

107TH CONGRESS
1ST SESSION

H. R. 2973

To amend title XVIII of the Social Security Act to provide for the expeditious coverage of new medical technology under the Medicare Program and to establish an Office of Technology and Innovation within the Centers for Medicare & Medicaid Services.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 2, 2001

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

A BILL

To amend title XVIII of the Social Security Act to provide for the expeditious coverage of new medical technology under the Medicare Program and to establish an Office of Technology and Innovation within the Centers for Medicare & Medicaid Services.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**
 2 **TENTS.**

3 (a) SHORT TITLE.—The amendments made by this
 4 Act may be cited as the “Medicare Innovation Responsive-
 5 ness Act of 2001”.

6 (b) REFERENCES.—Except as otherwise specified,
 7 whenever in this Act an amendment or repeal is expressed
 8 in terms of an amendment to or repeal of a section or
 9 other provision, the references shall be considered to be
 10 made to that section or other provision of the Social Secu-
 11 rity Act.

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

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

Sec. 2. Deadlines for implementing national coverage, coding, and payment de-
 terminations.

Sec. 3. Office of Technology and Innovation.

Sec. 4. Annual adjustments to Medicare payment systems for changes in tech-
 nology and medical practice using internal and external data.

Sec. 5. Recognition of new medical technologies under inpatient hospital PPS.

Sec. 6. Improvements to the HCPCS coding assignment, inpatient coding as-
 signment, and drg assignment processes.

Sec. 7. Improving inherent reasonableness.

14 **SEC. 2. DEADLINES FOR IMPLEMENTING NATIONAL COV-**
 15 **ERAGE, CODING, AND PAYMENT DETERMINA-**
 16 **TIONS.**

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

1 “(d)(1) In making a national coverage determination
2 (as defined in paragraph (1)(B) of section 1869(f)) the
3 Secretary shall ensure 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), the assumptions underlying that basis; and

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

22 “(2)(A) Subject to the succeeding provisions of this
23 paragraph, in making a national coverage determination,
24 upon receipt of a request for the national coverage deter-
25 mination from an interested party, the Secretary shall

1 make the national coverage determination under subpara-
2 graph (B) and implement (if applicable) the determination
3 pursuant to subparagraph (C) for that new technology
4 within the following timeframes:

5 “(i) In the case of a national coverage deter-
6 mination that does not require a technology assess-
7 ment described in subparagraph (E), not later than
8 the end of the 6-month period that begins on the
9 date a request for the national coverage determina-
10 tion has been received by the Secretary, notwith-
11 standing the receipt by the Secretary of new evi-
12 dence (if any) during such period.

13 “(ii) In the case of a national coverage deter-
14 mination that requires such a technology assess-
15 ment, not later than the end of the 12-month period
16 that begins on the date a request for the national
17 coverage determination has been received by the Sec-
18 retary.

19 In this subparagraph, the term ‘interested party’ means
20 individuals entitled to benefits under part A, or enrolled
21 under part B, or both, who are in need of the items or
22 services that are the subject of the coverage determination,
23 providers of services, physicians, practitioners, suppliers,
24 and manufacturers of such items 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) With respect to the implementation a national
13 coverage determination made under subparagraph (B)(i),
14 the Secretary shall—

15 “(i) determine what code, if any, is assigned to
16 the particular item or service;

17 “(ii) determine the amount of payment to be
18 made under this title for the item or service;

19 “(iii) in the case of inpatient hospital services
20 for which payment is made under section 1886(d),
21 assign the item or service, and codes for the item or
22 service, to appropriate diagnosis related groups;

23 “(iv) incorporate the coverage, coding, and pay-
24 ment determinations into the information processing

1 systems of the Secretary and fiscal intermediaries
2 and carriers; and

3 “(v) take such other steps as are necessary to
4 make payments for the item or service no later than
5 the end of the applicable period described in sub-
6 paragraph (A).

7 “(D) If the Secretary fails to take an action under
8 subparagraph (B) within the applicable period under sub-
9 paragraph (A), the Secretary shall issue a notice that in-
10 cludes the following information:

11 “(i) A statement that a national coverage deter-
12 mination under subparagraph (B) cannot be made
13 and (if applicable) implemented under subparagraph
14 (C) within the applicable time period.

15 “(ii) The identification of substantive issues
16 outstanding.

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

19 “(iv) The date by which the Secretary will make
20 a national coverage determination under subpara-
21 graph (B) and (if applicable) implement the national
22 coverage determination under subparagraph (C).

23 “(E)(i) A technology assessment referred to in sub-
24 paragraph (A) is a formal, written technology assessment,
25 conducted by an entity or organization other than the Cen-

1 ters for Medicare & Medicaid Services (in this subpara-
2 graph referred to as the ‘CMS’), or review by an advisory
3 committee appointed to advise the Administrator of the
4 CMS on matters relating to the interpretation, applica-
5 tion, or implementation of subsection (a), that the Admin-
6 istrator reasonably finds, in a written notice issued before
7 the end of the 6-month period specified in subparagraph
8 (A)(i), that such an assessment or review is necessary for
9 the Administrator to make the national coverage deter-
10 mination.

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

14 “(F) In making a national coverage determination
15 under subparagraph (B), the Secretary shall include all
16 the information described in subparagraphs (C) and (D)
17 of paragraph (1), and in the case of the implementation
18 of the national coverage determination, applicable codes
19 and payment amounts for the new item or service.”.

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

22 (c) EFFECTIVE DATE.—The amendments made by
23 this section shall take effect on the date of the enactment
24 of this Act, and apply to requests for national coverage

1 determinations made on or after the date that is 90 days
2 after such effective date.

3 **SEC. 3. OFFICE OF TECHNOLOGY AND INNOVATION.**

4 (a) ESTABLISHMENT.—Not later than 90 days after
5 the date of enactment of this Act, the Secretary of Health
6 and Human Services shall establish an Office of Tech-
7 nology and Innovation in the Centers for Medicare & Med-
8 icaid Services.

9 (b) DIRECTOR.—The Office of Technology and Inno-
10 vation shall be headed by a Director appointed by the Sec-
11 retary. The Director shall be in direct line of authority
12 to the Administrator of the Centers for Medicare & Med-
13 icaid Services. The Director shall be a noncareer appointee
14 in the Senior Executive Service (as defined in section
15 3132(a)(7) of title 5, United States Code).

16 (c) DUTIES.—The duties of the Director are as fol-
17 lows:

18 (1) PROMOTING ACCESS TO NEW TECH-
19 NOLOGIES.—The Director shall promote access by
20 medicare beneficiaries to new medical technologies
21 and innovations.

22 (2) IMPROVEMENT AND OVERSIGHT OF IMPLE-
23 MENTATION OF COVERAGE DETERMINATIONS.—The
24 Director shall—

1 (A) improve collaboration and coordination
2 between officials responsible for the coverage,
3 coding, and payment processes in order to fa-
4 cilitate timely access to new items and services
5 for beneficiaries;

6 (B) monitor the decisionmaking of the Sec-
7 retary on coverage, coding, and payment for
8 new items or services;

9 (C) INFORMATION CENTER.—The Director
10 shall serve as a source of information for inter-
11 ested parties regarding the Secretary’s activities
12 concerning new items or services, including as-
13 sisting such parties in securing determinations,
14 and the implementation of determinations, re-
15 specting coverage, coding, and payment under
16 title XVIII of the Social Security Act, including
17 implementation of the steps described in section
18 1869(f)(4)(A) of such Act (42 U.S.C.
19 1395ff(f)(4)(A)).

20 (D) PREPARATION OF REPORTS TO CON-
21 GRESS.—The Director shall prepare reports to
22 Congress required under section 1869(f)(7) of
23 such Act (42 U.S.C. 1395ff(f)(7)), and shall
24 make such reports available to the public.

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

5 (a) INPATIENT PPS.—Section 1886(d)(4) (42 U.S.C.
6 1395ww(d)(4)) is amended by adding at the end the fol-
7 lowing new subparagraph:

8 “(D)(i)(I) In determining annual adjustments under
9 subparagraph (C), the Secretary may not decline to use
10 data held by the Secretary in the administration of the
11 program established under this title if the data reflect a
12 representative sample of cases or may not establish a uni-
13 form period of time (such as one year) from which such
14 data must be drawn.

15 “(II) The Secretary shall establish a reasonable dead-
16 line for the submission of a request for adjustment based
17 on data held by the Secretary to be used in making the
18 adjustments required by subparagraph (C). In no event
19 may the deadline established under this paragraph be
20 more than 8 months before the first day of the payment
21 update period for which the adjustment or adjustments
22 to which the data relate would be effective.

23 “(ii)(I) Subject to the succeeding provisions of this
24 clause, in determining the adjustments under subpara-
25 graph (C), the Secretary shall utilize data other than data
26 held by the Secretary in the administration of the program

1 established under this title if such other data are based
2 on a representative sample of cases.

3 “(II) In determining the adjustments under subpara-
4 graph (C), the Secretary may not decline to use data other
5 than data held by the Secretary if such other data enable
6 the Secretary to identify or refine data held by the Sec-
7 retary for use in making such an adjustment and such
8 data are based on a representative sample of cases; or may
9 not establish a uniform period of time (such as one year)
10 from which such data must be drawn.

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

19 “(IV) The Secretary shall establish a reasonable
20 deadline for the submission of data other than data held
21 by the Secretary to be used in making the adjustments
22 required by subparagraph (C). In no event may the dead-
23 line established under this subclause be more than 10
24 months before the first day of the payment update period

1 for which the adjustment or adjustments to which the data
2 relate would be effective.

3 “(V) For purposes of this clause, the term ‘sufficient
4 external data’ means data that can reasonably be provided
5 by the sponsor of the application for additional payment,
6 or that is derived from an investigation conducted under
7 section 520(g) of the Federal Food, Drug, and Cosmetic
8 Act.”.

9 (b) PHYSICIAN FEE SCHEDULE.—Section 1848(c)(2)
10 (42 U.S.C. 1395w-4(c)(2)) is amended by adding at the
11 end the following new subparagraph:

12 “(H) USE OF DATA.—

13 “(i) INTERNAL DATA HELD BY THE
14 SECRETARY.—

15 “(I) IN GENERAL.—In deter-
16 mining annual adjustments under
17 subparagraph (B)(ii), the Secretary
18 may not decline to use data held by
19 the Secretary in the administration of
20 the program established under this
21 title if the data reflect a representa-
22 tive sample of cases or may not estab-
23 lish a uniform period of time (such as
24 one year) from which such data must
25 be drawn.

1 “(II) DEADLINE FOR SUPPLYING

2 INTERNAL DATA.—The Secretary
3 shall establish a reasonable deadline
4 for the submission of a request for ad-
5 justment based on data held by the
6 Secretary to be used in making the
7 adjustments required by subparagraph
8 (B)(ii). In no event may the deadline
9 established under this paragraph be
10 more than 8 months before the first
11 day of the payment update period for
12 which the adjustment or adjustments
13 to which the data relate would be ef-
14 fective.

15 “(ii) EXTERNAL DATA.—

16 “(I) IN GENERAL.—Subject to
17 the succeeding provisions of this
18 clause, in determining the adjust-
19 ments under subparagraph (B)(ii), the
20 Secretary shall utilize data other than
21 data held by the Secretary in the ad-
22 ministration of the program estab-
23 lished under this title if such other
24 data are based on a representative
25 sample of cases.

1 “(II) EXTERNAL DATA FACILI-
2 TATING THE USE OF INTERNAL
3 DATA.—In determining the adjust-
4 ments under subparagraph (B)(ii), the
5 Secretary may not decline to use data
6 other than data held by the Secretary
7 if such other data enable the Sec-
8 retary to identify or refine data held
9 by the Secretary for use in making
10 such an adjustment and such data are
11 based on a representative sample of
12 cases; or may not establish a uniform
13 period of time (such as one year) from
14 which such data must be drawn.

15 “(III) CLARIFICATION.—Nothing
16 in this clause shall be construed as re-
17 quiring the Secretary to identify all
18 claims submitted under the payment
19 system established under this section
20 involving the use of a medical tech-
21 nology before the Secretary may make
22 the adjustments under this subpara-
23 graph with respect to such technology;
24 or as authorizing the Secretary to

1 defer action on such an adjustment
2 until all such claims are identifiable.

3 “(IV) DEADLINE FOR SUPPLYING
4 EXTERNAL DATA.—The Secretary
5 shall establish a reasonable deadline
6 for the submission of data other than
7 data held by the Secretary to be used
8 in making the adjustments required
9 by subparagraph (B)(ii). In no event
10 may the deadline established under
11 this subclause be more than 10
12 months before the first day of the
13 payment update period for which the
14 adjustment or adjustments to which
15 the data relate would be effective.

16 “(V) DEFINITION.—For purposes
17 of this clause, the term ‘sufficient ex-
18 ternal data’ means data that can rea-
19 sonably be provided by the sponsor of
20 the application for additional pay-
21 ment, or that is derived from an in-
22 vestigation conducted under section
23 520(g) of the Federal Food, Drug,
24 and Cosmetic Act.”.

1 (c) AMBULATORY SURGICAL CENTER PAYMENTS.—

2 Section 1833(i)(2) (42 U.S.C. 1395l(i)(2)) is amended by

3 adding at the end the following new subparagraphs:

4 “(D) The Secretary shall review not less often than

5 annually and revise the updates under subparagraphs (A)

6 and (B) to take into account changes in medical practice,

7 changes in technology, the addition of new services, new

8 cost data, and other relevant information and factors.

9 “(E)(i)(I) In revising the updates under subpara-

10 graph (D), the Secretary may not decline to use data held

11 by the Secretary in the administration of the program es-

12 tablished under this title if the data reflect a representa-

13 tive sample of cases or may not establish a uniform period

14 of time (such as one year) from which such data must

15 be drawn.

16 “(II) The Secretary shall establish a reasonable dead-

17 line for the submission of a request for revised updates

18 based on data held by the Secretary to be used in making

19 the revised updates under subparagraph (D). In no event

20 may the deadline established under this paragraph be

21 more than 8 months before the first day of the payment

22 update period for which the adjustment or adjustments

23 to which the data relate would be effective.

24 “(ii)(I) Subject to the succeeding provisions of this

25 clause, in determining the revised updates under subpara-

1 graph (D), the Secretary shall utilize data other than data
2 held by the Secretary in the administration of the program
3 established under this title if such other data are based
4 on a representative sample of cases.

5 “(II) In determining the revised updates under sub-
6 paragraph (D), the Secretary may not decline to use data
7 other than data held by the Secretary if such other data
8 enable the Secretary to identify or refine data held by the
9 Secretary for use in making such an adjustment and such
10 data are based on a representative sample of cases; or may
11 not establish a uniform period of time (such as one year)
12 from which such data must be drawn.

13 “(III) Nothing in this clause shall be construed as
14 requiring the Secretary to identify all claims submitted
15 under the payment system established under this para-
16 graph involving the use of a medical technology before the
17 Secretary may make the revised adjustments under sub-
18 paragraph (D) with respect to such technology; or as au-
19 thorizing the Secretary to defer action on such a revised
20 update until all such claims are identifiable.

21 “(IV) The Secretary shall establish a reasonable
22 deadline for the submission of data other than data held
23 by the Secretary to be used in making the revised updates
24 required by subparagraph (D). In no event may the dead-
25 line established under this subclause be more than 10

1 months before the first day of the payment update period
 2 for which the adjustment or adjustments to which the data
 3 relate would be effective.

4 “(V) For purposes of this clause, the term ‘sufficient
 5 external data’ means data that can reasonably be provided
 6 by the sponsor of the application for additional payment,
 7 or that is derived from an investigation conducted under
 8 section 520(g) of the Federal Food, Drug, and Cosmetic
 9 Act.”.

10 (d) OUTPATIENT PPS.—Section 1833(t)(9) (42
 11 U.S.C. 1395l(t)(9)) is amended by adding at the end the
 12 following new subparagraph:

13 “(D) USE OF DATA.—

14 “(i) INTERNAL DATA HELD BY THE
 15 SECRETARY.—

16 “(I) IN GENERAL.—In deter-
 17 mining annual adjustments under
 18 subparagraph (A), the Secretary may
 19 not decline to use data held by the
 20 Secretary in the administration of the
 21 program established under this title if
 22 the data reflect a representative sam-
 23 ple of cases or may not establish a
 24 uniform period of time (such as one

1 year) from which such data must be
2 drawn.

3 “(II) DEADLINE FOR SUPPLYING
4 INTERNAL DATA.—The Secretary
5 shall establish a reasonable deadline
6 for the submission of a request for ad-
7 justment based on data held by the
8 Secretary to be used in making the
9 adjustments required by subparagraph
10 (A). In no event may the deadline es-
11 tablished under this paragraph be
12 more than 8 months before the first
13 day of the payment update period for
14 which the adjustment or adjustments
15 to which the data relate would be ef-
16 fective.

17 “(ii) EXTERNAL DATA.—

18 “(I) IN GENERAL.—Subject to
19 the succeeding provisions of this
20 clause, in determining the adjust-
21 ments under subparagraph (A), the
22 Secretary shall utilize data other than
23 data held by the Secretary in the ad-
24 ministration of the program estab-
25 lished under this title if such other

1 data are based on a representative
2 sample of cases.

3 “(II) EXTERNAL DATA FACILI-
4 TATING THE USE OF INTERNAL
5 DATA.—In determining the adjust-
6 ments under subparagraph (A), the
7 Secretary may not decline to use data
8 other than data held by the Secretary
9 if such other data enable the Sec-
10 retary to identify or refine data held
11 by the Secretary for use in making
12 such an adjustment and such data are
13 based on a representative sample of
14 cases; or may not establish a uniform
15 period of time (such as one year) from
16 which such data must be drawn.

17 “(III) CLARIFICATION.—Nothing
18 in this clause shall be construed as re-
19 quiring the Secretary to identify all
20 claims submitted under the payment
21 system established under this sub-
22 section involving the use of a medical
23 technology before the Secretary may
24 make the adjustments under this sub-
25 paragraph with respect to such tech-

1 nology; or as authorizing the Sec-
2 retary to defer action on such an ad-
3 justment until all such claims are
4 identifiable.

5 “(IV) DEADLINE FOR SUPPLYING
6 EXTERNAL DATA.—The Secretary
7 shall establish a reasonable deadline
8 for the submission of data other than
9 data held by the Secretary to be used
10 in making the adjustments required
11 by subparagraph (A). In no event may
12 the deadline established under this
13 subclause be more than 10 months be-
14 fore the first day of the payment up-
15 date period for which the adjustment
16 or adjustments to which the data re-
17 late would be effective.

18 “(V) DEFINITION.—For purposes
19 of this clause, the term ‘sufficient ex-
20 ternal data’ means data that can rea-
21 sonably be provided by the sponsor of
22 the application for additional pay-
23 ment, or that is derived from an in-
24 vestigation conducted under section

1 520(g) of the Federal Food, Drug,
2 and Cosmetic Act.”.

3 (e) EFFECTIVE DATES.—The amendments made by
4 this section shall apply with respect to items and services
5 furnished on or after October 1, 2002.

6 **SEC. 5. RECOGNITION OF NEW MEDICAL TECHNOLOGIES**
7 **UNDER INPATIENT HOSPITAL PPS.**

8 Subparagraphs (K) and (L) of section 1886(d)(5)
9 (42 U.S.C. 1395ww(d)(5)) are amended to read as follows:

10 “(K)(i) The Secretary shall by regulation
11 establish a mechanism under which new medical
12 services and technologies are incorporated into
13 the payment system established under this sub-
14 section. Such mechanism shall—

15 “(I) meet the requirements of this
16 subparagraph and subparagraph (L); and

17 “(II) apply to all discharges occurring
18 on or after October 1, 2002.

19 The Secretary may establish such mechanism
20 by interim final regulation (in the publications
21 required by subsection (e)(5) for a fiscal year or
22 otherwise).

23 “(ii) The Secretary—

24 “(I) shall accept an application for in-
25 corporation of a new medical service or

1 technology into such system that is sub-
2 mitted on or after the date on which a re-
3 quest is made for assignment of an inpa-
4 tient hospital code (as defined in clause
5 (viii)(I)) for the service or technology;

6 “(II) shall permit an applicant to sub-
7 mit a separate application with respect to
8 each diagnosis-related group established
9 under paragraph (4) that the applicant be-
10 lieves (based on principal and secondary
11 diagnoses and other variables used to as-
12 sign specific hospital discharges to such
13 groups) will involve the use of such service
14 or technology or to include all such groups
15 in a single, consolidated application;

16 “(III) shall identify all such groups
17 (established under paragraph (4)) that the
18 Secretary determines (based on principal
19 and secondary diagnoses and other vari-
20 ables used to assign specific hospital dis-
21 charges to such groups) will involve the use
22 of such service or technology and, if any
23 groups so identified are groups other than
24 those included in such application, shall
25 notify the applicant and invite the appli-

1 cant to revise, expand, or resubmit the ap-
2 plication (or a portion thereof) to include
3 information with respect to such group or
4 groups; and

5 “(IV) shall make a separate deter-
6 mination under clause (iii), with respect to
7 such service or technology, for each diag-
8 nosis-related group identified by the Sec-
9 retary under subclause (III) for which an
10 application has been submitted, at such
11 time after receipt of such application as
12 will ensure that the service or technology is
13 incorporated into such system not later
14 than 8 months (in the case of an applica-
15 tion supported by sufficient internal data
16 (as determined under paragraph
17 (4)(D)(i))) or 10 months (in the case of an
18 application supported by sufficient external
19 data (as defined in paragraph
20 (4)(D)(ii)(V))) after the deadline estab-
21 lished for receipt of such applications.

22 “(iii) After identifying diagnosis-related
23 groups under clause (ii)(III), the Secretary
24 shall determine, with respect to each such
25 group for which an application has been re-

1 ceived, whether payment shall be made under
2 such system, with respect to discharges involv-
3 ing such service or technology that would be
4 classified within such group, based on—

5 “(I) in the case of a group with re-
6 spect to which the requirements of clause
7 (v) are met, such diagnosis-related group;
8 or

9 “(II) in the case of a group with re-
10 spect to which the requirements of clause
11 (v) are not met, a new-technology group
12 established under subparagraph (L).

13 “(iv) In making the determination de-
14 scribed in clause (iii), the Secretary shall
15 compare—

16 “(I) the estimated average cost in-
17 curred (determined by the Secretary taking
18 into account data submitted in support of
19 an application) for discharges of patients
20 receiving care involving a new medical
21 service or technology who were (or would
22 have been) classified within a diagnosis-re-
23 lated group (based on principal and sec-
24 ondary diagnoses and variables used to as-

1 sign specific hospital discharges to such
2 group), with

3 “(II) the discharge-weighted average
4 of the national DRG prospective payment
5 rates established under paragraph (3) for
6 hospitals located in large urban and other
7 areas (described in subparagraph (A)(iv) of
8 such subparagraph) for such diagnosis-re-
9 lated group.

10 “(v) The Secretary shall provide that pay-
11 ment for discharges of patients with the same
12 diagnoses and variables that are used to classify
13 specific hospital discharges to a diagnosis-re-
14 lated group established under paragraph (4)
15 and involving a new medical service or tech-
16 nology will be based on the diagnosis-related
17 group if—

18 “(I) the discharge-weighted average
19 national DRG prospective payment rate
20 determined under clause (iv)(II) for such
21 group equals or exceeds 90 percent of the
22 estimated average cost determined under
23 clause (iv)(I); and

24 “(II) the amount (if any) by which
25 the estimated average cost determined

1 under clause (iv)(I) exceeds the discharge-
2 weighted average national DRG prospec-
3 tive payment rate determined under clause
4 (iv)(II) for such group is not greater than
5 \$2,500.

6 “(vi) The Secretary shall provide that, if
7 the requirements of subclause (I) and (II) of
8 clause (v) are not met with respect to a diag-
9 nosis-related group established under paragraph
10 (4) and discharges involving a service or tech-
11 nology that would (but for this subparagraph)
12 be classified within such group—

13 “(I) payment for such discharges will
14 be based on a new-technology group estab-
15 lished under subparagraph (L); and

16 “(II) such discharges will be classified
17 within a group established under subpara-
18 graph (L) for which the rates established
19 under such subparagraph meet the require-
20 ments of subparagraph (K)(v) (determined
21 by applying the methodology specified in
22 subparagraph (K)(iv) to such rates).

23 “(vii) The Secretary shall—

24 “(I) treat a medical service or tech-
25 nology as ‘new’ for purposes of this sub-

1 paragraph for the 3-year period beginning
2 on the date on which an inpatient hospital
3 code is assigned with respect to the service
4 or technology (and, in the case of a service
5 or technology for which such a code was
6 assigned before the date of the enactment
7 of this paragraph, for any portion of such
8 period that occurs on or after the effective
9 date of this subparagraph);

10 “(II) determine payment for such
11 service or technology on the basis described
12 in clause (v) or (vi), as the case may be,
13 during such period (or portion thereof);
14 and

15 “(III) provide for the collection of
16 data with respect to the costs incurred
17 during such period (or portion thereof)
18 with respect to such service or technology
19 for use in making adjustments under para-
20 graph (4)(C) and in determining the ap-
21 propriate diagnosis-related group to which
22 discharges involving such service or tech-
23 nology will be classified after such period.

24 “(viii) For purposes of this
25 subparagraph—

1 “(I) the term ‘inpatient hospital code’
2 means any code that is used with respect
3 to inpatient hospital services for which
4 payment may be made under this sub-
5 section and includes an alphanumeric code
6 issued under the International Classifica-
7 tion of Diseases, 9th Revision, Clinical
8 Modification (‘ICD–9–CM’) and its subse-
9 quent revisions; and

10 “(II) the term ‘new medical service or
11 technology’ means a medical service or
12 technology that, when compared with exist-
13 ing medical services and technologies, sub-
14 stantially improves the diagnosis or treat-
15 ment provided to individuals entitled to
16 benefits under this title.

17 “(L)(i) Before the beginning of each fiscal
18 year (beginning with fiscal year 2003), the Sec-
19 retary shall establish new-technology groups
20 into which discharges involving a new medical
21 service or technology will be classified as pro-
22 vided in subparagraph (K)(vi).

23 “(ii) Such groups shall, using the applica-
24 ble standardized amounts under this subsection
25 and appropriate weighting factors, produce pro-

1 spective payment rates that reflect such cost co-
 2 horts as the Secretary determines will be nec-
 3 essary to assure that a new-technology group
 4 described in subparagraph (K)(vi)(II) will be
 5 available during such fiscal year to assign dis-
 6 charges involving a new service or technology
 7 for which no diagnosis-related group established
 8 under paragraph (4) satisfies the requirements
 9 of subclauses (I) and (II) of subparagraph
 10 (K)(v).

11 “(iii) The prospective payment rates estab-
 12 lished under clause (ii) shall be adjusted in the
 13 same manner as national DRG prospective pay-
 14 ment rates determined under paragraph (3).”.

15 **SEC. 6. IMPROVEMENTS TO THE HCPCS CODING ASSIGN-**
 16 **MENT, INPATIENT CODING ASSIGNMENT, AND**
 17 **DRG ASSIGNMENT PROCESSES.**

18 (a) INPATIENT PPS.—Section 1886(d)(5)(K) (42
 19 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the
 20 end the following new clauses:

21 “(vii) The Secretary shall by regulation establish a
 22 process that provides for the assignment of inpatient hos-
 23 pital codes (as defined in clause (iii)) each calendar quar-
 24 ter for new medical services and technologies. Such proc-
 25 ess shall—

1 “(I) ensure that new codes are assigned and
 2 implemented no later than 180 days after a request
 3 is received; and

4 “(II) provide for the opportunity to apply for
 5 the assignment of an inpatient hospital code under
 6 subclause (I) to items that are the subject of an ap-
 7 plication submitted for investigation under section
 8 520(g) of the Federal Food, Drug and Cosmetic Act
 9 (21 U.S.C. 360j(g)).

10 The assignment of any inpatient hospital code shall affect
 11 a weighting factor described in paragraph (4)(B) only at
 12 the time of an adjustment under paragraph (4)(C)(i).”.

13 (b) HCPCS LEVEL II CODES.—

14 (1) PROCESS FOR ASSIGNMENT OF CODES FOR
 15 NEW TECHNOLOGIES.—The Secretary shall by regu-
 16 lation establish a process that provides for the as-
 17 signment of HCPCS Level II codes each calendar
 18 quarter for new medical services and technologies.
 19 Such process shall ensure that codes are assigned
 20 and implemented no later than 180 days after a for-
 21 mal application for such a code is received.

22 (2) DEFINITION.—In this subsection, the term
 23 “HCPCS Level II codes” means the level II alpha-
 24 numeric codes under the Health Care Financing Ad-

1 ministration Common Procedure Coding System
2 (HCPCS).

3 (c) PERMANENT RETENTION OF HCPCS LEVEL III
4 CODES.—Section 532(a) of the Medicare, Medicaid, and
5 SCHIP Benefits Improvement and Protection Act of 2000
6 (114 Stat. 2763A–547), as enacted into law by section
7 1(a)(6) of Public Law 106–554, is amended by striking
8 “through December 31, 2003,”.

9 (d) EFFECTIVE DATE.—The amendments made sub-
10 sections (a) and (b) shall apply with respect to applica-
11 tions for new ICD–9–CM codes received on or after Octo-
12 ber 1, 2002.

13 **SEC. 7. IMPROVING INHERENT REASONABLENESS.**

14 (a) IN GENERAL.—Section 1842(b)(8) (42 U.S.C.
15 1395u(b)(8)) is amended—

16 (1) in subparagraph (A)(i), by inserting “and
17 valid data” after “factors” each place it appears;

18 (2) in subparagraph (A)(ii)—

19 (A) by striking “apply factors that would”;

20 (B) by striking “during any year”; and

21 (C) by striking “from such payment during
22 the preceding year” and inserting in lieu there-
23 of, “over any 5-consecutive-year period”;

24 (3) in subparagraph (B)—

1 (A) by striking “of the payment amount
2 for a year” and inserting “over any 5-consecu-
3 tive-year period”; and

4 (B) by redesignating clause (iii) as clause
5 (iv), by striking “and” at the end of clause (ii),
6 and by inserting after such clause (ii) the fol-
7 lowing new clause:

8 “(iii) the Secretary’s determination is based on
9 valid data, and”; and

10 (4) by adding at the end the following new sub-
11 paragraph:

12 “(E) As used in this paragraph and paragraph (9):

13 “(i) The term ‘valid data’ means, with respect
14 to an item or service, data that—

15 “(I) are representative of market data for
16 the most common appropriate form of such
17 item or service used by, or on behalf of, individ-
18 uals entitled to benefits under this part, taking
19 into account each mode of distribution through
20 which such form of such item or service is made
21 available for use by, or on behalf of, such enti-
22 tled individuals;

23 “(II) are collected and analyzed in a con-
24 sistent manner, as specified by the terms of a
25 written protocol;

1 “(III) constitute valid retail data if the
 2 item or service is available in a retail setting;
 3 and

4 “(IV) satisfy such additional requirements
 5 as the Secretary may by regulation describe.

6 “(ii) The term ‘valid retail data’ means survey
 7 data on retail prices for the items or services that—

8 “(I) satisfy the requirements of subclauses
 9 (I) and (II) of clause (i) and any applicable re-
 10 quirement described by the Secretary under
 11 subclause (IV) of such clause; and

12 “(II) are derived from a random represent-
 13 ative sampling of all retail prices for such items
 14 and services at stores in the United States
 15 (with such sampling accomplished by means of
 16 inspections of such items and services on the
 17 premises of stores, as specified by the terms of
 18 a written protocol).

19 “(iii) The term ‘5-consecutive-year period’ in-
 20 cludes a portion of such period.”.

21 (b) EFFECTIVE DATE.—The amendments made by
 22 subsection (a) shall apply with respect to any determina-
 23 tion, or proposed determination, made on or after January
 24 1, 2002.

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