

108TH CONGRESS
1ST SESSION

S. 823

To amend title XVIII of the Social Security Act to provide for the expeditious coverage of new medical technology under the medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 8, 2003

Mr. SANTORUM (for himself and Mrs. LINCOLN, Mr. JEFFORDS, Mr. KYL, Mr. COLEMAN, and Mrs. CLINTON) 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 the expeditious coverage of new medical technology 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; REFERENCES; TABLE OF CON-**
4 **TENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Medicare Innovation Responsiveness Act of 2003”.

7 (b) REFERENCES.—Except as otherwise specified,
8 whenever in this Act an amendment or repeal is expressed
9 in terms of an amendment to or repeal of a section or

1 other provision, the references shall be considered to be
 2 made to that section or other provision of the Social Secu-
 3 rity Act.

4 (c) TABLE OF CONTENTS.—The table of contents for
 5 this Act is as follows:

Sec. 1. Short title; references; table of contents.

TITLE I—PROVISIONS RELATING TO COVERAGE

Sec. 101. Deadlines for implementing national coverage, coding, and payment determinations.

Sec. 102. Council for Technology and Innovation.

Sec. 103. Improvements to the medicare coverage determination appeals process.

Sec. 104. Medicare coverage of routine costs associated with certain clinical trials.

TITLE II—PROVISIONS RELATING TO CODING

Sec. 201. Improvements to the HCPCS coding assignment, inpatient coding assignment, and DRG assignment processes.

Sec. 202. Process for adoption of ICD-10-PCS as data standard.

TITLE III—PROVISIONS RELATING TO PAYMENT

Sec. 301. Use of internal and external data for annual adjustments to hospital payment systems.

Sec. 302. Limitation on use of foreign payer data in determining medicare payment amounts.

Sec. 303. Recognition of new medical technologies under inpatient hospital PPS.

Sec. 304. Preservation of local medical review process under medicare administrative contractor reforms.

Sec. 305. Inherent reasonableness.

1 **TITLE I—PROVISIONS RELATING**
2 **TO COVERAGE**

3 **SEC. 101. DEADLINES FOR IMPLEMENTING NATIONAL COV-**
4 **ERAGE, CODING, AND PAYMENT DETERMINA-**
5 **TIONS.**

6 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y)
7 is amended by inserting after subsection (c) the following
8 new subsection:

9 “(d)(1)(A)(i) Subject to the succeeding provisions of
10 this paragraph, upon receipt of a request for a national
11 coverage determination from an interested party, the Sec-
12 retary shall make and implement (if applicable) the na-
13 tional coverage determination for that new technology
14 within the following time frames:

15 “(I) In the case of a national coverage deter-
16 mination that does not require a technology assess-
17 ment described in subparagraph (D), not later than
18 the end of the 6-month period that begins on the
19 date a request for the national coverage determina-
20 tion has been received by the Secretary, notwith-
21 standing the receipt by the Secretary of new evi-
22 dence (if any) during such period.

23 “(II) In the case of a national coverage deter-
24 mination that requires such a technology assess-
25 ment, not later than the end of the 12-month period

1 that begins on the date a request for the national
2 coverage determination has been received by the Sec-
3 retary.

4 “(ii) In this subparagraph—

5 “(I) the term ‘implement’ includes determining
6 what code, if any, is assigned to the particular item
7 or service; determining the amount of payment to be
8 made under this title for the item or service; assign-
9 ing the item or service, and codes for the item or
10 service, to appropriate payment groups; incor-
11 porating the coverage, coding, and payment deter-
12 minations into the information processing systems of
13 the Secretary and fiscal intermediaries and carriers;
14 and taking such other steps as are necessary to
15 make payments for the item or service no later than
16 the end of the applicable period described in clause
17 (i); and

18 “(II) the term ‘interested party’ means individ-
19 uals entitled to benefits under part A, or enrolled
20 under part B, or both, who are in need of the items
21 or services that are the subject of the coverage de-
22 termination, providers of services, physicians, practi-
23 tioners, suppliers, and manufacturers of such items
24 or services.

1 “(B) In making a national coverage determination
2 under this subsection, the Secretary shall take one of the
3 following actions:

4 “(i) Issue a national coverage determination,
5 with or without limitations.

6 “(ii) Issue a national noncoverage determina-
7 tion.

8 “(iii) Issue a determination that no national
9 coverage or noncoverage determination is appro-
10 priate as of the end of such period with respect to
11 national coverage of such items or services.

12 “(C) If the Secretary fails to take an action under
13 subparagraph (B) within the applicable period under sub-
14 paragraph (A)(i), the Secretary shall issue a notice that
15 includes the following information:

16 “(i) A statement that the Secretary cannot
17 make and (if applicable) implement (as defined in
18 subparagraph (A)(ii)(I)) a national coverage deter-
19 mination within the applicable time period.

20 “(ii) The identification of substantive issues
21 outstanding.

22 “(iii) A statement of what is required, including
23 the process involved, to resolve those issues.

24 “(iv) The date by which the Secretary will make
25 a national coverage determination under subpara-

1 graph (B) and (if applicable) implement the national
2 coverage determination.

3 “(D)(i) A technology assessment referred to in sub-
4 paragraph (A) is a formal, written technology assessment,
5 conducted by an entity or organization other than the Cen-
6 ters for Medicare & Medicaid Services (in this subpara-
7 graph referred to as the ‘CMS’), or review by an advisory
8 committee appointed to advise the Administrator of the
9 CMS on matters relating to the interpretation, applica-
10 tion, or implementation of subsection (a), that the Admin-
11 istrator reasonably finds, in a written notice issued before
12 the end of the 6-month period specified in subparagraph
13 (A)(i), that such an assessment or review is necessary for
14 the Administrator to make the national coverage deter-
15 mination.

16 “(ii) Such technology assessment or review shall only
17 be considered necessary if the CMS lacks adequate exper-
18 tise to evaluate the matter itself.

19 “(E) In making a national coverage determination
20 under subparagraph (B), the Secretary shall include all
21 the information described in subparagraphs (C) and (D)
22 of paragraph (2), and in the case of the implementation
23 of the national coverage determination, applicable codes
24 and payment amounts for the new item or service.

1 “(2) In making a national coverage determination (as
2 defined in section 1869(f)(1)(B)) the Secretary shall en-
3 sure that—

4 “(A) the public is afforded notice and oppor-
5 tunity to comment prior to implementation by the
6 Secretary of the determination;

7 “(B) meetings of advisory committees estab-
8 lished under section 1114(f) with respect to the de-
9 termination are made on the record;

10 “(C) in making the determination, the Sec-
11 retary has considered applicable information (includ-
12 ing clinical experience and medical, technical, and
13 scientific evidence) with respect to the subject mat-
14 ter of the determination;

15 “(D) in issuing the determination, provide a
16 clear statement of the basis for the determination
17 (including responses to comments received from the
18 public) and the assumptions underlying that basis;
19 and

20 “(E) make available to the public the data
21 (other than proprietary data) considered in making
22 the determination.”.

23 (b) CONFORMING AMENDMENT.—Subsection (a) of
24 such section is amended by striking the third sentence.

1 (c) EFFECTIVE DATE.—The amendments made by
 2 this section shall take effect on the date of the enactment
 3 of this Act, and apply to requests for national coverage
 4 determinations made on or after the date that is 90 days
 5 after such effective date.

6 **SEC. 102. COUNCIL FOR TECHNOLOGY AND INNOVATION.**

7 Section 1868 (42 U.S.C. 1395ee) is amended—

8 (1) by adding at the end of the heading the fol-
 9 lowing: “; COUNCIL FOR TECHNOLOGY AND
 10 INNOVATION”;

11 (2) by inserting “PRACTICING PHYSICIANS AD-
 12 VISORY COUNCIL.—(1)” after “(a)”;

13 (3) in paragraph (1), as so redesignated under
 14 paragraph (2), by striking “in this section” and in-
 15 serting “in this subsection”;

16 (4) by redesignating subsections (b) and (c) as
 17 paragraphs (2) and (3), respectively; and

18 (5) by adding at the end the following new sub-
 19 section:

20 “(c) COUNCIL FOR TECHNOLOGY AND INNOVA-
 21 TION.—

22 “(1) ESTABLISHMENT.—The Secretary shall es-
 23 tablish a Council for Technology and Innovation
 24 within the Centers for Medicare & Medicaid Services
 25 (in this section referred to as ‘CMS’).

1 “(2) COMPOSITION.—The Council shall be com-
2 posed of senior CMS staff and clinicians and shall
3 be chaired by the Executive Coordinator for Tech-
4 nology and Innovation (appointed or designated
5 under paragraph (4)).

6 “(3) DUTIES.—The Council shall coordinate the
7 activities of coverage, coding, and payment processes
8 with respect to new technologies and procedures, in-
9 cluding new drug therapies, under this title in order
10 to expedite patient access to new technologies and
11 therapies.

12 “(4) EXECUTIVE COORDINATOR FOR TECH-
13 NOLOGY AND INNOVATION.—The Secretary shall ap-
14 point (or designate) a noncareer appointee (as de-
15 fined in section 3132(a)(7) of title 5, United States
16 Code) who shall serve as the Executive Coordinator
17 for Technology and Innovation. Such executive coor-
18 dinator shall report to the Administrator of CMS,
19 shall chair the Council, shall oversee the execution of
20 its duties, shall serve as a single point of contact for
21 outside groups and entities regarding the coverage,
22 coding, and payment processes under this title, and
23 shall prepare reports to Congress required under
24 section 1869(f)(7).”.

1 **SEC. 103. IMPROVEMENTS TO THE MEDICARE COVERAGE**

2 **DETERMINATION APPEALS PROCESS.**

3 (a) IN GENERAL.—Section 1869(f) (42 U.S.C.
4 1395ff(f)) is amended—

5 (1) in paragraph (1)(A)(iii)—

6 (A) in subclause (I)—

7 (i) by inserting “(in all forms, includ-
8 ing written and oral depositions, interrog-
9 atories, and requests for admission)” after
10 “discovery”; and

11 (ii) by inserting “and shall determine
12 when any new evidence not previously con-
13 sidered by the Centers for Medicare &
14 Medicaid Services (hereafter in this sub-
15 section referred to as ‘CMS’) is material
16 and should first be considered by CMS”
17 after “determination” the second place it
18 appears; and

19 (B) by redesignating subclauses (II) and
20 (III) as subclauses (III) and (IV), respectively,
21 and inserting after subclause (I) the following:

22 “(II) shall determine when a
23 complaint has become moot;”;

24 (2) in paragraph (1)(A)(v), by adding at the
25 end the following: “Such a decision shall be imple-
26 mented not later than 30 days after receipt of the

1 decision, and any request for a stay of such imple-
 2 mentation pending further appeal or reconsideration
 3 shall be supported by evidence demonstrating a ma-
 4 terial risk of irreparable harm.”;

5 (3) in paragraph (2)(A)(i)—

6 (A) in subclause (I)—

7 (i) by inserting “(in all forms, includ-
 8 ing but not limited to, written and oral
 9 depositions, interrogatories, and requests
 10 for admission)” after “discovery”; and

11 (ii) by inserting “and shall determine
 12 when any new evidence not previously con-
 13 sidered by CMS material and should first
 14 be considered by CMS” after “determina-
 15 tion” the second place it appears; and

16 (B) by redesignating subclauses (II) and
 17 (III) as subclauses (III) and (IV), respectively,
 18 and inserting after subclause (I) the following:

19 “(II) shall determine when a
 20 complaint has become moot;”;

21 (4) by adding at the end of paragraph (2)(A)
 22 the following:

23 “(v) Any request for a stay of a deci-
 24 sion pending further appeal or reconsider-
 25 ation shall be supported by evidence dem-

1 onstrating a material risk of irreparable
2 harm.”;

3 (5) in paragraph (5)—

4 (A) by inserting “(or the heirs or assignees
5 of such individuals)” after “individuals”; and

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

7 “For purposes of the preceding sentence, indi-
8 viduals ‘in need of an item or service’ include
9 individuals for whom a claim for the item or
10 service is denied prior to appeal, without regard
11 to whether or not such individual obtains such
12 item or service after such denial.”; and

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

14 “(9) PROMULGATION OF REGULATIONS.—The
15 Departmental Appeals Board (and any successor en-
16 tity) shall have the exclusive authority to promulgate
17 regulations interpreting this subsection. Such regula-
18 tions shall not be subject to review by the Secretary
19 or the Office of Management and Budget, but are
20 instead deemed to be subject to the review process
21 established by sections 801 through 808 of title 5,
22 United States Code. No regulations shall be issued
23 to interpret this subsection unless such regulations
24 are issued by the Departmental Appeals Board.”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 subsection (a) shall apply to any local or national coverage
3 determination made on or after January 1, 2004.

4 **SEC. 104. MEDICARE COVERAGE OF ROUTINE COSTS ASSO-**
5 **CIATED WITH CERTAIN CLINICAL TRIALS.**

6 (a) IN GENERAL.—With respect to the coverage of
7 routine costs of care for beneficiaries participating in a
8 qualifying clinical trial, as set forth on the date of the en-
9 actment of this Act in National Coverage Determination
10 30–1 of the Medicare Coverage Issues Manual, the Sec-
11 retary shall deem clinical trials conducted in accordance
12 with an investigational device exemption approved under
13 section 520(g) of the Federal Food, Drug, and Cosmetic
14 Act (42 U.S.C. 360j(g)) to be automatically qualified for
15 such coverage.

16 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
17 tion shall be construed as authorizing or requiring the Sec-
18 retary to modify the regulations set forth on the date of
19 the enactment of this Act at subpart B of part 405 of
20 title 42, Code of Federal Regulations, or subpart A of part
21 411 of such title, relating to coverage of, and payment
22 for, a medical device that is the subject of an investiga-
23 tional device exemption by the Food and Drug Adminis-
24 tration (except as may be necessary to implement sub-
25 section (a)).

1 (c) EFFECTIVE DATE.—This section shall apply to
 2 clinical trials begun before, on, or after the date of the
 3 enactment of this Act and to items and services furnished
 4 on or after such date.

5 **TITLE II—PROVISIONS** 6 **RELATING TO CODING**

7 **SEC. 201. IMPROVEMENTS TO THE HCPCS CODING ASSIGN-** 8 **MENT, INPATIENT CODING ASSIGNMENT, AND** 9 **DRG ASSIGNMENT PROCESSES.**

10 (a) INPATIENT PPS.—Section 1886(d)(5)(K) (42
 11 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the
 12 end the following new clause:

13 “(vii)(I) The Secretary shall by regu-
 14 lation establish a process that provides for
 15 the assignment of inpatient hospital codes
 16 (as defined in clause (iii)) for new medical
 17 services and related technologies as of
 18 April 1 of each year (beginning with
 19 2003).

20 “(II) Such process shall provide for
 21 the opportunity to apply for the assign-
 22 ment of an inpatient hospital code to items
 23 that are the subject of an application sub-
 24 mitted for investigation under section

1 520(g) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 360j(g)).

3 “(III) The assignment of codes as of
4 the date specified in subclause (I) shall not
5 require the Secretary to adjust the pay-
6 ment (or diagnosis-related group classifica-
7 tion) under this subsection until the first
8 fiscal year that begins after such date.”.

9 (b) HCPCS LEVEL II CODES.—

10 (1) PROCESS FOR ASSIGNMENT OF CODES FOR
11 NEW TECHNOLOGIES.—The Secretary of Health and
12 Human Services (in this section referred to as the
13 “Secretary”) shall by regulation establish a process
14 that provides for the assignment of HCPCS Level II
15 codes each calendar quarter for new medical services
16 and technologies. Such process shall ensure that
17 codes are assigned and implemented no later than
18 180 days after a formal application for such a code
19 is received.

20 (2) ELIMINATION OF MINIMUM PERIOD OF MAR-
21 KETING EXPERIENCE REQUIREMENT.—The Sec-
22 retary may not condition consideration or approval
23 of an application for a HCPCS Level II code on hav-
24 ing a minimum period of marketing experience with

1 the item or product that is the subject of the appli-
2 cation.

3 (3) DEFINITION.—In this subsection, the term
4 “HCPCS Level II codes” means the level II alpha-
5 numeric codes under the Healthcare Common Proce-
6 dure Coding System (HCPCS).

7 (c) PROCEDURES FOR ISSUANCE OF TEMPORARY NA-
8 TIONAL HCPCS CODES.—Not later than December 31,
9 2003, the Secretary shall implement revised procedures
10 for the issuance of temporary national HCPCS codes for
11 use in the submission of claims for items and services
12 under Part B of title XVIII of the Social Security Act.
13 Such procedures shall provide for—

14 (1) the issuance of a determination with respect
15 to a temporary national HCPCS coding request
16 within 90 days of receipt of a request from any in-
17 terested party;

18 (2) the implementation of any codes subject to
19 a positive determination under paragraph (1) not
20 later than 180 days after receipt of the submission
21 of the original coding request;

22 (3) upon the receipt of a request from a fiscal
23 intermediary with an agreement under section 1816
24 of the Social Security Act (42 U.S.C. 1395h) or a
25 carrier with a contract under section 1842 of such

1 Act (42 U.S.C. 1395u), the automatic issuance of
 2 temporary national HCPCS codes for any item or
 3 service that is the subject of a local medical review
 4 policy issued by such intermediary or carrier with re-
 5 spect to whether such item or service is covered
 6 under title XVIII of such Act in a geographic area
 7 served by such intermediary or carrier; and

8 (4) the public posting of, and opportunity for
 9 public comment on, pending coding requests.

10 **SEC. 202. PROCESS FOR ADOPTION OF ICD-10-PCS AS DATA**
 11 **STANDARD.**

12 Section 1172(f) (42 U.S.C. 1320d-1(f)) is amended
 13 by inserting after the first sentence the following: “Not-
 14 withstanding the preceding sentence, if the National Com-
 15 mittee on Vital and Health Statistics has not made a rec-
 16 ommendation to the Secretary before April 1, 2003, with
 17 respect to the adoption of the International Classification
 18 of Diseases, 10th Revision, Procedure Coding System
 19 (‘ICD-10-PCS’) as a standard under this part for the re-
 20 porting of inpatient hospital services, the Secretary may
 21 adopt ICD-10-PCS as such a standard on or after such
 22 date without receiving such a recommendation.”.

TITLE III—PROVISIONS RELATING TO PAYMENT

SEC. 301. USE OF INTERNAL AND EXTERNAL DATA FOR ANNUAL ADJUSTMENTS TO HOSPITAL PAYMENT SYSTEMS.

(a) INPATIENT HOSPITAL PPS.—Section 1886(d)(4) (42 U.S.C. 1395ww(d)(4)) is amended by adding at the end the following new subparagraphs:

“(D)(i) In determining annual adjustments under subparagraph (C), the Secretary may not—

“(I) decline to use internal data if the data reflect a representative sample of cases; or

“(II) establish a minimum period of time (such as one year) from which such data must be drawn.

“(ii) The Secretary shall establish a reasonable deadline for the submission of a request for adjustment based on internal data to be used in making the adjustments required by subparagraph (C). In no event may the deadline established under this clause be more than 8 months before the first day of the payment update period for which the adjustment or adjustments to which the data relate would be effective.

“(E)(i) Subject to the succeeding provisions of this subparagraph, in determining the adjustments under sub-

1 paragraph (C), the Secretary shall utilize external data if
2 such data are based on a representative sample of cases.

3 “(ii) In determining the adjustments under subpara-
4 graph (C), the Secretary may not—

5 “(I) decline to use external data submitted for
6 consideration under the process established under
7 clause (iv) if such data enable the Secretary to iden-
8 tify or refine internal data for use in making such
9 an adjustment and such data are based on a rep-
10 resentative sample of cases; or

11 “(II) establish a minimum period of time (such
12 as one year) from which such data must be drawn.

13 “(iii) Nothing in this clause shall be construed as re-
14 quiring the Secretary to identify all claims submitted
15 under the payment system established under this sub-
16 section involving the use of a medical technology before
17 the Secretary may make the adjustments under subpara-
18 graph (C) with respect to such technology; or as author-
19 izing the Secretary to defer action on such an adjustment
20 until all such claims are identifiable.

21 “(iv) The Secretary shall establish a process for the
22 submission of external data by interested parties. Such
23 process shall include reasonable deadline for the submis-
24 sion of external data to be used in making the adjustments
25 required by subparagraph (C). In no event may the dead-

1 line established under this subclause be more than 10
 2 months before the first day of the payment update period
 3 for which the adjustment or adjustments to which the data
 4 relate would be effective.

5 “(F) For purposes of subparagraphs (D) and (E)—

6 “(i) the term ‘external data’ means data from
 7 sources other than data collected by the Secretary in
 8 the administration of the program established under
 9 this title;

10 “(ii) the term ‘interested party’ means individ-
 11 uals entitled to benefits under part A, or enrolled
 12 under part B, or both, who are in need of the items
 13 or services that are the subject of the coverage de-
 14 termination, providers of services, physicians, practi-
 15 tioners, suppliers, and manufacturers of such items
 16 or services; and

17 “(iii) the term ‘internal data’ means data that
 18 is collected by the Secretary in the administration of
 19 the program established under this title.”.

20 (b) OUTPATIENT HOSPITAL PPS.—Section
 21 1833(t)(9) (42 U.S.C. 1395l(t)(9)) is amended by adding
 22 at the end the following new subparagraphs:

23 “(D) USE OF INTERNAL DATA COLLECTED
 24 BY THE SECRETARY.—

1 “(i) IN GENERAL.—In determining
2 annual adjustments under subparagraph
3 (A), the Secretary may not use internal
4 data that does not—

5 “(I) reflect a representative sam-
6 ple of cases that include the specific
7 procedure that is subject to such ad-
8 justment; and

9 “(II) accurately reflect the costs
10 of providing the item or service, based
11 on all forms of information that is
12 available to the Secretary.

13 “(ii) DEADLINE FOR SUPPLYING IN-
14 TERNAL DATA.—The Secretary shall estab-
15 lish a reasonable deadline for the submis-
16 sion of a request for adjustment based on
17 internal data to be used in making the ad-
18 justments required by subparagraph (A).
19 In no event may the deadline established
20 under this paragraph be more than 8
21 months before the first day of the payment
22 update period for which the adjustment or
23 adjustments to which the data relate would
24 be effective.

25 “(E) EXTERNAL DATA.—

1 “(i) IN GENERAL.—Subject to the
 2 succeeding provisions of this subparagraph,
 3 in determining the adjustments under sub-
 4 paragraph (A), the Secretary shall utilize
 5 external data submitted for consideration
 6 under the process established under clause
 7 (iv) if such data are based on a representa-
 8 tive sample of cases.

9 “(ii) EXTERNAL DATA FACILITATING
 10 THE USE OF INTERNAL DATA.—In deter-
 11 mining the adjustments under subpara-
 12 graph (A), the Secretary may not—

13 “(I) decline to use external data
 14 if such data enable the Secretary to
 15 identify or refine data so collected for
 16 use in making such an adjustment
 17 and such data are based on a rep-
 18 resentative sample of cases; or

19 “(II) establish a minimum period
 20 of time (such as one year) from which
 21 such data must be drawn.

22 “(iii) CLARIFICATION.—Nothing in
 23 this subparagraph shall be construed as re-
 24 quiring the Secretary to identify all claims
 25 submitted under the payment system es-

1 tablished under this subsection involving
 2 the use of a medical technology before the
 3 Secretary may make the adjustments
 4 under this subparagraph with respect to
 5 such technology; or as authorizing the Sec-
 6 retary to defer action on such an adjust-
 7 ment until all such claims are identifiable.

8 “(iv) DEADLINE FOR SUPPLYING EX-
 9 TERNAL DATA.—The Secretary shall estab-
 10 lish a process for the submission of exter-
 11 nal data by interested parties. Such proc-
 12 ess shall include a reasonable deadline for
 13 the submission of external data to be used
 14 in making the adjustments required by
 15 subparagraph (A). In no event may the
 16 deadline established under this subclause
 17 be more than 10 months before the first
 18 day of the payment update period for
 19 which the adjustment or adjustments to
 20 which the data relate would be effective.

21 “(F) DEFINITIONS.—For purposes of sub-
 22 paragraphs (D) and (E)—

23 “(i) the term ‘external data’ means
 24 data from sources other than data col-
 25 lected by the Secretary in the administra-

tion of the program established under this title;

“(ii) the term ‘interested party’ means individuals entitled to benefits under part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination, providers of services, physicians, practitioners, suppliers, and manufacturers of such items or services; and

“(iii) the term ‘internal data’ means data that is collected by the Secretary in the administration of the program established under this title.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to items and services furnished on or after October 1, 2003.

SEC. 302. LIMITATION ON USE OF FOREIGN PAYER DATA IN DETERMINING MEDICARE PAYMENT AMOUNTS.

(a) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may not, in determining the amount to be paid for any item or service for which payment is made under title XVIII of the Social Security Act (42 U.S.C. 1395b et seq.)

1 that is furnished in the United States, take into account
 2 or utilize (or authorize an administrative contractor to
 3 take into account or utilize) any data or information on
 4 the amount that is paid by any payer for the same (or
 5 a similar) item or service provided outside the United
 6 States.

7 (b) DEFINITIONS.—For purposes of this section—

8 (1) the term “administrative contractor” means
 9 an entity with a contract under section 1816 of the
 10 Social Security Act (42 U.S.C. 1395h), section 1842
 11 of such Act (42 U.S.C. 1395u), or any other provi-
 12 sion of such title to determine the amount to be paid
 13 for any item or service provided under such title or
 14 to make payments for such services; and

15 (2) the term “United States” has the meaning
 16 given to such term in section 1862(a)(4) of the So-
 17 cial Security Act (42 U.S.C. 1395y(a)(4)).

18 **SEC. 303. RECOGNITION OF NEW MEDICAL TECHNOLOGIES**

19 **UNDER INPATIENT HOSPITAL PPS.**

20 (a) ELIGIBILITY STANDARD.—

21 (1) MINIMUM PERIOD FOR RECOGNITION OF
 22 NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi)
 23 (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

24 (A) by inserting “(I)” after “(vi)”; and

1 (B) by adding at the end the following new
 2 subclause:

3 “(II) Under such criteria, a service or technology may
 4 not be denied treatment as a new service or technology
 5 on the basis that the service or technology has been on
 6 the market or available for a period of not less than 2
 7 years and not more than 3 years unless during the entire
 8 period—

9 “(aa) the service or technology is available for
 10 use as a service or technology cleared for marketing
 11 under section 510(k) of the Federal Food, Drug,
 12 and Cosmetic Act or approved for market under sec-
 13 tion 515 of such Act; and

14 “(bb) a code facilitating data collection is in ef-
 15 fect with respect to the service or technology.

16 For purposes of the preceding sentence, a ‘code facilitating
 17 data collection’ means, with respect to a service or tech-
 18 nology, a code under the ICD–9–CM coding system (or
 19 a successor coding system) that enables the collection of
 20 data on the costs of the service or technology in a signifi-
 21 cant sample of specific discharges in which the service or
 22 technology is used.”.

23 (2) ADJUSTMENT OF THRESHOLD.—Section
 24 1886(d)(5)(K)(ii)(I) (42 U.S.C.
 25 1395ww(d)(5)(K)(ii)(I)) is amended by inserting

1 “(applying a threshold computed by the Secretary
 2 that is the lesser of 50 percent of the national average
 3 standardized amount for operating costs of inpatient
 4 hospital services for all hospitals and all diagnosis-
 5 related groups or one standard deviation for the diag-
 6 nosis-related group involved)” after “is inadequate”.

7 (3) CRITERIA FOR SUBSTANTIAL IMPROVE-
 8 MENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C.
 9 1395ww(d)(5)(K)(vi)), as amended by paragraph
 10 (1), is further amended by adding at the end the fol-
 11 lowing subclause:

12 “(III) The Secretary shall by regulation provide for
 13 further clarification of the criteria applied to determine
 14 whether a new service or technology represents an advance
 15 in medical technology that substantially improves the diag-
 16 nosis or treatment of beneficiaries. Under such criteria,
 17 in determining whether a new service or technology rep-
 18 resents an advance in medical technology that substan-
 19 tially improves the diagnosis or treatment of beneficiaries,
 20 the Secretary shall deem a service or technology as meet-
 21 ing such requirement if the service or technology is a drug
 22 or biological that is designated under section 506 or 526
 23 of the Federal Food, Drug, and Cosmetic Act, approved
 24 under section 314.510 or 601.41 of title 21, Code of Fed-
 25 eral Regulations, or designated for priority review when

1 the marketing application for such drug or biological was
 2 filed or is a medical device for which an exemption has
 3 been granted under section 520(m) of such Act, or for
 4 which priority review has been provided under section
 5 515(d)(5) of such Act. Nothing in the preceding sentence
 6 shall be construed as limiting the application of section
 7 1862(a)(1) to a new service or technology described in
 8 such sentence or as limiting the authority of the Secretary
 9 to make determinations under such section with respect
 10 to such a service or technology.”.

11 (b) PREFERENCE FOR USE OF DRG ADJUST-
 12 MENT.—Section 1886(d)(5)(K) (42 U.S.C.
 13 1395ww(d)(5)(K)), as amended by section 201, is further
 14 amended by adding at the end the following new clause:
 15 “(viii) Before establishing any additional payment
 16 under this subparagraph with respect to a new technology,
 17 the Secretary shall seek to identify one or more diagnosis-
 18 related groups associated with such technology, based on
 19 similar clinical or anatomical characteristics and the cost
 20 of the technology. Within such groups the Secretary shall
 21 assign an eligible new technology into a diagnosis-related
 22 group where the average costs of care most closely approx-
 23 imate the costs of care of using the new technology. In
 24 such case, whether the DRG prospective payment rate
 25 that would otherwise be made under this subsection is in-

1 adequate for purposes of clause (ii)(I) shall be determined
 2 with respect to the diagnosis-related group to which it is
 3 assigned under this clause, and any additional expendi-
 4 tures resulting from such assignment shall be taken into
 5 account in making the determination required by para-
 6 graph (4)(C)(iii) (and not in the application of any annual
 7 limit on aggregate payments under this subparagraph).”.

8 (c) IMPROVEMENT IN PAYMENT FOR NEW TECH-
 9 NOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C.
 10 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after
 11 “the estimated average cost of such service or technology”
 12 the following: “(based on the marginal rate applied to
 13 costs under subparagraph (A))”.

14 (d) REQUIRED MODIFICATIONS TO MECHANISM.—
 15 The last sentence of section 1886(d)(5)(K)(i) (42 U.S.C.
 16 1395ww(d)(5)(K)(i)) is amended to read as follows: “The
 17 mechanism established pursuant to this clause (as it be-
 18 came effective on October 9, 2001) shall be modified to
 19 meet the requirements of subclauses (II) and (III) of
 20 clause (vi), clauses (vii) and (viii), and the parenthetical
 21 expressions in subclauses (I) and (III) of clause (iii) that
 22 were added after such date.”.

23 (e) EFFECTIVE DATE.—

24 (1) IN GENERAL.—The Secretary shall imple-
 25 ment the amendments made by this section by regu-

1 lations issued on an interim, final basis if the Sec-
 2 retary determines that the issuance of regulations on
 3 such basis is necessary to ensure that such amend-
 4 ments will apply to classifications for (and payments
 5 for discharges occurring in) fiscal years beginning
 6 with fiscal year 2004.

7 (2) RECONSIDERATIONS OF APPLICATIONS FOR
 8 FISCAL YEARS 2003 AND 2004 THAT ARE DENIED.—

9 In the case of an application for a classification of
 10 a medical service or technology as a new medical
 11 service or technology under section 1886(d)(5)(K) of
 12 the Social Security Act (42 U.S.C.
 13 1395ww(d)(5)(K)) that was filed for fiscal year
 14 2003 or fiscal year 2004 and that is denied—

15 (A) the Secretary shall automatically re-
 16 consider the application as an application for
 17 fiscal year 2005 under the amendments made
 18 by this section; and

19 (B) the maximum time period otherwise
 20 permitted for such classification of the service
 21 or technology shall be extended by 12 months.

1 **SEC. 304. PRESERVATION OF LOCAL MEDICAL REVIEW**
 2 **PROCESS UNDER MEDICARE ADMINISTRA-**
 3 **TIVE CONTRACTOR REFORMS.**

4 (a) PART A.—Section 1816(c) (42 U.S.C. 1395h(c))
 5 is amended by adding at the end the following:

6 “(4) An agreement with any agency or organization
 7 under this section to perform the function of making local
 8 coverage determinations (as defined in section
 9 1869(f)(2)(B)), making determinations of payment
 10 amounts, or making both such types of determinations,
 11 shall provide that such contractor or entity shall—

12 “(A) designate at least one different individual
 13 to serve as medical director for every two States (or
 14 portions thereof) for which such agency or organiza-
 15 tion performs such function or functions;

16 “(B) utilize such medical director in the per-
 17 formance of such function or functions; and

18 “(C) appoint an advisory committee with re-
 19 spect to each such State (or portion thereof) to pro-
 20 vide a formal mechanism for physicians in the State
 21 to be informed of, and participate in, the develop-
 22 ment of local coverage determinations in an advisory
 23 capacity.”.

24 (b) PART B.—Section 1842(c) (42 U.S.C. 1395u(c))
 25 is amended by adding at the end the following:

1 “(7) Any contract with a carrier under this section
2 to perform the function of making local coverage deter-
3 minations (as defined in section 1869(f)(2)(B)), making
4 determinations of payment amounts, or making both such
5 types of determinations, shall provide that such carrier
6 shall—

7 “(A) designate at least one different individual
8 to serve as medical director for every two States (or
9 portions thereof) for which such carrier performs
10 such function or functions;

11 “(B) utilize such medical director in the per-
12 formance of such function or functions; and

13 “(C) appoint an advisory committee with re-
14 spect to each such State (or portion thereof) to pro-
15 vide a formal mechanism for physicians in the State
16 to be informed of, and participate in, the develop-
17 ment of local coverage determinations in an advisory
18 capacity.”.

19 (c) EFFECTIVE DATE.—The amendments made by
20 this section shall apply to agreements and contracts en-
21 tered into or renewed on or after the date of the enactment
22 of this Act.

1 **SEC. 305. INHERENT REASONABLENESS.**

2 (a) IN GENERAL.—Section 1842(b)(8)(A) (42 U.S.C.
3 1395u(b)(8)(A)) is amended by adding at the end the fol-
4 lowing:

5 “(iii) The Secretary shall ensure adequate notice to
6 the public with respect to any determination under this
7 paragraph, including—

8 “(I) before conducting any survey to evaluate
9 the factors in subclause (I) or (II) of clause (i), pub-
10 lication of a notice explaining, and soliciting public
11 comment on, the proposed methodology and design
12 of such survey,

13 “(II) publication of any proposed determina-
14 tion, together with an explanation of the results of
15 any survey and any other relevant factors taken into
16 account in making the determination, information on
17 how the public may obtain survey data, and an op-
18 portunity for public comment on the proposed deter-
19 mination, and

20 “(III) publication of a notice of a final deter-
21 mination under this paragraph.

22 “(iv) The requirements of clause (iii) shall apply to
23 any determination that is made by—

24 “(I) two or more carriers, acting concurrently,
25 or in concert, with respect to the same particular
26 item or service, or

1 “(II) any regional carrier designated by the
 2 Secretary under section 1834(a)(12) of this part or
 3 under section 4554(a)(1)(B) of the Balanced Budget
 4 Act of 1997.”.

5 (b) APPEALS.—Section 1869(f) (42 U.S.C. 1395ff(f))
 6 is amended—

7 (1) in the matter preceding paragraph (1), by
 8 inserting “AND INHERENT REASONABLENESS DE-
 9 TERMINATIONS” after “REVIEW OF COVERAGE DE-
 10 TERMINATIONS”;

11 (2) in paragraph (1)—

12 (A) in the heading, by inserting “; NA-
 13 TIONAL INHERENT REASONABLENESS DETER-
 14 MINATIONS” after “NATIONAL COVERAGE DE-
 15 TERMINATIONS”;

16 (B) in the matter preceding clause (i) of
 17 subparagraph (A) by inserting “or national in-
 18 herent reasonableness determination” after
 19 “any national coverage determination”; and

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

21 “(C) DEFINITION OF NATIONAL INHERENT
 22 REASONABLENESS DETERMINATION.—For pur-
 23 poses of this section, the term ‘national inher-
 24 ent reasonableness determination’ means a de-

1 termination by the Secretary in accordance with
 2 section 1842(b)(8).”;

3 (3) in paragraph (2)—

4 (A) in the heading, by inserting “; LOCAL
 5 INHERENT REASONABLENESS DETERMINA-
 6 TIONS” after “LOCAL COVERAGE DETERMINA-
 7 TIONS”;

8 (B) in the matter preceding clause (i) of
 9 subparagraph (A), by inserting “or local inher-
 10 ent reasonableness determination” after “any
 11 local coverage determination”; and

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

13 “(C) DEFINITION OF LOCAL INHERENT
 14 REASONABLENESS DETERMINATION.—For pur-
 15 poses of this section, the term ‘local inherent
 16 reasonableness determination’ means a deter-
 17 mination by a carrier in accordance with section
 18 1842(b)(8).”; and

19 (4) in paragraph (5)—

20 (A) by striking “coverage determination”
 21 the first place it appears;

22 (B) by inserting “and any national or local
 23 inherent reasonableness determination” after
 24 “local coverage determination”; and

- 1 (C) by striking “of the coverage determina-
- 2 tion” and inserting “of the determination”.

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