

106TH CONGRESS
1ST SESSION

S. 1626

To amend title XVIII of the Social Security Act to improve the process by which the Secretary of Health and Human Services makes coverage determinations for items and services furnished under the medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 23 (legislative day, SEPTEMBER 22), 1999

Mr. HATCH (for himself, Mr. NICKLES, Mr. BREAU, Mr. GRASSLEY, Mr. MURKOWSKI, and Mr. BAYH) 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 improve the process by which the Secretary of Health and Human Services makes coverage determinations for items and services furnished under the medicare program, and for other purposes.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Patient Access to Technology Act of 1999”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Establishment of Medicare Access to Technology Advisory Committee.
- Sec. 4. Annual adjustments to medicare payment systems for changes in technology and medical practice.
- Sec. 5. Treatment of new medical technologies under medicare OPD PPS.
- Sec. 6. Clarification of standard for medicare coverage of drugs and biologicals.
- Sec. 7. Process for making and implementing certain coding modifications.
- Sec. 8. Retention of HCPCS level III codes.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) In order to ensure genuine access of medi-
 4 care beneficiaries to medical technologies, the Sec-
 5 retary of Health and Human Services has an obliga-
 6 tion to integrate and coordinate its medical tech-
 7 nology coverage policy determination process with
 8 agency policies and practices that govern assignment
 9 of procedure codes, establishment and adjustment of
 10 payment levels and groupings, and issuance of time-
 11 ly instructions to contractors.

12 (2) The effectiveness of the medicare program
 13 in meeting beneficiary needs is compromised if ac-
 14 cess to state-of-the-art medical care is denied as a
 15 result of ineffective agency performance in the cov-
 16 erage, coding, or payment processes; or in the ineff-
 17 ective administrative execution of medical tech-
 18 nology decisions.

19 (3) The Secretary of Health and Human Serv-
 20 ices owes medicare beneficiaries the assurance that
 21 the various medicare payment systems (in both the

1 fee-for-service and managed care areas) are operated
2 in a way that reflects developments in, and improve-
3 ments upon, medical technology by properly setting
4 and adjusting payment levels and payment groups.

5 (4) Clear, predictable, and well-functioning cov-
6 erage, coding, and payment systems are particularly
7 critical to this Nation's small medical technology
8 companies, which are the originators of most med-
9 ical product innovations.

10 (5) Unless the administrators of the coverage,
11 coding, and payment systems under the medicare
12 program review products promptly, apply standards
13 appropriate for medical technology, and provide rea-
14 sonable reimbursement levels, small medical tech-
15 nology companies will experience difficulties in
16 bringing the benefits of medical innovation to medi-
17 care beneficiaries.

18 (6) By creating an internal task force to exam-
19 ine methods for integrating coverage, coding, and
20 payment decisions, the Secretary of Health and
21 Human Services has taken an important first step
22 toward preserving innovation, and should continue to
23 work to bring these 3 processes together.

1 **SEC. 3. ESTABLISHMENT OF MEDICARE ACCESS TO TECH-**
 2 **NOLOGY ADVISORY COMMITTEE.**

3 (a) IN GENERAL.—Title XVIII of the Social Security
 4 Act (42 U.S.C. 1395 et seq.) is amended by adding at
 5 the end the following:

6 “MEDICARE ACCESS TO TECHNOLOGY ADVISORY
 7 COMMITTEE

8 “SEC. 1897. (a) MEDICARE ACCESS TO TECHNOLOGY
 9 ADVISORY COMMITTEE.—

10 “(1) ESTABLISHMENT.—

11 “(A) IN GENERAL.—Not later than July 1,
 12 2001, the Secretary shall establish the Medicare
 13 Access to Technology Advisory Committee (in
 14 this subsection referred to as the ‘Committee’)
 15 under section 9(a)(1) of the Federal Advisory
 16 Committee Act for the purpose of securing ad-
 17 vice and recommendations on issues related to
 18 coverage, payment, and coding decisions.

19 “(B) CONSULTATION.—The Secretary
 20 shall consult with the Committee, and may con-
 21 sult directly with any panel of the Committee
 22 established under subsection (b)(1).

23 “(2) DUTIES.—The Committee, and the panels
 24 of the Committee, shall provide advice and rec-
 25 ommendations to the Secretary with respect to—

1 “(A) the issues referred to the Medicare
2 Coverage Advisory Committee (established by
3 the Secretary on November 24, 1998, notice of
4 which was published in the Federal Register on
5 December 14, 1998 (63 Fed. Reg. 68780));

6 “(B) policies regarding payment issues and
7 policies regarding coding issues under this title,
8 including identification of—

9 “(i) policies and mechanisms to help
10 ensure that payment and coding decisions
11 are made—

12 “(I) in a way that encourages ac-
13 cess to high-quality medical care
14 under this title;

15 “(II) through processes that
16 allow for significant public participa-
17 tion; and

18 “(III) expeditiously, in accord-
19 ance with specified timeframes for
20 each significant step in the process of
21 making such decisions;

22 “(ii) an equitable mechanism for de-
23 termining fee schedule payment amounts
24 for items and services, except for physi-

1 cians’ services (as defined in section
2 1861(q)); and

3 “(iii) processes for reconsideration
4 and appeal of determinations of fee sched-
5 ule payment amounts; and

6 “(C) the integration of policies on cov-
7 erage, payment, and coding under this title into
8 a process that ensures timely access to high-
9 quality medical care.

10 “(3) POLICIES REGARDING CODING ISSUES.—

11 “(A) For purposes of paragraph (2)(B),
12 policies regarding coding issues include any pol-
13 icy resulting from an action described in clause
14 (i) of subparagraph (B).

15 “(B)(i) An action described in this clause
16 is the action of any person to create, revise, up-
17 date, modify, adopt, edit, abridge, or otherwise
18 affect the form of a code used by the Secretary
19 in the operation of the program under this title.

20 “(ii) As used in clause (i), the term ‘code’
21 means any code included in level I or II of the
22 Health Care Financing Administration Com-
23 mon Procedure Coding System.

1 “(4) DURATION.—Section 14(a)(2)(B) of the
2 Federal Advisory Committee Act shall not apply to
3 the Committee.

4 “(b) COMMITTEE PROCEDURES.—In administering
5 the Committee under this section, the Secretary shall—

6 “(1) organize the Committee into panels of ex-
7 perts;

8 “(2) ensure participation on the Committee of
9 individuals who—

10 “(A) are experts in a variety of medical
11 specialties and fields of science, including—

12 “(i) specific areas of medical tech-
13 nology, including suppliers and manufac-
14 turers of clinical and diagnostic testing
15 supplies and durable medical equipment;

16 “(ii) medical research generally, in-
17 cluding experts in the study of treatment
18 outcomes; and

19 “(iii) other areas relevant to the du-
20 ties assigned to the Committee (taking into
21 account, as appropriate, any affiliations in-
22 dividuals may have with organizations pos-
23 sessing information, expertise, and other
24 resources that would contribute signifi-

1 cantly to the work of the Committee and
2 its panels);

3 “(B) are qualified by training and experi-
4 ence to evaluate the matters referred to the
5 Committee, including a representative of con-
6 sumer interests and a representative of the in-
7 terests of manufacturers of medical technology
8 on each panel; and

9 “(C) have adequately diversified back-
10 grounds so that the Committee will provide bal-
11 anced advice and recommendations;

12 “(3) permit each panel to independently advise
13 the Secretary with regard to matters referred to the
14 panel, without the need to obtain the concurrence of
15 the full Committee;

16 “(4) provide for—

17 “(A) full public participation, to the extent
18 required or permitted under law, in any meet-
19 ing of the Committee or its panels;

20 “(B) publication of notice of any such
21 meeting on the official Internet site of the De-
22 partment of Health and Human Services at
23 least 60 days before such meeting, including—

24 “(i) a statement of the issues to be
25 considered by the Committee or panel;

1 “(ii) a description of the specific in-
2 formation that is relevant to such issues;
3 and

4 “(iii) the text of any proposals the
5 Secretary will ask the Committee or panel
6 to consider;

7 “(C) consideration by the Committee or
8 panel of relevant information or testimony that
9 is submitted by the public;

10 “(D) public access in a central repository
11 to the information described in subparagraph
12 (C) at least 20 days before the meeting; and

13 “(E) the panels to meet at least once every
14 3 months unless there is no business to con-
15 duct;

16 “(5) require the Committee and its panels to
17 provide, with any recommendation, a summary of
18 the reasons for the recommendation and a summary
19 of the data upon which the recommendation is
20 based; and

21 “(6) make a verbatim transcript of each Com-
22 mittee and panel proceeding (other than those por-
23 tions that are closed to the public in accordance with
24 law) available to the public within 14 days on the of-

1 ficial Internet site of the Department of Health and
2 Human Services.”.

3 (b) TRANSITION, CONTINUING RESPONSIBILITY FOR
4 UNFINISHED DUTIES.—

5 (1) IN GENERAL.—Effective on the date the
6 Medicare Access to Technology Advisory Committee
7 is established, the Secretary of Health and Human
8 Services shall provide for the transfer to such com-
9 mittee of any assets and staff of the Medicare Cov-
10 erage Advisory Committee, without any loss of bene-
11 fits or seniority by virtue of such transfers.

12 (2) AVAILABILITY OF FUNDS.—Fund balances
13 available to the Medicare Coverage Advisory Com-
14 mittee for any period shall be available to the Medi-
15 care Access to Technology Advisory Committee for
16 such period for like purposes.

17 (c) REPORTING REQUIREMENTS.—

18 (1) Not later than December 1 of each year, be-
19 ginning with 2000, the Secretary of Health and
20 Human Services shall submit to Congress a report
21 describing the timeliness of the Secretary’s national
22 coverage policy decisionmaking during the preceding
23 fiscal year measured by the timeframes the Sec-
24 retary has published for the national coverage policy
25 determination process, and such report shall include

1 the actual time periods that were necessary to com-
2 plete and fully implement national coverage policy
3 determinations and each significant step in the proc-
4 ess.

5 (2) Not later than July 1, 2000, the Secretary
6 of Health and Human Services shall submit to Con-
7 gress a report, on the nature of the coverage policy
8 determination processes used by Medicare+Choice
9 organizations established under part C of title XVIII
10 of the Social Security Act (42 U.S.C. 1395w-21 et
11 seq.), including a detailed explanation of any steps
12 taken to ensure that the coverage policy determina-
13 tion processes under the Medicare+Choice program
14 established under such part—

15 (A) produce results consistent with the
16 coverage policy determinations reached under
17 parts A and B of such title (42 U.S.C. 1395 et
18 seq.); and

19 (B) treat any medical device being inves-
20 tigated under section 520(g) of the Federal
21 Food, Drug, and Cosmetic Act (42 U.S.C.
22 360j(g)), in a manner consistent with the treat-
23 ment afforded such medical device under parts
24 A and B of the Social Security Act (42 U.S.C.
25 1395 et seq.).

1 **SEC. 4. ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT**
2 **SYSTEMS FOR CHANGES IN TECHNOLOGY**
3 **AND MEDICAL PRACTICE.**

4 (a) IN GENERAL.—Title XVIII of the Social Security
5 Act (42 U.S.C. 1395 et seq.) is amended by inserting after
6 section 1888 the following:

7 “ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT SYS-
8 TEMS FOR CHANGES IN TECHNOLOGY AND MEDICAL
9 PRACTICE

10 “SEC. 1889. (a) IN GENERAL.—Notwithstanding any
11 other provision of this title, the Secretary shall adjust the
12 appropriate elements of the payment systems established
13 under sections 1833(i)(2)(A), 1833(t), 1848, and 1886(d)
14 (including relative payment weights, relative value units,
15 weighting factors, classifications, and case assignments) at
16 least annually to ensure that payments, classifications,
17 and assignments under such systems—

18 “(1) appropriately reflect changes in medical
19 technology and medical practice affecting the items
20 and services for which payment may be made under
21 such systems; and

22 “(2) promote the efficient and effective delivery
23 of high-quality health care.

24 “(b) RULES FOR DETERMINING ADJUSTMENTS.—
25 Except as provided in subsection (c), the provisions of sec-
26 tions 1833(i)(2)(A), 1833(t)(7), 1848(c)(2)(B), and

1 1886(d)(4)(C) shall apply to the annual adjustments re-
 2 quired by this section in the same manner and to the same
 3 extent as they apply to the adjustments of relative pay-
 4 ment weights, relative value units, weighting factors, clas-
 5 sification, and assignments, respectively, that are author-
 6 ized or required by such sections.

7 “(c) USE OF INTERNAL DATA COLLECTED BY THE
 8 SECRETARY.—

9 “(1) IN GENERAL.—In determining the adjust-
 10 ments required by this section, the Secretary may
 11 not—

12 “(A) decline to make an adjustment that is
 13 based on data collected by the Secretary in the
 14 administration of the program established
 15 under this title if the data reflect a representa-
 16 tive sample of cases that is statistically valid;
 17 and

18 “(B) establish a uniform period of time
 19 (such as 1 year) from which such data must be
 20 drawn.

21 “(2) DEADLINE FOR SUPPLYING INTERNAL
 22 DATA.—

23 “(A) IN GENERAL.—Subject to subpara-
 24 graph (B), the Secretary shall establish a rea-
 25 sonable deadline for the submission of data col-

1 lected by the Secretary to be used in making
2 the adjustments required by this section.

3 “(B) LIMITATION.—In no event may the
4 deadline established under subparagraph (A) be
5 more than 7 months before the first day of the
6 provider payment update period for which the
7 adjustment or adjustments to which the data
8 relates would be effective.

9 “(d) USE OF EXTERNAL DATA.—

10 “(1) IN GENERAL.—Subject to paragraph (2),
11 in determining the adjustments required by this sec-
12 tion, the Secretary shall utilize data other than data
13 collected by the Secretary in the administration of
14 the program established under this title if—

15 “(A) data collected by the Secretary in the
16 administration of such program are not avail-
17 able at the time such adjustments are being de-
18 termined; and

19 “(B) such other data are reliable and
20 verifiable.

21 “(2) EXTERNAL DATA FACILITATING THE USE
22 OF INTERNAL DATA.—In determining the adjust-
23 ments required by this section, the Secretary may
24 not—

1 “(A) decline to use data other than data
2 collected by the Secretary if such other data—

3 “(i) enable the Secretary to identify or
4 refine data collected by the Secretary for
5 use in making such an adjustment; and

6 “(ii) are based on a representative
7 sample of cases that is statistically valid;
8 or

9 “(B) establish a uniform period of time
10 (such as 1 year) from which such data must be
11 drawn.

12 “(3) ALTERNATIVE SOURCES OF DATA.—In de-
13 termining the adjustments required by this section,
14 the Secretary shall use data, that otherwise meets
15 the requirements of this subsection, collected by (or
16 on behalf of)—

17 “(A) private payers;

18 “(B) manufacturers of medical tech-
19 nologies;

20 “(C) suppliers;

21 “(D) groups representing physicians and
22 other health care professionals;

23 “(E) groups representing providers;

24 “(F) clinical trials; and

1 “(G) such other sources as the Secretary
2 determines to be appropriate.

3 “(4) CLARIFICATION.—Nothing in this title
4 shall be construed as—

5 “(A) requiring the Secretary to identify all
6 claims submitted under a payment system es-
7 tablished under section 1833(i)(2)(A), 1833(t),
8 1848, or 1886(d), involving the use of a medical
9 technology before the Secretary may make the
10 adjustments under this section (or under sec-
11 tion 1833(i)(2)(A), 1833(t), 1848, or 1886(d))
12 with respect to such technology; or

13 “(B) authorizing the Secretary to defer ac-
14 tion on such an adjustment until all such claims
15 are identifiable.

16 “(5) DEADLINE FOR SUPPLYING EXTERNAL
17 DATA.—The Secretary shall establish a reasonable
18 deadline for the submission of data other than data
19 collected by the Secretary to be used in making the
20 adjustments required by this section. In no event
21 may the deadline established under this paragraph
22 be more than 9 months before the first day of the
23 provider payment update period for which the ad-
24 justment or adjustments to which the data relates
25 would be effective.

1 “(e) TIMING OF ADJUSTMENTS.—

2 “(1) IN GENERAL.—The annual adjustments
3 required by this section shall—

4 “(A) apply to provider payment update pe-
5 riods beginning on or after October 1, 2000;
6 and

7 “(B) be described in the proposed and
8 final rules published by the Secretary with re-
9 spect to changes to a payment system estab-
10 lished under section 1833(i)(2)(A), 1833(t),
11 1848, or 1886(d), for the provider payment up-
12 date period to which they relate, together with
13 a description of the data on which such adjust-
14 ments are based.

15 “(2) PROVIDER PAYMENT UPDATE PERIOD DE-
16 FINED.—For purposes of this section, the term ‘pro-
17 vider payment update period’ means—

18 “(A) in the case of the payment systems
19 established under sections 1833(t) and 1848, a
20 calendar year; and

21 “(B) in the case of the payment systems
22 established under sections 1833(i)(2)(A) and
23 1886(d), a fiscal year beginning on October 1.”.

24 (b) CONFORMING AMENDMENTS.—

1 (1) AMBULATORY SURGICAL CENTERS.—Section
 2 1833(i)(2)(A) of the Social Security Act (42 U.S.C.
 3 1395l(i)(2)(A)) is amended by striking “Each” in
 4 the second sentence and inserting “Subject to sec-
 5 tion 1889, each”.

6 (2) OUTPATIENT HOSPITAL PROSPECTIVE PAY-
 7 MENT SYSTEM.—Section 1833(t)(6)(A) of such Act
 8 (42 U.S.C. 1395l(t)(6)(A)) is amended by striking
 9 “The” and inserting “Subject to section 1889, the”.

10 (3) PHYSICIAN PAYMENT.—Section
 11 1848(e)(2)(B)(i) of such Act (42 U.S.C. 1395w-
 12 4(c)(2)(B)(i)) is amended by striking “The” and in-
 13 serting “Subject to section 1889, the”.

14 (4) INPATIENT HOSPITAL PROSPECTIVE PAY-
 15 MENT SYSTEM.—Section 1886(d)(4)(C)(i) of such
 16 Act (42 U.S.C. 1395ww(d)(4)(C)(i)) is amended by
 17 striking “The” and inserting “Subject to section
 18 1889, the”.

19 **SEC. 5. TREATMENT OF NEW MEDICAL TECHNOLOGIES**
 20 **UNDER MEDICARE OPD PPS.**

21 (a) TEMPORARY EXCLUSION OF CERTAIN MEDICAL
 22 TECHNOLOGIES.—

23 (1) IN GENERAL.—Section 1833(t)(1) of the
 24 Social Security Act (42 U.S.C. 1395l(t)(1)) is
 25 amended—

1 (A) in subparagraph (B)(iii)—

2 (i) by inserting “(I)” after “include”;

3 (ii) by striking “or ambulance serv-
4 ices” and inserting “, (II) ambulance serv-
5 ices”; and

6 (iii) by striking “1834(l).” and insert-
7 ing “1834(l), or (III) for the time period
8 specified in clause (ii) of subparagraph
9 (C), the medical technologies described in
10 clause (i) of such subparagraph, except
11 that this subclause shall not be construed
12 to constitute the sole basis on which any
13 such medical technologies may be excluded
14 from the payment system established
15 under this subsection.”; and

16 (B) by adding at the end the following:

17 “(C) MEDICAL TECHNOLOGIES SUBJECT
18 TO TEMPORARY EXCLUSION.—

19 “(i) MEDICAL TECHNOLOGIES DE-
20 SCRIBED.—Subject to clause (v), the med-
21 ical technologies described in this clause
22 are the following:

23 “(I) Any medical technology that
24 was reimbursed as a hospital out-
25 patient service under this part during

1 1996 for which sufficient, reliable,
2 and verifiable data drawn from such
3 year is not available.

4 “(II) Any medical technology
5 that was not reimbursed as a hospital
6 outpatient service under this part dur-
7 ing 1996 but was reimbursed as such
8 a service as of the day before the date
9 on which the system established under
10 this subsection first took effect.

11 “(III) Subject to clause (iv), any
12 medical technology that was not reim-
13 bursed as a hospital outpatient service
14 under this part as of the day before
15 such system took effect but that is
16 payable as such a service on or after
17 the date on which such system first
18 took effect.

19 “(IV) Drugs or biological prod-
20 ucts used as treatment or supportive
21 care for patients with cancer, includ-
22 ing chemotherapeutic agents,
23 antiemetics, hematopoietic growth fac-
24 tors, colony stimulating factors, and
25 biological response modifiers.

1 “(V) Drugs or biological products
2 designated as a drug for a rare dis-
3 ease or condition under section 526 of
4 the Federal Food, Drug and Cosmetic
5 Act (21 U.S.C. 360bb) and approved
6 or licensed for introduction into inter-
7 state commerce by the Commissioner
8 of Food and Drugs.

9 “(VI) Drugs or biological prod-
10 ucts used for the treatment of end-
11 stage renal disease not included in the
12 composite rate under section 1881
13 and for which a payment methodology
14 is not specifically established by this
15 Act, other than by section 1842(o).

16 “(VII) Radiopharmaceutical
17 drugs or biological products used in
18 diagnostic, monitoring, and thera-
19 peutic nuclear medicine procedures.

20 “(VIII)(aa) Blood components
21 and blood products, including any
22 such component or product derived
23 from plasma fractionation or bio-
24 technology analog of such component
25 or product; and

1 “(bb) Any medical technology or
2 service used in connection with blood
3 transfusion, blood product exchange,
4 or other blood-related therapy, includ-
5 ing plasmapheresis, photopheresis,
6 hematopoietic stem cell collection or
7 replacement therapy.

8 “(IX) Drugs or biological prod-
9 ucts with respect to which the mean
10 cost for a dose exceeds the otherwise
11 applicable fee schedule amount under
12 the system established under this sub-
13 section by 2 standard deviations from
14 such mean.

15 “(ii) TIME PERIOD SPECIFIED.—Sub-
16 ject to clause (iii), the time periods speci-
17 fied in this clause are not less than—

18 “(I) for a medical technology de-
19 scribed in subclause (I) or (II) of
20 clause (i), the period that begins with
21 the date on which the system estab-
22 lished under this subsection first takes
23 effect and ends with (and includes)
24 the last day of the fourth calendar

1 year to begin on or after such date;
2 and

3 “(II) for a medical technology de-
4 scribed in subclause (III) of clause (i),
5 the period that begins with the date
6 on which a claim is first submitted
7 under this part with respect to such
8 technology and ends with (and in-
9 cludes) the last day of the fourth cal-
10 endar year to begin on or after such
11 date.

12 “(iii) PROCESS FOR INCLUSION OF
13 EXCLUDED MEDICAL TECHNOLOGIES.—No
14 medical technology excluded under clause
15 (i) may be designated as a covered OPD
16 service unless the Secretary completes the
17 following steps:

18 “(I) The Secretary shall assign a
19 unique code to the medical technology
20 to be designated as a covered OPD
21 service.

22 “(II) The Secretary shall issue
23 instructions for using any code as-
24 signed under subclause (I) and docu-
25 ment the usage of the medical tech-

1 nology to which the code is assigned
2 in the hospital outpatient department.

3 “(III) The Secretary shall require
4 hospitals to use the codes assigned
5 under subclause (I) for not less than
6 2 years.

7 “(IV) The Secretary shall obtain
8 sufficient, reliable, and verifiable cost
9 and utilization data from a represent-
10 ative group of hospitals that use the
11 medical technology, including hos-
12 pitals of different sizes, geographic lo-
13 cations, degrees of specialization,
14 case-mix, and the dependence of the
15 hospitals on funds provided under the
16 medicare program under this title and
17 the medicaid program under title
18 XIX.

19 “(V) The Secretary, based on the
20 data obtained under subclause (IV),
21 shall develop a proposed OPD service
22 classification for the medical tech-
23 nology, paying particular attention to
24 the potential of the proposed classi-
25 fication to create economic incentives

1 that could reduce patient access to the
2 medical technology.

3 “(VI) The Secretary shall publish
4 in the Federal Register a proposed
5 rule regarding the classification de-
6 scribed under subclause (V) and sup-
7 porting cost and utilization data.

8 “(VII) The Secretary shall pro-
9 vide for a comment period of not less
10 than 90 days, beginning on the date
11 on which the Secretary publishes the
12 proposed rule and supporting data de-
13 scribed in subclause (V).

14 “(iv) NEW TECHNOLOGIES DE-
15 SCRIBED.—As of the effective date of this
16 clause, the technologies to which clause
17 (i)(III) applies include—

18 “(I) existing technologies not
19 previously reimbursed as hospital out-
20 patient services;

21 “(II) newly developed tech-
22 nologies approved or licensed for in-
23 troduction into interstate commerce
24 by the Commissioner of Food and
25 Drugs after December 31, 1995; and

1 “(III) new applications of exist-
2 ing technologies.

3 “(v) LOW-COST MEDICAL TECH-
4 NOLOGIES.—The medical technologies de-
5 scribed in clause (i) do not include any
6 medical technology if the cost of such tech-
7 nology is insignificant in relation to the
8 OPD fee schedule amount (as calculated
9 under paragraph (3)(D)) payable for the
10 service (or group of services).

11 “(vi) MEDICAL TECHNOLOGY DE-
12 FINED.—For purposes of this subsection,
13 the term ‘medical technology’ means any
14 discrete and identifiable regimen or modal-
15 ity used to diagnose or treat illness, pre-
16 vent disease, maintain patient well-being,
17 or facilitate the provision of health care
18 services.

19 “(D) TREATMENT OF IMPLANTABLE DE-
20 VICES.—

21 “(i) PAYMENT BASIS DURING AND
22 AFTER EXCLUSION PERIOD.—If a medical
23 technology that is an implantable device is
24 excluded from the payment system estab-

lished under this subsection pursuant to
subparagraph (B)(iii)(III), such device—

“(I) shall be paid on the basis
described in subsection (a)(2)(B)(i)
during the period of such exclusion;
and

“(II) shall be paid for under the
system established under this sub-
section during the period following
such exclusion (and not under a fee
schedule established under subsection
(a) or (h) of section 1834).

“(ii) PAYMENT BASIS FOR DEVICES
WITH NO EXCLUSION PERIOD.—If a med-
ical technology that is an implantable de-
vice was not excluded from the payment
system established under this subsection
pursuant to subparagraph (B)(iii)(III)—

“(I) such device shall be included
in such system (and not a fee sched-
ule established under subsection (a) or
(h) of section 1834); and

“(II) in determining the relative
payment weights (described in para-
graph (2)(C)) for the service or group

1 of services within which such device is
 2 classified under such system, the Sec-
 3 retary shall meet the requirements of
 4 clause (iii).

5 “(iii) DETERMINATION OF RELATIVE
 6 PAYMENT WEIGHTS.—Subject to para-
 7 graph (11), in determining the relative
 8 payment weights described in clause
 9 (ii)(II) for an implantable device, the
 10 Secretary—

11 “(I) may not substitute data on
 12 the amount that would be paid for
 13 such device under a fee schedule es-
 14 tablished under subsection (a) or (h)
 15 of section 1843 for data on the
 16 amounts paid for such device under
 17 subsection (a)(2)(B)(i); and

18 “(II) shall rely solely on data on
 19 the amounts paid for such item or
 20 service under such subsection
 21 (a)(2)(B)(i).”.

22 (2) ADMINISTRATIVE AND JUDICIAL REVIEW.—
 23 Section 1833(t)(9) of the Social Security Act (42
 24 U.S.C. 1395l(t)(9)) is amended—

1 (A) by striking “LIMITATION ON RE-
 2 VIEW.—There” and inserting “LIMITATION ON
 3 REVIEW.—

4 “(A) IN GENERAL.—Subject to subpara-
 5 graph (B), there”; and

6 (B) by adding at the end the following:

7 “(B) RULE OF CONSTRUCTION.—This
 8 paragraph shall not be construed as limiting ad-
 9 ministrative or judicial review of determinations
 10 of whether a medical technology is required to
 11 be excluded from the payment system estab-
 12 lished under this subsection pursuant to para-
 13 graph (1)(B)(iii)(III).”.

14 (b) LIMITING VARIATION IN THE COSTS OF SERV-
 15 ICES CLASSIFIED WITHIN THE SAME GROUP.—Section
 16 1833(t)(2) of the Social Security Act (42 U.S.C.
 17 1395l(t)(2)) is amended by adding at the end the fol-
 18 lowing:

19 “For purposes of subparagraph (B), items and serv-
 20 ices within a group shall not be treated as ‘com-
 21 parable with respect to the use of resources’ if the
 22 highest mean cost for an item or service within the
 23 group is more than 2 times greater than the lowest
 24 mean cost for an item or service within the group.”.

1 (c) ANNUAL REVIEW OF OPD PPS COMPONENTS.—
 2 Section 1833(t)(6)(A) of the Social Security Act (42
 3 U.S.C. 1395l(t)(6)(A)) (as amended by section 4(b)(2))
 4 is amended by striking “may periodically review” and in-
 5 serting “shall review not less than annually”.

6 (d) SPECIAL RULES FOR EXCLUDED SERVICES.—

7 (1) UNADJUSTED CO-PAYMENT AMOUNT.—Sec-
 8 tion 1833(t)(3)(B) of the Social Security Act (42
 9 U.S.C 13951(t)(3)(B)) is amended—

10 (A) in clause (i), by inserting “or to a
 11 service excluded under paragraph (1)(C)” after
 12 “(or group of such services)”;

13 (B) in clause (ii), by inserting “or excluded
 14 service under paragraph (1)(C)” after “fur-
 15 nished in a year”; and

16 (C) by adding at the end the following:

17 “(iv) RULES FOR EXCLUDED SERV-
 18 ICES.—The Secretary shall establish rules
 19 for the establishment of an unadjusted co-
 20 payment amount for medical technologies
 21 excluded under paragraph (1)(C)(i) for
 22 which no national median of charges is
 23 available based on the unadjusted copay-
 24 ment amount for medical technologies with
 25 similar average wholesale prices.”.

1 (2) BENEFICIARY COST SHARING.—Section
 2 1833(t) of the Social Security Act (42 U.S.C.
 3 13951(t)) is amended.—

4 (A) by redesignating paragraphs (6)
 5 through (9) (as amended by subsections (a)(2)
 6 and (c) and section 4(b)(2)) as paragraphs (7)
 7 through (10), respectively; and

8 (B) by inserting after paragraph (5) the
 9 following:

10 “(6) PAYMENT AMOUNTS FOR EXCLUDED
 11 SERVICES—

12 “(B) COPAYMENT AMOUNT FOR EXCLUDED
 13 SERVICES—

14 “(i) IN GENERAL.—Except as pro-
 15 vided in clause (ii), the copayment amount
 16 for services excluded under subparagraph
 17 (1)(C) shall be the unadjusted copayment
 18 amount for such services as determined
 19 under paragraph (3)(B).

20 “(ii) EXCEPTION.—If the copayment
 21 amount determined under clause (i) is less
 22 than 20 percent of the reasonable cost as
 23 determined under subparagraph (A), the
 24 copayment amount shall be 20 percent of
 25 the reasonable cost as so determined.”.

1 (3) CONFORMING AMENDMENT.—Section
 2 1833(a)(2)(B)(i) is amended by striking “furnished
 3 before January 1, 1999,”.

4 (e) PAYMENT.—Section 1833(t) of the Social Secu-
 5 rity Act (42 U.S.C. 1395l(t)) is amended—

6 (1) by redesignating paragraph (10) (as redes-
 7 ignated by subsection (d)(2)(A)) as paragraph (12);
 8 and

9 (2) by inserting after paragraph (9) the fol-
 10 lowing:

11 “(10) PAYMENT DURING AND AFTER EXCLU-
 12 SION PERIOD.—

13 “(A) IN GENERAL.—Notwithstanding any
 14 other provision of this title, items and services
 15 excluded from the system established under this
 16 subsection pursuant to paragraph
 17 (1)(B)(iii)(III) (other than any implantable de-
 18 vices to which paragraph (1)(D) applies)—

19 “(i) shall be paid on the basis de-
 20 scribed in subsection (a)(2)(B)(i) during
 21 the period of such exclusion; and

22 “(ii) shall be paid for under the sys-
 23 tem established under this subsection dur-
 24 ing the period following such exclusion.

“(B) DETERMINING RELATIVE PAYMENT WEIGHTS.—Subject to paragraph (11), in determining the relative payment weights (described in paragraph (2)(C)) for the service or group of services within which an item or service is classified pursuant to the payment system established under this subsection, the Secretary—

“(i) may not substitute data on the amount that would be paid for such item or service under a fee schedule established under subsection (a) or (h) of section 1843 for data on the amounts paid for such device under subsection (a)(2)(B)(i); and

“(ii) shall rely solely on data on the amounts paid for such item or service under such subsection (a)(2)(B)(i).

“(11) EXCLUSION OF DATA FOR CERTAIN MEDICAL TECHNOLOGIES.—The Secretary may not utilize data with respect to a device for which an exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is in effect—

“(A) in determining whether there is adequate data with respect to the device for pur-

1 poses of clauses (i)(I) and (iii) of paragraph
2 (1)(C); or

3 “(B) in determining the relative payment
4 weights for the device pursuant to paragraph
5 (1)(D)(iii) or (10)(B).”.

6 (f) REQUIRED CONSULTATION BEFORE LIMITING
7 COVERAGE BY SITE OF SERVICE.—

8 (1) IN GENERAL.—Notwithstanding any other
9 provision of law, the Secretary may not implement
10 on or after September 8, 1998, any regulatory guid-
11 ance of the type described in paragraph (2) until the
12 Secretary has consulted with groups representing
13 hospitals, physicians, beneficiaries under the medi-
14 care program under title XVIII of the Social Secu-
15 rity Act (42 U.S.C. 1395 et seq.), and manufactur-
16 ers of medical technologies.

17 (2) REGULATORY GUIDANCE.—The types of
18 regulatory guidance described in this paragraph are
19 proposed, interim final, and final regulations, man-
20 ual instructions, statements of policy, and other
21 forms of regulatory guidance that would—

22 (A) deny coverage or payment for an item
23 or service under title XVIII of the Social Secu-
24 rity Act (42 U.S.C. 1395 et seq.) unless the

1 item or service is furnished on an inpatient
2 basis; or

3 (B) deny coverage or payment for an item
4 or service under such title unless the item or
5 service is furnished on an outpatient basis.

6 (g) BASIS FOR DETERMINING WEIGHTING FAC-
7 TORS.—Section 1833(t)(2)(C) of the Social Security Act
8 (42 U.S.C. 1395l(t)(2)(C)) is amended by striking “me-
9 dian” and inserting “mean”.

10 (h) BUDGET NEUTRALITY ADJUSTMENT.—The Sec-
11 retary of Health and Human Services shall make such ad-
12 justments to the amounts payable under section 1833(t)
13 of the Social Security Act (42 U.S.C. 1395l(t)) as may
14 be necessary to ensure that there is no increase or de-
15 crease in the expenditures under title XVIII of the Social
16 Security Act (42 U.S.C. 1395 et seq.) as a result of the
17 amendments made by this section.

18 (i) MONITORING ACCESS TO MEDICAL TECH-
19 NOLOGY.—

20 (1) MONITORING AND ANNUAL REPORTS OF
21 THE SECRETARY.—

22 (A) MONITORING ACCESS.—The Secretary
23 of Health and Human Services shall monitor
24 the utilization of medical technology in hospital
25 outpatient departments.

(B) ANNUAL REPORTS.—The Secretary of Health and Human Services shall annually submit to Congress a report on the utilization of the medical technology monitored under subparagraph (A) together with an analysis of the extent to which access by beneficiaries under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to new medical technologies is affected by the inclusion or exclusion of such technologies in the payment system established under section 1833(t) of such Act (42 U.S.C. 1395l(t)).

(2) COMMENTS AND REPORTS OF MEDPAC.—

(A) COMMENTS.—The Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) (in this paragraph referred to as “MedPAC”) shall submit to the Secretary of Health and Human Services comments on any proposed rule regarding the classification of medical technologies excluded from the prospective payment system established under section 1833 of the Social Security Act (42 U.S.C. 1395l(t)).

(B) ANNUAL REPORTS.—

1 (i) IN GENERAL.—MedPAC shall an-
2 nually submit to the appropriate commit-
3 tees of Congress a report on the changes
4 in utilization of and access to medical tech-
5 nologies furnished under title XVIII of the
6 Social Security Act (42 U.S.C. 1395 et
7 seq.) together with its recommendations
8 for such legislation and administrative ac-
9 tions as it considers appropriate to improve
10 access of beneficiaries under the medicare
11 program under title XVIII of the Social
12 Security Act (42 U.S.C. 1395 et seq.) to
13 appropriate medical technologies.

14 (ii) CONSULTATION.—In preparing
15 the annual report under clause (i),
16 MedPAC shall convene and consult a panel
17 of experts to evaluate the implications of
18 medical technology utilization patterns for
19 the quality of and access to care of bene-
20 ficiaries under the medicare program
21 under title XVIII of the Social Security
22 Act (42 U.S.C. 1395 et seq.).

23 (j) EFFECTIVE DATES.—The amendments made by
24 subsections (a), (b), (c), (d), (e), and (g) take effect as
25 if included in the amendments made by section 4523(a)

1 of the Balanced Budget Act of 1997 (Public Law 105–
2 33; 111 Stat. 445).

3 **SEC. 6. CLARIFICATION OF STANDARD FOR MEDICARE**
4 **COVERAGE OF DRUGS AND BIOLOGICALS.**

5 (a) IN GENERAL.—Section 1862(a) of the Social Se-
6 curity Act (42 U.S.C. 1395y(a)) is amended by adding at
7 the end the following: “A drug or biological may not be
8 excluded from coverage under this title by reason of para-
9 graph (1)(A) if the drug or biological has been approved
10 by the Food and Drug Administration and is prescribed
11 for a use that has been approved by the Food and Drug
12 Administration or that is supported by 1 or more citations
13 that are included (or approved for inclusion) in 1 or more
14 of the compendia referred to in section
15 1861(t)(2)(B)(ii)(I).”.

16 (b) EFFECTIVE DATE.—The amendment made by
17 subsection (a) shall apply to coverage determinations
18 made on or after the date of enactment of this Act.

19 **SEC. 7. PROCESS FOR MAKING AND IMPLEMENTING CER-**
20 **TAIN CODING MODIFICATIONS.**

21 (a) TIMELY ASSIGNMENT OF CODES.—

22 (1) IN GENERAL.—Notwithstanding title XVIII
23 of the Social Security Act (42 U.S.C. 1395 et seq.),
24 the Secretary of Health and Human Services (in this
25 section referred to as the “Secretary”) shall—

1 (A) accept recommendations for HCPCS
2 level II code modifications from the public
3 throughout the year;

4 (B) cause determinations on recommenda-
5 tions received during the 3 months immediately
6 preceding the last month of a calendar quarter
7 to be made not later than the first day of the
8 following calendar quarter; and

9 (C) implement approved modifications to
10 HCPCS level II codes established under title
11 XVIII of the Social Security Act (including the
12 medicare fee schedule database) with respect to
13 the payment system not later than 180 days
14 after the date on which the determination ap-
15 proving a modification was made.

16 (2) SPECIAL RULE FOR CERTAIN MEDICAL
17 TECHNOLOGIES.—For purposes of subparagraph
18 (C), any modification to a HCPCS level II code that
19 is implemented with respect to the payment systems
20 established under title XVIII of the Social Security
21 Act (including the medicare fee schedule database)
22 and that relates to a medical technology described in
23 section 1833(t)(1)(C)(i) of such Act shall be in ef-
24 fect only for—

1 (A) the purpose of permitting data to be
 2 collected with respect to such technology on the
 3 basis described in paragraph (1)(D)(i) or
 4 (10)(A)(i) (as amended by this Act) of section
 5 1833(t) of such Act; and

6 (B) the period for which such technology is
 7 excluded from such system pursuant to para-
 8 graph (1)(B)(iii)(III) of such section.

9 (b) ELIMINATION OF MARKETING EXPERIENCE RE-
 10 QUIREMENT.—Notwithstanding any provision of title
 11 XVIII of the Social Security Act, the Secretary may not
 12 require a minimum period of marketing experience with
 13 respect to a drug or device as a condition of consideration
 14 or approval of a recommendation for a HCPCS level II
 15 code modification for such drug or device.

16 (c) HCPCS LEVEL II CODE MODIFICATION DE-
 17 FINED.—For purposes of this section, the term “HCPCS
 18 level II code modification” means an addition, deletion,
 19 or change to the alpha-numeric codes for items not in-
 20 cluded in level I or level III of the Health Care Financing
 21 Administration Common Procedure Coding System
 22 (HCPCS).

23 (d) REPORT.—

24 (1) IN GENERAL.—Not later than 180 days
 25 after the date of enactment of this Act, the Sec-

1 retary of Health and Human Services shall submit
 2 to Congress a report on the feasibility and desir-
 3 ability of opening meetings of the Alpha-Numeric
 4 Editorial Panel of the Department of Health and
 5 Human Services to the public.

6 (2) REASONS FOR DETERMINATION.—If the
 7 Secretary determines that opening such meetings to
 8 the public is not feasible or desirable, the Secretary
 9 shall include in the report a detailed explanation of
 10 the reasons for such determination.

11 (e) EFFECTIVE DATE.—This section takes effect on
 12 January 1, 2000.

13 **SEC. 8. RETENTION OF HCPCS LEVEL III CODES.**

14 (a) IN GENERAL.—The Secretary of Health and
 15 Human Services shall maintain and continue the use of
 16 HCPCS level III codes (as in effect on June 1, 1999),
 17 and shall make such codes available to the public.

18 (b) HCPCS LEVEL III CODES DEFINED.—For pur-
 19 poses of this section, the term “HCPCS level III codes”
 20 means the alpha-numeric codes for local use under the
 21 Health Care Financing Administration Common Proce-
 22 dure Coding System (HCPCS).

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