Chris - first cut. Ending to Peter, as well.

THERESA M. FORSTER
Staff Director

United States Senate
Special Committee on Aging

G-31 Dirksen Building
Washington, D. C. 20510
(202) 224-5364

Subtitle A—Coverage of Outpatient Prescription Drugs in Medicare

SEC. 2000. REFERENCES IN SUBTITLE.

(a) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this subtitle an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(b) REFERENCES TO OBRA.—In this title, the terms "OBRA–1986", "OBRA–1987", "OBRA–1989", "OBRA–1990", and "OBRA–1993" refer to the Omnibus Budget Reconciliation Act of 1986 (Public Law 99–509), the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203), the Omnibus Budget Reconciliation Act of 1989 (Public Law 101–239), the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508), and the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66), respectively.

PART 1—COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS

SEC. 2001. COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS.

(a) COVERED OUTPATIENT DRUGS AS MEDICAL AND OTHER HEALTH SERVICES.—Section 1861(s)(2)(J) (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) (42 U.S.C. 1395x(t)) is amended—

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

(2) in paragraph (1)—

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

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

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 medi-

cal 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.

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

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

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

"(A) which is administered through infusion in a setting described in paragraph (5)(A)(ii) 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 (other than physicians' services or services which would be physicians' services if furnished by a physician); or

"(C) which is listed under paragraph (2) of section 1927(d) (other than subparagraph (B), (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 dispensed to an individual that—

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

"(ii) is administered—

"(I) in the individual's home,

"(II) an institution used as the individual's home, but only if the drug is administered during an inpatient day for which payment is not made to the institution under part A for inpatient or extended care services furnished to the individual, or

"(III) in a facility other than the individual's home if the administration of the drug at the facility is determined by the Secretary to be cost-effective (in accordance with such criteria as the Secretary may establish); and

"(iii) with respect to a drug furnished in a home setting—

"(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 such a 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 such a setting.

"(B) Not later than January 1, 1998, (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) CONFORMING AMENDMENTS REPEALING SEPARATE COVERAGE OF CERTAIN DRUGS AND PRODUCTS.—(1) Effective January 1, 1998, section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(A) in subparagraph (A), by striking "(including drugs" and all that follows through "self-administered)";

(B) by striking subparagraphs (G) and (I);

(C) by adding "and" at the end of subparagraph (M); and

(D) by striking subparagraphs (O), (P), and (Q).

(2) Effective January 1, 1998, section 1861 (42 U.S.C. 1395x) is amended by striking the subsection (jj) added by section 4156(a)(2) of OBRA–1990.

(3) Effective January 1, 1998, section 1881(b) (42 U.S.C. 1395rr(b)) is amended—

(A) 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;

(B) in paragraph (11)—

(i) by striking "(11)(A)" and inserting "(11)", and

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

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

(a) IN GENERAL.—Section 1834 (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 1998, an amount equal to $500, 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 the previous year; and

"(II) for any succeeding year, the amount applicable under this subparagraph 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 the previous year.

"(ii) The Secretary shall promulgate the deductible amount for 1998 and each succeeding year not later than October 1 of the previous year.

"(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 1998, $1200, 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 the previous year; and

"(II) for any succeeding year, the amount applicable under this subparagraph 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 the previous year.

"(ii) The Secretary shall promulgate the out-of-pocket limit for 1998 and each succeeding year not later than October 1 of the previous year.

"(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 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.

"(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) INITIAL PAYMENT CALCULATION PERIOD.—Subject to clause (ii), the Secretary shall determine, for the dispensing of a covered outpatient drug product in the payment calculation period beginning January 1, 1998, the estimated acquisition cost for the drug product, based upon—

"(I) in the case of a single source drug or multiple source drug with a restrictive prescription, based upon information from the period beginning in 1994 updated (in a compound manner) by the percentage change in the consumer price index for all urban consumers (U.S. city average) for the 4 12-month periods ending with June 1997; or

"(II) in the case of a multiple source drug without a restrictive prescription, based upon information

from the most recent year for which data is available.

"(ii) LIMITATION.—With respect to any covered outpatient drug product, the estimated acquisition cost in the payment calculation period described in clause (i) may not exceed 93 percent of the published average wholesale price for the drug, as determined one month prior to the beginning of the payment calculation period.

"(iii) SUBSEQUENT PERIODS.—The estimated acquisition cost for a covered outpatient drug product applicable under this subparagraph for the dispensing of a drug product in a payment calculation period beginning in January of each year (beginning with 1999) shall be equal to the estimated acquisition cost for the product determined under this subparagraph for the period ending in January of the previous year, increased by the [uniform percentage increase determined under section 8206(a)] for the class of services that includes prescription drugs for the year involved. Notwithstanding the previous sen-

tence, with respect to any covered outpatient drug product, such cost may not exceed 93 percent of the published average wholesale price for the drug, as determined one month prior to the beginning of the payment calculation period.

"(iv) 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 clauses (i), (ii), or (iii), 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), (ii), or (iii) shall not be disclosed except as the Secretary determines to be necessary to

carry out the purposes of this part and to permit the Comptroller General and the Director of the Congressional Budget Office to review the information provided.

"(D) UPDATES TO PAYMENT LIMITS.—Notwithstanding any other provision of this paragraph, the payment limit determined under this paragraph with respect to a payment calculation period may not exceed the payment limit for the preceding year, increased by the percentage increase computed under section [8206(b) of the Health Security Act].

"(5) ADMINISTRATIVE ALLOWANCE FOR PURPOSES OF PAYMENT LIMIT.—

"(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the administrative allowance established under this paragraph is—

"(i) for 1998, an amount equal to $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.

"(C) NO DISPENSING FEE FOR CERTAIN DRUGS AND PRODUCTS.—No administrative allowance may be provided under this paragraph with respect to any of the following covered outpatient drugs:

"(i) Erythropoietin provided to dialysis patients.

"(ii) Drugs and biologicals provided as an incident to a physician's service or to a service which would be a physician's service if furnished by a physician.

"(iii) Covered home infusion drugs.

"(6) SHARING OF SAVINGS FROM MAIL ORDER PHARMACIES WITH BENEFICIARIES.—An individual that receives a drug dispensed by a mail order phar-

macy shall receive a rebate or a contribution toward the individual's cost sharing in an amount equal to 25 percent of the excess of the payment limit determined in accordance with paragraph (4) over the amount charged by the mail order pharmacy for such drug.

"(7) ASSURING APPROPRIATE PRESCRIBING AND DISPENSING PRACTICES.—

"(A) IN GENERAL.—[Effective January 1, 2000,] the Secretary shall develop a program to—

"(i) provide on-line prospective review of prescriptions on a 24-hour basis (in accordance with subparagraph (B)) and retrospective review of claims;

"(ii) establish standards for counseling individuals to whom covered outpatient drugs are prescribed; and

"(iii) identify (and to educate physicians, patients, 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) PROSPECTIVE REVIEW.—

"(i) IN GENERAL.—The program under this paragraph shall provide for on-line prospective review of each covered outpatient drug prescribed for a patient before the prescription is filled or the drug is furnished, including screening for potential drug therapy problems due to therapeutic duplication, drug-to-drug interactions, and incorrect drug dosage or duration of drug treatment.

"(ii) DISCUSSION OF APPROPRIATE USE.—In conducting prospective review under this subparagraph, any individual or entity that dispenses a covered outpatient drug shall offer to discuss with the patient to whom the drug is furnished or the patient's caregiver (in person if practicable,

or through access to a toll-free telephone service) information regarding the appropriate use of the drug, potential interactions between the drug and other drugs dispensed to the individual, and such other matters as the Secretary may require.

"(iii) ADDITIONAL DUTIES.—In carrying out this subparagraph, the Secretary shall—

"(I) develop public domain software which could be used by carriers and pharmacies to provide the on-line prospective review; and

"(II) study the feasibility and desirability of requiring patient diagnosis codes on prescriptions and the feasibility of expanding the prospective review program to include the identification of drug-disease contraindications, interactions with over-the-counter drugs, and drug-allergy interactions.

"(C) PRIOR AUTHORIZATION.—

"(i) DEVELOPMENT OF LIST OF MISUSED DRUGS.—The Secretary shall develop

(and periodically) update a list of covered outpatient drugs which the Secretary has determined, based on data collected, may be subject to misuse or inappropriate use. The Secretary shall provide a means for manufacturers to appeal an initial decision to include a drug on the list.

"(ii) PRIOR AUTHORIZATION FOR DRUGS ON LIST.—The Secretary shall establish a process under which (subject to clause (iii)) the Secretary may require advance approval for any covered outpatient drug included on the list developed under clause (i).

"(iii) RESTRICTIONS ON DENIAL OF APPROVAL.—The Secretary may not deny the approval of a drug under the process established under clause (ii) before its dispensing unless the process—

"(I) provides responses by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

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

ered outpatient prescription drug in emergency situations.

"(iv) STUDY OF EXPANSION TO OTHER DRUGS.—The Secretary shall study the feasibility and desirability of requiring advance approval under this subparagraph of the dispensing of a covered outpatient drug in cases where a more cost-effective therapeutically or generically equivalent drug is available.

"(D) DRUG USE REVIEW.—As part of the program established under subparagraph (A), the Secretary shall provide for a drug use review program to provide for the ongoing periodic examination of claims data and other records on covered outpatient drugs furnished to patients under this title in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients.

"(E) REQUIREMENTS RELATING TO CONTROLLED SUBSTANCES AND ILLEGAL USES.—The Secretary shall require an entity furnishing covered outpatient drugs under this part to report electronically to the appropriate State

agency on any covered outpatient drugs dispensed to individuals enrolled under this part that are controlled substances under schedules II through V of the Controlled Substance Act, and on the illegal use or diversion of any such drugs furnished by the entity.

"(F) REPORTS ON DEATHS AND INJURIES RESULTING FROM USE OF DRUGS.—

"(i) IN GENERAL.—The Secretary shall require individuals and entities furnishing items and services for which payment may be made under this title to report electronically to the Secretary on any incidents within the knowledge of the individual or entity of death or serious injury (including initial or prolonged hospitalization, impairment, damage or disruption in the patient's body function, congenital anomaly, or life-threatening outcome) resulting from the prescribing, dispensing, or administration of a covered outpatient drug dispensed to an individual enrolled under this part.

"(ii) PRIVACY PROTECTION.—The Secretary shall establish standards to pro-

tect from public disclosure the identity of individuals or institutions that report information under this subparagraph and the identity of any individual (whether a patient or an individual involved in the prescribing, dispensing, or administration of the drug) who is the subject of such information.

"(G) EXCEPTION FOR MANAGED CARE PROGRAMS.—The Secretary may waive the application of any provision of this paragraph to the dispensing of covered outpatient drugs by an organization described in section 1833(a)(1)(A) or an entity with a contract in effect under section 1876 to the extent the Secretary finds that the organization has in effect a program that meets the objectives of such provision.

"(H) ADOPTION OF MEDICAID PROGRAMS.—To the extent considered appropriate by the Secretary, the program developed under this paragraph with respect to drugs furnished in a State may include elements applicable to the furnishing of covered outpatient drugs

under the State medicaid program under section 1927.

"(8) ADMINISTRATIVE IMPROVEMENTS.—The Secretary shall develop, in consultation with the National Council of Prescription Drug Programs and representatives of pharmacies and of other interested persons, a standard claims form for covered outpatient drugs in accordance with [title X of the Health Security Act].

"(9) BILLING REQUIREMENTS.—

"(A) MANDATORY ASSIGNMENT.—(i) Payment under this part for a covered outpatient drug may only be made on an assignment-related basis.

"(ii) Except for deductible, coinsurance, or copayment amounts applicable under this part, no person may bill or collect any amount from an individual enrolled under this part or other person for a covered outpatient drug for which payment may be made under this part, and no such individual or person is liable for payment of any amounts billed in violation of this clause. If a person knowingly and willfully bills or collects an amount in violation of the previous sentence, the Secretary may apply sanctions

against such person in accordance with section 1842(j)(2). Paragraph (4) of section 1842(j) shall apply in this clause in the same manner as such paragraph applies to such section.

"(B) USE OF ELECTRONIC SYSTEM.—The Secretary shall establish, by not later than January 1, 1997, a point-of-sale electronic system for use by carriers and pharmacies in the submission of information respecting covered outpatient drugs dispensed to medicare beneficiaries under this part. Such system shall be consistent with the standards established by the National Council of Prescription Drug Programs.

"(10) REQUIRING PHARMACY SUPPLIER NUMBERS.—

"(A) IN GENERAL.—Payment may not be made under this part with respect to a covered outpatient drug furnished by an entity unless the entity has obtained a supplier number from the Secretary.

"(B) STANDARDS FOR ISSUING SUPPLIER NUMBERS.—The Secretary may not issue a supplier number to an entity for purposes of subparagraph (A) unless the entity demonstrates to

the Secretary that it will maintain patient records (in accordance with such standards as the Secretary may impose) and meet the other applicable requirements of this subsection and section 1848(g).

"(11) STUDY ON PHARMACEUTICAL CARE SERVICES.—The Secretary shall study and develop, in consultation with actively practicing pharmacists, a payment methodology which is based upon and reflects the reasonable charges for varying levels of pharmacist services, including patient consultations provided to individuals under this section. Such payment would be in addition to the administrative allowance established under paragraph (5). The Secretary shall submit a report to Congress on the methodology developed under this paragraph not later than September 30, 1997.

"(12) 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), except that the reference in such section to a 'covered outpatient drug' shall be considered a reference to a covered outpatient drug under this part.

"(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 a calendar year.".

(b) REQUIRING PHARMACIES TO SUBMIT CLAIMS.—Section 1848(g)(4) (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 (or 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) (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) ADDITIONAL FUNCTIONS.—Section 1842(b)(3) (42 U.S.C. 1395u(b)(3)) is amended—

(A) by striking "and" at the end of subparagraph (H);

(B) by adding "and" at the end of subparagraph (L);

(C) by redesignating subparagraph (L) as subparagraph (I); and

(D) by inserting after subparagraph (I) (as so redesignated) the following new subparagraphs:

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

"(i) receive information transmitted under the electronic system established under section 1834(d)(8)(B), and

"(ii) respond to requests by 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(d)(1)(A) for a year; and

"(K) 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 section 1834(d)(8)(B) for covered outpatient drugs under this part;".

(3) PAYMENT ON OTHER THAN A COST BASIS.—Section 1842(c)(1)(A) (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.".

(4) BATCH PROMPT PROCESSING OF CLAIMS.—Section 1842(c) (42 U.S.C. 1395u(c)) is amended—

(A) in paragraphs (2)(A) and (3)(A), by striking "Each" and inserting "Except as provided in paragraph (4), each";

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

"(4)(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.".