#### 106TH CONGRESS 1ST SESSION

# H. R. 1796

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

## IN THE HOUSE OF REPRESENTATIVES

May 13, 1999

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

# A BILL

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

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Medicare Chronic Dis-
- 5 ease Prescription Drug Benefit Act of 1999".
- 6 SEC. 2. MEDICARE CHRONIC DISEASE PRESCRIPTION
- 7 DRUG BENEFIT.
- 8 (a) Coverage.—

1	(1) In General.—Section 1832(a)(2) of the
2	Social Security Act (42 U.S.C. 1395k(a)(2)) is
3	amended—
4	(A) by striking "and" at the end of sub-
5	paragraph (I);
6	(B) by striking the period at the end of
7	subparagraph (J) and inserting "; and; and
8	(C) by adding at the end the following new
9	subparagraph:
10	"(K) subject to subsection (b), prescription
11	drugs for treatment of certain chronic condi-
12	tions (as defined in section 1861(uu)(1)).".
13	(2) Provision of Benefits through exist-
14	ING NON-MEDICAID STATE PRESCRIPTION DRUG
15	BENEFIT PROGRAMS.—Section 1832 of such Act (42
16	U.S.C. 1395k) is further amended—
17	(1) by redesignating subsection (b) as sub-
18	section (e); and
19	(2) by inserting after subsection (a) the
20	following new subsection:
21	"(b)(1) Prescription drug benefits shall not be avail-
22	able under subsection (a)(2)(K) to an individual to the ex-
23	tent that the individual receives benefits for the prescrip-
24	tion drugs under a State non-medicaid prescription drug
25	benefit program if the following requirements are met:

- 1 "(A) The program is sponsored or financially 2 underwritten by a State, but Federal financial as-3 sistance under title XIX is not available for expendi-4 tures under the program.
- 5 "(B) The program is in operation as of May 1, 6 1999.
- 7 "(C) The State elects to receive payment (de-8 scribed in paragraph (2)) for providing benefits 9 under this subsection.
- "(D) The deductible and coinsurance applicable does not exceed the deductible and coinsurance otherwise applicable to the prescription drug benefit described in subsection (a)(2)(K).
- 14 "(2) The Secretary shall provide for payment to a 15 State that operates a program that meets the requirements of paragraph (1) of an amount (agreed to by the 16 17 State) that does not exceed the Secretary's estimate of the 18 amount of payment that would have been made under this 19 part (taking into account the application of a deductible 20 and coinsurance) for prescription drugs for which coverage 21 is provided under such program, if this subsection did not
- 23 (b) Definition of Benefit.—

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apply.".

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(1) In General.—Section 1861 of such Act
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        (42 U.S.C. 1395x) is amended by adding at the end
 3
        the following new subsection:
     "Prescription Drugs for Treatment of Certain Chronic
 4
 5
                           Conditions
 6
        "(uu)(1) The term 'prescription drugs for treatment
   of certain chronic conditions' means, subject to paragraph
 8
   (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
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   who has been diagnosed by a physician as having that con-
   dition):
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13
             "(A) Hypertension.
14
             "(B) Diabetes.
             "(C) Congestive or ischemic heart disease.
15
             "(D) Major depression.
16
17
             "(E) Rheumatoid arthritis.
18
        "(2) Prescription drugs described in this paragraph
19
   are—
             "(A) a prescription drug that meets the require-
20
21
        ment of clause
                           (i),
                                  (ii),
                                       or
                                            (iii)
                                                  of section
22
        1927(k)(2)(A);
             "(B) a biological product described in section
23
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        1927(k)(2)(B); or
             "(C) insulin described in section 1927(k)(2)(C).
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1	"(3) The term 'prescription drugs for treatment of
2	certain chronic conditions' does not include any product—
3	"(A) which may be distributed to individuals
4	without a prescription;
5	"(B) when furnished as part of, or as incident
6	to, a diagnostic service or any other item or service
7	for which payment may be made under this title;
8	"(C) that was covered under this title on the
9	day before the date of enactment of the Medicare
10	Chronic Disease Prescription Drug Benefit Act of
11	1999; or
12	"(D) that is a therapeutically equivalent re-
13	placement for a product described in subparagraph
14	(B) or (C), as determined by the Secretary.".
15	(2) Process for identification of covered
16	DRUGS.—The Secretary of Health and Human Serv-
17	ices shall implement a process for the timely identi-
18	fication of prescription drugs for treatment of cer-
19	tain chronic conditions that should be covered under
20	section 1861(uu) of the Social Security Act, as
21	added by paragraph (1). Under such process—
22	(A) within 60 days after the date of the
23	enactment of this Act, the Agency for Health
24	Care Policy and Research shall complete an ini-
25	tial review of the available data on the preva-

1	lence of conditions described in such section in
2	the population of medicare beneficiaries, the
3	adequacy of data demonstrating the effective-
4	ness of different prescription drugs in treating
5	such conditions, and the severity of potential
6	complications in using such drugs;
7	(B) within 6 months after the date of the
8	enactment of this Act, the Secretary shall speci-
9	fy by rule the initial prescription drugs that
10	shall be covered under such section;
11	(C) thereafter the Secretary, taking into
12	consideration recommendations made under
13	subsection (e), may by rule change the prescrip-
14	tion drugs that are so covered; and
15	(D) the Secretary may, on an emergency
16	basis, provide for the replacement of a prescrip-
17	tion drug on the list if another drug (for the
18	treatment of the same condition) is recalled.
19	(3) Construction.—Nothing in this section
20	(or the amendments made by this section) shall be
21	construed—
22	(A) as preventing medicare beneficiaries
23	from purchasing prescription drugs not identi-
24	fied under paragraph (2), including through

1	coverage under a group health plan or medicare
2	supplemental policy; and
3	(B) the coverage under a medicare supple-
4	mental policy of prescription drugs for condi-
5	tions not specified on the list complied under
6	paragraph (2) shall not be considered to dupli-
7	cate benefits under title XVIII of such Act, for
8	purposes of applying section 1882(d)(3) of such
9	Act $(42 \text{ U.S.C. } 1395 \text{ss}(d)(3)).$
10	(c) Selection of Entity To Provide Drug Ben-
11	EFIT; PAYMENT.—Part B of title XVIII of the Social Se-
12	curity Act is amended by adding at the end the following
13	new section:
14	"SEC. 1849. SELECTION OF ENTITIES TO PROVIDE OUT-
15	PATIENT DRUG BENEFIT; PAYMENT.
16	"(a) Establishment of Bidding Process.—
17	"(1) In general.—The Secretary shall estab-
18	lish procedures under which the Secretary accepts
	lish procedures under which the Secretary accepts bids from eligible entities and awards contracts to
<ul><li>18</li><li>19</li><li>20</li></ul>	
19 20	bids from eligible entities and awards contracts to
19	bids from eligible entities and awards contracts to such entities in order to provide covered outpatient
19 20 21	bids from eligible entities and awards contracts to such entities in order to provide covered outpatient drugs to eligible beneficiaries in an area. Such con-

1	"(A) REGIONAL BASIS.—The contract en-
2	tered into between the Secretary and an eligible
3	entity shall require the eligible entity to provide
4	covered outpatient drugs on a regional basis.
5	"(B) Determination.—In determining
6	coverage areas under this section, the Secretary
7	shall take into account the number of eligible
8	beneficiaries in an area in order to encourage
9	participation by eligible entities.
10	"(3) Submission of Bids.—Each eligible enti-
11	ty desiring to provide covered outpatient drugs
12	under this section shall submit a bid to the Sec-
13	retary at such time, in such manner, and accom-
14	panied by such information as the Secretary may
15	reasonably require. Such bids shall include the
16	amount the eligible entity will charge enrollees under
17	subsection (e)(2) for covered outpatient drugs under
18	the contract.
19	"(4) Access.—The Secretary shall ensure
20	that—
21	"(A) an eligible entity complies with the
22	access requirements described in subsection
23	(f)(5);
24	"(B) if an eligible entity employs
25	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.

1	"(5) Beneficiaries residing in different
2	LOCATIONS.—The Secretary shall develop procedures
3	to ensure that an eligible beneficiary that resides in
4	different regions in a year is provided benefits under
5	this section throughout the entire year.
6	"(c) Providing Information to Bene-
7	FICIARIES.—The Secretary shall provide for activities
8	under this section to broadly disseminate information to
9	medicare beneficiaries on the coverage provided under this
10	section. Such activities shall be similar to the activities
11	performed by the Secretary under section 1851(d).
12	"(d) Payments to Eligible Entities.—The Sec-
13	retary shall establish procedures for making payments to
14	an eligible entity under a contract.
15	"(e) Cost-Sharing.—
16	"(1) Annual deductible.—Benefits under
17	this section shall not begin in a year until the eligi-
18	ble beneficiary has met a \$250 deductible.
19	"(2) Copayment.—
20	"(A) In general.—Subject to subpara-
21	graph (B), the eligible beneficiary shall be re-
22	sponsible for making payments in an amount
23	not greater than 20 percent of the cost (as stat-
24	ed in the contract) of any covered outpatient
25	drug that is provided to the beneficiary. Pursu-

ant to subsection (a)(4)(B), an eligible entity
may reduce the payment amount that an eligible beneficiary is responsible for making to the
entity.

- 5 "(B) NO COPAYMENT FOR GENERICS.—
  6 The copayment amount under subparagraph
  7 (A) shall be zero in the case of a covered out8 patient drug that is a drug approved under sec9 tion 505(j) of the Federal Food Drug and Cos10 metic Act.
- "(f) 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:
- 17 "(1) QUALITY AND FINANCIAL STANDARDS.—
  18 The eligible entity meets quality and financial stand19 ards 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.

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1	"(3) Education.—The eligible entity estab-
2	lishes educational programs that meet the criteria
3	established by the Secretary pursuant to subsection
4	(g)(1).
5	"(4) Procedures to ensure proper utili-
6	ZATION AND TO AVOID ADVERSE DRUG REAC-
7	TIONS.—The eligible entity has in place procedures
8	to ensure the—
9	"(A) appropriate utilization by eligible
10	beneficiaries of the benefits to be provided
11	under the contract; and
12	"(B) avoidance of adverse drug reactions
13	among eligible beneficiaries enrolled with the
14	entity.
15	"(5) Access.—The eligible entity ensures that
16	the covered outpatient drugs are accessible and con-
17	venient to eligible beneficiaries covered under the
18	contract, including by offering the services in the fol-
19	lowing manner:
20	"(A) Services during emergencies.—
21	The offering of services 24 hours a day and 7
22	days a week for emergencies.
23	"(B) Contracts with retail phar-
24	MACIES.—The offering of services—

1	"(i) at a sufficient (as determined by
2	the Secretary) number of retail phar-
3	macies; and
4	"(ii) to the extent feasible, at retail
5	pharmacies located throughout the eligible
6	entity's service area.
7	"(6) Rules relating to provision of Bene-
8	FITS.—
9	"(A) Provision of Benefits.—In pro-
10	viding benefits under a contract under this sec-
11	tion, an eligible entity may—
12	"(i) employ mechanisms to provide
13	benefits economically, including the use
14	of—
15	"(I) formularies (pursuant to
16	subparagraph (B));
17	"(II) alternative methods of dis-
18	tribution; and
19	"(III) generic drug substitution;
20	and
21	"(ii) use incentives to encourage eligi-
22	ble beneficiaries to select less costly means
23	of receiving drugs.

1	"(B) FORMULARIES.—If an eligible entity
2	uses a formulary to contain costs under this
3	Act—
4	"(i) the eligible entity shall—
5	"(I) ensure participation of prac-
6	ticing physicians and pharmacists in
7	the development of the formulary;
8	"(II) include in the formulary at
9	least 1 drug from each therapeutic
10	class from the drugs identified under
11	section 2(b)(2) of the Medicare
12	Chronic Disease Prescription Drug
13	Benefit Act of 1999 and provide at
14	least 1 generic equivalent, if available;
15	"(III) provide for coverage of
16	otherwise covered non-formulary
17	drugs when recommended by pre-
18	scribing providers; and
19	"(IV) disclose to current and
20	prospective beneficiaries and to pro-
21	viders in the service area the nature
22	of the formulary restrictions, includ-
23	ing information regarding the drugs
24	included in the formulary, copayment
25	amounts, and any difference in the

1	cost-sharing for different types of
2	drugs; but
3	"(ii) nothing shall preclude an entity
4	from—
5	"(I) requiring higher cost-sharing
6	for drugs provided under clause
7	(i)(III), subject to limits established
8	in subsection (e)(2)(A), except that an
9	entity shall provide for coverage of a
10	nonformulary drug on the same basis
11	as a drug within the formulary if such
12	nonformulary drug is determined by
13	the prescribing provider to be medi-
14	cally indicated;
15	"(II) educating prescribing pro-
16	viders, pharmacists, and beneficiaries
17	about medical and cost benefits of for-
18	mulary products; and
19	"(III) requesting prescribing pro-
20	viders to consider a formulary product
21	prior to dispensing of a nonformulary
22	drug, as long as such request does not
23	unduly delay the provision of the
24	drug.

1 "(7) Procedures to compensate phar-2 MACISTS FOR COUNSELING.—The eligible entity shall 3 compensate pharmacists for providing the counseling 4 described in subsection (g)(2)(B). "(8) CLINICAL OUTCOMES.— 5 "(A) REQUIREMENT.—The eligible entity 6 7 shall comply with clinical quality standards as 8 determined by the Secretary. 9 "(B) DEVELOPMENT OF STANDARDS.— 10 The Secretary, in consultation with appropriate 11 medical specialty societies, shall develop clinical 12 quality standards that are applicable to eligible 13 entities. Such standards shall be based on cur-14 rent standards of care. 15 "(9) Procedures regarding denials of 16 CARE.—The eligible entity has in place procedures to 17 ensure— 18 "(A) the timely review and resolution of 19 denials of care and complaints (including those 20 regarding the use of formularies under para-21 graph (6)) by enrollees, or providers, phar-22 macists, and other individuals acting on behalf 23 of such individual (with the individual's con-24 sent) in accordance with requirements (as es-

tablished by the Secretary) that are comparable

1	to such requirements for Medicare+Choice or-
2	ganizations under part C;
3	"(B) that beneficiaries are provided with
4	information regarding the appeals procedures
5	under this section at the time of enrollment
6	and
7	"(C) that providers receive information or
8	the entity's procedures for coverage of otherwise
9	covered non-formulary and alternative prescrip-
10	tion drugs for treatment of certain chronic con-
11	ditions.
12	"(g) Educational Requirements To Ensure Ap-
13	PROPRIATE UTILIZATION.—
14	"(1) Establishment of program cri-
15	TERIA.—The Secretary shall establish a model for
16	comprehensive educational programs in order to as-
17	sure the appropriate—
18	"(A) prescribing and dispensing of covered
19	outpatient drugs under this section; and
20	"(B) use of such drugs by eligible bene-
21	ficiaries.
22	"(2) Elements of model.—The model estab-
23	lished under paragraph (1) shall include the fol-
24	lowing elements:

1	"(A) On-line prospective review available
2	24 hours a day and 7 days a week in order to
3	evaluate each prescription for drug therapy
4	problems due to duplication, interaction, or in-
5	correct dosage or duration of therapy.
6	"(B) Consistent with State law, guidelines
7	for counseling eligible beneficiaries enrolled
8	under a contract under this section regarding—
9	"(i) the proper use of prescribed cov-
10	ered outpatient drugs; and
11	"(ii) interactions and contra-indica-
12	tions.
13	"(C) Methods to identify and educate pro-
14	viders, pharmacists, and eligible beneficiaries
15	regarding—
16	"(i) instances or patterns concerning
17	the unnecessary or inappropriate pre-
18	scribing or dispensing of covered out-
19	patient drugs;
20	"(ii) instances or patterns of sub-
21	standard care;
22	"(iii) potential adverse reactions to
23	covered outpatient drugs;
24	"(iv) inappropriate use of antibiotics:

1	"(v) appropriate use of generic prod-
2	ucts; and
3	"(vi) the importance of using covered
4	outpatient drugs in accordance with the in-
5	struction of prescribing providers.
6	"(h) Protection of Patient Confidentiality.—
7	Insofar as an eligible organization maintains individually
8	identifiable medical records or other health information re-
9	garding enrollees under a contract entered into under this
10	section, the organization shall—
11	"(1) safeguard the privacy of any individually
12	identifiable enrollee information;
13	"(2) maintain such records and information in
14	a manner that is accurate and timely; and
15	"(3) assure timely access of such enrollees to
16	such records and information.
17	"(i) Definitions.—In this section:
18	"(1) Covered outpatient drug.—
19	"(A) IN GENERAL.—Except as provided in
20	subparagraph (B), the term 'covered outpatient
21	drug' means prescription drugs for treatment of
22	certain chronic conditions (as defined in section
23	1861(uu)(1)).
24	"(B) Exclusion.—The term 'covered out-
25	patient drug' does not include any product—

1	"(i) which may be distributed to indi-
2	viduals without a prescription;
3	"(ii) when furnished as part of, or as
4	incident to, a diagnostic service or any
5	other item or service for which payment
6	may be made under this title;
7	"(iii) that was covered under this title
8	on the day before the date of enactment of
9	the Medicare Chronic Disease Prescription
10	Drug Benefit Act of 1999; or
11	"(iv) that is a therapeutically equiva-
12	lent replacement for a product described in
13	clause (ii) or (iii), as determined by the
14	Secretary.
15	"(2) Eligible beneficiary.—The term 'eligi-
16	ble beneficiary' means an individual that is enrolled
17	under part B of this title.
18	"(3) Eligible entity.—The term 'eligible en-
19	tity' means any entity that the Secretary determines
20	to be appropriate, including—
21	"(A) pharmaceutical benefit management
22	companies;
23	"(B) wholesale and retail pharmacist deliv-
24	ery systems;
25	"(C) insurers;

1	"(D) other entities; or
2	"(E) any combination of the entities de-
3	scribed in subparagraphs (A) through (D).".
4	(2) No application to regular part b de-
5	DUCTIBLE.—Section 1833(b) of such Act (42 U.S.C.
6	1395l(b)) is amended—
7	(A) in paragraph (1), by inserting "or for
8	prescription drugs for treatment of certain
9	chronic conditions" after "section
10	1861(s)(10)(A)"; and
11	(B) in paragraph (2), by inserting "and
12	shall not apply with respect to prescription
13	drugs for treatment of certain chronic condi-
14	tions' after "section 1861(kk)))".
15	(3) Payment conforming amendment.—Sec-
16	tion 1832(a) of such Act (42 U.S.C. 1395k(a)) is
17	amended—
18	(A) in paragraph (2)(A), by striking "and
19	(I)" and inserting "(I), and (K)";
20	(B) by striking "and" at the end of para-
21	graph (8);
22	(C) by striking the period at the end of
23	subparagraph (9) and inserting "; and"; and
24	(D) by adding at the end the following new
25	paragraph:

1 "(10) with respect to prescription drugs for 2 treatment of certain chronic conditions, the amounts 3 provided under section 1849;". 4 (d) Analysis of Benefit.— (1) IN GENERAL.—The Secretary of Health and 6 Human Services shall enter into an arrangement 7 with the Institute of Medicine of the National Acad-8 emy of Sciences under which the Institute on an on-9 going basis collects and analyzes data, and submits 10 annual reports to the Secretary and Congress, on— 11 (A) the effectiveness of the benefits pro-12 vided under the amendments made by this sec-13 tion in reducing demand for acute medical serv-14 ices; 15 (B) the annual cost of the benefits and the 16 annual savings in acute medical services; and 17 (C) additional diagnoses, and additional 18 prescription drugs, for which such benefits 19 should be provided, using the criteria described 20 in section 2(b)(2)(A) of this Act. 21 (2) Consultation.—In carrying out para-22 graph (1)(C), the Secretary shall establish a process 23 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 2000), the Secretary shall provide for such funding as the Sec-

- 1 retary determines necessary for the conduct of the
- 2 analyses conducted under this subsection.
- 3 (e) Effective Date.—Benefits shall first be made
- 4 available under the amendments made by this section for
- 5 prescription drugs furnished on or after January 1, 2001.
- 6 SEC. 3. MEDICAID COVERAGE OF MEDICARE PRESCRIP-
- 7 TION DRUG COST SHARING FOR SLMBS.
- 8 Section 1902(a)(10)(E)(iii) of the Social Security Act
- 9 (42 U.S.C. 1396a(a)(10)(E)(iii)) by inserting "and medi-
- 10 care cost-sharing described in subparagraphs (B) and (C)
- 11 of section 1905(p)(3) with respect to the deductible and
- 12 copayment described in section 1849(e)" after "section
- 13 1905(p)(4),".

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