amendments made to such title by this Act as if the effective date of such amendments were January 1, 1997.

SEC. 3022. RELATION BETWEEN PACKAGE AND CERTAIN STATE LAWS.

(a) PERMITTING STATES TO REQUIRE BENEFITS UNDER CERTIFIED HEALTH PLANS TO BE FURNISHED BY CERTAIN PROVIDERS.—Nothing in this subtitle may be construed to prohibit a State from requiring that an item or service covered under the guaranteed national benefit package be furnished to an individual enrolled in a certified health plan by any particular class or type of provider who is legally authorized to provide such item or service under the law of the State (or under a State regulatory mechanism provided by State law) in which the item or service is provided.

(b) REQUIRING HEALTH PLANS TO OFFER BENEFITS IN EXCESS OF NATIONAL PACKAGE.—No State may require a certified health plan to offer any item or service not included in the guaranteed national benefit package.

(c) COVERAGE OF SERVICES NOT FURNISHED BY MEDICARE PROVIDERS.—

(1) IN GENERAL.—Nothing in this subtitle shall be construed to prohibit coverage of an item or service otherwise described in section 3001 under the guaranteed national benefit package furnished to an individual under a certified health plan solely on the ground that the individual or entity providing the item or service is not an eligible medicare provider, so long as the individual or entity is legally authorized to provide such item or service under the law of the State (or under a State regulatory mechanism provided by State law) in which the item or service is provided.

(2) ELIGIBLE MEDICARE PROVIDER DEFINED.—In paragraph (1), an "eligible medicare provider" is an individual or entity providing an item or service for which payment may be made under title XVIII of the Social Security Act who is participating in such title or otherwise eligible to receive payment for providing such an item or service under such title.

SEC. 3023. PROVISION OF ITEMS OR SERVICES CONTRARY TO RELIGIOUS BELIEF OR MORAL CONVICTION.

A health professional or a health facility may not be required to provide an item or service in the guaranteed national benefit package if the professional or facility objects to doing so on the basis of a religious belief or moral conviction.

SEC. 3024. ESTABLISHMENT OF COMMISSIONS.

(a) ADVISORY COMMISSION ON MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES.—

(1) ESTABLISHMENT OF COMMISSION.—

(A) IN GENERAL.—The Director of the Office of Technology Assessment (hereafter in this section referred to as the "Director" and the "Office", respectively) shall provide for the appointment of an Advisory Commission on Mental Health and Substance Abuse Services (hereafter in this subsection referred to as the "Commission") to be composed of individuals appointed by the Director without regard to the provisions of title 5, United States Code, governing appointments in the competitive service.

(B) NUMBER; TIMING OF APPOINTMENT.—The Commission shall consist of 15 individuals. Members of the Commission shall first be appointed not later than 1 year after the date of the enactment of this subsection for a term of 3 years, except that the Director may provide initially for such shorter terms as will insure that (on a continuing basis) the terms of no more than 4 members expire in any one year.

(C) COMPOSITION.—The membership of the Commission shall include (but need not be limited to)—

(i) physicians,

(ii) other health professionals,

(iii) individuals with knowledge of and experience in the delivery of mental health and substance abuse services,

(iv) representatives of public mental health and substance abuse treatment service systems, and

(v) consumers.

To the greatest extent feasible, the membership of the Commission shall reflect the racial, ethnic, and gender composition of the population of the United States.

(2) ISSUES STUDIED BY COMMISSION.—The Commission shall examine the following issues:

(A) The variety of mental health and substance abuse services provided in the United States, together with the types of providers furnishing such services and the methods under which the providers receive payment for furnishing such services.

(B) The means available to appropriately manage the delivery of mental health and substance abuse services and coordinate the delivery of such services with the delivery of other health services, and to achieve parity in the scope of mental health and substance abuse services covered under the guaranteed national benefit package under this title with the scope of other health services covered under the package.

(C) The variations in the utilization of and costs associated with mental health and substance abuse services among different geographic regions and demographic groups.

(D) The incidence and prevalence of severe mental illness and substance abuse among incarcerated adults and juveniles and the relation between the mental health and substance abuse treatment provided to these individuals and the length of time these individuals are incarcerated.

(E) The standards for training and certifying providers of mental health and substance abuse services.

(F) The standards used to measure the quality of mental health and substance abuse services and to review the utilization of such services.

(G) Such other issues relating to mental health and substance abuse services in the United States as the Commission considers appropriate.

(3) SUBMISSION OF ANNUAL REPORT.—Not later than January 1, 1998 (and not later than January 1 of the first 4 years thereafter), the Commission shall submit to Congress a report—

(A) describing the issues examined by the Commission under paragraph (2) during the preceding year;

(B) evaluating the effectiveness of the guaranteed national benefit package under this subtitle in assuring adequate coverage for mental health and substance abuse services;

(C) analyzing the progress made in achieving parity in the delivery of mental health and substance abuse services and the delivery of other health services for individuals in the United States;

(D) evaluating State comprehensive managed mental health programs operated during the preceding year under section 1981 of the Public Health Service Act and the extent of the integration of public and private systems of mental health and substance abuse treatment services in the State;

(E) analyzing trends in the delivery of mental health and substance abuse services and the costs associated with the delivery of such services; and

(F) analyzing whether any distinctions in limitations on coverage and determinations of payment amounts be-

tween mental health and substance abuse services and other services in the guaranteed national benefit package under this subtitle should be maintained, modified, or eliminated.

(4) APPLICABILITY OF OTHER ADMINISTRATIVE PROVISIONS.—The following provisions of section 1886(e)(6) of the Social Security Act shall apply to the Commission in the same manner as such provisions apply to the Prospective Payment Assessment Commission:

(A) Subparagraph (C) (relating to staffing and administration generally).

(B) Subparagraph (D) (relating to compensation of members).

(C) Subparagraph (F) (relating to access to information).

(D) Subparagraph (G) (relating to use of funds).

(E) Subparagraph (H) (relating to periodic GAO audits).

(F) Subparagraph (J) (relating to requests for appropriations).

(5) TERMINATION.—The Commission shall terminate 30 days after submitting the final report required under paragraph (3).

(b) NATIONAL HEALTH ADVISORY COMMISSION.—

(1) ESTABLISHMENT OF COMMISSION.—

(A) IN GENERAL.—The Director of the Office of Technology Assessment (hereafter in this section referred to as the "Director" and the "Office", respectively) shall provide for the appointment of a National Health Advisory Commission (hereafter in this subsection referred to as the "Commission").

(B) COMPOSITION.—The Commission shall consist of the following individuals:

(i) The Chair and Vice-Chair of the Prospective Payment Assessment Commission.

(ii) The Chair and Vice-Chair of the Physician Payment Review Commission.

(iii) The Chair and Vice-Chair of the Prescription Drug Payment Review Commission.

(iv) The Chair and Vice-Chair of the Advisory Commission on Mental Health and Substance Abuse Services.

(v) 3 other individuals appointed by the Director (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service) with expertise in health economics, health insurance, benefits, and provider reimbursement.

To the greatest extent feasible, the membership of the Commission shall reflect the racial, ethnic, and gender composition of the population of the United States.

(C) TIMING OF APPOINTMENT.—Members of the Commission shall first be appointed not later than 15 months after the date of the enactment of this subsection for a term of 3 years, except that the Director may provide initially for such shorter terms as will insure that (on a continuing basis) the terms of no more than 4 members expire in any one year.

(2) DUTIES.—Based on detailed information provided by the Commissions referred to in paragraph (1), the Commission shall monitor the impact of this Act on individuals, employers, and governments.

(3) ANNUAL REPORTS.—Not later than January 1, 1998, and each January 1 thereafter, the Commission shall submit to Congress a report on the impact of this Act on individuals, employers, and governments, and shall include in the report recommendations for changes in this Act, including (but not

limited to) changes in the guaranteed national benefit package described in this subtitle.

(4) APPLICABILITY OF OTHER ADMINISTRATIVE PROVISIONS.—The following provisions of section 1886(e)(6) of the Social Security Act shall apply to the Commission in the same manner as such provisions apply to the Prospective Payment Assessment Commission:

(A) Subparagraph (C) (relating to staffing and administration generally).

(B) Subparagraph (D) (relating to compensation of members).

(C) Subparagraph (F) (relating to access to information).

(D) Subparagraph (G) (relating to use of funds).

(E) Subparagraph (H) (relating to periodic GAO audits).

(F) Subparagraph (J) (relating to requests for appropriations).

SEC. 3025. STUDY ON COVERAGE OF EMERGENCY DENTAL SERVICES.

(a) STUDY.—The Secretary of Health and Human Services shall conduct a study to determine whether coverage for emergency dental services should be included in the guaranteed national benefit package under this subtitle.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a), and shall include in the report such recommendations as the Secretary considers appropriate regarding the conditions under which emergency dental services should be covered and the methodology under which payment may be made for such services.

SEC. 3026. STUDY ON COVERAGE OF SCREENING FOR ADULT DIABETES.

(a) STUDY.—The Secretary of Health and Human Services shall conduct a study to determine the appropriateness and cost-effectiveness of screening for adult diabetes for purposes of determining whether coverage for such service should be included in the guaranteed national benefit package under this subtitle.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a), and shall include in the report such recommendations as the Secretary considers appropriate regarding the conditions under which screening for adult diabetes should be covered and the methodology under which payment may be made for such service.

Subtitle B—Coverage of Outpatient Prescription Drugs and Other Changes in Medicare Benefits

PART 1—COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS

SEC. 3101. 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 medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

"(B) A biological product which—

"(i) may only be dispensed upon prescription,

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

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

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

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

"(E) Medical foods (other than enteral nutrients described in subparagraph (D)) that comply with the requirements of the Federal Food, Drug, and Cosmetic Act and that are prescribed by a physician for persons with Phenylketonuria (PKU) and other inborn errors of metabolism, in accordance with guidelines established by the Secretary.

An item described in subparagraph (D) or (E) shall not be considered a covered outpatient drug for purposes of section 1850.

"(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, a diagnostic 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);

"(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; or

"(D) which is a contraceptive drug described in section 1861(s)(21).

"(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.

"(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 for purposes of 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. 3102. 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, increased by the average annual percentage increase in private sector per capita outpatient prescription drug expenditures (as determined by the Secretary) during each of the years 1994 through 1997; and

"(II) for any succeeding year, the amount applicable under this subparagraph for the previous year, increased by the percentage increase computed under section 8206(b) of the Guaranteed Health Insurance Act of 1994 for that succeeding 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, $1000, increased by the average annual percentage increase in private sector per capita outpatient prescription drug expenditures (as determined by the Secretary) during each of the years 1994 through 1997; and

"(II) for any succeeding year, the amount applicable under this subparagraph for the previous year, increased by the percentage increase computed under section 8206(b) of the Guaranteed Health Insurance Act of 1994 for that succeeding 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) of the Guaranteed Health Insurance Act of 1994 for the class of services that includes prescription drugs for the year involved. Notwithstanding the previous sentence, 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 Guaranteed Health Insurance Act of 1994.

"(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, adjusted by the percentage change in the consumer price index for all urban consumers (U.S. city average) for the 2 12-month periods ending with June 1997; 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) ASSURING APPROPRIATE PRESCRIBING AND DISPENSING PRACTICES.—

"(A) IN GENERAL.—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) IN GENERAL.—The Secretary shall establish a process under which (subject to clause (ii)) the Secretary may require advance approval for any covered outpatient drug.

"(ii) RESTRICTIONS ON DENIAL OF APPROVAL.—The Secretary may not deny the approval of a drug under the process established under clause (i) 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 covered outpatient prescription drug in emergency situations.

"(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) 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 eligible organization with an agreement 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.

"(F) 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.

"(7) ADMINISTRATIVE AND REPORTING REQUIREMENTS.—

"(A) 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.

"(B) 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 protect 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.

"(C) OBTAINING INFORMATION ON FEDERAL ASSISTANCE FOR DRUG DEVELOPMENT.—The Secretary may request that any Federal department or agency provide the Secretary with information on the amount of assistance provided by the department or agency for the research, development, or manufacture of any drug or drug product.

"(D) STANDARD CLAIMS FORM.—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 IX of the Guaranteed Health Insurance Act of 1994.

"(8) 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.—Carriers and pharmacies shall submit information respecting covered outpatient drugs in accordance with the applicable information system established under subtitle B of title IX of the Guaranteed Health Insurance Act of 1994.

"(9) REQUIRING PHARMACY SUPPLIER NUMBERS.—Payment may not be made under this part with respect to a covered outpatient drug dispensed by a pharmacy unless—

"(A) the entity has obtained a supplier number from the Secretary; and

"(B) 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).

"(10) 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 referred to in 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 referred to in 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.".

(5) USE OF OTHER ENTITIES FOR COVERED OUTPATIENT DRUGS.—Section 1842(f) (42 U.S.C. 1395u(f)) is amended—

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

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

(C) by adding at the end the following:

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

(6) DESIGNATED CARRIERS TO PROCESS CLAIMS OF RAILROAD RETIREES.—Section 1842(g) (42 U.S.C. 1395u(g)) is amended by inserting "(other than functions related to covered outpatient drugs)" after "functions".

(d) CONFORMING AMENDMENTS.—

(1)(A) Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) 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) (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) (42 U.S.C. 1395l(b)(2)) is amended by inserting "or with respect to covered outpatient drugs" before the comma.

(3) Section 1834(j)(3)(F) (42 U.S.C. 1395m(j)(4)(F)), as added by section 8421(a)(1) and as redesignated by section 8423(a), is amended—

(A) in clause (i), by adding "and" at the end;

(B) by striking clauses (ii), (iv), and (v) and redesignating clause (iii) as clause (ii); and

(C) in clause (ii) (as so redesignated), by striking the comma at the end and inserting a period.

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

(5) The first sentence of section 1866(a)(2)(A) (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. 3103. MEDICARE REBATES FOR COVERED OUTPATIENT DRUGS.

(a) IN GENERAL.—Part B of title XVIII is amended by adding at the end the following new section:

"REBATES FOR OUTPATIENT DRUGS

"Sec. 1850. (a) REQUIREMENT FOR REBATE AGREEMENT.—In order for payment to be available under this part for drugs of a manufacturer dispensed or provided on or after January 1, 1998, 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), and must meet the requirements of section 1927(a)(1).

"(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.—

"(i) IN GENERAL.—Except as provided in clause (ii), drugs subject to a rebate with respect to a calendar quarter are covered outpatient drugs which are single source and innovator multiple source drugs, and contraceptive drugs described in section 1861(s)(21), which are dispensed or provided during such quarter to individuals (other than individuals enrolled with an eligible organization with a contract under section 1876) eligible for benefits under this part, as reported to the Secretary.

"(ii) EXCEPTION FOR CERTAIN BIOLOGICAL PRODUCTS.—A covered outpatient drug consisting of a biological product is not subject to a rebate under this section if payment was made for the product under part B prior to the date of the enactment of this section.

"(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 described in paragraph (1)(B), of units of each dosage form, strength, and package size dispensed or provided 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 nonretail price for each dosage form and strength of each covered outpatient drug described in paragraph (1)(B) for the quarter.

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

"(C) VERIFICATION OF AVERAGE MANUFACTURER PRICE.—The Secretary may inspect the records of manufacturers, and survey wholesalers, pharmacies, and institutional purchasers of drugs, as necessary to verify prices reported under subparagraph (A).

"(D) PENALTIES.—

"(i) CIVIL MONEY PENALTIES.—The Secretary may impose a civil money penalty on a manufacturer with an agreement under this section—

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

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

"(III) for provision, pursuant to subparagraph (A) or (B), of information that the manufacturer

knows or should know is false, in an amount up to $100,000 per item of information.

Such civil money penalties are in addition to any other penalties prescribed by law. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional 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 renewed for a period of not less than one year unless terminated under subparagraph (B).

"(B) TERMINATION.—

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

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

"(iii) EFFECTIVE DATE OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

"(iv) NOTICE TO PHARMACIES.—In the case of a termination under this subparagraph, the Secretary shall notify pharmacies and physician organizations not less than 30 days before the effective date of such termination.

"(c) AMOUNT OF REBATE.—

"(1) BASE 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 outpatient 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)(i) in the case of a single-source drug or an innovator-multiple source drug (other than insulin furnished over-the-counter), 15 percent of the average manufacturer retail price, or

"(ii) in the case of insulin furnished over-the-counter, 10 percent of the average manufacturer retail price.

"(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 single-source drug or an innovator-multiple source 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 such 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) 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 (or a carrier), except—

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

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

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

"(e) AGREEMENT TO GIVE EQUAL ACCESS TO DISCOUNTS.—An agreement under this subsection by a manufacturer of covered outpatient drugs shall guarantee that the manufacturer will offer, to each wholesaler or retailer (or other purchaser representing a group of such wholesalers or retailers) that purchases such drugs on substantially the same terms (including such terms as prompt payment, cash payment, volume purchase, single-site delivery, the use of formularies by purchasers, and any other terms effectively reducing the manufacturer's costs) as any other purchaser (including any institutional purchaser) the same price for such drugs as is offered to such other purchaser. In determining a manufacturer's compliance with the previous sentence, there shall not be taken into account prices that are merely nominal in amount or prices excluded under section 1927(c)(1)(C)(i).

"(f) DEFINITIONS.—For purposes of this section—

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

"(2) AVERAGE MANUFACTURER NON-RETAIL PRICE.—The term 'average manufacturer non-retail price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the weighted average price (inclusive of discounts for cash payment, prompt payment, volume purchases, and rebates (other than rebates under this section), but exclusive of nominal prices) paid to the manufacturer for the drug in the United States by hospitals and other institutional purchasers that purchase drugs for institutional use and not for resale.

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

"(4) DRUG.—The terms 'innovator multiple source drug', 'noninnovator 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.

"(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) EXCLUSIONS FROM COVERAGE.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

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

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

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

"(17) consisting of a covered outpatient drug (as described in section 1861(t)) 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.".

SEC. 3104. PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION.

Part B of title XVIII is amended by adding at the end the following new section:

"PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION

"SEC. 1847. (a) APPOINTMENT; MEMBERSHIP.—(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, 1996, for a term of 3 years, except that the Director may provide initially for such shorter terms as will insure 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 prescription drug reimbursement, as well as at least one individual who is a medicare beneficiary and one individual representing a research-based pharmaceutical and biotechnology company. To the greatest extent feasible, the membership of the Commission shall reflect the racial, ethnic, and gender composition of the population of the United States.

"(b) REPORTS.—(1) The Commission shall submit to Congress an annual report no later than May 1 of each year, beginning with 1997, concerning methods of determining payment for covered outpatient drugs under this part, including recommendations on the prescription drug allocation of national private and medicare health care expenditure estimates for a year and the annual target rate of increase for such allocation under title VI of the Guaranteed Health Insurance Act of 1994.

"(2) The report described in paragraph (1), in 1998 and thereafter, shall include, with respect to the previous year, information on—

"(A) the relation between the costs of covered outpatient drugs and the costs of other items and services provided for the treatment of similar illnesses and conditions,

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

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

"(3) The first report submitted by the Commission under paragraph (1) shall include an analysis of—

"(A) the feasibility and desirability of excluding manufacturers from the requirement to provide a rebate under section 1850 on the basis of the manufacturers' discounts, rate of increase in prices charged, profits, and other appropriate criteria;

"(B) the appropriateness of the payment methodology provided under this part for the professional services of pharmacists, including the reasonableness of the charges for varying levels of services (including patient consultation); and

"(C) the appropriateness of providing for public disclosure of the information submitted to the Secretary under section 1850 by manufacturers of covered outpatient drugs on the prices charged and other similar information, and the effect of such disclosure on the competitiveness of such prices.

"(c) CONSUMER GUIDE.—The Commission shall publish a consumer guide to prescription drugs to assist individuals in reducing expenditures for covered outpatient drugs and to assist providers in determining the cost-effectiveness of such drugs.

"(d) ADMINISTRATION.—Section 1845(c)(1) shall apply to the Commission in the same manner as it applies to the Physician Payment Review Commission.

"(e) AUTHORIZATION OF APPROPRIATIONS.—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 and the Medicare Part C Trust Fund under section 2124, in an allocation that reasonably reflects the proportion of expenditures for outpatient prescription drugs under this part and under title XXI.".

SEC. 3105. COVERAGE OF HOME INFUSION DRUG THERAPY SERVICES.

(a) IN GENERAL.—Section 1832(a)(2)(A) (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 (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 setting described in section 1861(t)(5)(A)(ii),

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

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

"(2) The items and services described in this paragraph are such nursing, pharmacy, and related services (including medical supplies, intravenous fluids, delivery, and equipment) as are necessary to conduct safely and effectively a drug regimen through use of a covered home infusion drug (as defined in subsection (t)(5)), but do not include such covered home infusion drugs.

"(3) The term 'qualified home infusion drug therapy provider' means any entity that the Secretary determines meets the follow-

ing requirements (or, in the case of a home health agency or an entity with respect to which the only items and services described in paragraph (2) furnished by the entity are enteral nutrition therapy services, meets any of the following requirements which the Secretary considers appropriate):

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

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

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

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

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

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

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

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

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

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

(c) PAYMENT.—

(1) IN GENERAL.—Section 1833 (42 U.S.C. 1395l) is amended—

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

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

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

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

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

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

(2) AMOUNT DESCRIBED.—Section 1834 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.—

"(A) IN GENERAL.—The Secretary shall establish by regulation before the beginning of 1998 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.

"(B) ADJUSTMENT FOR SERVICES FURNISHED BY INSTITUTIONS.—The fee schedule established by the Secretary under subparagraph (A) shall provide for adjustments in the case of home infusion drug therapy services for which payment is made under this part that are furnished by a provider of services to avoid duplicative payments under this title for the service costs associated with such services.".

(d) CERTIFICATION.—Section 1835(a)(2) (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) (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 (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) (42 U.S.C. 1395aa(a)) is amended—

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

(B) in the second sentence—

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

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

(4) APPLICATION OF INTERMEDIATE SANCTIONS.—Section 1846 (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 (42 U.S.C. 1395h) is amended by adding at the end the following new subsection:

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

(g) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(B) (42 U.S.C. 1395m(h)(4)(B)) is amended by striking ", except that" and all that follows through "equipment".

(2) Section 1861(n) (42 U.S.C. 1395x(n)) is amended by adding at the end the following: "Such term does not include any home infusion drug therapy services described in section 1861(ll) or any covered outpatient drug used as a supply related to the furnishing of an item of durable medical equipment.".

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

(h) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 1998.

PART 2—CHANGES IN MEDICARE BENEFITS TO CONFORM TO GUARANTEED NATIONAL BENEFIT PACKAGE

SEC. 3111. IMPOSITION OF CAP ON OUT-OF-POCKET EXPENDITURES.

(a) IN GENERAL.—Title XVIII is amended by adding at the end the following new section:

"LIMIT ON COST-SHARING INCURRED DURING YEAR

"SEC. 1894. (a) IN GENERAL.—Notwithstanding any other provision of this title, the total amount of cost-sharing incurred by an individual in a year (beginning with 2004) with respect to items and services provided to the individual under this title shall be subject to a limit equal to—

"(1) with respect to items and services furnished in 2004, an amount equal to $5,500, increased by the average annual percentage increase in the per capita gross domestic product (in current dollars, as published by the Secretary of Commerce) during each of the years 1994 through 1998 and by the national medicare growth factors established for each of the years 1999 through 2004 under section 8201(c) of the Guaranteed Health Insurance Act of 1994; and

"(2) with respect to items and services furnished in any succeeding year, the amount determined under this paragraph for the previous year, increased by the national medicare growth factor established for the year under section 8201(c) of the Guaranteed Health Insurance Act of 1994.

"(b) NOTICE FOR BENEFICIARIES REACHING LIMIT.—The Secretary shall provide each individual, who is determined to have incurred (or has had paid on the individual's behalf) cost-sharing in a calendar year in the amount described in subsection (a) with a notice that states that the individual has reached the limit on out-of-pocket cost-sharing for the year.

"(c) COST-SHARING DEFINED.—In subsection (a), the term 'cost-sharing' means expenses incurred by an individual that are attributable to—

"(1) the deductibles and coinsurance described in section 1813;

"(2) the deductibles established under section 1833(b); and

"(3) the difference between the payment amount provided under part B and the payment amount that would be provided if '100 percent' and '0 percent' were substituted for '80 percent' and '20 percent', respectively, each place either appears in sections 1833(a), 1833(i)(2), 1833(i)(3), 1833(n)(1)(B)(i)(II), 1834(a)(1)(A), 1834(c)(1)(C), 1834(h)(1)(A), 1834(i)(1), 1835(b)(2), 1866(a)(2)(A), 1881(b)(2), and 1881(b)(3).".

(b) LIMIT ON CHARGES WHEN CAP REACHED.—Section 1866(a)(2)(A) (42 U.S.C. 1395cc(a)(2)(A)) is amended by adding at the end the following new sentence: "A provider of services may not impose a charge under the first sentence of this subparagraph for services furnished to an individual during a year after the amount of cost-sharing incurred by the individual during the year reaches the limit on such cost-sharing established under section 1894.".

SEC. 3112. REPEAL OF LIMIT ON LIFETIME RESERVE DAYS OF INPATIENT HOSPITAL SERVICES.

(a) IN GENERAL.—Section 1812(a)(1) (42 U.S.C. 1395d(a)(1)) is amended by striking "for up to" and all that follows through "payment made)".

(b) CONFORMING AMENDMENTS.—Section 1812 (42 U.S.C. 1395d) is further amended—

(1) in subsection (b), by striking paragraph (1);

(2) by striking subsection (c); and

(3) in subsection (e), by striking "subsections (b) and (c)" and all that follows through "extended care services" and inserting "subsection (b), services".

(c) ADMINISTRATION; TRANSITION.—The Secretary of Health and Human Services may take such actions as the Secretary finds appropriate to adjust the payments made to hospitals under title XVIII of the Social Security Act for hospital services to take into account the amendments made by this section.

SEC. 3113. COVERAGE OF SERVICES FOR INFANTS AND CHILDREN.

(a) SERVICES DESCRIBED.—Section 1861(s) (42 U.S.C. 1395x(s)(2)) is amended—

(1) by striking "and" at the end of paragraph (12);

(2) by striking the period at the end of paragraph (14) and inserting "; and"; and

(3) by inserting after paragraph (14) the following new paragraphs:

"(15) newborn and well-baby services (as defined in subsection (oo)(1));".

"(16) well-child services (as defined in subsection (pp)(1)) provided to an individual who is under 19 years of age; and

"(17) medically necessary and appropriate hearing aids provided to an individual who is under 19 years of age (in accordance with such periodicity schedule as the Secretary may establish in consultation with the Academy of Otolaryngology-Head and Neck Surgery and the American Speech-Language Hearing Association).".

(b) SERVICES DEFINED.—

(1) IN GENERAL.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Newborn and Well-Baby Services

"(oo)(1) The term 'newborn and well-baby services' means well-baby care, including routine office visits, routine immunizations (including the vaccine itself), routine laboratory tests (including lead screening), and includes the services of pediatricians during high-risk delivery (as determined in accordance with criteria established by the Secretary).

"(2) The Secretary, in consultation with the American Academy of Pediatrics and other entities considered appropriate by the Secretary, shall establish a schedule of periodicity which reflects the appropriate frequency with which the services referred to in paragraph (1) should be provided."

"Well-Child Services

"(pp)(1) The term 'well-child services' means well-child care, including routine office visits, routine immunizations (including the vaccine itself), routine laboratory tests (including lead screening in accordance with recommendations of the Centers for Disease Control and Prevention), child abuse assessment, and dental care (including preventive dental services described in paragraph (2), routine fillings, and oral surgery), provided in accordance with the periodicity schedule established with respect to the services under paragraph (3).

"(2) In paragraph (1), the term 'preventive dental services' means oral dental examinations, radiographs, dental sealants, fluoride application, and dental prophylaxis.

"(3) The Secretary, in consultation with the American Academy of Pediatrics, the Academy of Pediatric Dentistry, and other entities considered appropriate by the Secretary, shall establish a schedule of periodicity which reflects the appropriate frequency with which the services referred to in paragraph (1) should be provided to healthy children.".

(2) CONFORMING AMENDMENTS.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (E), by striking "and" at the end,

(ii) in subparagraph (F), by striking the semicolon at the end and inserting a comma, and

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

"(G) in the case of newborn and well-baby services, which are performed more frequently than is provided under the schedule of periodicity established by the Secretary under section 1861(oo)(2) for such services, and

"(H) in the case of well-child services, which are provided more frequently than is provided under the schedule of periodicity established by the Secretary under section 1861(pp)(2) for such services;"; and

(B) in paragraph (7), by striking "section 1861(s)(10) and paragraph (1)(B) or under paragraph (1)(F)" and inserting "section 1861(s)(10), section 1861(s)(17), and subparagraphs (B), (F), (G), or (H) of paragraph (1)".

(3) PAYMENT; WAIVER OF COST-SHARING.—

(A) AMOUNT OF PAYMENT; WAIVER OF COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)), as amended by section 3102(d)(1)(A), is amended—

(i) by striking "and (Q)" and inserting "(Q)"; and

(ii) by striking the semicolon at the end and inserting the following: ", (R) with respect to newborn and well-baby services (as described in section 1861(oo)(1)), the amounts paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, and (S) with respect to well-child services (as described in section 1861(pp)(1)), the amounts paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph;"

(B) WAIVER OF DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(i) by striking "and (5)" and inserting "(5)"; and

(ii) by striking the period at the end and inserting the following: ", (6) such deductible shall not apply with respect to newborn and well-baby services (as described in section 1861(oo)(1)), and (7) such deductible shall not apply with respect to well-child services (as described in section 1861(pp)(1))."

(4) COVERAGE OF SERVICES UNDER MAINTENANCE OR PREVENTION PROGRAM FOR CERTAIN CHILDREN AS REHABILITATION SERVICES.—Section 1861(p) (42 U.S.C. 1395x(p)) is amended by adding at the end the following: "In the case of a child under 19 years of age with a congenital condition, the term 'outpatient physical therapy services' shall include the following rehabilitation services that are used to prevent deterioration of, or restore or maintain, functional capacity:

"(A) The initial evaluation and periodic oversight of the patient's needs by a qualified rehabilitation health professional.

"(B) the designing by such professional of a maintenance or prevention program that is appropriate to the capacity and tolerance of the patient and the treatment objectives;

"(C) the instruction of the patient, family members, and any personnel providing rehabilitation-related assistance to the individual, in carrying out such program; and

"(D) reevaluations of such program.".

(c) GENERAL CONFORMING AMENDMENTS.—The Social Security Act is amended—

(1) in section 1861(s)(2)(C) (42 U.S.C. 1395x(s)(2)(C)), by striking "(C)" and inserting "(C) subject to section 1890(b),";

(2) in section 1861(s)(3) (42 U.S.C. 1395x(s)(3)), by striking "(3)" and inserting "(3) subject to section 1890(a)";

(3) by striking the second and third sentences of section 1861(s); and

(4) by inserting after section 1889 the following new section:

"SPECIAL RULES FOR LABORATORY AND DIAGNOSTIC TESTS AND SERVICES

"SEC. 1890. (a) REQUIRING DIAGNOSTIC LABORATORY AND SCREENING TESTS TO BE FURNISHED IN CERTIFIED SETTINGS.—No payment may be made under this title for any diagnostic and screening test performed in any laboratory (including a laboratory that is part of a rural health clinic or any institution considered a hospital for purposes of section 1814(d)), including a routine laboratory test for purposes of section 1861(oo)(1) or section 1861(pp)(1), unless such laboratory meets the following requirements:

"(1) If the laboratory is situated in any State in which State or applicable local law provides for licensing of establishments of this nature, the laboratory—

"(A) is licensed pursuant to such law, or

"(B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing.

"(2) The laboratory meets—

"(A) the certification requirements under section 353 of the Public Health Service Act; and

"(B) such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

"(b) EXCLUSION OF DIAGNOSTIC SERVICES NOT MEETING REQUIREMENTS FOR INPATIENT HOSPITAL SERVICES.—

"(1) IN GENERAL.—No item or service may be included as a diagnostic service specified in section 1861(s)(2)(C) if the item or service would not be included as an inpatient hospital service under section 1861(b) if furnished to an inpatient of a hospital.

"(2) EXCEPTION FOR PHYSICIANS' SERVICES.—Paragraph (1) shall not apply with respect to any service consisting of a physicians' service."; and

(5) by striking "paragraphs (15) and (16) of section 1861(s)" each place it appears in section 1864(a) and the third sentence of section 1865(a) and inserting "subsections (a) and (b) of section 1890".

SEC. 3114. EXPANDING COVERAGE OF PREVENTIVE BENEFITS.

(a) SCREENING MAMMOGRAPHY.—

(1) PROVIDING ANNUAL SCREENING MAMMOGRAPHY FOR WOMEN OVER AGE 49.—SECTION 1834(C)(2)(A) (42 U.S.C. 1395M(C)(2)(A)) IS AMENDED—

(A) in clause (iv), by striking "but under 65 years of age,"; and

(B) by striking clause (v).

(2) WAIVER OF DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)), as amended by section 3113(b)(3), is amended—

(A) by striking "and (7)" and inserting "(7)"; and

(B) by striking the period at the end and inserting the following: ", and (8) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj))."

(3) CONFORMING AMENDMENT.—Section 1834(c)(1)(C) (42 U.S.C. 1395m(c)(1)(C)) is amended by striking ", subject to the deductible established under section 1833(b),".

(b) COVERAGE OF SCREENING PAP SMEAR AND PELVIC EXAMS.—

(1) COVERAGE OF PELVIC EXAM; INCREASING FREQUENCY OF COVERAGE OF PAP SMEAR.—Section 1861(nn) (42 U.S.C. 1395x(nn)) is amended—

(A) in the heading, by striking "Smear" and inserting "Smear; Screening Pelvic Exam";

(B) by striking "(nn)" and inserting "(nn)(1)";

(C) by striking "3 years" and all that follows and inserting "3 years, or during the preceding year in the case of a woman described in paragraph (3)."; and

(D) by adding at the end the following new paragraphs:

"(2) The term 'screening pelvic exam' means an pelvic examination provided to a woman if the woman involved has not had such an examination during the preceding 3 years, or during the preceding year in the case of a woman described in paragraph (3), and includes a clinical breast examination.

"(3) A woman described in this paragraph is a woman who—

"(A) is of childbearing age and has not had a test described in this subsection during each of the preceding 3 years that did not indicate the presence of cervical cancer; or

"(B) is at high risk of developing cervical cancer (as determined pursuant to factors identified by the Secretary).".

(2) WAIVER OF DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)), as amended by section 3113(b)(3) and subsection (a)(2), is amended—

(A) by striking "and (8)" and inserting "(8)"; and

(B) by striking the period at the end and inserting the following: ", and (9) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn))."

(3) CONFORMING AMENDMENTS.—(A) Section 1861(s)(14) (42 U.S.C. 1395x(s)(14)) is amended by inserting "and screening pelvic exam" after "screening pap smear".

(B) Section 1862(a)(1)(F) (42 U.S.C. 1395y(a)(1)(F)) is amended by inserting "and screening pelvic exam" after "screening pap smear".

(c) COVERAGE OF COLORECTAL SCREENING.—

(1) IN GENERAL.—Section 1834 (42 U.S.C. 1395m), as amended by section 3102(a), is amended by inserting after subsection (d) the following new subsection:

"(e) FREQUENCY AND PAYMENT LIMITS FOR SCREENING FECAL-OCCULT BLOOD TESTS, SCREENING FLEXIBLE SIGMOIDOSCOPIES, AND SCREENING COLONOSCOPY.—

"(1) SCREENING FECAL-OCCULT BLOOD TESTS.—

"(A) LIMITING COVERAGE FOR NON-ELDERLY TO HIGH-RISK INDIVIDUALS.—No payment may be made under this part for a screening fecal-occult blood test provided for the purpose of early detection of colon cancer to an individual who is under 65 years of age unless the individual is at high risk for colorectal cancer (as determined in accordance with criteria established by the Secretary).

"(B) FREQUENCY LIMITS.—Subject to revision by the Secretary under paragraph (4), no payment may be made under this part for a screening fecal-occult blood test provided to an individual for the purpose of early detection of colon cancer if the test is performed—

"(i) in the case of an individual under 65 years of age, more frequently than is provided in a periodicity schedule established by the Secretary for purposes of this subparagraph; or

"(ii) in the case of any other individual, within the 11 months following the month in which a previous screening fecal-occult blood test was performed.

"(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

"(A) PAYMENT AMOUNT.—The Secretary shall establish a payment amount under section 1848 with respect to screening flexible sigmoidoscopies provided for the purpose of early detection of colon cancer that is consistent with payment amounts under such section for similar or related services, except that such payment amount shall be established without regard to subsection (a)(2)(A) of such section.

"(B) LIMITING COVERAGE FOR NON-ELDERLY TO HIGH-RISK INDIVIDUALS.—No payment may be made under this part for a screening flexible sigmoidoscopy provided for the purpose of early detection of colon cancer to an individual who is under 65 years of age unless the individual is at high risk for colorectal cancer (as determined in accordance with criteria established by the Secretary).

"(C) FREQUENCY LIMITS.—Subject to revision by the Secretary under paragraph (4), no payment may be made under this part for a screening flexible sigmoidoscopy provided to an individual for the purpose of early detection of colon cancer if the procedure is performed—

"(i) in the case of an individual under 65 years of age, more frequently than is provided in a periodicity schedule established by the Secretary for purposes of this subparagraph; or

"(ii) in the case of any other individual, within the 59 months following the month in which a previous screening flexible sigmoidoscopy was performed.

"(3) SCREENING COLONOSCOPY FOR INDIVIDUALS AT HIGH RISK FOR COLORECTAL CANCER.—

"(A) PAYMENT AMOUNT.—The Secretary shall establish a payment amount under section 1848 with respect to screening colonoscopy for individuals at high risk for colorectal cancer (as determined in accordance with criteria established by the Secretary) provided for the purpose of early detection of colon cancer that is consistent with payment amounts under such section for similar or related services, except that such payment amount shall be established without regard to subsection (a)(2)(A) of such section.

"(B) FREQUENCY LIMIT.—Subject to revision by the Secretary under paragraph (4), no payment may be made under this part for a screening colonoscopy for individuals at high risk for colorectal cancer provided to an individual for the purpose of early detection of colon cancer if the procedure is performed within the 47 months following the month in which a previous screening colonoscopy was performed.

"(C) FACTORS CONSIDERED IN ESTABLISHING CRITERIA FOR DETERMINING INDIVIDUALS AT HIGH RISK.—In establishing criteria for determining whether an individual is at high risk for colorectal cancer for purposes of this paragraph, the Secretary shall take into consideration family history, prior experience of cancer, a history of chronic digestive disease condition, and the presence of any appropriate recognized gene markers for colorectal cancer.

"(4) REVISION OF FREQUENCY.—

"(A) REVIEW.—The Secretary shall review periodically the appropriate frequency for performing screening fecal-

occult blood tests, screening flexible sigmoidoscopies, and screening colonoscopy based on age and such other factors as the Secretary believes to be pertinent.

"(B) REVISION OF FREQUENCY.—The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which such tests and procedures may be paid for under this subsection, but no such revision shall apply to tests or procedures performed before January 1, 2002.

"(5) LIMITING CHARGES OF NONPARTICIPATING PHYSICIANS.—

"(A) IN GENERAL.—In the case of a screening flexible sigmoidoscopy provided to an individual for the purpose of early detection of colon cancer or a screening colonoscopy provided to an individual at high risk for colorectal cancer for the purpose of early detection of colon cancer for which payment may be made under this part, if a nonparticipating physician provides the procedure to an individual enrolled under this part, the physician may not charge the individual more than the limiting charge (as defined in section 1848(g)(2)).

"(B) ENFORCEMENT.—If a physician or supplier knowing and willfully imposes a charge in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2).".

(2) CONFORMING AMENDMENTS.—(A) Paragraphs (1)(D) and (2)(D) of section 1833(a) (42 U.S.C. 1395l(a)) are each amended by striking "subsection (h)(1)," and inserting "subsection (h)(1) or section 1834(e)(1),".

(B) Clauses (i) and (ii) of section 1848(a)(2)(A) (42 U.S.C. 1395w–4(a)(2)(A)) are each amended by striking "a service" and inserting "a service (other than a screening flexible sigmoidoscopy provided to an individual for the purpose of early detection of colon cancer or a screening colonoscopy provided to an individual at high risk for colorectal cancer for the purpose of early detection of colon cancer)".

(C) Section 1861(s) (42 U.S.C. 1395x(s)) as amended by section 3113(a), is amended—

(i) by striking "and" at the end of paragraph (16);

(ii) by striking the period at the end of paragraph (17) and inserting "; and"; and

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

"(18) screening fecal-occult blood tests, screening flexible sigmoidoscopies, and screening colonoscopy provided for the purpose of early detection of colon cancer."

(D) Section 1862(a) (42 U.S.C. 1395y(a)), as amended by section 3113(b)(2), is amended—

(i) in paragraph (1)—

(I) in subparagraph (G), by striking "and" at the end;

(II) in subparagraph (H), by striking the semicolon at the end and inserting ", and"; and

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

"(I) in the case of screening fecal-occult blood tests, screening flexible sigmoidoscopies, and screening colonoscopy provided for the purpose of early detection of colon cancer, which are performed more frequently than is covered under section 1834(e);"; and

(ii) in paragraph (7), by striking "or (H)" and inserting "(H), or (I)".

(d) COVERAGE OF SCREENING FOR SEXUALLY-TRANSMITTED DISEASES.—

(1) IN GENERAL.—Section 1861(s) (42 U.S.C. 1395x(s)(2)), as amended by section 3113(a) and subsection (c)(2)(C), is amended—

(A) by striking "and" at the end of paragraph (17);

(B) by striking the period at the end of paragraph (18) and inserting "; and"; and

(C) by inserting after paragraph (18) the following new paragraph:

"(19) screening for sexually-transmitted diseases for an individual over 12 years of age and under 50 years of age who is at risk for sexually-transmitted disease (as determined pursuant to factors identified by the Secretary) and who has not had such a screening during the preceding 1-year period.".

(2) AMOUNT OF PAYMENT; WAIVER OF COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)), as amended by section 3102(f), section 3113(b)(3), and subsection (b)(2), 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 screening for sexually-transmitted diseases (as described in section 1861(s)(19)), the amounts paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph;".

(3) WAIVER OF DEDUCTIBLE.—The first sentence of section 1833(b), (42 U.S.C. 1395l(b)) as amended by section 3113(b)(3), subsection (a)(2), and subsection (b)(2), is amended—

(A) by striking "and (9)" and inserting "(9)"; and

(B) by striking the period at the end and inserting the following: ", and (10) such deductible shall not apply with respect to screening for sexually-transmitted diseases (as described in section 1861(s)(19))."

(4) CONFORMING AMENDMENT.—Section 1862(a) (42 U.S.C. 1395y(a)), as amended by section 3113(b)(2) and subsection (c)(2)(C), is amended—

(A) in paragraph (1)—

(i) in subparagraph (H), by striking "and" at the end;

(ii) in subparagraph (I), by striking the semicolon at the end and inserting ", and"; and

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

"(J) in the case of screening for sexually-transmitted diseases, which is performed more frequently than is covered under section 1861(s)(19);"; and

(B) in paragraph (7), by striking "or (I)" and inserting "(I), or (J)".

(e) COVERAGE OF SCREENING FOR TUBERCULOSIS.—

(1) IN GENERAL.—Section 1861(s) (42 U.S.C. 1395x(s)(2)), as amended by section 3113(a), subsection (c)(2)(C), and subsection (d)(1), is amended—

(A) by striking "and" at the end of paragraph (18);

(B) by striking the period at the end of paragraph (19) and inserting "; and", and

(C) by inserting after paragraph (19) the following new paragraph:

"(20) screening for tuberculosis for an individual who is at risk for tuberculosis (as determined pursuant to factors identified by the Secretary) and who has not had such a screening during the preceding 1-year period."

(2) AMOUNT OF PAYMENT; WAIVER OF COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)), as amended by sections 3102(f), 3113(b)(3), and subsection (d)(2), is amended—

(A) by striking "and (T)" and inserting "(T)"; and

(B) by striking the semicolon at the end and inserting the following: ", and (U) with respect to screening for tu-

berculosis (as described in section 1861(s)(20)), the amounts paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph:".

(3) WAIVER OF DEDUCTIBLE.—The first sentence of section 1833(b), (42 U.S.C. 1395l(b)) as amended by section 3113(b)(3), subsection (a)(2), subsection (b)(3), and subsection (d)(3), is amended—

(A) by striking "and (10)" and inserting "(10)"; and

(B) by striking the period at the end and inserting the following: ", and (11) such deductible shall not apply with respect to screening for tuberculosis (as described in section 1861(s)(20))."

(4) CONFORMING AMENDMENT.—Section 1862(a) (42 U.S.C. 1395y(a)), as amended by section 3113(b)(2), subsection (c)(2)(C), and subsection (a)(4), is amended—

(A) in paragraph (1)—

(i) in subparagraph (I), by striking "and" at the end;

(ii) in subparagraph (J), by striking the semicolon at the end and inserting ", and"; and

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

"(K) in the case of screening for tuberculosis, which is performed more frequently than is covered under section 1861(s)(20);"; and

(B) in paragraph (7), by striking "or (J)" and inserting "(J), or (K)".

SEC. 3115. COVERAGE OF PREGNANCY-RELATED SERVICES AND FAMILY PLANNING.

(a) IN GENERAL.—Section 1861(s) (42 U.S.C. 1395x(s)(2)), as amended by sections 3113(a), 3114(c)(2)(C), 3114(d)(1), and 3114(e)(1) is amended—

(1) by striking "and" at the end of paragraph (19);

(2) by striking the period at the end of paragraph (20) and inserting "; and"; and

(3) by inserting after paragraph (20) the following new paragraphs:

"(21) pregnancy-related services furnished by an individual or entity legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law); and

"(22) voluntary family planning services, including contraceptive drugs and devices that—

"(A) may only be dispensed upon prescription, and

"(B) are subject to approval by the Secretary under the Federal Food, Drug, and Cosmetic Act.".

(b) WAIVER OF COINSURANCE AND DEDUCTIBLE FOR CERTAIN SERVICES.—

(1) WAIVER OF COINSURANCE FOR PRENATAL SERVICES.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)), as amended by sections 3102(f), 3113(b)(3), section 3114(d)(2), and section 3114(e)(2), is amended—

(A) by striking "and (U)" and inserting "(U)"; and

(B) by striking the semicolon at the end and inserting the following: ", and (V) with respect to pregnancy-related services (as described in section 1861(s)(20)), the amounts paid shall be 80 percent (or, in the case of services consisting of prenatal services, 100 percent) of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph;".

(2) WAIVER OF DEDUCTIBLE FOR PRENATAL AND FAMILY PLANNING SERVICES.—The first sentence of section 1833(b), (42

U.S.C. 1395l(b)) as amended by sections 3113(b)(3), 3114(a)(2), 3114(b)(3), and 3114(d)(3), is amended—

(A) by striking "and (11)" and inserting "(11)"; and

(B) by striking the period at the end and inserting the following: ", and (12) such deductible shall not apply with respect to pregnancy-related services consisting of prenatal services (described in section 1861(s)(21)) or to voluntary family planning services (described in section 1861(s)(22)).".

(c) CONFORMING AMENDMENT.—Section 1862(a) (42 U.S.C. 1395y(a)), as amended by section 3113(b)(2), section 3114(c)(2)(C), section 3114(d)(4), and section 3114(e)(2), is amended—

(A) in paragraph (1)—

(i) in subparagraph (J), by striking "and" at the end;

(ii) in subparagraph (K), by striking the semicolon at the end and inserting ", and"; and

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

"(L) in the case of pregnancy-related services, which do not meet the requirements of section 1861(s)(21);

"(M) in the case of voluntary family planning services, which do not meet the requirements of section 1861(s)(22);"; and

(B) in paragraph (7), by striking "or (K)" and inserting "(K), (L), or (M)".

SEC. 3116. EXPANDING COVERAGE OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES.

(a) INPATIENT PSYCHIATRIC HOSPITAL SERVICES.—

(1) SERVICES COVERED.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(A) by striking "and" at the end of paragraph (3);

(B) by striking the period at the end of paragraph (4) and inserting "; and"; and

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

"(5) inpatient hospital services furnished primarily for the diagnosis or treatment of mental illness or substance abuse for up to 60 days during a year."

(2) LIMITATION ON COVERAGE.—Section 1812(b)(3) (42 U.S.C. 1395d(b)) is amended to read as follows:

"(3) inpatient hospital services furnished primarily for the diagnosis or treatment of mental illness or substance abuse that are furnished to the individual during a year after such services have been furnished to the individual for a total of 60 days during the year.".

(3) CONFORMING AMENDMENTS.—(A) Section 1812(a)(1) (42 U.S.C. 1395d(a)(1)) is amended by inserting "(other than services described in paragraph (5))" after "inpatient hospital services" the first place it appears.

(B) Section 1812(b)(1) (42 U.S.C. 1395d(b)(1)) is amended by inserting "(other than services described in paragraph (3))" after "inpatient hospital services" the first place it appears.

(C) Section 1812 (42 U.S.C. 1395d) is amended by striking subsection (c).

(D) Section 1814(a) (42 U.S.C. 1395f(a)) is amended—

(i) in paragraph (2), by striking subparagraph (A);

(ii) in paragraph (3), by striking "(other than inpatient psychiatric hospital services)"; and

(iii) by striking paragraph (4).

(E) Section 1861 (42 U.S.C. 1395x) is amended by striking subsection (c).

(4) EFFECTIVE DATE; TRANSITION.—The amendments made by this section shall take effect January 1, 1998, except that—

(A) an individual who at any time prior to such date has been furnished inpatient psychiatric hospital services (as defined for purposes of title XVIII of the Social Security Act as of the date of the enactment of this Act) for 190

consecutive days is not entitled to any services under section 1812(a)(5) (as added by paragraph (1)(C)); and

(B) in the case of an individual who is not described in subparagraph (A) and is receiving inpatient psychiatric hospital services (as defined for purposes of title XVIII of the Social Security Act as of the date of the enactment of this Act) on December 31, 1997, for which payment may be made under section 1812 of such Act, the number of days of services for which the individual is entitled under section 1812(a)(5) (and the number of days applicable under section 1812(b)(3)) shall be equal to the greater of 60 or the difference between 190 days and the number of days of such inpatient psychiatric hospital services furnished to the individual prior to January 1, 1998.

(b) INTENSIVE RESIDENTIAL SERVICES.—

(1) COVERAGE UNDER PART A.—Section 1812(a) (42 U.S.C. 1395d(a)), as amended by subsection (a)(1), is amended—

(A) by striking "and" at the end of paragraph (4);

(B) by striking the period at the end of paragraph (5) and inserting "; and"; and

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

"(6) intensive residential services (as described in section 1861(qq)) furnished to an individual for up to 120 days during any calendar year, except that such services may be furnished to the individual for additional days during the year if necessary for the individual to complete a course of treatment to the extent that the number of days of inpatient hospital services described in paragraph (5) that may be furnished to the individual during the year (as reduced under such paragraph) is not less than 15.".

(2) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by section 3113(b), is further amended by adding at the end the following new subsection:

"Intensive Residential Services

"(qq)(1) Subject to paragraph (2), the term 'intensive residential services' means inpatient services provided in any of the following facilities:

"(A) Residential detoxification centers.

"(B) Crisis residential programs or mental illness residential treatment programs.

"(C) Therapeutic family or group treatment homes.

"(D) Residential centers for substance abuse treatment.

"(2) No service may be treated as an intensive residential service under paragraph (1) unless the facility at which the service is provided—

"(A) is legally authorized to provide such service under the law of the State (or under a State regulatory mechanism provided by State law) in which the facility is located or is certified to provide such service by an appropriate accreditation entity approved by the State in consultation with the Secretary; and

"(B) meets such other requirements as the Secretary may impose to assure the quality of the intensive residential services provided.

"(3) No service may be treated as an intensive residential service under paragraph (1) unless the service is furnished in accordance with standards established by the Secretary for the management of such services.".

(3) REDUCTION IN DAYS OF COVERAGE FOR INPATIENT SERVICES.—Section 1812(a)(5) and section 1812(b)(3), as amended by subsection (a), are each amended by striking the period at the end and inserting the following: ", reduced by a number of days determined by the Secretary so that the actuarial value of providing such number of days of services under this paragraph to the individual is equal to the actuarial value of the

days of inpatient residential services furnished to the individual under paragraph (6) during the year after such services have been furnished to the individual for 120 days during the year (rounded to the nearest day).".

(4) AMOUNT OF PAYMENT.—Section 1814 (42 U.S.C. 1395f) is amended—

(A) in subsection (b) in the matter preceding paragraph (1), by inserting "other than intensive residential services," after "hospice care,"; and

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

"Payment for Intensive Residential Services

"(m) The amount of payment under this part for intensive residential services under section 1812(a)(6) shall be equal to—

"(1) the lesser of—

"(A) the reasonable cost of such services, as determined under section 1861(v), or

"(B) the customary charges with respect to such services,

less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A):

"(2) if such services are furnished by a public provider of services or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, the amount determined in accordance with subsection (b)(2); and

"(3) if (and for so long as) the conditions described in subsection (b)(3) are met, the amounts determined under the reimbursement system described in such section.".

(c) LOWERING COINSURANCE FOR CERTAIN OUTPATIENT MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES.—

(1) IN GENERAL.—Section 1833(c) (42 U.S.C. 1395l(c)) is amended by striking "mental, psychoneurotic, and personality disorders" and all that follows through "are incurred" and inserting the following: "mental illness or substance abuse of an individual who, at the time such expenses are incurred, is over 18 years of age, is not an inpatient of a hospital, and has received 5 or more sessions of such treatment during the calendar year,".

(2) REQUIRING SERVICES TO BE FURNISHED IN ACCORDANCE WITH MANAGEMENT STANDARDS.—Section 1862(a) (42 U.S.C. 1395y(a)), as amended by section 3103(b), is amended—

(A) by striking "and" at the end of paragraph (16);

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

(C) by inserting after paragraph (17) the following:

"(18) in the case of any items or services furnished under part B for the treatment of mental illness or emotional disturbance (including substance abuse), if the services are not furnished in accordance with standards established by the Secretary for the management of such services.".

(d) INTENSIVE COMMUNITY-BASED SERVICES.—

(1) COVERAGE.—

(A) IN GENERAL.—Section 1832(a)(2)(J) (42 U.S.C. 1395k(a)(2)(J)) is amended to read as follows:

"(J) intensive community-based services (as described in section 1861(ff))—

"(i) for an unlimited number of days during any calendar year, in the case of services described in section 1861(ff)(2)(E) that are furnished to an individual who is a seriously mentally ill adult, a seriously emotionally disturbed child, or an adult or child with serious substance abuse disorder (as determined in accordance with criteria established by the Secretary),