I

107TH CONGRESS
2D SESSION

H. R. 5219

To amend part B of title XVIII of the Social Security Act to provide for a chronic disease prescription drug benefit and for coverage of disease management services under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2002

Mr. CARDIN (for himself, Mrs. MORELLA, and Ms. HOOLEY of Oregon) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend part B of title XVIII of the Social Security Act to provide for a chronic disease prescription drug benefit and for coverage of disease management services under the Medicare Program.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Essential Medicines for Medicare Act of 2002''.

SEC. 2. MEDICARE CHRONIC DISEASE PRESCRIPTION DRUG BENEFIT.

(a) COVERAGE.—

(1) IN GENERAL.—Section 1832(a)(2) of the Social Security Act (42 U.S.C. 1395k(a)(2)) is amended—

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

(B) by striking the period at the end of subparagraph (J) and inserting ''; and''; and

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

''(K) subject to subsection (b), prescription drugs for treatment of certain chronic conditions (as defined in section 1861(uu)(1)).''.

(2) PROVISION OF BENEFITS THROUGH EXISTING NON-MEDICAID STATE PRESCRIPTION DRUG BENEFIT PROGRAMS.—Section 1832 of such Act (42 U.S.C. 1395k) is further amended—

(1) by redesignating subsection (b) as subsection (c); and

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

''(b)(1) Prescription drug benefits shall not be available under subsection (a)(2)(K) to an individual to the extent that the individual receives benefits for the prescrip-

tion drugs under a State non-medicaid prescription drug benefit program if the following requirements are met:

''(A) The program is sponsored or financially underwritten by a State, but Federal financial assistance under title XIX is not available for expenditures under the program.

''(B) The program is in operation as of May 1, 2002.

''(C) The State elects to receive payment (described in paragraph (2)) for providing benefits under this subsection.

''(D) The deductible and coinsurance applicable do not exceed the deductible and coinsurance otherwise applicable to the prescription drug benefit described in subsection (a)(2)(K).

''(2) The Secretary shall provide for payment to a State that operates a program that meets the requirements of paragraph (1) of an amount (agreed to by the State) that does not exceed the Secretary's estimate of the amount of payment that would have been made under this part (taking into account the application of a deductible and coinsurance) for prescription drugs for which coverage is provided under such program, if this subsection did not apply.''.

(b) DEFINITION OF BENEFIT.—

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

"Prescription Drugs for Treatment of Certain Chronic Conditions

"(uu)(1) The term 'prescription drugs for treatment of certain chronic conditions' means, subject to paragraph (3), prescription drugs described in paragraph (2) that have been shown to have a demonstrable effect in treating any of the following conditions (in the case of an individual who has been diagnosed by a physician as having that condition):

"(A) Hypertension.

"(B) Diabetes.

"(C) Congestive or ischemic heart disease.

"(D) Major depression.

"(E) Rheumatoid arthritis.

"(2) Prescription drugs described in this paragraph are—

"(A) a prescription drug that meets the requirement of clause (i), (ii), or (iii) of section 1927(k)(2)(A);

"(B) a biological product described in section 1927(k)(2)(B); or

"(C) insulin described in section 1927(k)(2)(C).

''(3) The term 'prescription drugs for treatment of certain chronic conditions' does not include any product—

''(A) which may be distributed to individuals without a prescription;

''(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;

''(C) that was covered under this title on the day before the date of enactment of the Essential Medicines for Medicare Act of 2002; or

''(D) that is a therapeutically equivalent replacement for a product described in subparagraph (B) or (C), as determined by the Secretary.''.

(2) PROCESS FOR IDENTIFICATION OF COVERED DRUGS.—The Secretary of Health and Human Services shall implement a process for the timely identification of prescription drugs for treatment of certain chronic conditions that should be covered under section 1861(uu) of the Social Security Act, as added by paragraph (1). Under such process—

(A) within 60 days after the date of the enactment of this Act, the Agency for Healthcare Research and Quality shall complete an initial review of the available data on the prevalence of conditions described in such sec-

tion in the population of medicare beneficiaries, the adequacy of data demonstrating the effectiveness of different prescription drugs in treating such conditions, and the severity of potential complications in using such drugs;

(B) within 6 months after the date of the enactment of this Act, the Secretary shall specify by rule the initial prescription drugs that shall be covered under such section;

(C) thereafter the Secretary, taking into consideration recommendations made under subsection (e), may by rule change the prescription drugs that are so covered; and

(D) the Secretary may, on an emergency basis, provide for the replacement of a prescription drug on the list if another drug (for the treatment of the same condition) is recalled.

(3) CONSTRUCTION.—Nothing in this section (or the amendments made by this section) shall be construed—

(A) as preventing medicare beneficiaries from purchasing prescription drugs not identified under paragraph (2), including through coverage under a group health plan or medicare supplemental policy; and

(B) the coverage under a medicare supplemental policy of prescription drugs for conditions not specified on the list compiled under paragraph (2) shall not be considered to duplicate benefits under title XVIII of such Act, for purposes of applying section 1882(d)(3) of such Act (42 U.S.C. 1395ss(d)(3)).

(c) SELECTION OF ENTITIES TO PROVIDE DRUG BENEFIT; PAYMENT.—

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

"SEC. 1849. SELECTION OF ENTITIES TO PROVIDE OUTPATIENT DRUG BENEFIT; PAYMENT.

''(a) ESTABLISHMENT OF BIDDING PROCESS.—

''(1) IN GENERAL.—The Secretary shall establish procedures under which the Secretary accepts bids from eligible entities and awards contracts to such entities in order to provide covered outpatient drugs to eligible beneficiaries in an area. Such contracts may be awarded based on shared risk, capitation, or performance.

''(2) AREA.—

''(A) REGIONAL BASIS.—

"(i) IN GENERAL.—Subject to clause (ii), the contract entered into between the Secretary and an eligible entity shall require the eligible entity to provide covered outpatient drugs on a regional basis.

"(ii) PARTIAL REGIONAL BASIS.—

"(I) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit such to be provided in a partial region determined appropriate by the Secretary.

"(II) REQUIREMENTS.—If the Secretary permits coverage pursuant to subclause (I), the Secretary shall ensure that the partial region in which coverage is provided is at least the size of the commercial service area of the eligible entity for that area and is not smaller than a State.

"(B) DETERMINATION.—In determining coverage areas under this section, the Secretary shall—

"(i) take into account the number of eligible beneficiaries in an area in order to

encourage participation by eligible entities; and

"(ii) ensure that there are at least 10 different regions in the United States.

"(C) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of coverage areas under this part shall not be subject to administrative or judicial review.

"(3) SUBMISSION OF BIDS.—

"(A) SUBMISSION.—

"(i) IN GENERAL.—Subject to clause (ii), each eligible entity desiring to offer a plan under this part in an area shall submit a bid with respect to such plan to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

"(ii) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an eligible entity to submit a single bid for multiple areas if the bid is applicable to all such areas.

"(B) REQUIRED INFORMATION.—The bids described in subparagraph (A) shall include—

"(i) a proposal for the estimated prices of covered outpatient drugs and the projected annual increases in such prices, including differentials between formulary and nonformulary prices, if applicable;

"(ii) a statement regarding the amount that the entity will charge the Secretary for administering and delivering the benefits under the contract;

"(iii) a detailed description of access to pharmacy services provided under the plan; and

"(iv) such other information that the Secretary determines is necessary in order to carry out this part, including information relating to the bidding process under this part.

"(4) ACCESS.—The Secretary shall ensure that—

"(A) an eligible entity complies with the access requirements described in subsection (f)(5);

"(B) if an eligible entity employs formularies pursuant to subsection (f)(6)(A),

such entity complies with the requirements of subsection (f)(6)(B);

''(C) an eligible entity makes available to each beneficiary covered under the contract at least one drug in each therapeutic class from those approved by the Secretary for the treatment of certain chronic conditions and at least one generic equivalent for each drug, if available; and

''(D) an eligible entity makes available to each such beneficiary alternative prescription drugs for the treatment of certain chronic conditions when a physician certifies that, because of a drug allergy or other documented medical condition, that none of the drugs approved by the Secretary for the treatment of these conditions can adequately treat the patient and that these drugs are medically necessary.

''(5) DURATION OF CONTRACTS.—Each contract under this section shall be for a term of at least 2 years but not more than 5 years, as determined by the Secretary.

''(b) ENROLLMENT.—

''(1) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary

shall make an election to enroll with any eligible entity that has been awarded a contract under this section and serves the geographic area in which the beneficiary resides. In establishing such process, the Secretary shall use rules similar to the rules for enrollment and disenrollment with a Medicare+Choice plan under section 1851.

''(2) REQUIREMENT OF ENROLLMENT.—An eligible beneficiary not enrolled in a Medicare+Choice plan under part C must enroll with an eligible entity under this section in order to be eligible to receive covered outpatient drugs under this title.

''(3) ENROLLMENT IN ABSENCE OF ELECTION BY ELIGIBLE BENEFICIARY.—In the case of an eligible beneficiary that fails to make an election pursuant to paragraph (1), the Secretary shall provide, pursuant to procedures developed by the Secretary, for the enrollment of such beneficiary with an eligible entity that has a contract under this section that covers the area in which such beneficiary resides.

''(4) AREAS NOT COVERED BY CONTRACTS.—The Secretary shall develop procedures for the provision of covered outpatient drugs under this title to eligible beneficiaries that reside in an area that is not covered by any contract under this section.

''(5) BENEFICIARIES RESIDING IN DIFFERENT LOCATIONS.—The Secretary shall develop procedures to ensure that an eligible beneficiary that resides in different regions in a year is provided benefits under this section throughout the entire year.

''(c) AWARDING OF CONTRACTS.—

''(1) NUMBER OF CONTRACTS.—The Secretary shall, consistent with the requirements of this part and the goal of containing costs under this title, award in a competitive manner at least 2 contracts to offer a plan in an area, unless only 1 bidding entity (and the plan offered by the entity) meet the minimum standards specified under this part and by the Secretary.

''(2) DETERMINATION.—In determining which of the eligible entities that submitted bids that meet the minimum standards specified under this part and by the Secretary to award a contract, the Secretary shall consider the comparative merits of each bid, as determined on the basis of the past performance of the entity and other relevant factors, with respect to—

''(A) how well the entity (and the plan offered by the entity) meet such minimum standards;

"(B) the amount that the entity will charge the Secretary for administering and delivering the benefits under the contract;

"(C) the proposed negotiated prices of covered outpatient drugs and annual increases in such prices;

"(D) prior experience of the entity in administering a prescription drug benefit program;

"(E) effectiveness of the entity and plan in containing costs through pricing incentives and utilization management; and

"(F) such other factors as the Secretary deems necessary to evaluate the merits of each bid.

"(3) EXCEPTION TO CONFLICT OF INTEREST RULES.—In awarding contracts under this part, the Secretary may waive conflict of interest laws generally applicable to Federal acquisitions (subject to such safeguards as the Secretary may find necessary to impose) in circumstances where the Secretary finds that such waiver—

"(A) is not inconsistent with the—

"(i) purposes of the programs under this title; or

"(ii) best interests of beneficiaries enrolled under this part; and

"(B) permits a sufficient level of competition for such contracts, promotes efficiency of benefits administration, or otherwise serves the objectives of the program under this part.

"(4) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of the Secretary to award or not award a contract to an eligible entity with respect to a plan under this part shall not be subject to administrative or judicial review.

"(d) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The provisions of section 1851(h) shall apply to marketing material and application forms under this part in the same manner as such provisions apply to marketing material and application forms under part C.

"(e) PROVIDING INFORMATION TO BENEFICIARIES.—The Secretary shall provide for activities under this section to broadly disseminate information to medicare beneficiaries on the coverage provided under this section. Such activities shall be similar to the activities performed by the Secretary under section 1851(d).

"(f) PAYMENTS TO ELIGIBLE ENTITIES.—

''(1) IN GENERAL.—The Secretary shall establish procedures for making payments to an eligible entity under a contract consistent with this subsection.

''(2) RISK REQUIREMENT.—A portion of payments made to an eligible entity under this section shall be based on performance goals established by the Secretary, including the following:

''(A) QUALITY SERVICE.—The entity provides eligible beneficiaries enrolled in the plan that is covered by the contract under this part with quality services, as measured by such factors as—

''(i) sustained pharmacy network access;

''(ii) timeliness and accuracy of service delivery in claims processing and card production;

''(iii) pharmacy and member service support access;

''(iv) response time in mail delivery service; and

''(v) timely action with regard to appeals and current beneficiary service surveys.

''(B) QUALITY CLINICAL CARE.—The entity provides such beneficiaries with quality clinical care, as measured by such factors as providing—

''(i) notification to such beneficiaries and to providers in order to prevent adverse drug reactions; and

''(ii) specific clinical suggestions to improve health and patient and prescriber education as appropriate.

''(C) CONTROL OF MEDICARE COSTS.—The entity contains costs to the Federal Supplementary Medical Insurance Trust Fund as measured by generic substitution rates, price discounts, and other factors determined appropriate by the Secretary that do not reduce the access of beneficiaries to medically necessary covered outpatient drugs.

''(3) PERCENTAGE OF PAYMENT TIED TO RISK.—

''(A) IN GENERAL.—The Secretary shall determine the percentage of the administrative payments to an eligible entity that will be tied to the performance goals.

''(B) LIMITATION ON RISK TO ENSURE PROGRAM STABILITY.—In order to provide for program stability, the Secretary may not establish a percentage to be adjusted under this subsection at a level that jeopardizes the ability of an eligible entity to administer and deliver the benefits under this part or administer and deliver such benefits in a quality manner.

''(g) COST-SHARING.—

''(1) ANNUAL DEDUCTIBLE.—Benefits under this section shall not begin in a year until the eligible beneficiary has met a $250 deductible.

''(2) COPAYMENT.—

''(A) IN GENERAL.—Subject to subparagraph (B), the eligible beneficiary shall be responsible for making payments in an amount not greater than 20 percent of the cost (as stated in the contract) of any covered outpatient drug that is provided to the beneficiary. Pursuant to subsection (a)(4)(B), an eligible entity may reduce the payment amount that an eligible beneficiary is responsible for making to the entity.

''(B) NO COPAYMENT FOR GENERICS.—The copayment amount under subparagraph

(A) shall be zero in the case of a covered outpatient drug that is a drug approved under section 505(j) of the Federal Food Drug and Cosmetic Act.

''(h) CONDITIONS FOR AWARDING CONTRACT.—The Secretary shall not award a contract to an eligible entity under subsection (a) unless the Secretary finds that the eligible entity is in compliance with such terms and conditions as the Secretary shall specify, including the following:

''(1) QUALITY AND FINANCIAL STANDARDS.—The eligible entity meets quality and financial standards specified by the Secretary.

''(2) INFORMATION.—The eligible entity provides the Secretary with information that the Secretary determines is necessary in order to carry out the bidding process under this section, including data needed to implement subsection (a)(6) and data regarding utilization, expenditures, and costs.

''(3) EDUCATION.—The eligible entity establishes educational programs that meet the criteria established by the Secretary pursuant to subsection (i)(1).

''(4) PROCEDURES TO ENSURE PROPER UTILIZATION AND TO AVOID ADVERSE DRUG REAC-

TIONS.—The eligible entity has in place procedures to ensure the—

"(A) appropriate utilization by eligible beneficiaries of the benefits to be provided under the contract; and

"(B) the avoidance of adverse drug reactions among such beneficiaries, including problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse and misuse.

"(5) PATIENT PROTECTIONS.—

"(A) ACCESS.—The eligible entity ensures that the covered outpatient drugs are accessible and convenient to eligible beneficiaries covered under the contract, including by offering the services in the following manner:

"(i) SERVICES DURING EMERGENCIES.—The offering of services 24 hours a day and 7 days a week for emergencies.

"(ii) CONTRACTS WITH RETAIL PHARMACIES.—The offering of services—

"(I) at a sufficient (as determined by the Secretary) number of retail pharmacies; and

"(II) to the extent feasible, at retail pharmacies located throughout the eligible entity's service area.

"(B) ENSURING THAT BENEFICIARIES ARE NOT OVERCHARGED.—The eligible entity has procedures in place to ensure that—

"(i) the total charge for each covered outpatient drug dispensed to an eligible beneficiary enrolled in the plan covered by the contract does not exceed the negotiated price for the drug; and

"(ii) the retail pharmacy dispensing the drug does not charge (or collect from) such beneficiary an amount that exceeds the beneficiary's obligation (as determined in accordance with the provisions of this part) of the negotiated price.

"(C) RETAIL PHARMACY MEETS MINIMUM QUALITY AND TECHNOLOGY STANDARDS.—The eligible entity ensures that any retail pharmacy

that it contracts with to deliver benefits under this part meets minimum quality and technology standards (as established by the Secretary).

''(6) RULES RELATING TO PROVISION OF BENEFITS.—

''(A) PROVISION OF BENEFITS.—In providing benefits under a contract under this section, an eligible entity may—

''(i) employ mechanisms to provide benefits economically, including the use of—

''(I) formularies (pursuant to subparagraph (B));

''(II) alternative methods of distribution; and

''(III) generic drug substitution; and

''(ii) use incentives to encourage eligible beneficiaries to select less costly means of receiving drugs.

''(B) FORMULARIES.—If an eligible entity uses a formulary to contain costs under this Act—

''(i) the eligible entity shall—

''(I) ensure participation of practicing physicians and pharmacists in the development of the formulary;

''(II) include in the formulary at least 1 drug from each therapeutic class from the drugs identified under section 2(b)(2) of the Essential Medicines for Medicare Act of 2002 and provide at least 1 generic equivalent, if available;

''(III) provide for coverage of otherwise covered non-formulary drugs when recommended by prescribing providers; and

''(IV) disclose to current and prospective beneficiaries and to providers in the service area the nature of the formulary restrictions, including information regarding the drugs included in the formulary, copayment amounts, and any difference in the cost-sharing for different types of drugs; but

''(ii) nothing shall preclude an entity from—

''(I) requiring higher cost-sharing for drugs provided under clause (i)(III), subject to limits established in subsection (g)(2)(A), except that an entity shall provide for coverage of a nonformulary drug on the same basis as a drug within the formulary if such nonformulary drug is determined by the prescribing provider to be medically indicated;

''(II) educating prescribing providers, pharmacists, and beneficiaries about medical and cost benefits of formulary products; and

''(III) requesting prescribing providers to consider a formulary product prior to dispensing of a nonformulary drug, as long as such request does not unduly delay the provision of the drug.

''(7) PROCEDURES TO COMPENSATE PHARMACISTS FOR COUNSELING.—The eligible entity shall compensate pharmacists for providing the counseling described in subsection (i)(2)(B).

''(8) CLINICAL OUTCOMES.—

"(A) REQUIREMENT.—The eligible entity shall comply with clinical quality standards as determined by the Secretary.

"(B) DEVELOPMENT OF STANDARDS.—The Secretary, in consultation with appropriate medical specialty societies, shall develop clinical quality standards that are applicable to eligible entities. Such standards shall be based on current standards of care.

"(9) PROCEDURES REGARDING DENIALS OF CARE.—The eligible entity has in place procedures to ensure—

"(A) the timely review and resolution of denials of care and complaints (including those regarding the use of formularies under paragraph (6)) by enrollees, or providers, pharmacists, and other individuals acting on behalf of such individual (with the individual's consent) in accordance with requirements (as established by the Secretary) that are comparable to such requirements for Medicare+Choice organizations under part C;

"(B) that beneficiaries are provided with information regarding the appeals procedures

under this section at the time of enrollment; and

''(C) that providers receive information on the entity's procedures for coverage of otherwise covered non-formulary and alternative prescription drugs for treatment of certain chronic conditions.

''(i) EDUCATIONAL REQUIREMENTS TO ENSURE APPROPRIATE UTILIZATION.—

''(1) ESTABLISHMENT OF PROGRAM CRITERIA.—The Secretary shall establish a model for comprehensive educational programs in order to assure the appropriate—

''(A) prescribing and dispensing of covered outpatient drugs under this section; and

''(B) use of such drugs by eligible beneficiaries.

''(2) ELEMENTS OF MODEL.—The model established under paragraph (1) shall include the following elements:

''(A) On-line prospective review available 24 hours a day and 7 days a week in order to evaluate each prescription for drug therapy problems due to duplication, interaction, or incorrect dosage or duration of therapy.

''(B) Consistent with State law, guidelines for counseling eligible beneficiaries enrolled under a contract under this section regarding—

''(i) the proper use of prescribed covered outpatient drugs; and

''(ii) interactions and contra-indications.

''(C) Methods to identify and educate providers, pharmacists, and eligible beneficiaries regarding—

''(i) instances or patterns concerning the unnecessary or inappropriate prescribing or dispensing of covered outpatient drugs;

''(ii) instances or patterns of substandard care;

''(iii) potential adverse reactions to covered outpatient drugs;

''(iv) inappropriate use of antibiotics;

''(v) appropriate use of generic products; and

''(vi) the importance of using covered outpatient drugs in accordance with the instruction of prescribing providers.

''(j) PROTECTION OF PATIENT CONFIDENTIALITY.—Insofar as an eligible organization maintains individually identifiable medical records or other health information regarding enrollees under a contract entered into under this section, the organization shall—

''(1) safeguard the privacy of any individually identifiable enrollee information;

''(2) maintain such records and information in a manner that is accurate and timely;

''(3) assure timely access of such enrollees to such records and information; and

''(4) otherwise comply with applicable laws relating to patient confidentiality.

''(k) DEFINITIONS.—In this section:

''(1) COVERED OUTPATIENT DRUG.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered outpatient drug' means prescription drugs for treatment of certain chronic conditions (as defined in section 1861(uu)(1)).

''(B) EXCLUSION.—The term 'covered outpatient drug' does not include any product—

''(i) which may be distributed to individuals without a prescription;

''(ii) 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;

''(iii) that was covered under this title on the day before the date of enactment of the Essential Medicines for Medicare Act of 2002; or

''(iv) that is a therapeutically equivalent replacement for a product described in clause (ii) or (iii), as determined by the Secretary.

''(2) ELIGIBLE BENEFICIARY.—The term 'eligible beneficiary' means an individual that is enrolled under part B of this title.

''(3) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity that the Secretary determines to be appropriate, including—

''(A) pharmaceutical benefit management companies;

''(B) wholesale and retail pharmacist delivery systems;

''(C) insurers;

''(D) other entities; or

''(E) any combination of the entities described in subparagraphs (A) through (D).''.

(2) NO APPLICATION TO REGULAR PART B DEDUCTIBLE.—Section 1833(b) of such Act (42 U.S.C. 1395l(b)) is amended—

(A) in paragraph (1), by inserting ''or for prescription drugs for treatment of certain chronic conditions'' after ''section 1861(s)(10)(A)''; and

(B) in paragraph (2), by inserting ''and shall not apply with respect to prescription drugs for treatment of certain chronic conditions' after ''section 1861(kk)))''.

(3) PAYMENT CONFORMING AMENDMENT.—Section 1832(a) of such Act (42 U.S.C. 1395k(a)) is amended—

(A) in paragraph (2)(A), by striking ''and (I)'' and inserting ''(I), and (K)'';

(B) by striking ''and'' at the end of paragraph (8);

(C) by striking the period at the end of subparagraph (9) and inserting ''; and''; and

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

''(10) with respect to prescription drugs for treatment of certain chronic conditions, the amounts provided under section 1849;''.

(d) ANALYSIS OF BENEFIT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into an arrangement with the Institute of Medicine of the National Academy of Sciences under which the Institute on an ongoing basis collects and analyzes data, and submits annual reports to the Secretary and Congress, on—

(A) the effectiveness of the benefits provided under the amendments made by this section in reducing demand for acute medical services;

(B) the annual cost of the benefits and the annual savings in acute medical services; and

(C) additional diagnoses, and additional prescription drugs, for which such benefits should be provided, using the criteria described in section 2(b)(2)(A) of this Act.

(2) CONSULTATION.—In carrying out paragraph (1)(C), the Secretary shall establish a process through which health care providers, advocacy groups, and other interested parties may submit evi-

dence to the Institute of Medicine and the Institute shall consider such evidence.

(3) CONSIDERATIONS.—Analyses under this subsection shall consider both the short term and long term benefits, and costs to the medicare program of any change in benefits.

(4) SECRETARIAL RECOMMENDATIONS.—The Secretary, taking into account the annual reports submitted under this subsection, may submit to Congress recommendations regarding changes in the chronic conditions for which prescription drug coverage is available under the medicare program.

(5) HEARINGS.—The Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate shall conduct hearings to consider the reports and recommendations submitted under this subsection before making any change in covered prescription drug benefits under the medicare program.

(6) FUNDING.—From funds appropriated to the Department of Health and Human Services for each fiscal year (beginning with fiscal year 2004), the Secretary shall provide for such funding as the Sec-

retary determines necessary for the conduct of the analyses conducted under this subsection.

(e) EFFECTIVE DATE.—Benefits shall first be made available under the amendments made by this section for prescription drugs furnished on or after January 1, 2004.

SEC. 3. MEDICAID COVERAGE OF MEDICARE PRESCRIPTION DRUG COST SHARING FOR SLMBS.

Section 1902(a)(10)(E)(iii) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)(iii)) by inserting ''and medicare cost-sharing described in subparagraphs (B) and (C) of section 1905(p)(3) with respect to the deductible and copayment described in section 1849(g)'' after ''section 1905(p)(4),''.

SEC. 4. DISEASE MANAGEMENT SERVICES.

Title XVIII of the Social Security Act is amended by inserting after section 1866B the following new section:

''DISEASE MANAGEMENT SERVICES

''SEC. 1866C. (a) IN GENERAL.—

''(1) PROGRAM AUTHORITY.—The Secretary, beginning January 1, 2003, may implement a program (in this section referred to as the 'program') in accordance with the provisions of this section under which certain eligible individuals may, in appropriate circumstances, receive disease management services from entities designated by the Secretary

with respect to diagnoses that the Secretary determines are amenable to such management.

''(2) ADMINISTRATION BY CONTRACT.—Except as otherwise specifically provided, the Secretary may administer the program under this section in accordance with section 1866B, including subsection (b)(2) of such section (relating to the discretion of the Secretary as to the scope of the program).

''(b) INDIVIDUALS WHO MAY RECEIVE DISEASE MANAGEMENT SERVICES.—No individual shall be eligible for enrollment in a disease management program under this section unless the Secretary finds the following with respect to the individual:

''(1) DIAGNOSIS AND RELATED CHARACTERISTICS.—

''(A) IN GENERAL.—The individual has been diagnosed with congestive heart failure, chronic obstructive pulmonary disease, diabetes, hypertension, rheumatoid arthritis, or major depression.

''(B) ADDITIONAL FACTORS.—Where required by the Secretary, the individual also has certain clinical characteristics or conditions, exhibits certain patterns of utilization, or mani-

fests other factors indicating the need for and potential effectiveness of disease management.

''(2) REFERRAL BY QUALIFIED INDIVIDUAL OR ENTITY.—The individual has been referred for consideration for such services by an individual or entity furnishing health care items or services, or by an entity administering benefits under this act.

''(c) PROCEDURES TO FACILITATE ENROLLMENT.—The Secretary shall develop and implement procedures designed to facilitate enrollment of eligible individuals in the program under this section.

''(d) ENROLLMENT OF INDIVIDUALS WITH DISEASE MANAGEMENT ORGANIZATIONS.—

''(1) EFFECTIVE DATE AND DURATION.—Enrollment of an individual in the program under this section shall remain in effect for 1 month (or such longer period as the Secretary may specify), and shall be automatically renewed for additional periods, unless terminated in accordance with such procedures as the Secretary shall establish by regulation.

''(2) LIMITATION ON REENROLLMENT.—The Secretary may establish limits on an individual's eligibility to reenroll in the program under this section

if the individual has disenrolled from the program more than once during a specified time period.

''(e) DISEASE MANAGEMENT REQUIREMENT.—Notwithstanding any other provision of this title, the Secretary may provide that an individual enrolled in the program under this section may be entitled to payment under this title for any specified health care items or services only if the items or services have been furnished by the disease management organization, or coordinated through the disease management services program. Under such provision, the Secretary shall prescribe exceptions for emergency medical services as described in section 1852(d)(3), and other exceptions determined by the Secretary for the delivery of timely and needed care.

''(f) DISEASE MANAGEMENT SERVICES.—

''(1) IN GENERAL.—Subject to the cost-effectiveness criteria specified in subsection (b)(1), disease management services provided to an individual under this section may include—

''(A) initial and periodic health screening and assessment;

''(B) management (including coordination with other providers) of, and referral for, medical and other health services related to the managed diagnosis (which may include referral

for provision of such services by the disease management organization);

''(C) monitoring and control of medications (including coordination with the whatever entity may be managing prescription drug benefit for the individual under this title);

''(D) patient education and counseling;

''(E) nursing or other health professional home visits, as appropriate;

''(F) providing access for consultations by telephone with physicians or other appropriate medical professionals, including 24-hour availability for emergency consultations;

''(G) managing and facilitating the transition to other care arrangements in preparation for termination of the disease management enrollment; and

''(H) such other services for which payment would not otherwise be made under this title as the Secretary shall determine to be appropriate.

''(2) VARIATIONS IN SERVICE PACKAGES.—The types and combinations of disease management services furnished under agreements under this section may vary (as permitted or required by the Sec-

retary) according to the types of diagnoses, conditions, patient profiles being managed, expertise of the disease management organization, and other factors the Secretary finds appropriate.

''(3) REDUCTION OR ELIMINATION OF COST-SHARING.—Notwithstanding any other provision of law, subject to the cost-effectiveness criteria specified in subsection (b)(1), the Secretary may provide for the reduction or elimination of beneficiary cost-sharing (such as deductibles, copayments, and coinsurance) with respect to any of the items or services furnished under this title (other than those furnished under a service package developed under paragraph (2)), and may limit such reduction or elimination to particular service areas.

''(g) AGREEMENTS WITH DISEASE MANAGEMENT ORGANIZATIONS.—

''(1) ENTITIES ELIGIBLE.—Entities qualified to enter into agreements with the Secretary for the provision of disease management services under this section include entities that have demonstrated the ability to meet the performance standards and other criteria established by the Secretary with respect to—

''(A) the management of each diagnosis and condition with respect to which the entity, if designated, would furnish disease management services under this section; and

''(B) the implementation of each disease management approach that the entity, if designated, would implement under this section.

''(2) CONDITIONS OF PARTICIPATION.—In order to be eligible to provide disease management services under this section, an entity shall—

''(A) have in effect an agreement with the Secretary setting forth such obligations of the entity as a disease management organization under this section as the Secretary shall prescribe;

''(B) meet the standards established by the Secretary under subsection (h); and

''(C) meet such other conditions as the Secretary may establish.

''(3) SECRETARY'S OPTION FOR NONCOMPETITIVE DESIGNATION.—The Secretary may designate an entity to provide disease management services under this section without regard to the requirements of section 5 of title 41, United States Code.

''(h) STANDARDS.—

''(1) QUALITY.—The Secretary shall establish standards for, and procedures for assessing, the quality of care provided by disease management organizations under this section, which shall include—

''(A) performance standards with respect to the processes or outcomes of health care or the health status of enrolled individuals, including procedures for establishing a baseline and measuring changes in health care processes or health outcomes with respect to managed diseases or health conditions;

''(B) a requirement that the organization meet such licensure and other accreditation standards as the Secretary may find appropriate; and

''(C) such other quality standards, including patient satisfaction, as the Secretary may find appropriate.

''(2) COST MANAGEMENT.—The Secretary shall establish a performance standard with respect to management or reduction of the aggregate costs of health care items and services related to managed health conditions furnished to enrolled individuals, including procedures for establishing a baseline and

measuring changes in costs for such items and services.

''(i) PAYMENT.—

''(1) TERMS OF PAYMENT.—The Secretary may negotiate or otherwise establish payment terms and rates for service packages developed under subsection (f)(2).

''(2) WITHHOLDING OF PAYMENTS.—An agreement under subsection (g) may provide that the Secretary may withhold up to 10 percent of the amount due a disease management organization under the basis of payment established under paragraph (1) until such time as such organization meets a standard or standards specified in such agreement.''.

(b) COVERAGE OF DISEASE MANAGEMENT SERVICES AS A PART B MEDICAL SERVICE.—

(1) IN GENERAL.—Section 1861(s) of the Social Security Act (42 U.S.C. 1395x(s)) is amended—

(A) in the second sentence, by redesignating paragraphs (16) and (17) as clauses (i) and (ii), respectively; and

(B) in the first sentence—

(i) in paragraph (14), by striking ''and'' at the end;

(ii) in paragraph (15), by striking the period at the end and inserting ''; and''; and

(iii) by inserting after paragraph (15) the following new paragraph:

''(16) disease management services furnished in accordance with section 1866C.''.

(2) PART B COINSURANCE AND DEDUCTIBLE NOT APPLICABLE TO DISEASE MANAGEMENT SERVICES.—

(A) COINSURANCE.—Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)) is amended—

(i) by striking ''and (U)'' and inserting ''(U)''; and

(ii) by inserting before the semicolon at the end the following: '', and (V) with respect to disease management services described in section 1861(s)(16), the amounts paid shall be 100 percent of the payment amounts established under section 1866C''.

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

(i) by striking ''and (6)'' and inserting ''(6)''; and

(ii) by inserting before the period at the end the following: '', and (7) such deductible shall not apply with respect to disease management services (as described in section 1861(s)(16))''.

○