

(B) by inserting after subparagraph (A) the following new subparagraph:

"(B) Non-duplication of medicare rebate. Covered drugs furnished to an individual eligible for benefits under part B of title XVIII and enrolled in a State plan under this title shall not be included in the determination of units of covered outpatient drugs subject to rebate under this section.".

(b) Effective Date. The amendments made by subsection (a) shall apply to quarters beginning on or after January 1, 1996.

Section 2007 EFFECTIVE DATE.

Except as otherwise provided, the amendments made by this subtitle shall apply to items and services furnished on or after January 1, 1996.

Title II, Subtitle B

Subtitle B Long-Term Care

Part 1 STATE PROGRAMS FOR HOME AND COMMUNITY-BASED SERVICES FOR INDIVIDUALS WITH DISABILITIES

Section 2101 STATE PROGRAMS FOR HOME AND COMMUNITY-BASED SERVICES FOR INDIVIDUALS WITH DISABILITIES.

(a) In General. Each State that has a plan for the home and community-based services to individuals with disabilities submitted to and approved by the Secretary under section 2102(b) is entitled to payment in accordance with section 2108.

(b) No Individual Entitlement Established. Nothing in this part shall be construed to create an entitlement for individuals or a requirement that a State with such an approved plan expend the entire amount of funds to which it is entitled in any year.

Section 2102 STATE PLANS.

(a) Plan Requirements. In order to be approved under subsection (b), a State plan for home and community-based services for individuals with disabilities must meet the following requirements:

(1) Eligibility.

(A) In general. Within the amounts provided by the State (and under section 2108) for such plan, the plan shall provide that services under the plan will be available to individuals with disabilities (as defined in section 2103(a)) in the State.

(B) Initial screening. The plan shall provide a process for the initial screening of individuals who appear to have some reasonable likelihood of being an individual with disabilities.

(C) Restrictions. The plan may not limit the eligibility of individuals with disabilities based on

(i) income,

(ii) age,

(iii) geography,

(iv) nature, severity, or category of disability,

(v) residential setting (other than an institutional setting), or

(vi) other grounds specified by the Secretary.

(D) Maintenance of effort. The plan must provide assurances that, in the case of an individual receiving medical assistance for home and community-based services under the State medicaid plan as of the date of the enactment of this Act, the State will continue to make available (either under this plan, under the State medicaid plan, or otherwise) to such individual an appropriate level of assistance for home and community-based services, taking into account the level of assistance provided as of such date and the individual's need for home and community-based services.

(2) Services.

(A) Specification. Consistent with section 2104, the plan shall specify

(i) the services made available under the plan,

(ii) the extent and manner in which such services are allocated and made available to individuals with disabilities, and

(iii) the manner in which services under the plan are coordinated with each other and with health and long-term care services available outside the plan for individuals with disabilities.

(B) Allocation. The State plan

(i) shall specify how it will allocate services under the plan, during and after the 7-fiscal-year phase-in period beginning with fiscal year 1996, among covered individuals with disabilities, and

(ii) may not allocate such services based on the income or other financial resources of such individuals.

(C) Limitation on licensure or certification. The State may not subject consumer-directed providers of personal assistance services to licensure, certification, or other requirements which the Secretary finds not to be necessary for the health and safety of individuals with disabilities.

(D) Consumer choice. To the extent possible, the choice of an individual with disabilities (and that individual's family) regarding which covered services to receive and the providers who will provide such services shall be followed.

(E) Requirement to serve low-income individuals.The plan shall assure that

(i) the proportion of the population of low-income individuals with disabilities in the State that represents individuals with disabilities who are provided home and community-based services either under the plan, under the State medicaid plan, or under both, is not less than

(ii) the proportion of the population of the State that represents individuals who are low-income individuals.

(3) Cost sharing. The plan shall impose cost sharing with respect to covered services only in accordance with section 2105.

(4) Types of providers and requirements for participation. The plan shall specify

(A) the types of service providers eligible to participate in the program under the plan, which shall include consumer-directed providers, and

(B) any requirements for participation applicable to each type of service provider.

(5) Budget. The plan shall specify how the State will manage Federal and State funds available under the plan for each fiscal year during the period beginning with fiscal year 1996 and ending with fiscal year 2003 and for each 5-fiscal-year periods thereafter to serve all categories of individuals with disabilities and meet the requirements of this subsection. If the Secretary makes an adjustment under section 2109(a)(5)(C) for a year, each State shall update the specifications under this paragraph to reflect the impact of such an adjustment.

(6) Provider reimbursement.

(A) Payment methods. The plan shall specify the payment methods to be used to reimburse providers for services furnished under the plan. Such methods may include retrospective reimbursement on a fee-for-service basis, prepayment on a capitation basis, payment by cash or vouchers to individuals with disabilities, or any combination of these methods. In the case of the use of cash or vouchers, the plan shall specify how the plan will assure compliance with applicable employment tax provisions.

(B) Payment rates. The plan shall specify the methods and criteria to be used to set payment rates for services furnished under the plan (including rates for cash payments or vouchers to individuals with disabilities).

(C) Plan payment as payment in full. The plan shall restrict payment under the plan for covered services to those providers that agree to accept the payment under the plan (at the rates established pursuant to subparagraph (B)) and any cost sharing permitted or provided for under section 2105 as payment in full for services furnished under the plan.

(7) Quality assurance and safeguards. The State plan shall provide for quality assurance and safeguards for applicants and beneficiaries in accordance with section 2106.

(8) Advisory group. The State plan shall

(A) assure the establishment and maintenance of an advisory group under section 2107(b), and

(B) include the documentation prepared by the group under section 2107(b)(4).

(9) Administration.

(A) State agency. The plan shall designate a State agency or agencies to administer (or to supervise the administration of) the plan.

(B) Administrative expenditures. Effective beginning with fiscal year 2003, the plan shall contain assurances that not more than 10 percent of expenditures under the plan for all quarters in any fiscal year shall be for administrative costs.

(C) Coordination. The plan shall specify how the plan

(i) will be integrated with the State medicaid plan, titles V and XX of the Social Security Act, programs under the Older Americans Act of 1965, programs under the Developmental Disabilities Assistance and Bill of Rights Act, the Individuals with Disabilities Education Act, and any other Federal or State programs that provide services or assistance targeted to individuals with disabilities, and

(ii) will be coordinated with health plans.

(10) Reports and information to secretary; audits. The plan shall provide that the State will furnish to the Secretary

(A) such reports, and will cooperate with such audits, as the Secretary determines are needed concerning the State's administration of its plan under this part, including the
processing of claims under the plan, and

(B) such data and information as the Secretary may require in order to carry out the Secretary's responsibilities.

(11) Use of state funds for matching. The plan shall provide assurances that Federal funds will not be used to provide for the State share of expenditures under this part.

(12) Health care worker redeployment requirement. The plan provides for compliance with the requirement of section 3074(a).

(b) Approval of Plans. The Secretary shall approve a plan submitted by a State if the Secretary determines that the plan

(1) was developed by the State after consultation with individuals with disabilities and representatives of groups of such individuals, and

(2) meets the requirements of subsection (a). The approval of such a plan shall take effect as of the first day of the first fiscal year beginning after the date of such approval (except that any approval made before January 1, 1996, shall be effective as of January 1, 1996). In order to budget funds allotted under this part, the Secretary may establish a deadline for the submission of such a plan before the beginning of a fiscal year as a condition of its approval effective with that fiscal year.

(c) Monitoring. The Secretary shall monitor the compliance of State plans with the eligibility requirements of section 2103 and may monitor the compliance of such plans with other requirements of this part.

(d) Regulations. The Secretary shall issue such regulations as may be appropriate to carry out this part on a timely basis.

Section 2103 INDIVIDUALS WITH DISABILITIES DEFINED.

(a) In General. In this part, the term "individual with disabilities" means any individual within one or more of the following 4 categories of individuals:

(1) Individuals requiring help with activities of daily living. An individual of any age who

(A) requires hands-on or standby assistance, supervision, or cueing (as defined in regulations) to perform three or more activities of daily living (as defined in subsection (c)), and

(B) is expected to require such assistance, supervision, or cueing over a period of at least 100 days.

(2) Individuals with severe cognitive or mental impairment. An individual of any age

(A) whose score, on a standard mental status protocol (or protocols) appropriate for measuring the individual's particular condition specified by the Secretary, indicates either severe cognitive impairment or severe mental impairment, or both;

(B) who

(i) requires hands-on or standby assistance, supervision, or cueing with one or more activities of daily living,

(ii) requires hands-on or standby assistance, supervision, or cueing with at least such instrumental activity (or activities) of daily living related to cognitive or mental impairment as the Secretary specifies, or

(iii) displays symptoms of one or more serious behavioral problems (that is on a list of such problems specified by the Secretary) which create a need for supervision to prevent harm to self or others; and

(C) whose is expected to meet the requirements of subparagraphs (A) and (B) over a period of at least 100 days.

(3) Individuals with severe or profound mental retardation. An individual of any age who has severe or profound mental retardation (as determined according to a protocol specified by the Secretary).

(4) Severely disabled children. An individual under 6 years of age who

(A) has a severe disability or chronic medical condition,

(B) but for receiving personal assistance services or any of the services described in section 2104(d)(1), would require institutionalization in a hospital, nursing facility, or
intermediate care facility for the mentally retarded, and

(C) is expected to have such disability or condition and require such services over a period of at least 100 days.

(b) Determination.

(1) In general. The determination of whether an individual is an individual with disabilities shall be made, by persons or entities specified under the State plan, using a uniform protocol consisting of an initial screening and assessment specified by the Secretary. A State may collect additional information, at the time of obtaining information to make such determination, in order to provide for the assessment and plan described in section 2104(b) or for other purposes. The State shall establish a fair hearing process for appeals of such determinations.

(2) Periodic reassessment.The determination that an individual is an individual with disabilities shall be considered to be effective under the State plan for a period of not more than 12 months (or for such longer period in such cases as a significant change in an individual's condition that may affect such determination is unlikely). A reassessment shall be made if there is a significant change in an individual's condition that may affect such

determination.

(c) Activity of Daily Living Defined. In this part, the term "activity of daily living" means any of the following: eating, toileting, dressing, bathing, and transferring.

Section 2104 HOME AND COMMUNITY-BASED SERVICES COVERED UNDER STATE PLAN.

(a) Specification.

(1) In general. Subject to the succeeding provisions of this section, the State plan under this part shall specify

(A) the home and community-based services available under the plan to individuals with disabilities (or to such categories of such individuals), and

(B) any limits with respect to such services.

(2) Flexibility in meeting individual needs. The services shall be specified in a manner that permits sufficient flexibility for providers to meet the needs of individuals with disabilities in a cost effective manner. Subject to subsection (e)(1)(B), such services may be delivered in an individual's home, a range of community residential arrangements, or outside the home.

(b) Requirement for Needs Assessment and Plan of Care.

(1) In general. The State plan shall provide for home and community-based services to an individual with disabilities only if

(A) a comprehensive assessment of the individual's need for home and community-based services (regardless of whether all needed services are available under the plan) has been made,

(B) an individualized plan of care based on such assessment is developed, and

(C) such services are provided consistent with such plan of care.

(2) Involvement of individuals. The individualized plan of care under paragraph (1)(B) for an individual with disabilities shall

(A) be developed by qualified individuals (specified under the State plan),

(B) be developed and implemented in close consultation with the individual and the individual's family,

(C) be approved by the individual (or the individual's representative), and

(D) be reviewed and updated not less often than every 6 months.

(3) Plan of care. The plan of care under paragraph (1)(B) shall

(A) specify which services specified under the individual plan will be provided under the State plan under this part,

(B) identify (to the extent possible) how the individual will be provided any services specified under the plan of care and not provided under the State plan, and

(C) specify how the provision of services to the individual under the plan will be coordinated with the provision of other health care services to the individual. The State shall make reasonable efforts to identify and arrange for services described in subparagraph (B). Nothing in this subsection shall be construed as requiring a State (under the State plan or otherwise) to provide all the services specified in such a plan.

(c) Mandatory Coverage of Personal Assistance Services. The State plan shall include, in the array of services made available to each category of individuals with disabilities, both agency-administered and consumer-directed personal assistance services (as defined in subsection (g)).

(d) Additional Services.

(1) Types of services. Subject to subsection (e), services available under a State plan under this part shall include any (or all) of the following:

(A) Case management.

(B) Homemaker and chore assistance.

(C) Home modifications.

(D) Respite services.

(E) Assistive devices.

(F) Adult day services.

(G) Habilitation and rehabilitation.

(H) Supported employment.

(I) Home health services.

(J) Any other care or assistive services (approved by the Secretary) that the State determines will help individuals with disabilities to remain in their homes and communities.

(2) Criteria for selection of services.The State plan shall specify

(A) the methods and standards used to select the types, and the amount, duration, and scope, of services to be covered under the plan and to be available to each category of individuals with disabilities, and

(B) how the types, and the amount, duration, and scope, of services specified meet the needs of individuals within each of the 4 categories of individuals with disabilities.

(e) Exclusions and Limitations.

(1) In general. A State plan may not provide for coverage of

(A) room and board,

(B) services furnished in a hospital, nursing facility, intermediate care facility for the mentally retarded, or other institutional setting specified by the Secretary, or

(C) items and services to the extent coverage is provided for the individual under a health plan or the medicare program.

(2) Taking into account informal care. A State plan may take into account, in determining the amount and array of services made available to covered individuals with disability, the availability of informal care.

(f) Payment for Services. A State plan may provide for the use of

(1) vouchers,

(2) cash payments directly to individuals with disabilities,

(3) capitation payments to health plans, and

(4) payment to providers, to pay for covered services.

(g) Personal Assistance Services.

(1) In general. In this section, the term "personal assistance services" means those services specified under the State plan as personal assistance services and shall include at least hands-on and standby assistance, supervision, and cueing with activities of daily living, whether agency-administered or consumer-directed (as defined in paragraph (2)).

(2) Consumer-directed; agency-administered. In this part:

(A) The term "consumer-directed" means, with reference to personal assistance services or the provider of such services, services that are provided by an individual who is selected and managed (and, at the individual's option, trained) by the individual receiving the services.

(B) The term "agency-administered" means, with respect to such services, services that are not consumer-directed.

Section 2105 COST SHARING.

(a) No or Nominal Cost Sharing for Poorest. The State plan may not impose any cost sharing (other than nominal cost sharing) for individuals with income (as determined under subsection (c)) less than 150 percent of the official poverty line (referred to in section 1902(25)(A)) applicable to a family of the size involved (determined without regard to section 1902(25)(B)).

(b) Sliding Scale for Remainder. The State plan shall impose cost sharing in the form of coinsurance (based on the amount paid under the State plan for a service)

(1) at a rate of 10 percent for individuals with disabilities with income not less than 150 percent, and less than 200 percent, of such official poverty line (as so applied);

(2) at a rate of 20 percent for such individuals with income not less than 200 percent, and less than 250 percent, of such official poverty line (as so applied); and

(3) at a rate of 25 percent for such individuals with income equal to at least 250 percent of such official poverty line (as so applied).

(c) Determination of Income for Purposes of Cost Sharing. The State plan

shall specify the process to be used to determine the income of an individual with disabilities for purposes of this section. Such process shall be consistent with standards specified by the Secretary.

Section 2106 QUALITY ASSURANCE AND SAFEGUARDS.

(a) Quality Assurance. The State plan shall specify how the State will ensure and monitor the quality of services, including

(1) safeguarding the health and safety of individuals with disabilities,

(2) the minimum standards for agency providers and how such standards will be enforced,

(3) the minimum competency requirements for agency provider employees who provide direct services under this part and how the competency of such employees will be enforced,

(4) obtaining meaningful consumer input, including consumer surveys that measure the extent to which participants receive the services described in the plan of care and participant satisfaction with such services,

(5) participation in quality assurance activities, and

(6) specifying the role of the long-term care ombudsman (under the Older Americans Act of 1965) and the Protection and Advocacy Agency (under the Developmental Disabilities Assistance and Bill of Rights Act) in assuring quality of services and protecting the rights of individuals with disabilities.

(b) Safeguards.

(1) Confidentiality. The State plan shall provide safeguards which restrict the use or disclosure of information concerning applicants and beneficiaries to purposes directly connected with the administration of the plan (including performance reviews under section 2602).

(2) Safeguards against abuse. The State plans shall provide safeguards against physical, emotional, or financial abuse or exploitation (specifically including appropriate safeguards in cases where payment for program benefits is made by cash payments or vouchers given directly to individuals with disabilities).

Section 2107 ADVISORY GROUPS.

(a) Federal Advisory Group.

(1) Establishment. The Secretary shall establish an advisory group, to advise the Secretary and States on all aspects of the program under this part.

(2) Composition. The group shall be composed of individuals with disabilities and their representatives, providers, Federal and State officials, and local community implementing agencies. A majority of its members shall be individuals with disabilities and their representatives.

(b) State Advisory Groups.

(1) In general. Each State plan shall provide for the establishment and maintenance of an advisory group to advise the State on all aspects of the State plan under this part.

(2) Composition. Members of each advisory group shall be appointed by the Governor (or other chief executive officer of the State) and shall include individuals with disabilities and their representatives, providers, State officials, and local community implementing agencies. A majority of its members shall be individuals with disabilities and their representatives.

(3) Selection of members. Each State shall establish a process whereby all residents of the State, including individuals with disabilities and their representatives, shall be given the opportunity to nominate members to the advisory group.

(4) Particular concerns. Each advisory group shall

(A) before the State plan is developed, advise the State on guiding principles and values, policy directions, and specific components of the plan,

(B) meet regularly with State officials involved in developing the plan, during the development phase, to review and comment on all aspects of the plan,

(C) participate in the public hearings to help assure that public comments are addressed to the extent practicable,

(D) document any differences between the group's recommendations and the plan,

(E) document specifically the degree to which the plan is consumer-directed, and

(F) meet regularly with officials of the designated State agency (or agencies) to provide advice on all aspects of implementation and evaluation of the plan.

Section 2108 PAYMENTS TO STATES.

(a) In General. Subject to section 2102(a)(9)(B) (relating to limitation on payment for administrative costs), the Secretary, in accordance with the Cash Management Improvement Act, shall authorize payment to each State with a plan approved under this part, for each quarter (beginning on or after January 1, 1996), from its allotment under section 2109(b), amount equal to

(1) the Federal matching percentage (as defined in subsection (b)) of amount demonstrated by State claims to have been expended during the quarter for home and community-based services under the plan for individuals with disabilities; plus

(2) an amount equal to 90 percent of amount expended during the quarter under the plan for activities (including preliminary screening) relating to determination of eligibility and performance of needs assessment; plus

(3) an amount equal to 90 percent (or, beginning with quarters in fiscal year 2003, 75 percent) of the amount expended during the quarter for the design, development, and installation of mechanical claims processing systems and for information retrieval; plus

(4) an amount equal to 50 percent of the remainder of the amounts expended during the quarter as found necessary by the Secretary for the proper and efficient administration of the State plan.

(b) Federal Matching Percentage.

(1) In general. In subsection (a), the term "Federal matching percentage" means, with respect to a State, the reference percentage specified in paragraph (2) increased by 28 percentage points, except that the Federal matching percentage shall in no case be less than 78 percent or more than 95 percent.

(2) Reference percentage.

(A) In general.The reference percentage specified in this paragraph is 100 percent less the State percentage specified in subparagraph (B), except that

(i) the percentage under this paragraph shall in no case be less than 50 percent or more than 83 percent, and

(ii) the percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 50 percent.

(B) State percentage. The State percentage specified in this subparagraph is that percentage which bears the same ratio to 45 percent as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii.

(c) Payments on Estimates with Retrospective Adjustments.The method of computing and making payments under this section shall be as follows:

(1) The Secretary shall, prior to the beginning of each quarter, estimate the amount to be paid to the State under subsection (a) for such quarter, based on a report filed by the State containing its estimate of the total sum to be expended in such quarter, and such other information as the Secretary may find necessary.

(2) From the allotment available therefore, the Secretary shall provide for payment of the amount so estimated, reduced or increased, as the case may be, by any sum (not previously adjusted under this section) by which the Secretary finds that the estimate of the amount to be paid the State for any prior period under this section was greater or less than the amount which should have been paid.

(d) Application of Rules Regarding Limitations on Provider-Related Donations and Health Care Related Taxes.The provisions of section 1903(w) of the Social Security Act shall apply to payments to States under this section in the same manner as they apply to payments to States under section 1903(a) of such Act.