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I

109TH CONGRESS
2D SESSION

H. R. 5369

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

IN THE HOUSE OF REPRESENTATIVES

MAY 11, 2006

Mr. FERGUSON (for himself, Mr. ENGLISH of Pennsylvania, Mr. RUSH, and Mr. THOMPSON of California) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

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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 Clinical Laboratory Fee Schedule Improvement Act of 2006".

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

TITLE I—NEAR-TERM CHANGES

SEC. 101. 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 con-

tractor' 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 pursu-

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

"(I) are or may be in the possession of the Secretary or an 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 subject 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 determinations 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. 102. 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. 103. 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. 104. 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 notice 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, 2007, and shall apply to inherent reasonableness adjustments that have not been proposed as of such date.

TITLE II—FUTURE REFORM

SEC. 201. 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); or

(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; 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 other health professionals 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 clinical laboratory cost accounting (both macro and micro); 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 mem-

ber 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 direct and indirect laboratory costs (including test acquisition costs) of 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.

(c) 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 direct and indirect laboratory costs (including test acquisition costs), the expected impact of the test on 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 dem-

onstration, which shall include a listing of data elements necessary to support a request and a standardized procedure for collecting and submitting data on typical costs to the panel;

(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) cost intervals or cost 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 cost intervals or cost 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, COST INTERVALS OR COST BANDS.—Nothing in this section shall be construed as limiting the authority of the standing panel to recommend, or the Secretary to adopt, new cost intervals or cost 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 sub-

section (c)(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 cost intervals or cost 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 cost interval or cost band that most closely approximates the typical direct and indirect costs (including test acquisition costs) of the test for a laboratory. 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(c)).

(2) PANEL RECOMMENDATIONS; SECRETARIAL DETERMINATIONS.—

(A) RECOMMENDATIONS; SECRETARIAL DETERMINATIONS.—The standing panel shall recommend to the Secretary a cost interval or cost 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 direct and indirect costs (including test acquisition costs) of the test.

(B) EXPLANATION OF DETERMINATION THAT DIFFERS FROM RECOMMENDATION.—If the Secretary assigns a test to a cost 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 interested 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 2007 through 2012, such sums as may be necessary to carry out this section.

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AdvaMed
Advanced Medical Technology Association

October 6, 2006

Via Electronic and U.S. Mail

Leslie V. Norwalk, Esq.
Deputy Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop: C5-11-24
Baltimore, MD 21244

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (CMS-1321-P)

Dear Ms. Norwalk:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 (CMS-1321-P, *Federal Register*, Vol. 71, No. 162, Tuesday, August 22, 2006, p. 48981). AdvaMed is the world's largest association representing manufacturers that produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule we remain concerned with others. AdvaMed supports the establishment of payment rates under the physician fee schedule that are adequate and ensure access to advanced medical technologies by Medicare beneficiaries. We will comment on the following issues raised in the proposed 2007 PFS Rule:

1. Deficit Reduction Act Proposals
2. Bone Mass Measurement (BMM) tests

3. Resource Based Practice Expense RVU Proposals
4. Clinical Diagnostic Lab Tests
5. ASP Issues

PROVISIONS

I. DRA Proposals

Proposed Adjustments for Payment to Imaging Services

A. Payment for Multiple Imaging Procedures for 2007

The Deficit Reduction Act (DRA) of 2005 contained two provisions affecting imaging services paid under the Medicare physician fee schedule. Among these was a mandate that budget neutrality provisions be waived for reductions in payment for contiguous body part imaging. Initially, CMS proposed to reduce payments for these services by 50 percent beginning in 2006. However, in the final rule CMS decided to phase in the 50 percent reduction over a period of two years. Consequently, a 25 percent reduction went into effect for 2006 and an additional 25 percent reduction was expected to be phased in as of January 1, 2007.

In the proposed 2007 PFS rule, CMS has indicated that it would be prudent to maintain the imaging discount at 25 percent for 2007 while continuing to evaluate the appropriate payment for the multiple image procedures subject to the discount. AdvaMed is pleased with this decision and commends CMS for not moving to the 50 percent discount. AdvaMed encourages CMS to be vigilant in obtaining and evaluating data relating to the costs of these procedures so that the most accurate cost information can be used in making any future determinations regarding reductions in the price of imaging services.

B. Reduction in Technical Component for Imaging services Under the PFS to OPD Payment Amount

The DRA requires that, effective January 1, 2007, the payments for the technical component of certain imaging procedures performed in a physician office be capped at the lesser of the Medicare physician fee schedule or the outpatient department (OPD) reimbursement rate. AdvaMed is concerned that capping the technical component payment at the OPD rate will lead to significant reductions in the payment for imaging procedures performed in the physician office setting and may reduce beneficiary access to these procedures.

These findings are supported by a recent report conducted by The Moran Company (Moran) in which they analyzed the impact of the DRA provisions.[1] The Moran report

1 See Assessing the Deficit Reduction Act Limits on Image Reimbursement: Cross-Site Comparisons of Cost and Reimbursement, The Moran Company, September 2006
http://www.imagingaccess.org/reports/index.cfm

found that 87% of the procedures whose payments will be affected by the DRA caps would be paid at an amount that is less than the estimated cost of performing the procedure in the office setting. According to the Moran report, several procedures including image guided ultrasound procedures used in the diagnosis of breast cancer, PET/CT exams used to diagnose cancerous tumors, bone density studies used to diagnose osteoporosis, and MR angiography used to locate aneurysms will be cut 35% to upwards of 50% if the DRA changes are enacted. These cuts may result in diagnosis and treatment delays, increased wait times, and reduced access for patients in rural areas to critical imaging services.

AdvaMed is concerned with the impact of the DRA provisions on image guided treatment procedures. CMS has interpreted the DRA provisions regarding imaging issues as relating to both "*diagnostic*" and "*image guided*" procedures. However, this interpretation is not borne out by the MedPAC recommendations, which focus specifically on increased utilization of diagnostic imaging services. In fact, in its March 2005 report to Congress MedPAC cites the efficacy of two image guided procedures, biopsies for bone-cancer and coronary angioplasty, as examples of image guided procedures which benefit patients.[2] The MedPAC analysis did not determine whether growth in imaging utilization was due to over-utilization or appropriate expansion of imaging as a diagnostic tool.

The March 2005 MedPAC report makes several recommendations based on its review of *diagnostic* imaging services including the imposition of coding edits to detect unbundled *diagnostic* imaging services and setting standards for physicians who bill Medicare for interpreting *diagnostic* imaging studies.[3] The content of the MedPAC report coupled with their recommendations suggest that they did not identify issues related to image guided treatment procedures.

AdvaMed is concerned that capping the technical component of imaging procedures, in accordance with the DRA mandate, may interfere with patient access to necessary care. We therefore recommend that caps to the technical component of imaging services not be applied to image guided treatment procedures.[4] In order to reduce adverse patient impact, we further recommend that any caps to the technical component of imaging services be applied in the most prudent manner possible.

AdvaMed is also concerned that several Category III CPT imaging codes are incorrectly included on the list of DRA cap-eligible procedures (Addendum F). Category III CPT codes are dedicated to emerging technologies, are primarily intended for tracking purposes only, and are not assigned RVU values at the national level. While some Category III

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2 See Report to the Congress: Medicare Payment Policy, MedPAC, Page 155 (March 2005).

3 See Report to the Congress: Medicare Payment Policy, MedPAC, Pages 159 and 163 (March 2005).

4 Approximately 18 image guided treatment procedures would be affected by the DRA caps. These codes are all done in conjunction with a surgical or other procedure. Eliminating these codes from the DRA cap would have nominal impact, estimated at 2%, on total projected savings.

CPT codes are covered under Medicare and are Medicare Carrier-priced, they do not have physician fee schedule technical components and therefore would not be subject to the DRA mandated caps. Therefore, AdvaMed urges CMS to remove all Category III CPT codes from the proposed CPT/HCPCS imaging codes list.

C. Interaction of the Multiple Imaging Payment Reduction and the OPPS Cap

The proposed rule recommends that the 25% multiple procedure imaging reduction be applied prior to the OPPS cap in the case of procedures impacted by both the multiple procedure discounts and the OPPS cap. The OPPS cap would then be applied to the reduced amount. CMS has indicated that this method is being applied because the OPPS rates may already include implicit discounts. The proposed methodology would be implemented while CMS continues to explore the issue. Given the uncertainty of the OPPS data we encourage CMS to take an approach that fairly reflects the costs involved in performing imaging tests.

Proposed Addition of Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)

AdvaMed is pleased that, pursuant to DRA requirements, CMS will be including screening for AAA as a covered benefit for Medicare beneficiaries meeting the established criteria effective January 1, 2007. Providing this potentially life saving screening exam is important to beneficiaries. The coverage criterion for the benefit identifies and adequately addresses the needs of the Medicare population most at risk for AAA. AdvaMed is also pleased with the recommendation to pay for this service at the same level as CPT code 76775—a service requiring resources and work intensity comparable to that of the screening procedure.

II. Bone Mass Measurement (BMM) Tests

The proposed rule revises the definition of bone mass measurement (BMM)to remove coverage for single photon absorptiometry (SPA) and to include coverage for axial skeleton measures (DXA). This change is guided by the shift in technology from SPA to DXA. AdvaMed is please that CMS recognizes the technological developments which have led to the use of DXA and other technology in accurately assessing BMM. As such, AdvaMed would also like to commend CMS for its proposal to allow use of the NCD process to identify other BMM systems which can be used to monitor patients with osteoporosis and those requiring confirmatory baseline measurements. An NCD is already in place relating to the identification of BMM indications and coverage. Allowing new devices to go through the NCD process will create consistent coverage determinations for these treatments.

AdvaMed strongly supports CMS's coverage improvement, but is concerned that reductions in the reimbursement for BMM procedures utilizing DXA technologies may compromise patient access to the technology. Specifically, we are concerned with proposed reductions in the payments for CPT codes 76075, 76077, and 76977 in 2007. In

the proposed regulation, CMS supports its decision to use DXA to monitor bone mineral density by stating that, "DXA is precise, safe, and low in radiation exposure, and permits more accurate and reliable monitoring of individuals over time." However, continuing reimbursement decreases for procedures utilizing DXA technology may limit patient access to this monitoring method and the benefits associated with its use. Therefore, AdvaMed encourages CMS to take steps to correct and prevent further reductions in payment for procedures utilizing DXA technology.

III. Resource-Based Practice Expense (PE) RVU Proposals

Payment for Splint and Cast Supplies

AdvaMed supports CMS' proposal to reinstate separate coding and payment for cast, splint, and strapping supplies under the Medicare Physician Fee Schedule in calendar year (CY) 2007. We agree with CMS' conclusion that these supplies are considered medically necessary not only for the management of fractures and dislocations, but also for serial casting, wound care, and protection. Assigning distinct HCPCS billing codes for these supplies, when furnished incident to specified professional services, will enable contractors to identify with greater accuracy those instances in which cast, splint, and strapping supplies are medically necessary and eligible for payment.

CMS has requested input from medical specialties and contractors on its proposal to pay separately for splint and casting supplies billed with Q-codes. See Federal Register, Vol. 71, No. 162 page 48987. AdvaMed is aware of a related coding issue that may result in underpayment for supplies used in wound care procedures.

As proposed, CMS' refinements to the practice expense (PE) database would exclude cast, splint, and strapping supplies used in compression therapy for venous leg ulcers from the list of separately paid supplies. Currently, CMS proposes to use HCPCS Q-codes to identify those supplies that would receive separate fee schedule payment amounts, and for which supply inputs would be excluded from the PE database. However, paste bandage supplies (also referred to as Unna-boot supplies) are currently assigned HCPCS A-codes, not HCPCS Q-codes. As a result, contractors would be unable to determine whether to make separate fee schedule payments for these supplies when billed with CPT 29580, application of paste boot. In addition, because payment for paste bandage supplies would be excluded from the PE database for CPT 29580, physicians would be underpaid for use of these supplies. AdvaMed recommends that CMS instruct contractors to make separate payment for paste bandage supplies when reported on the CMS-1500 claim form with the HCPCS A-codes listed below.

HCPCS	Paste bandage supply
A6441	Padding bandage, width >=3" but <5", per yard
A6442	Conforming bandage, non-sterile, width <3", per yard

HCPCS	Paste bandage supply
A6443	Conforming bandage, non-sterile, width >=3"but <5", per yard
A6444	Conforming bandage, non-sterile, width >=5", per yard
A6445	Conforming bandage, sterile, width <3", per yard
A6446	Conforming bandage, sterile, width >=3" but <5", per yard
A6447	Conforming bandage, sterile, width >=5", per yard
A6448	Light compression bandage, width <3", per yard
A6449	Light compression bandage, width >=3" but <5", per yard
A6450	Light compression bandage, width >=5", per yard
A6451	Moderate compression bandage, width >=3" but <5", per yard
A6452	High compression bandage, width >=3" but <5", per yard
A6453	Self-adherent bandage, width <3", per yard
A6454	Self-adherent bandage, width >=3" but <5", per yard
A6455	Self-adherent bandage, width >=5", per yard
A6456	Zinc paste impregnated bandage, width >=3" but <5", per yard

Impact of Practice Expense Changes

Changes in the PE relative value units resulting from the incorporation of supplemental survey data are expected to have a significant impact on some specialties. Other specialties' PE values will be negatively impacted as a result of the transition to a bottom-up methodology. The impact of the PE changes, though anticipated, is especially difficult given the proposal to reduce the conversion factor by 5.1% in 2007.[5] CMS has proposed to phase in the PE changes over a four-year period, 2007-2010, to avoid adverse impacts on specialty fees. However, the proposed changes will result in significant reductions in the reimbursement for several procedures and could adversely impact patient access. For example, Medicare payments for a complete course of partial breast irradiation in a freestanding center would decrease by (19% in 2007 and 56% in 2010). These decreases could result in both reduced access and options for Medicare beneficiaries. AdvaMed urges CMS to take steps to ensure that patients continue to have access to the treatments and technologies that improve their quality of life and encourages implementation of the PE changes in the most practical manner possible.

IV. Clinical Diagnostic Lab Tests

AdvaMed also wishes to comment on the implementation of section 942 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which specified improvements to CMS's current process for developing clinical laboratory fee schedule (CLFS) payment rates for new or substantially revised pathology or laboratory CPT codes. Many of AdvaMed's member companies develop clinical laboratory tests that substantially improve the quality of life for Medicare beneficiaries through the prevention and early diagnosis of disease.

5 Prior to publication of the proposed PFS rule the conversion factor was expected to be reduced by approximately 4.6%.

We appreciate the progress CMS has made to date in improving its process for developing payment rates for new or substantially revised CPT codes for clinical laboratory services under the Clinical Laboratory Services Fee Schedule (CLFS). We commend the agency for holding its annual "Laboratory Public Meeting," which provides the public a forum to present views on the tests and services that will be included in the following year's edition of CPT. We have appreciated the opportunity to present our comments at this annual public meeting for the past few years.

We believe that providing opportunities for public discussion of agency payment policy activities is crucial to an open, transparent process. The expertise that stakeholder groups offer at these meetings has resulted in more clinically appropriate payment determinations. Further, we appreciate and commend the action the agency has taken to post proposed new clinical lab payment determinations for comment, after receiving public input at the open public meeting. These measures are consistent with MMA section 942, and we believe they represent a significant improvement to CMS's process for determining new test payments.

Notwithstanding these improvements, the MMA included other provisions relating to the process for determining payment for new clinical laboratory tests that must be addressed. We will identify these provisions as we comment on the following areas: (i) the general CMS payment process for developing CLFS payment rates for new or substantially revised CPT codes; (ii) the gap-fill process; (iii)the cross-walk process ; and (iv) other overarching issues.

A. General Process Issues

a. Rationales, Data and Responses to Comments

In the preamble to the proposed PFS rule, CMS states that the "current process for providing public consultation on the establishment of payment amounts . . . is consistent with the requirements of section 1833(h)(8)(B)" of the Social Security Act (section 942 of the MMA) [71 Federal Register 49063 (Aug. 22, 2006)]. While CMS asserts that it is in full compliance with the statutory requirements, we note that both the law, and the proposed regulations [42 C.F.R. section 414.406], require that CMS post on the internet a list of proposed and final determinations of the payment amounts for tests "with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions from the public."

We support incorporation of this language in CMS's regulations. However, we note that CMS's current practice differs from this requirement. At present, CMS posts its proposed and final determinations, but does not post the rationale, data, or responses to comments from the public. Thus, there appears to be a discrepancy between what is required by law and CMS's assertion in the preamble to these regulations that they are currently complying with the law.

Making public the rationale and the data on which CMS's proposed and final determinations are based, in addition to the CMS responses to comments from the public, would be an additional positive step towards increasing transparency and openness in CMS's payment process. This is the approach CMS follows for its other payment systems, and we strongly urge CMS to conform its practices to both the statutory requirements and its own proposed regulatory language in implementing MMA section 942. Providing this information and an explanation for specific payment determinations via the CMS website (similar to the way CMS provides this information and explanation in the regulation preambles for other payment systems, including the physician fee schedule and the hospital outpatient prospective payment system) would be one way to implement this legislative requirement. If CMS is not able to provide the rationale, data, and its responses to public comments on the internet and elsewhere, we ask that CMS explain why the information is not publicly available.

b. Web-Posting of All Public Comments or Suggestions

Additionally, we note that in the past, CMS has not posted on the internet all of the public suggestions made to the agency regarding payment rates for new or substantially revised CPT codes. Posting all such comments or suggestions made to the agency, whether before or shortly after the Laboratory Public Meeting that CMS holds annually, would be another practice that could improve the CMS payment process.

c. Announcement of Meetings and Codes to be Discussed

While we recognize that CMS is required by the MMA to announce its annual Laboratory Public Meeting in the *Federal Register* "not fewer than 30 days" prior to the meeting, we recommend announcing the meeting – and making public the new or substantially revised CPT codes that will be the subject of the meeting earlier in the year – at least 60 days in advance of the meeting. Providing such advanced notice of the codes to be discussed at the meeting will allow for the development of more meaningful and well-considered public comments. We note that these comments often require technical expertise that is often difficult to obtain within only 30 days and thus extending the notice to 60 days in advance of the meeting would be a significant improvement.

B. Gap-Fill Issues

We are disappointed that CMS did not address the methodology that contractors should use in establishing local gap-fill payment rates for new test codes. AdvaMed members believe that it is imperative that CMS set forth a clear approach to pricing these new tests. As we have stated on record at several of the open public meetings for the CLFS, stakeholders often suggest that the cross-walk process be used for new test codes instead of the gap-fill process because the gap-fill methodology is neither well-defined, nor monitored by CMS.

In the limited, previous instances when gap-fill has been used, carriers made use of a wide variety of pricing techniques. Individual carriers set prices based on the following types of information or techniques, which illustrate some of the concerns we have with the gap-fill process:

- A consultant's recommendations;
- The payment level assigned to "related code(s)" already on the fee schedule, even though Medicare officials had chosen not to cross-walk the test and issued instructions to carriers to "gap-fill" the test;
- Carrier pricing formulas based variously on relative values imputed to the test, the customary charges associated with the test, and so forth;
- Considering prevailing charge data in the carrier area, and reducing these charges to a previously set NLA for the test to which it had been "cross-walked" (this was a test that had been cross-walked initially, but then subsequently gap-filled);
- Applying an arbitrary percentage reduction in local laboratory charges for the new test;
- Carrier surveys of the rates set by other carriers for the test, which were the basis for subsequent questionable "calculations" to set carrier "gap fill" rates (e.g., these "calculations" produced rates set at the median, average, or some arbitrary percentage of the carrier rates collected);
- Carrier surveys of physicians who may not have had any experience with the test at issue;
- Carrier use of unverified data from the internet that may not reflect actual cost of providing the test in a CLIA-approved laboratory;
- Contacting only one patient to determine the time associated with the test;
- Following the personal opinion of another Carrier Medical Director; and
- Carrier Medical Director discretion.

Without guidance from CMS on the methodology that should be used by carriers in setting "gap fill" payment rates for new tests, there will continue to be uncertainty and variation in the rates that are set by carriers, leading to issues with the new test payment rates. Unless the "gap fill" price-setting methodology is based on accepted principles, the payment rates that are computed will be viewed as arbitrary. Consequently, we recommend that CMS make the following changes to improve the gap-fill process:

- Provide more specific, step-by-step direction on the methodology Carriers should use when conducting data collection, including the incorporation of external data

provided by laboratory providers (of varying size, setting, and patient mix), manufacturers, private payers, and other stakeholders;

- Provide instructions on how to incorporate charges for a given new test,
- Specify the minimum requirements this data shall meet to ensure that the data collected is valid, meaningful, and unbiased, including establishing a reasonable standard for the volume of claims that a carrier should process in developing the gap-fill payment rate;
- When newer data is available, contractors should use that data, rather than using the least costly alternative or similar standard;[6]
- Monitor the carrier's (contractor's) methodology and data reporting, providing, where needed, oversight and feedback to contractors to ensure compliance with CMS instructions and that appropriate data is being collected;
- At the close of the data collection time period, make available for public inspection and comment the proposed new national payment amount. Using informal mechanisms for requesting comment, such as the agency's web site --
    i. To facilitate meaningful comment, provide the data and methodology upon which the gap-filled amount is based;
    ii. If based on claims data, provide specific information on the number of claims, and the localities from which those claims were filed;
    iii. Provide principles to be employed to ensure that the data used by carriers are statistically significant and alternatives to follow if statistically significant data are unavailable; and
    iv. Provide any other information or data that was factored into the decision-making;
- In cases where such a contractor fails to comply with some or all of CMS-prescribed directions on the gap-fill methodology (e.g., to address instances where contractors simply cross-walk or rely on prices determined by other contractors, as opposed to collecting data individually according to CMS-set methods), that contractor's payment rate (and any "data" used to calculate it) should be excluded from the calculation of the NLA;
- Establish a mechanism to receive and review additional data, including data provided by the laboratory industry, manufacturers, and other stakeholders, in order to adjust the proposed national payment amount for the new test. This is particularly important in cases where a substantial number of contractor payment rates are excluded from the NLA calculation due to concerns with the methodology used;
- After taking into account additional data and comments received, publish the final national payment amount for the new test, with a clear explanation of the basis for

6 In particular, we note that the Conference Report to the MMA specifies that "carriers and CMS cannot substitute an alternative service for a gap filled amount." Accordingly, the least costly alternative approach is inconsistent with this report language.

its determination, again using informal publication mechanisms, such as the web site; and

- Make public the specific data and methodology upon which the gap-filled amount was based, including a listing of the local amounts used to arrive at the NLA, and any additional data or information provided during the comment period, with an opportunity for public comment thereon.

We note that CMS is currently using the gap-fill process to develop a payment rate for CPT code 83037. We believe that CMS has discretion to accept and implement many of the above-mentioned recommendations, even for the current, on-going gap-fill process. We recommend that CMS evaluate and consider additional, external data in this context.

Absent the provision of additional direction to contractors and changes to the gap-fill process as recommended above, we recommend that CMS consider an alternative approach to setting payment rates for new clinical laboratory test codes. AdvaMed supports H.R. 5369, the Clinical Laboratory Fee Schedule Improvement Act of 2006, which authorizes a demonstration project that would test a new approach to setting payment for molecular diagnostic tests. This approach would set up a stakeholder panel to advise CMS on appropriate pricing of such tests through a deliberative process that takes into account relevant data, the expertise of stakeholders with an understanding of the complexity of the tests, clinical laboratory resources involved, and the estimated impact of the test on patient care management. We have attached H.R. 5369 for your reference. We urge CMS to consider undertaking such an alternative pricing approach for unique new tests to address the longstanding problems with the gap-fill process.

C. Cross-Walk Issues

As we mentioned above, the cross-walk process is the primary method recommended by interested parties for use in pricing new or substantially revised test codes for the Medicare Clinical Laboratory Fee Schedule. This is in part because some cross-walks are suggested by stakeholders because the gap-fill process is fraught with uncertainty. Nevertheless, we commend CMS for the way it has used the cross-walk process since it began considering stakeholder comments at open public meetings and has given careful consideration to public comments and expert opinions expressed at these meetings.

Nevertheless, we see two areas for improvement in the cross-walk process:

- First, we recommend that when CMS chooses to cross-walk new or revised codes to existing codes, the cross-walk should be made to the national limitation amount (NLA) of the existing code on the fee schedule, rather than the local carrier fee schedule amounts which often vary significantly from one geographic area to another. If CMS chooses to cross-walk new tests to the NLA of existing tests on the fee schedule, this policy will prevent the geographic variation problems inherent in the CLFS from worsening.

- Second, provided that CMS makes significant changes to the gap-fill process to improve its predictability (as recommended above), we recommend that CMS provide more regulatory specificity to guide the cross-walk process. A specific definition of what "comparable" means, with the particular criteria that CMS considers, would improve the payment process overall and would provide a framework for CMS ultimately to provide the rationale for its particular cross-walk decisions. For example, it would be helpful to receive clarification regarding whether "comparable" refers to resources involved in performing the test or service (e.g., supplies, equipment, lab staff time, etc.), the type of test or service performed, or clinical similarity, among other potential factors.

We note that MMA section 942 requires CMS to set forth criteria for making new payment determinations. The MMA conference report specified that such criteria "include whether a payment rate should be established through gap-filling or cross-walking to an existing code." Clarity on the definition of what is "comparable" would also shed light on the basis for CMS's decision to cross-walk or gap-fill a new or substantially revised test code. Clarification on this point would be helpful once CMS has made significant improvements in the gap-fill process as noted above.

D. Other Overarching Issues

In addition, we urge CMS to establish a formal, timely reconsideration process to allow stakeholders to seek review of the payment determinations made by CMS or its contractors in relation to a given test code. Stakeholders should be able to request and receive a reconsideration of:

- A CMS decision to crosswalk or gap-fill a new or revised test code;
- A CMS crosswalk determination;
- A contractor determination of a gap-fill price; and/or
- A CMS calculation of the NLA for a new test.

Finally, there is considerable uncertainty surrounding how Medicare contractor reform will affect the CLFS and the process for developing payment amounts for new or substantially revised CPT codes. To improve predictability in this area, we request that CMS clarify the following:

- How will local fees be handled when new Medicare Administrative Contractors (MACs) are chosen? Will the various local fee schedules be maintained or will they be collapsed into a single price for each of the new jurisdictions? If so, what process will be used to do this?
- If a new test is gap-fill priced where there is a new MAC, will gap-fill prices continue to be set for each of the previous contractor jurisdictions?
- Will the new MACs have a separate medical director for each of the previous contractor jurisdictions who will set gap-fill prices for new test codes and maintain existing local fee schedules?

V. ASP Issues

The proposed rule recommends changes in the way Group Purchasing Organizations (GPOs) administrative fees are recognized. CMS proposes to treat GPO fees that do not satisfy the definition of bona fide service fees as price concessions.[7] AdvaMed seeks to clarify whether the proposed changes could impact the ability of manufacturers and other entities to comply with the GPO safe harbor to the anti-kickback statute found at 42 C.F.R. §1001.952(j) and requests that implementation of any changes in the treatment of administrative fees not affect the existing GPO safe harbor.

Conclusion

AdvaMed urges CMS to carefully consider our comments as well as those submitted by our member companies, as they provide a unique source of information in developing appropriate PFS and clinical diagnostic lab test payment rates. We appreciate the opportunity to submit comments on the August 22, 2006 proposed PFS rule, and look forward to working with CMS to address our concerns.

Sincerely,

Ann-Marie Lynch
Executive Vice President

cc: Herb Kuhn
Tom Gustafson
Terry Kay
Liz Richter
Laurence Wilson

Enclosures

7 CMS proposes to define the term bona fide service fee as fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not that entity takes title to the drug.