II

110TH CONGRESS
1ST SESSION

S. 2404

To amend title XVIII of the Social Security Act to improve payments under the Medicare clinical laboratory fee schedule.

IN THE SENATE OF THE UNITED STATES

DECEMBER 3, 2007

Mr. SCHUMER introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to improve payments under the Medicare clinical laboratory fee schedule.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Advanced Laboratory Diagnostics Act of 2007''.

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

TITLE I—DEMONSTRATION PROJECT FOR NEW PAYMENT RATE-SETTING PROCESS

SEC. 101. ESTABLISHMENT OF MEDICARE DEMONSTRATION PROJECT TO EVALUATE NEW APPROACHES TO CODING AND PAYMENT FOR CERTAIN MOLECULAR DIAGNOSTIC TESTS.

(a) ESTABLISHMENT OF DEMONSTRATION.—

(1) DEMONSTRATION OF NEW APPROACHES TO CODING AND PAYMENT.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish a demonstration project under this section (in this section referred to as the ''demonstration'') to evaluate new approaches to coding and payment under the Medicare program for clinical diagnostic laboratory tests included in the demonstration (in this section referred to as ''included tests'').

(2) DURATION.—The demonstration and any payment amounts assigned under the demonstration shall apply solely to claims submitted for included tests during the 12-calendar-quarter period that begins with the first day of the first calendar quarter to begin at least 250 days after the date of the enactment of this Act.

(3) SCOPE.—The demonstration shall apply on a national basis to included tests in all settings for which payment for such tests would (but for the demonstration) be made under the fee schedules and limitation amounts established under section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)).

(4) ISSUANCE OF TEMPORARY HCPCS CODES; CONTINUED APPLICATION OF SUCH CODES.—The Secretary shall issue a temporary code or codes under the Health Care Procedure Coding System (HCPCS) when needed for an included test, and such code or codes—

(A) shall continue to apply to the test until a permanent code or codes is assigned; and

(B) shall not cease to apply solely because the demonstration ends.

(b) INCLUDED TESTS.—

(1) ELIGIBLE TESTS.—A clinical diagnostic laboratory test is eligible to be an included test under the demonstration if—

(A) the test is a new or existing molecular diagnostic test that (but for its inclusion in the demonstration) could be paid under the fee schedules and national limitation amount established under section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)) for the test; and

(B) there is the prospect—

(i) for wide usage of the test in multiple geographic areas; and

(ii) that development of a new code, or payment, or both, for the test under the demonstration will result in reduced administrative complexity and improved efficiency.

(2) INCLUDED TESTS.—A clinical diagnostic laboratory test shall be treated as an included test if—

(A) an interested party submits a request to the standing panel established under subsection (c) that the test be included in the demonstration; and

(B) the standing panel determines that the test is an eligible test under paragraph (1).

(3) DEFINITIONS.—For purposes of this section—

(A) the term ''molecular diagnostic test'' means a clinical diagnostic laboratory test performed on deoxyribonucleic (DNA), ribonucleic acid (RNA), or protein that is drawn from a human being or from a disease-causing organism for genomic or proteomic analysis; and

(B) the term ''interested party'' means, with respect to a request for inclusion of molecular diagnostic test in the demonstration, an individual entitled to benefits under title XVIII of the Social Security Act, a manufacturer of the test, a clinical laboratory offering the test, a professional society, the Centers for Medicare & Medicaid Services, a private payer for such test, and a physician or other health care practitioner.

(c) STANDING PANEL.—

(1) APPOINTMENT.—Not later than 60 days after the date of the enactment of this section, the Secretary shall appoint a standing panel (in this section referred to as the ''standing panel'' or ''panel'')

to determine whether a test is an included test and make recommendations to the Secretary on the appropriate coding of, and payment for, designated clinical diagnostic laboratory tests under the demonstration.

(2) COMPOSITION OF PANEL.—

(A) IN GENERAL.—The standing panel shall be comprised of 12 members. Two of such members shall be non-voting representatives of the Administrator of the Centers for Medicare & Medicaid Services. The Secretary shall appoint the other 10 members from—

(i) organizations representing large clinical laboratories;

(ii) organizations representing small clinical laboratories;

(iii) organizations representing physicians with expertise in clinical diagnostic laboratory tests;

(iv) organizations representing non-physician laboratorians with expertise in such tests;

(v) organizations representing manufacturers of such tests;

(vi) organizations representing individuals entitled to benefits under title XVIII of the Social Security Act;

(vii) organizations representing private payers for such tests (but not more than one member may be appointed to represent such organizations);

(viii) individuals with expertise in measuring resource utilization by clinical laboratories in performing tests; and

(ix) individuals with other relevant expertise.

(B) TERMS OF OFFICE.—Each member of the panel shall be appointed for the life of the panel, except that any individual appointed to fill a vacancy shall be appointed for the remainder of the term of the individual who is being replaced. Any vacancy shall be filled in the same manner, and with a representative of the same category under subparagraph (A), as the individual being replaced.

(3) RULES GOVERNING PANEL.—

(A) IN GENERAL.—The panel shall elect its chair. A quorum shall be required to conduct

the business of the panel, and eight members of the panel shall constitute a quorum.

(B) COMPENSATION.—While serving on the business of the panel (including travel time), a member of the panel shall be entitled to compensation at the per diem equivalent rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code, and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses as authorized by the chair of the panel.

(C) STAFFING.—

(i) DETAILING.—The panel may seek such assistance and support of its duties from appropriate Federal departments and agencies.

(ii) OUTSIDE EXPERTS.—The panel may retain the services of such outside experts as are necessary for the evaluation of a request under this section, and such experts shall not be voting members of the panel.

(D) MEETINGS.—The panel shall meet at the call of the chair and at such intervals

(which shall not be less than quarterly) as may be necessary for the conduct of its business. The agenda of each meeting and a notice of its date shall be published at least 30 days before the date the meeting occurs, and, except as provided in subparagraph (E), meetings of the panel shall be open to the public.

(E) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the panel, but the panel may close any portion of a meeting that could be closed if such Act applied.

(F) TERMINATION OF PANEL.—The panel shall terminate not more than 180 days after the close of the demonstration.

(d) FORM AND CONTENT OF REQUESTS FOR INCLUSION IN THE DEMONSTRATION.—A request for inclusion of a clinical diagnostic laboratory test in the demonstration shall be submitted in such form, and shall contain such information as the standing panel may require, including at least—

(1) any coding and payment determinations requested with respect to the test; and

(2) any documentation in support of—

(A) the eligibility of the test for inclusion in the demonstration; and

(B) any coding and payment determinations requested with respect to the test, including data on the typical resources necessary to perform the test.

The Secretary shall cause to have published in the Federal Register and on an appropriate Internet site public notice of each such request. Such information shall be supplied to the Secretary by the standing panel.

(e) CRITERIA FOR EVALUATING REQUESTS FOR DETERMINATIONS IN CODING AND PAYMENT.—

(1) IN GENERAL.—In determining whether a requested payment determination should be granted, and what the new payment amount for a test should be, the standing panel (in making its recommendations to the Secretary) and the Secretary (in determining whether to grant such a determination) shall take into account typical resources necessary to perform the test, the expected impact of the test on, and value of the test to, patient care management, and such other factors as the standing panel and the Secretary, respectively, determine to be relevant to the determination.

(2) STANDING PANEL.—Not later than 180 days after the appointment of all of the members of the panel, the panel shall, after consultation with the Secretary, establish and make available to the public—

(A) standards and parameters for determining whether to recommend to the Secretary a coding or payment determination specified in a request for inclusion of a test in the demonstration, which shall include a listing of data elements necessary to support a request and a standardized procedure for collecting and submitting data to the panel on typical resources necessary to perform a test;

(B) policies and procedures for protecting the confidentiality of financial and other proprietary data submitted to the panel in support of a request; and

(C) resource intervals or resource bands (as described in subsection (g)(1)) that the panel recommends that the Secretary should use for the assignment of included tests under the demonstration.

(3) SECRETARIAL DETERMINATIONS.—The Secretary shall develop and make available to public on

an Internet site guidance documents on the standards and parameters that will be applied in making Secretarial determinations and on the resource intervals or resource bands to be used under the demonstration and on whether to grant a request for a payment or coding determination. Such guidance documents shall be developed, which shall be made available to the public at least 10 days before the beginning of the demonstration, in a manner similar to the manner in which guidance documents are developed under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

(4) AUTHORITY TO RECOMMEND REVISIONS TO, AND TO REVISE, RESOURCE INTERVALS OR RESOURCE BANDS.—Nothing in this section shall be construed as limiting the authority of the standing panel to recommend, or the Secretary to adopt, new resource intervals or resource bands to accommodate changes in technology.

(f) REVIEW PROCESS.—

(1) REQUESTS FOR INCLUSION IN DEMONSTRATION.—An interested party may submit a request for inclusion of a test in the demonstration to the standing panel at any time during a calendar year for which the demonstration is in effect, except that

the standing panel may decline to review and make recommendations or determinations with respect to any request that would result in a requested coding or payment determination being effective for a period of less than 4 calendar quarters.

(2) RECOMMENDATIONS OF STANDING PANEL.—The standing panel shall review each request for a coding or payment determination that is made with respect to an included test. Applying the standards and parameters developed under subsection (e)(2)(A), the panel shall make a recommendation to the Secretary with respect to each requested determination.

(3) SECRETARIAL DETERMINATIONS.—

(A) QUARTERLY DETERMINATIONS.—The Secretary shall make determinations on whether to grant requested coding and payment determinations on a quarterly basis, but is not required to make such a determination for every request made (or with respect to which a recommendation is received from the standing panel) during a particular quarter.

(B) TIME FRAMES FOR DETERMINATIONS.—Determinations of the Secretary shall be made in a timely manner in accordance with

time frames developed by the standing panel taking into account factors such as when a request (and a recommendation with respect to the request) is made during a quarter, the particular type of test involved, and the staffing and resources that may be required to review the request.

(g) PAYMENT METHODOLOGY.—

(1) IN GENERAL.—Included tests shall be paid in accordance with a methodology, developed by the standing panel, that establishes resource intervals or resource bands in a manner similar to those that are used as new technology ambulatory payment classification groups for hospital outpatient services under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), with a test being assigned to the interval or band that most closely approximates the typical resources necessary for a laboratory to perform the test. Tests that are included tests for purposes of this section shall be excluded from any demonstration project under section 1847(e) of such Act (42 U.S.C. 1395w–3(e)).

(2) PANEL RECOMMENDATIONS; SECRETARIAL DETERMINATIONS.—

(A) RECOMMENDATIONS; SECRETARIAL DETERMINATIONS.—The standing panel shall recommend to the Secretary a resource interval or resource band to which an included test should be assigned, and the Secretary may assign such test to such band or interval or to another band or interval the Secretary determines to more closely approximate the typical resources necessary to perform the test.

(B) EXPLANATION OF DETERMINATION THAT DIFFERS FROM RECOMMENDATION.—If the Secretary assigns a test to an interval or band other than that recommended by the standing panel, the Secretary shall provide a detailed written explanation of the reasons for determining that such other interval or band is more appropriate.

(3) EFFECTIVE DATE OF SECRETARIAL DETERMINATION.—A determination by the Secretary with respect to a coding or payment determination for an included test shall become effective as of the first day of the calendar quarter following the calendar quarter in which the determination is made.

(4) PERIODIC LOOK-BACKS OF INTERVAL OR BAND ASSIGNMENTS.—At the request of the inter-

ested party that submitted the initial request for a test to be included in the demonstration or of a member of the standing panel, the standing panel may review the appropriateness of the payment interval or band to which the test is assigned and make a recommendation to the Secretary that the assignment be changed. The Secretary may accept or reject such recommendation, and if the recommendation is rejected, the Secretary shall provide a detailed explanation of the reasons for such rejection.

(5) PUBLICATION OF DETERMINATIONS.—The Secretary shall publish determinations under this subsection in a timely manner on an appropriate Internet site.

(h) REPORTS TO CONGRESS.—

(1) IN GENERAL.—The Secretary shall submit interim and final reports on the demonstration to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate. The interim report shall be submitted not later than the close of the second year of the demonstration, and the final report shall be submitted not later than 180 days after the close of the demonstration.

(2) CONTENT OF REPORTS.—The reports submitted under paragraph (1) shall include interim and final—

(A) determinations on whether coding and payment assignments under the demonstration provide for—

(i) more equitable and accurate payment for included tests; and

(ii) reduced administrative complexity, improved efficiency, and improved access to care; and

(B) recommendations on—

(i) whether the alternative mechanism for determining payment and coding for included tests should be continued for such tests beyond the 12-calendar-quarter period the demonstration is in effect; and

(ii) whether the application of such mechanism should be expanded to include other new clinical diagnostic laboratory tests for which payment would otherwise be made under the fee schedules and limits established under section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)).

(3) COMMENTS BY STANDING PANEL.—The standing panel shall submit comments to the committees referred to in paragraph (1) on the interim and final reports of the Secretary.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for each of fiscal years 2008 through 2013, such sums as may be necessary to carry out this section.

TITLE II—CHANGES TO THE MEDICARE CLINICAL LABORATORY FEE SCHEDULE

SEC. 201. FEE SCHEDULE AND NATIONAL LIMITATION AMOUNTS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

(a) IN GENERAL.—Section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)) is amended by adding at the end the following new paragraph:

''(9)(A) For purposes of this paragraph:

''(i) The term 'an amount determined under this subsection' means, with respect to a clinical laboratory test, the fee schedule amount determined under paragraph (2)(A)(i) for the test or the limitation amount determined under paragraph (4)(B) for the test.

''(ii) The terms 'appropriate medicare administrative contractor' and 'medicare administrative contractor' have the meaning given to such terms under section 1874A(a)(3).

''(iii) The term 'erroneous decision' means, with respect to the determination of an amount determined under this subsection, any decision, calculation, judgment or other action by the Secretary or a medicare administrative contractor that, based upon consideration of currently known facts, needs to be modified to produce a fair and equitable payment amount, except that such term does not include typographical or clerical errors.

''(iv) The term 'non-governmental party' includes—

''(I) a provider of services (as defined in section 1861(u)) that furnishes clinical diagnostic laboratory tests for which payment may be made under this subsection;

''(II) a supplier (as defined in section 1861(d)) that furnishes such tests; and

''(III) a manufacturer of a test or of any supplies or equipment that are used in performing such test.

''(B) An amount determined under this subsection may be changed solely on the basis of—

''(i) in the case of a change other than a change to correct an erroneous decision in determining such amount, the authority provided by the preceding provisions of this subsection, section 1842(b)(8), or any regulations, manual instructions, or other regulatory guidance implementing such provisions; or

''(ii) in the case of a change to correct an erroneous decision in determining such an amount, the authority provided by subparagraphs (C), (D), and (E).

''(C) Any erroneous decision in determining an amount under this subsection may be corrected only if—

''(i) a non-governmental party submits a request under subparagraph (D) or (E) for correction of the erroneous decision; and

''(ii) such party demonstrates, to an appropriate medicare administrative contractor under subparagraph (D) or the Secretary under subparagraph (E), that an erroneous decision clearly was made.

''(D)(i) Any non-governmental party may request (in such form and manner as the Secretary may require) that the appropriate medicare administrative contractor change a fee schedule amount determined under paragraph

(2)(A)(i) to correct an erroneous decision in determining such amount.

''(ii) Any request under this subparagraph shall include a statement of the basis for the non-governmental party's belief that an erroneous decision was made in determining such amount, together with supporting evidence and a description of any additional data (other than data already in the possession of the appropriate medicare administrative contractor) that—

''(I) is or may be in the possession of the Secretary or another medicare administrative contractor; and

''(II) is necessary to demonstrate that such an erroneous decision exists.

''(iii) If the Secretary or another medicare administrative contractor is identified as possessing or potentially possessing additional data identified by a non-governmental party in a request under this subparagraph, the Secretary or such contractor, as the case may be, shall make available to the non-governmental party within 30 days after the date of the submission of the request any data in their possession that meet the description of the additional data identified in such request, with appropriate safeguards to protect confidential and proprietary information.

''(iv) If additional data are made available to a non-governmental party under clause (iii), such party may amend its request under this subparagraph to incorporate such data within 30 days after the date such data are made available to such party.

''(v) An appropriate medicare administrative contractor to which a request is submitted under this subparagraph shall make a determination with respect to whether to correct the decision that is identified as erroneous in the request not later than 60 days after the date of the submission of such request, or if later, the date of the submission of an amended request under clause (iv). Such contractor shall determine that the non-governmental party submitting the request—

''(I) has demonstrated that an erroneous decision clearly was made, correct such erroneous decision, and increase the fee schedule amount as of the first day of the next calendar quarter to reflect the correction of such erroneous decision; or

''(II) has failed to demonstrate that an erroneous decision clearly was made and decline to change the fee schedule amount,

and shall provide to the non-governmental party a written explanation of the basis for such determination.

''(vi) An appropriate medicare administrative contractor to which a request is submitted under this subparagraph may not reduce a fee schedule amount pursuant to such request, and may reduce such an amount only pursuant to section 1842(b)(8).

''(E)(i) Any non-governmental party may request (in such form and manner as the Secretary may require) that the Secretary—

''(I) reverse a determination of a medicare administrative contractor under subparagraph (D) that is adverse to the non-governmental party requesting it;

''(II) correct an erroneous decision in the determination of a limitation amount under paragraph (4)(B); or

''(III) reverse a determination referred to in subclause (I) and correct an erroneous decision referred to in subclause (II).

''(ii) Any request under this subparagraph shall include a statement of the basis for the non-governmental party's belief that an erroneous decision was made in determining such amount, together with supporting evidence and a description of any additional data (other than data already in the possession of the Secretary or the appro-

priate medicare administrative contractor reviewing the request under subparagraph (D)) that–

''(I) are or may be in the possession of the Secretary or another medicare administrative contractor; and

''(II) are necessary to demonstrate that such an erroneous decision exists.

''(iii) If the Secretary or another medicare administrative contractor is identified as possessing or potentially possessing additional data identified by a non-governmental party in a request under this subparagraph, the Secretary or such contractor, as the case may be, shall make available to the non-governmental party within 30 days after the date of the submission of the request any data in their possession that meet the description of the additional data identified in such request, with appropriate safeguards to protect confidential and proprietary information.

''(iv) If additional data are made available to a non-governmental party under clause (iii), such party may amend its request under this subparagraph to incorporate such data within 30 days after the date such data are made available to such party.

''(v) The Secretary shall make a determination of whether to correct the erroneous decision that is the sub-

ject of a request submitted under this subparagraph not later than 60 days after the date of the submission of such request, or if later, the submission of an amended request under clause (iv). The Secretary shall determine that the non-governmental party submitting the request—

''(I) has demonstrated that an erroneous decision clearly was made, correct such erroneous decision, and increase the fee schedule amount as of the first day of the next calendar quarter to reflect the correction of such erroneous decision; or

''(II) has failed to demonstrate that an erroneous decision clearly was made and decline to change the fee schedule amount or national limitation amount, as the case may be,

and shall provide to the non-governmental party with a written explanation of the basis for such determination.

''(vi) The Secretary may not reduce a fee schedule amount pursuant to a request under this subparagraph and may reduce such an amount only pursuant to section 1842(b)(8).

''(F)(i) There shall be no administrative or judicial review under section 1869, 1878, or otherwise of any determination made under subparagraph (D) or (E).

''(ii) Nothing in this paragraph shall be construed as precluding administrative or judicial review of determina-

tions of the amount of benefits that are available to a Medicare beneficiary in a particular case.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply to requests for corrections submitted on or after such date, without regard to whether final regulations to carry out such amendment have been issued.

SEC. 202. ISSUANCE OF REGULATIONS ON GAP-FILLING FOR MEDICARE FEE SCHEDULE FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue final regulations specifying how an appropriate medicare administrative contractor (as defined in section 1874A(a)(3)(B) of the Social Security Act (42 U.S.C. 1395kk–1(a)(3)(B)) shall apply a gap-filling methodology in determining fee schedule amounts established under section 1833(h)(2)(A)(i) of such Act (42 U.S.C. 1395l(h)(2)(A)(i)). Such regulations shall specify—

(1) a process for ensuring that the resulting fee schedule amounts are fair, including a description of the types of data to be collected for use in such methodology and the minimum requirements such

data shall meet in order to ensure that the data are valid, meaningful, and unbiased;

(2) the principles to be employed to ensure that such data are statistically significant and alternatives to follow if statistically significant data are unavailable;

(3) the principles to be followed in using data to calculate fee schedule amounts, including principles for excluding data that do not meet the requirements of paragraph (1) and (2);

(4) the methods the Secretary will use to oversee the application of a gap filling methodology by such contractors and the remedies that will be available in cases in which such a contractor fails to comply with regulatory requirements; and

(5) a process that provides opportunities for the public to participate in the development of fee schedule amounts through the application of gap-filling methodologies, including release to the public of data collection protocols and the data derived from such protocols with an opportunity for public comment thereon.

SEC. 203. INCREASED TRANSPARENCY OF PROCESS FOR DETERMINING FEE SCHEDULE AMOUNTS FOR NEW TESTS.

Section 1833(h)(8) of the Social Security Act (42 U.S.C. 1395l(h)(8) is amended—

(1) in subparagraph (B)(iii), by inserting ''to be conducted in an inter-active format,'' after ''meeting,'';

(2) in subparagraph (B)(iv)—

(A) by inserting ''(I)'' after ''meeting,'';

(B) by striking ''determination,'' and inserting ''determination and''; and

(C) by striking ''a request for'' and inserting ''(II) publishes in the Federal Register a notice of a period of not less than 60 days during which the Secretary will receive''; and

(3) in subparagraph (C), by striking ''Under the procedures'' and inserting ''In the regulations''.

SEC. 204. ADVANCE NOTICE OF CLINICAL DIAGNOSTIC LABORATORY TEST AMOUNTS BEING CONSIDERED FOR ADJUSTMENT UNDER INHERENT REASONABLENESS AUTHORITY.

(a) LIMIT ON INHERENT REASONABLENESS AUTHORITY.—Section 1842(b)(9)(A) of the Social Security Act (42 U.S.C. 1395u(b)(9)(A)) is amended by adding at the end the following: ''Before publishing a proposed no-

tice under subparagraph (B) with respect to any clinical diagnostic laboratory test being considered for adjustment under paragraph (8), advance notice that such test is being considered for such an adjustment shall be provided to non-governmental parties (as defined in section 1833(h)(9)(A)(iv)) at the meeting required by section 1833(h)(8)(B)(iii), together with an opportunity for such representatives and other individuals to make oral comments on the appropriateness of such an adjustment for such test.''.

(b) CONFORMING CHANGE.—Section 1833(h)(8)(B) of such Act (42 U.S.C. 1395l(h)(8)(B)) is amended by adding at the end the following:

''At the meeting required by clause (iii), the Secretary shall provide advance notice of inherent reasonableness adjustments under section 1842(b)(8) that are being considered for clinical diagnostic laboratory tests, and afford an opportunity for non-governmental parties (as defined 1833(h)(9)(A)(iv)) at the meeting to comment orally on the appropriateness of such an adjustment.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall become effective on January 1, 2008, and shall apply to inherent reasonableness adjustments that have not been proposed as of such date.

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