I

106TH CONGRESS
1ST SESSION

H. R. 1109

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs under part B of the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 15, 1999

Mr. ENGEL (for himself, Mr. NADLER, Mr. OWENS, Mr. CROWLEY, Mr. RUSH, Mr. ACKERMAN Mr. WYNN, Mr. WEINER, and Mrs. MCCARTHY of New York) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs under part B of the Medicare Program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Outpatient Prescription Drug Coverage Act of 1999''.

SEC. 2. MEDICARE COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS.

(a) DESCRIPTION OF COVERED OUTPATIENT DRUGS.—

(1) COVERAGE.—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;''.

(2) DRUGS DESCRIBED.—Section 1861(t) of such Act (42 U.S.C. 1395x(t)) is amended—

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

(B) in paragraph (1)—

(i) by striking ''paragraph (2)'' and inserting ''the succeeding paragraphs of this subsection'', and

(ii) by striking the period at the end and inserting '', but only if used for a medically accepted indication (as described in paragraph (4)).''; and

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

''(2) Subject to paragraph (3), the term 'covered outpatient drug' means—

''(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—

''(A) any drug, biological product, or insulin when furnished as part of, or as incident to, a diag-

nostic service or any other item or service for which payment may be made under this title (other than physicians' services or services which would be physicians' services if furnished by a physician); or

''(B) any drug that is intravenously administered in a home setting.

''(4) For purposes of paragraph (2), the term 'medically accepted indication', with respect to the use of an outpatient drug, includes—

''(A) any use which has been approved by the Food and Drug Administration for the drug, and

''(B) any other use of the drug, unless the Secretary determines that such use is not medically appropriate.''.

(3) CONFORMING AMENDMENTS REPEALING SEPARATE COVERAGE OF CERTAIN DRUGS AND PRODUCTS.—(A) Effective January 1, 2001, section 1861(s)(2) of such Act (42 U.S.C. 1395x(s)(2)) is amended—

(i) in each of subparagraphs (A) and (B), by striking ''(including drugs'' and all that follows through ''self-administered)'';

(ii) by striking subparagraphs (G), (I), (O), (Q), and (T);

(iii) by adding ''and'' at the end of subparagraph (R); and

(iv) by striking ''; and'' at the end of subparagraph (S) and inserting a period.

(B) Effective January 1, 2001, section 1861 of such Act (42 U.S.C. 1395x) is amended by striking the subsection (kk).

(C) Effective January 1, 2001, section 1881(b) of such Act (42 U.S.C. 1395rr(b)) is amended—

(i) in the first sentence of paragraph (1)—

(I) by striking '', (B)'' and inserting '', and (B)''; and

(II) by striking '', and (C)'' and all that follows and inserting a period; and

(ii) in paragraph (11)—

(I) by striking ''(11)(A)'' and inserting ''(11)''; and

(II) by striking subparagraphs (B) and (C).

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

(A) by striking ''and (S)'' and inserting ''(S)''; and

(B) by striking the semicolon at the end and inserting the following ", and (T) with respect to expenses incurred for covered outpatient drugs, the amounts paid shall be the amounts determined under section 1834(e)(2);".

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

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

(A) in clause (1), by inserting "or for covered outpatient drugs" after "1861(s)(10)(A)", and

(B) in clause (2), by inserting "or with respect to covered outpatient drugs" after "1861(kk))".

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

"(e) PAYMENT FOR COVERED OUTPATIENT DRUGS.—

"(1) DEDUCTIBLE.—

"(A) APPLICATION.—

"(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), payment shall be made under paragraph (2) only with respect to expenses incurred by an in-

dividual for covered outpatient drugs during a calendar year on or after such date in the year as the Secretary determines that the individual has incurred expenses in the year for covered outpatient drugs (during a period in which the individual is entitled to benefits under this part) equal to the amount of the prescription drug deductible specified in subparagraph (C) for that year.

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

''(B) RESPONSE TO APPLICATION.—If the system described in section 1842(u)(4) has not been established and an individual applies to the Secretary to establish that the individual has met the requirement of subparagraph (A),

the Secretary shall promptly notify the individual (and, if the application was submitted by or through a participating pharmacy, the pharmacy) as to the date (if any) as of which the individual has met such requirement.

''(C) PRESCRIPTION DRUG DEDUCTIBLE AMOUNT.—The prescription drug deductible specified in this subparagraph for—

''(i) 2001 is $250, and

''(ii) any succeeding year, is the prescription drug deductible for the preceding year, increased by the percentage by which the monthly premium under section 1839 for months during the year exceeds the monthly premium under such section for months during the preceding year.

''(2) PAYMENT AMOUNT.—

''(A) IN GENERAL.—Subject to the prescription drug deductible established under paragraph (1)(A) and except as provided in subparagraph (B), the amounts payable under this part with respect to a covered outpatient drug is equal to 80 percent of the lesser of—

''(i) the actual charge for the drug, or

"(ii) the applicable payment limit established under paragraph (3).

"(B) TREATMENT OF CERTAIN COST-BASED PREPAID ORGANIZATIONS.—In applying subparagraph (A) in the case of a Medicare+Choice organization under part C, an organization under a reasonable cost reimbursement contract under section 1876, and in the case of an organization receiving payment under section 1833(a)(1)(A) and providing coverage of covered outpatient drugs, the Secretary shall provide for an appropriate adjustment in the payment amounts otherwise made to reflect the aggregate increase in payments that would otherwise be made with respect to enrollees in such an organization if payments were made other than under such clause or such a contract on an individual-by-individual basis.

"(3) PAYMENT LIMITS.—

"(A) PAYMENT LIMIT FOR NON-MULTIPLE SOURCE DRUGS AND MULTIPLE-SOURCE DRUGS WITH RESTRICTIVE PRESCRIPTIONS.—In the case of a drug that either is not a multiple source drug (as defined in paragraph (9)(A)) or is a multiple source drug and has a restrictive

prescription (as defined in paragraph (9)(B)), the payment limit for the drug under this paragraph for a payment calculation period is equal to the lesser of—

"(i) the 90th percentile of the actual charges (computed on a statewide basis, carrier-wide basis, or other appropriate geographic area basis, as specified by the Secretary) for the drug for the second previous payment calculation period, adjusted (as the Secretary determines to be appropriate) to reflect the number of tablets (or other dosage units) dispensed; or

"(ii) the amount of the administrative allowance (established under paragraph (4)) plus the product of—

"(I) the number of tablets (or other dosage units) dispensed, and

"(II) the per tablet or unit average wholesale price for such drug (as determined under subparagraph (C) for the period for purposes of this subparagraph).

"(B) PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS WITHOUT RESTRICTIVE PRE-

SCRIPTIONS.—In the case of a drug that is a multiple source drug but does not have a restrictive prescription, the payment limit for the drug under this paragraph for a payment calculation period is equal to the amount of the administrative allowance (established under paragraph (4)) plus the product of—

''(i) the number of tablets (or other dosage units) dispensed, and

''(ii) the unweighted median of the per tablet or unit average wholesale prices (determined under subparagraph (C) for purposes of this subparagraph) for such drug for the period.

''(C) DETERMINATION OF UNIT PRICE.—

''(i) IN GENERAL.—For purposes of this paragraph, the Secretary shall determine, with respect to the dispensing of a covered outpatient drug in a payment calculation period (beginning on or after January 1, 2001), the per tablet or unit average wholesale price for the drug.

''(ii) BASIS FOR DETERMINATIONS.—

''(I) DETERMINATION FOR NON-MULTIPLE-SOURCE DRUGS.—For pur-

poses of subparagraph (A), such determination shall be based on a biannual survey conducted by the Secretary of a representative sample of direct sellers, wholesalers, or pharmacies (as appropriate) of wholesale (or comparable direct) prices (excluding discounts to pharmacies); except that if, because of low volume of sales for the drug or other appropriate reasons or in the case of covered outpatient drugs during 2001, the Secretary determines that such a survey is not appropriate with respect to a specific drug, such determination shall be based on published average wholesale (or comparable direct) prices for the drug.

''(II) DETERMINATION FOR MULTIPLE-SOURCE DRUGS.—For purposes of subparagraph (B), the Secretary may base the determination under this subparagraph on the published average wholesale (or comparable direct) prices for the drug or on a bian-

nual survey conducted by the Secretary of a representative sample of direct sellers, wholesalers, or pharmacists (as appropriate) of wholesale (or comparable direct) prices (excluding discounts to pharmacies).

"(III) COMPLIANCE WITH SURVEY REQUIRED.—If a wholesaler or direct seller of a covered outpatient drug refuses, after being requested by the Secretary, to provide the information required in a survey under this clause, 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 such provisions apply to a penalty or proceeding under section 1128A(a). Information gathered pursuant to the survey shall not be

disclosed except as the Secretary determines to be necessary to carry out the purposes of this part.

''(iii) QUANTITY AND TIMING.—Such determination shall be based on the price or prices for purchases in reasonable quantities and shall be made for a payment calculation period based on prices for the first day of the first month of the previous payment calculation period.

''(iv) GEOGRAPHIC BASIS.—The Secretary shall make such determination, and calculate the payment limits under this paragraph, on a national basis.

''(v) ADJUSTMENT FOR GEOGRAPHIC VARIATIONS IN COSTS.—The Secretary shall adjust the payment limits under this paragraph to take account of limitations on the availability of drug products and variations among regions in the average wholesale prices for a drug product, using an appropriate index as determined by the Secretary.

''(4) ADMINISTRATIVE ALLOWANCE FOR PURPOSES OF PAYMENT LIMITS.—

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

"(i) 2001, the administrative allowance under this paragraph is—

"(I) $5.00 for drugs dispensed by a participating pharmacy, or

"(II) $3.00 for drugs dispensed by another pharmacy; or

"(ii) a subsequent year, the administrative allowance under this paragraph is the administrative allowance under this paragraph for the preceding year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce in its 'Survey of Current Business') over the 12-month period ending with August of such preceding year.

Any allowance determined under the clause (ii) which is not a multiple of 1 cent shall be rounded to the nearest multiple of 1 cent.

"(B) ADJUSTMENT IN ALLOWANCE FOR MAIL SERVICE PHARMACIES.—The Secretary may, by regulation and after consultation with pharmacists, elderly groups, and private insur-

ers, reduce the administrative allowances established under subparagraph (A) for any drug dispensed by a mail service pharmacy (as defined by the Secretary) based on differences between such pharmacies and other pharmacies with respect to operating costs and other economies.

''(5) 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; and

''(iii) potential adverse reactions.

''(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 es-

tablishing 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) PROHIBITION OF FORMULARY.—Nothing in this title (other than section 1862(c)) shall be construed as authorizing the Secretary to exclude from coverage or to deny payment—

''(i) for any specific covered outpatient drug, or specific class of covered outpatient drug; or

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

''(6) TREATMENT OF CERTAIN PREPAID ORGANIZATIONS.—

''(A) GENERAL RULE COUNTING PREPAID PLAN EXPENSES TOWARD THE PRESCRIPTION

DRUG DEDUCTIBLE.—Except as provided in subparagraph (B), expenses incurred by (or on behalf of) a medicare beneficiary for covered outpatient drugs shall be counted (consistent with subparagraph (C)) toward the prescription drug deductible established under paragraph (1) whether or not, at the time the expenses were incurred, the beneficiary was enrolled in a plan under section 1833(a)(1)(A), a Medicare+Choice plan under part C, or under section 1876.

"(B) TREATMENT OF DRUG BUY-OUT PLAN EXPENSES.—In the case of a medicare beneficiary enrolled in a month in a drug buy-out plan (as defined in subparagraph (D))—

"(i) expenses incurred by the beneficiary for covered outpatient drugs reimbursed under the plan shall not be counted toward the prescription drug deductible, but

"(ii) if the individual disenrolls from the plan during the year, the beneficiary is deemed to have incurred, for each month of such enrollment, expenses for covered outpatient drugs in an amount equal to the

actuarial value (with respect to such month) of the deductible for covered outpatient drugs (as computed by the Secretary for purposes of section 1876(e)(1)) applicable on the average to individuals in the United States.

''(C) TREATMENT OF EXPENSES FOR COVERED OUTPATIENT DRUGS INCURRED WHILE ENROLLED IN A PREPAID PLAN OTHER THAN A DRUG BUY-OUT PLAN.—The Secretary may not enter into a contract with a Medicare+Choice organization under part C, an organization under section 1876, or provide for payment under section 1833(a)(1)(A) with respect to an organization which provides reimbursement for covered outpatient drugs, with respect to a plan that is not a drug buy-out plan, unless the organization provides assurances, satisfactory to the Secretary, that—

''(i) the organization will maintain and make available, for its enrollees and in coordination with the appropriate carriers under this part, an accounting of expenses incurred by (or on behalf of) enrollees

under the plan for covered outpatient drugs; and

"(ii) the organization will take into account, in any deductibles established under the plan in a year with respect to covered outpatient drugs under this part, the amounts of expenses for covered outpatient drugs incurred in the year by (or on behalf of) the beneficiary and otherwise counted toward the prescription drug deductible in the year.

"(D) DRUG BUY-OUT PLAN DEFINED.—In this paragraph, the term 'drug buy-out plan' means a plan under section 1833(a)(1)(A) or offered by a Medicare+Choice organization under part C, or an organization under section 1876 and with respect to which—

"(i) the amount of any deductible under the plan with respect to covered outpatient drugs under this title,

is less than 50 percent of—

"(ii) the prescription drug deductible specified in paragraph (1)(C).

"(E) MEDICARE BENEFICIARY DEFINED.—In this subsection, the term 'Medicare bene-

ficiary' means, with respect to a month, an individual covered for benefits under this part for the month.

''(F) TREATMENT OF PLAN CHARGES.—In the case of covered outpatient drugs furnished by a Medicare+Choice organization under part C, an eligible organization under section 1876(b) or an organization described in section 1833(a)(1)(A) which does not impose charges on covered outpatient drugs dispensed to its members, for purposes of this subsection the actual charges of the organization shall be the organization's standard charges to members, and other individuals, not entitled to benefits with respect to such drugs.

''(7) PHYSICIAN GUIDE.—

''(A) IN GENERAL.—The Secretary shall develop, and update annually, an information guide for physicians concerning the comparative average wholesale prices of at least 500 of the most commonly prescribed covered outpatient drugs. Such guide shall, to the extent practicable, group covered outpatient drugs (including multiple source drugs) in a manner useful to physicians by therapeutic category or with

respect to the conditions for which they are prescribed. Such guide shall specify the average wholesale prices on the basis of the amount of the drug required for a typical daily therapeutic regimen.

''(B) MAILING GUIDE.—The Secretary shall provide for mailing, in January of each year (beginning with 2001), a copy of the guide developed and updated under subparagraph (A)—

''(i) to each hospital with an agreement in effect under section 1866;

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

''(iii) to Social Security offices, senior citizen centers, and other appropriate places.

''(8) REPORTS ON UTILIZATION AND EFFECTS ON PRICES.—

''(A) COMPILATION OF INFORMATION.—The Secretary shall compile information on—

''(i) manufacturers' prices for covered outpatient drugs, and on charges of pharmacists for covered outpatient drugs, and

''(ii) the use of covered outpatient drugs by individuals entitled to benefits under this part.

The information compiled under clause (i) shall include a comparison of the increases in prices and charges for covered outpatient drugs during each 6 month period (beginning with January 1999) with the semiannual average increase in such prices and charges during the 5 years beginning with 1993.

''(B) REPORTS.—The Secretary shall submit to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate a report, in May and November of 2000 and 2001 and in May of each succeeding year, providing the information compiled under subparagraph (A). For each such report submitted after 2002, the report shall include an explanation of the extent to which the increases in outlays for covered outpatient drugs under this part are due to the factors described in subparagraphs (A)(i) and (A)(ii).

''(9) DEFINITIONS.—In this subsection:

''(A) MULTIPLE SOURCE DRUG.—

"(i) IN GENERAL.—The term 'multiple source drug' means, with respect to a payment calculation period, a covered outpatient drug for which there are 2 or more drug products which—

"(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations');

"(II) except as provided in clause (ii), are pharmaceutically equivalent and bioequivalent, as defined in clause (iii) and as determined by the Food and Drug Administration; and

"(III) are sold or marketed during the period.

"(ii) EXCEPTION.—Subclause (II) of clause (i) shall not apply if the Food and Drug Administration changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for purposes of the publication described in clause (i)(I), in order for drug products to be

rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in clause (iii).

''(iii) DEFINITIONS.—For purposes of this subparagraph:

''(I) PHARMACEUTICALLY EQUIVALENT.—Drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity.

''(II) BIOEQUIVALENT.—Drugs are bioequivalent if they do not present a known or potential bioequivalence problem or, if they do present such a problem, are shown to meet an appropriate standard of bioequivalence.

''(III) SOLD OR MARKETED.—A drug is considered to be sold or marketed during a period if it is listed in the publications referred to in clause (i)(I), unless the Secretary determines

that such sale or marketing is not actually taking place.

"(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 the particular drug 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 the particular drug 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 pre-

scribing the drug and which indicates with such appropriate phrase that the particular drug 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.''.

(c) PARTICIPATING PHARMACIES; CIVIL MONEY PENALTIES.—

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

(A) in subsection (h)(1), by inserting before the period at the end of the second sentence the following: '', except that, with respect to a supplier of covered outpatient drugs, the term 'participating supplier' means a participating pharmacy (as defined in subsection (o)(1))'';

(B) in subsection (h)(4), by adding at the end the following: ''In publishing directories under this paragraph, the Secretary shall provide for separate directories (wherever appropriate) for participating pharmacies.''; and

(C) by inserting after subsection (t) the following new subsection:

''(u)(1) For purposes of this section, the term 'participating pharmacy' means, with respect to covered outpatient drugs dispensed on or after January 1, 2001, an entity which is authorized under a State law to dispense covered outpatient drugs and which has entered into an agreement with the Secretary, providing at least the following:

''(A) The entity agrees to accept payment under this part on an assignment-related basis for all covered outpatient drugs dispensed to an individual entitled to benefits under this part (in this subsection referred to as a 'Medicare beneficiary') during a year after—

''(i) the Secretary has notified the entity, through the electronic system described in paragraph (4); or

''(ii) in the absence of such a system, the entity is otherwise notified that the Secretary has determined,

that the individual has met the prescription drug deductible with respect to such drugs under section 1834(e)(1) for the year.

''(B) The entity agrees—

''(i) not to refuse to dispense covered outpatient drugs stocked by the entity to any medicare beneficiary; and

''(ii) not to charge Medicare beneficiaries (regardless of whether or not the beneficiaries are enrolled under a prepaid health plan, a Medicare+Choice organization under part C, or with eligible organization under section 1876) more for such drugs than the amount it charges to the general public (as determined by the Secretary in regulations).

''(C) The entity agrees to keep patient records (including records on expenses) for all covered outpatient drugs dispensed to all medicare beneficiaries.

''(D) The entity agrees to submit information (in a manner specified by the Secretary to be necessary to administer this title) on all purchases of covered outpatient drugs dispensed to medicare beneficiaries.

''(E) The entity agrees—

''(i) to offer to counsel, or to offer to provide information (consistent with State law respecting the provision of such information) to, each Medicare beneficiary on the appropriate use of a drug to be dispensed and whether there

are potential interactions between the drug and other drugs dispensed to the beneficiary; and

''(ii) to advise the beneficiary on the availability (consistent with State laws respecting substitution of drugs) of therapeutically equivalent covered outpatient drugs.

''(F) The entity agrees to provide the information requested by the Secretary in surveys under section 1834(e)(3)(C)(ii).

Nothing in this paragraph shall be construed as requiring a pharmacy operated by a Medicare+Choice organization under part C, an eligible organization (described in section 1876(b)) or an organization described in section 1833(a)(1)(A) for the exclusive benefit of its members to dispense covered outpatient drugs to individuals who are not members of the organization.

''(2) The Secretary shall provide to each participating pharmacy—

''(A) a distinctive emblem (suitable for display to the public) indicating that the pharmacy is a participating pharmacy; and

''(B) upon request, such electronic equipment and technical assistance (other than the costs of obtaining, maintaining, or expanding telephone service) as the Secretary determines may be necessary for

the pharmacy to submit claims using the electronic system established under paragraph (4).

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

''(A) compliance with the requirements for participation under this title; and

''(B) the accuracy of information submitted by the pharmacies under this title.

''(4) The Secretary shall establish, by not later than January 1, 2001, a point-of-sale electronic system for use by carriers and participating pharmacies in the submission of information respecting covered outpatient drugs dispensed to medicare beneficiaries under this part.

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

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

(A) in paragraph (2)(C), by inserting ''or to be a participating pharmacy under section 1842(u)'' after ''1842(h)(1)'';

(B) by striking '', or'' at the end of paragraph (6);

(C) by adding ''or'' at the end of paragraph (7); and

(D) by inserting after paragraph (7) the following new paragraph:

''(8) in the case of a participating or non-participating pharmacy (as defined for purposes of part B of title XVIII)—

''(A) presents or causes to be presented to any person a request for payment for covered outpatient drugs dispensed to an individual entitled to benefits 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 in regulations), or

''(B) fails to provide the information requested by the Secretary in a survey under section 1834(e)(3)(C)(ii);''.

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

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

(2) in paragraph (2)(A), by striking ''paragraph (1)'' and inserting ''subparagraph (A)'';

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

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

(5) by inserting ''(1)'' after ''(c)''; and

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

''(2) No payment may be made under part B for any expense incurred for a covered outpatient drug if the drug is dispensed in a quantity exceeding a supply of 30 days or such longer period of time (not to exceed 90 days, except in exceptional circumstances) as the Secretary may authorize.''.

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

(1) AUTHORIZING USE OF OTHER ENTITIES IN ELECTRONIC CLAIMS SYSTEM.—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 new paragraph:

''(3) with respect to implementation and operation (and related functions) of the electronic system established under subsection (u)(4), a voluntary association, corporation, partnership, or other nongovernmental organization, which the Secretary determines to be qualified to conduct such activities.''.

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

(A) by striking ''and'' at the end of subparagraph (I);

(B) by redesignating subparagraph (L) as subparagraph (J); and

(C) by inserting after subparagraph (J) (as so redesignated) the following new subparagraphs:

''(K) if it makes determinations or payments with respect to covered outpatient drugs, will—

''(i) receive information transmitted under the electronic system established under subsection (u)(4), and

''(ii) respond to requests by participating pharmacies (and individuals entitled to benefits under this part) as to whether or not such an individual has met the prescription drug deductible established under section 1834(e)(1)(A) for a year; and

''(L) will enter into such contracts with organizations described in subsection (f)(3) as the Secretary determines may be necessary to implement and operate (and for related functions with respect to) the electronic system established under subsection (u)(4) for covered outpatient drugs under this part.''.

(3) SPECIAL CONTRACT PROVISIONS FOR ELECTRONIC CLAIMS SYSTEM.—

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

(i) by inserting ''(A)'' after ''(c)(1)'';

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

(iii) by adding at the end the following new subparagraph:

"(B) To the extent that a contract under this section provides for implementation and operation (and related functions) of the electronic system established under subsection (u)(4) for covered outpatient drugs, the Secretary may provide for payment for such activities based on any method of payment determined by the Secretary to be appropriate.".

(B) APPLICATION OF DIFFERENT PERFORMANCE STANDARDS.—The Secretary of Health and Human Services, before entering into contracts under section 1842 of the Social Security Act with respect to the implementation and operation (and related functions) of the electronic system for covered outpatient drugs, shall establish standards with respect to performance with respect to such activities. The provisions of section 1153(e)(2) and paragraphs (1) and (2) of section 1153(h) of such Act shall apply to such activities in the same manner as they apply to contracts with peer review organi-

zations, instead of the requirements of the second and third sentences of section 1842(b)(2)(A) of such Act.

(C) USE OF REGIONAL CARRIERS.—Section 1842(b)(2)(A) of such Act (42 U.S.C. 1395u(b)(2)(A)) is amended by adding at the end the following new sentence: ''With respect to activities relating to implementation and operation (and related functions) of the electronic system established under subsection (u)(4), the Secretary may enter into contracts with carriers under this section to perform such activities on a regional basis.''.

(4) DELAY IN APPLICATION OF COORDINATED BENEFITS WITH MEDIGAP.—The provisions of subparagraph (B) of section 1842(h)(3) of the Social Security Act shall not apply to covered outpatient drugs (other than drugs described in section 1861(s)(2)(J) of such Act as of the date of the enactment of this Act) dispensed before January 1, 2002.

(5) BATCH PROMPT PROCESSING OF CLAIMS.—Section 1842(c) of such Act (42 U.S.C. 1395u(c)), is amended—

(A) by redesignating paragraph (6) as paragraph (7);

(B) in paragraphs (2)(A) and (3)(A), by striking ''Each'' and inserting ''Except as provided in paragraph (6), each''; and

(C) by inserting after paragraph (5) the following new paragraph:

''(6)(A) Each contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B), with respect to claims for payment for covered outpatient drugs shall provide for a payment cycle under which each carrier will, on a monthly basis, make a payment with respect to all claims which were received and approved for payment in the period since the most recent date on which such a payment was made with respect to the participating pharmacy or individual submitting the claim.

''(B) If payment is not issued, mailed, or otherwise transmitted within 5 days of when such a payment is required to be made under subparagraph (A), interest shall be paid at the rate used for purposes of section 3902(a) of title 31, United States Code (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after such 5-day period and ending on the date on which payment is made.''.

(f) MODIFICATION OF HMO/CMP CONTRACTS.—

(1) SEPARATE ACTUARIAL DETERMINATION FOR COVERED OUTPATIENT DRUG BENEFIT.—Section 1876(e)(1) of such Act (42 U.S.C. 1395mm(e)(1)) is amended by adding at the end thereof the following new sentence: ''The preceding sentence shall be applied separately with respect to covered outpatient drugs.''.

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

(g) CONFORMING AMENDMENTS.—

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

(A) by inserting ''1834(e),'' after ''1833(b),''; and

(B) by inserting ''and in the case of covered outpatient drugs, applicable coinsurance percent (specified in section 1834(e)(2)(C)) of the lesser of the actual charges for the drugs or the payment limit (established under section 1834(d)(3))'' after ''established by the Secretary)''.

(2) Section 1903(i)(5) (42 U.S.C. 1396b(i)(5)) is amended by striking ''section 1862(c)'' and inserting ''section 1862(c)(1)''.

(h) PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION.—Part B is amended by inserting after section 1844 the following new section:

''PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION

''SEC. 1845. (a)(1) The Director of the Congressional Office of Technology Assessment (in this section referred to as the 'Director' and the 'Office', respectively) shall provide for the appointment of a Prescription Drug Payment Review Commission (in this section referred to as the 'Commission'), to be composed of individuals with expertise in the provision and financing of covered outpatient drugs appointed by the Director (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service).

''(2) The Commission shall consist of 11 individuals. Members of the Commission shall first be appointed by no later than January 1, 2000, for a term of 3 years, except that the Director may provide initially for such shorter terms as will ensure that (on a continuing basis) the terms of no more than 4 members expire in any one year.

''(3) The membership of the Commission shall include recognized experts in the fields of health care economics, medicine, pharmacology, pharmacy, and prescrip-

tion drug reimbursement, as well as at least one individual who is a medicare beneficiary.

''(b)(1) The Commission shall submit to Congress an annual report no later than May 1 of each year, beginning with 2001, concerning methods of determining payment for covered outpatient drugs under this part.

''(2) Such report, in 2002 and thereafter, shall include, with respect to the previous year, information on—

''(A) increases in manufacturers' prices for covered outpatient drugs and in charges of pharmacists for covered outpatient drugs,

''(B) the level of utilization of covered outpatient drugs by medicare beneficiaries, and

''(C) administrative costs relating to covered outpatient drugs.

''(c) The following provisions of section 1805 shall apply to the Commission in the same manner as they apply to the Medicare Payment Advisory Commission:

''(1) Subsection (c)(4) (relating to compensation of members).

''(2) Subsection (d) (relating to staffing and administration).

''(3) Subsection (e) (relating to powers of the Commission generally).

''(4) Subsection (f)(1) (relating to requests for appropriations).

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

(i) DEVELOPMENT OF STANDARD MEDICARE CLAIMS FORM.—

(1) The Secretary shall develop, in consultation with representatives of pharmacies and other interested individuals, a standard claims form (and a standard electronic claims format) to be used in requests for payment for covered outpatient drugs under the medicare program and other third-party payors.

(2) Not later than October 1, 2000, the Secretary shall distribute official sample copies of the format developed under paragraph (1) to pharmacies and other interested parties and by not later than October 1, 2000, shall distribute official sample copies of the form developed under paragraph (1) to pharmacies and other interested parties.

(j) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by

this section shall apply to items dispensed on or after January 1, 2001.

(2) CARRIERS.—The amendments made by subsection (e) shall take effect on the date of the enactment of this Act; except that the amendments made by subsection (e)(5) shall take effect on January 1, 2002, but shall not be construed as requiring payment before February 1, 2002.

(3) HMO/CMP ENROLLMENTS.—The amendment made by subsection (f) shall apply to enrollments effected on or after January 1, 2001.

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