Medicare + Pharmaceuticals

II.A–1

[For Use of Drafting Group Only]

[Subtitle A of title II]

[Notice: Does Not Necessarily Reflect Current Policy]

MEDICARE DRUG BENEFIT

Generic rebates -- any (3)

II.A–2

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TITLE II—NEW BENEFITS

Subtitle A—Medicare Outpatient Prescription Drug Benefit

SEC. 2001. COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS.

(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 "OBRA–1993"), 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 fol-

lowing 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; and

"(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 which is intravenously administered in a home setting unless it is a covered home infusion drug (as described in paragraph (5)).

"(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 paragraph (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 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 his 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) EXCEPTIONS; EXCLUSIONS FROM COVERAGE.—Section 1862(a) of such Act (42 U.S.C. 1395y(a)), as amended by section 4117(b), is amended—

(1) by striking "and" at the end of paragraph (16),

(2) by striking the period at the end of paragraph (17) and inserting "; or", and

(3) by inserting after paragraph (17) the following new paragraph:

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

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

"(B) which is listed under paragraph (2) of section 1927(d) (other than subparagraph (I) or (J) of such paragraph) 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 this part.

(d) 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 OBRA–1993—

(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 OBRA–1993, is amended by striking "section 1861(s)(2)(P)" and inserting "section 1861(s)(2)(O)".

SEC. 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 individ-

uals 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 individ-

uals 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) for drugs furnished after 1996, 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.

"(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 under paragraph (4) is—

"(i) for 1996, $5 for a pharmacy that is a participating supplier, and $3 for any other pharmacy, 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.

only participating pharmacists now consistent w/ decision not to allow BR balance billing by docs. (approved by Ira) & run through political & public liaison).

I believe participating pharmacists get reimbursed at $4.50. EJ will get final #'s on 10/22

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) STANDARDS.—In carrying out the program under subparagraph (A), the Secretary shall establish for each covered outpatient drug standards for the prescribing of the drug which are based on accepted medical practice. In establishing such standards, the Secretary shall incorporate standards from such current authoritative compendia as the Secretary may select, except that the Secretary may modify such a standard by regulation on the basis of scientific and medical information that such standard is not consistent with the safe and effective use of the 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) 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. 1395w–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 substituting "; and" for the period at the end of paragraph (2), 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 1995 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 OBRA–1993, 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)".

SEC. 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

As a condition of Medicare participation?

I do think current language works OK if it is consistent w/ Medicaid rebate language.

Please check Medicaid statute re rebates. HCFA does not directly pay drug manufacturers, they just get back rebates after they pay pharmacists.

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 manufacturer 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 either—

"(i) dispensed by participating pharmacies during such quarter to individuals (other than individuals enrolled with an eli-

gible organization with a contract under section 1876) eligible for benefits under this part, as reported by such pharmacies to the Secretary, or

"(ii) dispensed by nonparticipating pharmacies to such individuals and included in claims for payment of benefits received by the Secretary during such quarter.

"(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 whole-

salers, 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 assessments) 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 re-

newed 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 that are participating suppliers under this part 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, 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 (4).

"(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, 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 para-

graph, for any covered outpatient drug 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 Secretary 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, or

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

"(4) 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, 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.

"(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 hos-

pitals 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 pursuant to section 510(e) of the Federal Food, Drug, and Cosmetic Act) appears on the 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) CONFORMING AMENDMENT RELATING TO EXCLUSIONS FROM COVERAGE.—Section 1862(a)(18) of such Act (42 U.S.C. 1395y(a)), as added by section 2001(c), is amended—

(A) by striking "or" at the end of subparagraph (A),

(B) by striking the period at the end of subparagraph (B) and inserting ", or", and

(C) by adding at the end the following new subparagraphs:

"(C) 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

"(D) 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).".

SEC. 2004. COUNSELING BY PARTICIPATING PHARMACIES.

Section 1842(h) of the Social Security Act (42 U.S.C. 1395u(h)) is amended by adding at the end the following:

"(8) A pharmacy that is a participating supplier under this part shall agree 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.".

SEC. 2005. 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 enrollers age 65 and over, as determined under subsection (a)(1) and applicable to such month, that is attributable to covered outpatient drugs.".

SEC. 2006. 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 outpatient 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, (A) is licensed pursuant to such law, or (B) 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 resect to home infusion drug therapy services, the amounts described in section 1834(j);",

(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 OBRA–1993, 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 OBRA–1993, 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," after "home health agency, or whether"; 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. 1395w–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.".

SEC. 2007. CIVIL MONEY PENALTIES FOR EXCESSIVE CHARGES.

Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)), as amended by sections 4041(a)(1), 4043(a)(1), and 4043(c), is amended—

(1) by striking ",or" at the end of paragraph (5) and adding a semicolon,

(3) by adding "or" at the end of paragraph (6), and

(4) by inserting after paragraph (6) the following:

"(7) in the case of a pharmacy, presents or causes to be presented to any person a request for payment for covered outpatient drugs (as defined in section 1861(t)) dispensed to an individual enrolled under part B of title XVIII and for which the amount charged by the pharmacy is greater than the amount the pharmacy charges the general public (as determined by the Secretary);".

SEC. 2008. 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. 1396r–8(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 the Social Security Act (42 U.S.C. 1396r–8(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 both part B of title XVIII and 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.

SEC. 2009. EFFECTIVE DATE.

The amendments made by this subtitle shall apply to items and services furnished on or after January 1, 1996.