104TH CONGRESS 1ST SESSION

S. 691

To amend title XVIII of the Social Security Act to provide for coverage of early detection of prostate cancer and certain drug treatment services under part B of the Medicare Program, to amend chapter 17 of title 38, United States Code, to provide for coverage of such early detection and treatment services under the programs of the Department of Veterans Affairs, and to expand research and education programs of the National Institutes of Health and the Public Health Service relating to prostate cancer.

IN THE SENATE OF THE UNITED STATES

APRIL 6 (legislative day, APRIL 5), 1995

Mr. Shelby (for himself, Mr. Stevens, Mr. Inouye, Mr. Thurmond, Mr. Heflin, and Mr. Mack) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to provide for coverage of early detection of prostate cancer and certain drug treatment services under part B of the Medicare Program, to amend chapter 17 of title 38, United States Code, to provide for coverage of such early detection and treatment services under the programs of the Department of Veterans Affairs, and to expand research and education programs of the National Institutes of Health and the Public Health Service relating to prostate cancer.

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 "Prostate Cancer Diag-
5	nosis and Treatment Act of 1995".
6	SEC. 2. MEDICARE COVERAGE OF EARLY DETECTION OF
7	PROSTATE CANCER AND CERTAIN DRUG
8	TREATMENTS.
9	(a) Coverage of Early Detection Services.—
10	(1) In General.—Section $1861(s)(2)$ of the
11	Social Security Act (42 U.S.C. $1395x(s)(2)$), as
12	amended by section 13553(a) of the Omnibus Budg-
13	et Reconciliation Act of 1993 (hereafter in this Act
14	referred to as "OBRA-1993"), is amended—
15	(A) by striking "and" at the end of sub-
16	paragraph (P);
17	(B) by adding "and" at the end of sub-
18	paragraph (Q); and
19	(C) by adding at the end the following new
20	subparagraph: "(R) services for early detection
21	of prostate cancer (as defined in subsection
22	(ll));".
23	(2) Services described.—Section 1861 of
24	such Act (42 U.S.C. 1395x) is amended—

1	(A) by redesignating the subsection (jj) in-
2	serted by section 4156(a)(2) of the Omnibus
3	Budget Reconciliation Act of 1990 as sub-
4	section (kk); and
5	(B) by inserting after such subsection the
6	following new subsection:
7	"Services for Early Detection of Prostate Cancer
8	"(ll) The term 'services for early detection of prostate
9	cancer' means the following procedures provided to a man $% \left(x\right) =\left(x\right) +\left(x\right) =\left(x\right) +\left(x\right) +\left$
10	for the purpose of early detection of prostate cancer:
11	"(1) Digital rectal examination.
12	"(2) Prostate-specific antigen blood test.
13	"(3) Transrectal ultrasonography.
14	"(4) Such other procedures as the Secretary
15	may designate as appropriate for early detection of
16	prostate cancer.".
17	(3) PAYMENT AMOUNTS; LIMITATIONS ON FRE-
18	QUENCY OF COVERAGE.—Section 1834 of such Act
19	(42 U.S.C. 1395m) is amended by inserting after
20	subsection (c) the following new subsection:
21	"(d) Payment Amounts and Frequency Limits
22	FOR SERVICES FOR EARLY DETECTION OF PROSTATE
23	CANCER.—
24	"(1) IN GENERAL.—Notwithstanding any other
25	provision of this part, with respect to expenses in-

1	curred for services for early detection of prostate
2	cancer (as defined in section 1861(ll))—
3	"(A) payment may be made only for serv-
4	ices provided consistent with the frequency per-
5	mitted under paragraph (2); and
6	"(B) the amount of the payment under
7	this part shall be equal to 80 percent of the
8	lesser of the actual charge for the service or-
9	"(i) in the case of services for early
10	detection of prostate cancer consisting of a
11	prostate-specific antigen blood test, the fee
12	schedule amount established for the service
13	under section 1833(h) (relating to pay-
14	ments for clinical diagnostic laboratory
15	tests); or
16	"(ii) in the case of any other services
17	for early detection of prostate cancer, the
18	amount provided under the fee schedule es-
19	tablished by the Secretary under para-
20	graph (3) (subject to the deductible estab-
21	lished under section 1833(b)).
22	"(2) Frequency covered.—
23	"(A) IN GENERAL.—Subject to subpara-
24	graph (B) and to revision by the Secretary
25	under subparagraph (C), no payment may be

1	made under this part for a service provided to
2	an individual for the purpose of early detection
3	of prostate cancer—
4	"(i) if the individual is under 50 years
5	of age; or
6	"(ii) if the service is provided within
7	the 11 months after a previous prostate
8	cancer detection service.
9	"(B) Exception for high risk individ-
10	UALS.—payment may be made under this part
11	for a service for early detection of prostate can-
12	cer provided to an individual more frequently
13	than the limit established under subparagraph
14	(A)(ii) if the individual is at a high risk of de-
15	veloping prostate cancer (as determined pursu-
16	ant to factors identified by the Secretary).
17	"(C) REVISION BY SECRETARY.—
18	"(i) REVIEW.—The Secretary, in con-
19	sultation with the Director of the National
20	Cancer Institute, shall review periodically
21	the appropriate frequency for performing
22	services for early detection of prostate can-
23	cer based on age and such other factors as
24	the Secretary believes to be pertinent.

1 "(ii) Revision of frequency.—The
2 Secretary, taking into consideration the re3 view made under clause (i), may revise
4 from time to time the frequency with
5 which such services may be paid for under
6 this subsection, but no such revision shall
7 apply to services performed before January
8 1, 1998.

"(3) Establishment of fee schedule.—

"(A) IN GENERAL.—The Secretary shall establish fee schedules (on such geographic basis as the Secretary considers appropriate) for payment for services for early detection of prostate cancer under this part (other than prostate-specific antigen blood tests), effective for services furnished after the expiration of the 90-day period beginning on the date the Secretary establishes the fee schedules.

"(B) FACTORS CONSIDERED.—In establishing fee schedules under subparagraph (A), the Secretary shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, together with

1	such other factors as may be appropriate to as-
2	sure that payment amounts are equitable.
3	"(4) Limiting charges of nonparticipating
4	PHYSICIANS.—
5	"(A) IN GENERAL.—In the case of a serv-
6	ice provided to an individual for the purpose of
7	early detection of prostate cancer for which
8	payment may be made under this part, if a
9	nonparticipating physician or supplier provides
10	the procedure to an individual enrolled under
11	this part, the physician or supplier may not
12	charge the individual more than the limiting
13	charge (as defined in section 1848(g)(2)).
14	"(B) Enforcement.—If a physician or
15	supplier knowingly and willfully imposes a
16	charge in violation of subparagraph (A), the
17	Secretary may apply sanctions against such
18	physician or supplier in accordance with section
19	1842(j)(2).''.
20	(4) Conforming amendments.—(A) Para-
21	graphs (1)(D) and (2)(D) of section 1833(a) of such
22	Act (42 U.S.C. 13951(a)) are each amended by
23	striking "subsection $(h)(1)$," and inserting "sub-

section (h)(1) or section 1834(d)(1)(B)(i),".

24

1	(B) Section 1833(a)(1) of such Act (42 U.S.C.
2	13951(a)(1)), as amended by section 13544(b)(2) of
3	OBRA-1993, is amended—
4	(i) by striking "and (P)" and insert "(P)";
5	and
6	(ii) by striking the semicolon at the end
7	and inserting the following: ", and (Q) with re-
8	spect to services for early detection of prostate
9	cancer (as defined in section 1861(ll)) (other
10	than prostate-specific antigen tests), the
11	amounts paid shall be the amounts described in
12	section 1834(d)(1);".
13	(C) Section 1833(a) of such Act (42 U.S.C.
14	13951(a)) is amended—
15	(i) by striking "and" at the end of para-
16	graph (6);
17	(ii) by striking the period at the end of
18	paragraph (7) and inserting "; and; and
19	(iii) by adding at the end the following new
20	paragraph:
21	"(8) in the case of services for early detection
22	of prostate cancer (as defined in section 1861(ll))
23	(other than prostate-specific antigen tests), the
24	amounts described in section 1834(d)(1).".

1	(D) Section 1833(h)(1)(A) of such Act (42
2	U.S.C. $13951(h)(1)(A)$ is amended by striking
3	"The Secretary" and inserting "Subject to section
4	1834(d), the Secretary".
5	(E) Section $1861(s)(2)(0)$ of such Act (42)
6	U.S.C. $1395x(s)(2)(0)$ is amended by striking
7	"(jj)" and inserting "(kk)".
8	(F) Section 1862(a) of such Act (42 U.S.C.
9	1395y(a)) is amended—
10	(i) in paragraph (1)—
11	(I) in subparagraph (E), by striking
12	"and" at the end,
13	(II) in subparagraph (F), by striking
14	the semicolon at the end and inserting ",
15	and", and
16	(III) by adding at the end the follow-
17	ing new subparagraph:
18	"(G) In the case of services (as defined in sec-
19	tion 1861(ll)) provided to an individual for the pur-
20	pose of early detection of prostate cancer, which are
21	performed more frequently than is covered under
22	section 1834(d)(2);"; and
23	(ii) in paragraph (7), by striking "para-
24	graph (1)(B) or under paragraph (1)(F)" and

inserting "subparagraphs (B), (F), or (G) of 1 2 paragraph (1)". 3 (b) COVERAGE OF CERTAIN DRUG TREATMENTS.— Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by subsection (a)(1), is further amended— 6 (1) by striking "and" at the end of subpara-7 graph (Q); 8 (2) by adding "and" at the end of subpara-9 graph (R); and 10 (3) by adding at the end the following new sub-11 paragraph: 12 "(S) an oral drug prescribed for the treatment 13 14 of prostate cancer, if the use of the drug for such 15 purpose is a medically accepted indication under subsection (t)(2);". 16 17 (c) Effective Date.—The amendments made by Section 1 shall apply to services provided on or after Janu-18 ary 1, 1996, without regard to whether or not the Sec-19 retary has established fee schedules under section 1834(d)(3) of the Social Security Act (as added by sub-21 section (a)(3)) or promulgated other regulations to carry

out such amendments by that date.

1	SEC. 3. COVERAGE OF SERVICES FOR EARLY DETECTION
2	AND TREATMENT OF PROSTATE CANCER IN
3	VETERANS.
4	(a) Prostate Cancer Early Detection and Di-
5	AGNOSIS DEFINED AS PREVENTIVE HEALTH SERVICES.—
6	Section 1701(9) of title 38, United States Code is amend-
7	ed—
8	(1) by redesignating subparagraphs (J) and (K)
9	as subparagraphs (K) and (L), respectively; and
10	(2) by inserting after subparagraph (I) the fol-
11	lowing new subparagraph (J):
12	"(J) early detection and diagnostic tests ap-
13	proved for prostate cancer,".
14	(b) Coverage of Early Detection and Treat-
15	MENT SERVICES FOR PROSTATE CANCER.—
16	(1) IN GENERAL.—Chapter 17 of title 38, Unit-
17	ed States Code, is amended by inserting after sec-
18	tion 1724 a new section as follows:
19	"§1725. Early Detection and Treatment of Prostate
20	Cancer
21	"(a) The Secretary shall include in the medical serv-
22	ices made available to veterans under this chapter appro-
23	priate services for early detection, counseling, treatment,
24	and information on prostate cancer. Based on the best
25	available medical evidence, the Secretary shall develop and
26	implement an appropriate schedule for early detection of

prostate cancer for those veterans confined to hospitals or

- other institutions. 3 "(b) for the purposes of this section— "(1) appropriate service for early detection of 4 5 prostate cancer means procedures provided to a man for the purpose of early detection of prostate cancer, 6 7 including digital rectal examinations, prostate-specific antigen 8 blood tests, and transactual ultrasonography; and 9 "(2) appropriate prostate cancer treatment in-10 cludes drugs approved by the Food and Drug Ad-11
- ministration for the treatment of prostate cancer.

 "(c) The Secretary may carry out research and research training in the diagnosis and treatment of prostate cancer based upon the prostate cancer services provided under this section and may develop guidelines outlining effective treatment regimens for prostate cancer."
- 18 (2) CLERICAL AMENDMENT.—The table of sec-19 tions at the beginning of such chapter is amended 20 by inserting after the item relating to section 1724 21 the following new item:

"1725. Early Detection and Treatment of Prostate Cancer.".

1	SEC. 4. RESEARCH AND EDUCATION REGARDING PROS-
2	TATE CANCER; CERTAIN PROGRAMS OF PUB-
3	LIC HEALTH SERVICE.
4	(a) NATIONAL INSTITUTES OF HEALTH.—Section
5	417B(c) of the Public Health Service Act (42 U.S.C.
6	285a-8(c)) is amended in the first sentence by striking
7	"72,000,000" and all that follows and inserting the follow-
8	ing: "\$86,000,000 for fiscal year 1996, \$100,000,000 for
9	fiscal year 1997, \$115,000,000 for fiscal year 1998, and
10	\$130,000,000 for fiscal year 1999.".
11	(b) Agency for Health Care Policy and Re-
12	SEARCH.—Section 902 of the Public Health Service Act
13	(42 U.S.C. 299a) is amended by adding at the end the
14	following subsection:
15	"(f) Activities Regarding Prostate Cancer.—
16	The Administrator shall, with respect to prostate cancer—
17	"(1) conduct and support research on the out-
18	comes, effectiveness, and appropriateness of health
19	services and procedures; and
20	"(2) in carrying out section 912(a), provide for
21	the development, periodic review, and updating of
22	clinically relevant guidelines, standards of quality,
23	performance measures, and medical review criteria.".