Provision of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)	Additional FY 2002 Medicare Home Health Estimated Expenditures Due to the BIPA Provision
Section 501—additional year delay of 15-percent reduction	$890 million.
Section 502—restoration of full home health market basket in FY 2001	$170 million.
Section 508—10-percent rural add-on for Medicare home health services furnished in a rural area	$310 million.

FY 2002 Update to Home Health PPS Rates Required by the Act	Additional FY 2002 Medicare Home Health Estimated Expenditures Due to Annual Update Required by Law
Section 1895(b)(3)(B) of the Act requires HH PPS rates increased by home health market basket minus 1.1 percentage points in FY 2002 (2.5% increase).	$350 million.

2. Effects on Providers

This notice with comment period will have a positive effect on providers of Medicare home health services by increasing their rate of Medicare payment. We do not anticipate specific effects on other providers. This notice with comment period reflects the statutorily required annual update to the HH PPS rates published in the July 3, 2000 final rule. Also, as discussed above, this notice with comment period provides an update to all Medicare HHAs. We do not believe there is a differential impact due to the consistent and aggregate nature of the update.

C. Alternatives Considered

As discussed in section II, this notice with comment period reflects an annual update to the HH PPS rates as required by statute. Due to the lack of discretion provided in the statutory requirements governing this notice with comment period, we believe the statute provides no latitude for alternatives other than the approach set forth in this notice reflecting the FY 2002 annual update to the HH PPS rates. Also, as discussed in section II for clarification, this notice addresses the 10 percent rural add-on required under section 508 of the BIPA for home health services furnished to beneficiaries who reside in a rural non-MSA area. Other than the positive effect of the market basket increase, this notice with comment will not have a significant economic impact nor will it impose an additional burden on small entities. When a regulation or notice imposes additional burden on small entities, we are required under the RFA to examine alternatives for reducing burden. Since this notice with comment period will not impose an additional burden, we have not examined alternatives.

D. Conclusion

We have examined the economic impact of this notice with comment period on small entities and have determined that the economic impact is positive, significant, and that all HHAs will be affected. To the extent that small rural hospitals are affiliated with HHAs, the impact on these facilities will also be positive. Finally, we have determined that the economic effects described above are largely the result of the BIPA provisions which this notice serves to announce.

We continue to analyze the appropriateness and accuracy of payments for differing case mixes. In the fall of 2001, we intend to undertake a re-evaluation of the OASIS reporting system's utility in ensuring more accurate and equitable PPS payments.

In accordance with the provisions of notice with comment Executive Order 12866, this was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 15, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: April 23, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–16384 Filed 6–28–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1186–N]

Medicare Program; Public Meeting for New Clinical Laboratory Tests—Payment Determinations for Calendar Year 2002

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to discuss the assignment of payment rates for specific new Current Procedural Terminology (CPT) codes for clinical laboratory tests. These codes will be included in Medicare's Clinical Laboratory Fee Schedule for calendar year 2002, which will be effective on January 1, 2002. The meeting is directed towards the discussion of technical issues relating to payment determinations for a specified list of new codes, and discussion will be limited to the codes on that list.

DATES: *The Meeting:* August 6, 2001, from 8:30 a.m. until 4 p.m., E.D.T.

Deadline for Registration: Individuals may register by sending a fax to the attention of Anita Greenberg at (410) 786–0169, no later than July 25, 2001. Please provide name, company name, address, telephone number, and indicate whether interested in making an oral presentation.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, should notify Anita Greenberg at fax number (410) 786–0169 or at telephone number (410) 786–4601 so that accommodations can be made.

ADDRESSES: *The Meeting:* The meeting will be held at the Health Care Financing Administration (HCFA) Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

Website: A summary of the meeting will be posted on HCFA's Internet website (*www.hcfa.gov*) within 1 month after the meeting.

General Information: The meeting will be held in a government building; therefore, security measures will be applicable. Anyone without government identification will need to present photo identification, sign-in, and supply registration information.

FOR FURTHER INFORMATION CONTACT: Anita Greenberg (410) 786–4601 (telephone); (410) 786–0169 (fax).

SUPPLEMENTARY INFORMATION: On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554. Section 531 of BIPA mandates that we establish, no later than 1 year after the date of enactment, procedures for coding and payment determinations for new clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act (the Act) that permit public consultation. In addition, section 531 specifies that the procedures for coding and payment that permit public consultation be conducted in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD–9–CM). The procedures to be implemented according to section 531 of BIPA are still under development. The public meeting announced in this notice will provide experience that will help inform the development of the procedures mandated by section 531 of BIPA for public consultation on payment of new clinical laboratory tests.

Meeting Topic

The introduction of new codes requires us to determine the rates at which the new codes will be paid. The meeting is intended to provide us with expert input on the nature of new tests before these determinations are made so that these decisions can be better informed. Discussion will be limited to the codes listed below. The nature of the payment determinations is described more fully in the background section, which follows.

The following is a list of new codes that will be discussed at the meeting. Final determinations for the actual numbering of the codes had not yet been completed at the time of publication of this notice. However, the identifying information we have included in this notice should be sufficient for those knowledgeable in coding for clinical laboratory services to be able to discuss the assignment of payment for the new codes. The list of newly created CPT codes for the calendar year 2002 is as follows:

Chemistry

- Code 82xxx: Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1–3 simultaneous determinations.
- Code 86683: (deleted).
- Code 83xxx: Oncoprotein, HER–2 neu (For tissue, see codes 88342 and 88365).

Immunology

- Code 86140: C-reactive protein; Code xxxxx: high sensitivity (hsCRP).
- Code 863xx: Inhibin A.
- Code 871xx: Cytomegalovirus direct fluorescent antibody (DFA).
- Code 871xx: Enterovirus direct fluorescent antibody (DFA).

Microbiology

- Code 878xx: Infectious agent antigen detection by immunoassay with direct optical observation; Streptococcus, group B.

  Code xxxxx: Clostridium difficile toxin A.

  Code xxxxx: Influenza.
- Code 87901: Infectious agent genotype analysis by nucleic acid (DNA or RNA): HIV1, reverse transcriptase and protease.

  Code xxxxx: Hepatitis C virus.

Procedure and Agenda

This meeting is open to the public. The on-site registration will be held from 8:30 a.m. to 9 a.m., followed by opening remarks. Registered persons from the public may present discussion and individual recommendations on payment determinations for specific new Current Procedural Terminology (CPT) codes for the 2002 Clinical Laboratory Fee Schedule, which is to become effective January 1, 2002. A newly created CPT code can either represent a refinement or modification of existing test methods, or a substantially new test method. Decisions regarding payment levels or methods for determining them for the newly created CPT codes will not be made at this meeting. However, the meeting will provide an opportunity for us to receive public input before we determine payments for the new codes. All discussions should be brief, and a written version should accompany any oral presentation. Information we find helpful for presenters to address includes the nature of the test method, applications, costs, and any recommendation the presenter may have regarding the method for establishing a payment rate (as discussed below). Due to time constraints, we may limit the number and duration of oral presentations to fit the time available.

Background

The Deficit Reduction Act of 1984 (DEFRA) established prospectively set local fee schedules for outpatient clinical diagnostic laboratory services to be paid under the Medicare Part B benefit under section 1833(h) of the Act. According to section 1833 of the Act, payment for those services is the lower of the submitted charge, the national limitation amount, or the local fee schedule amount for a laboratory service. Each local fee schedule is developed by the carrier, that is, the local contractor that processes Medicare Part B claims for a designated geographic area, using the 1983 customary charge data for existing payment codes.

Carriers continue to pay laboratory claims primarily from independent freestanding laboratories and physician office laboratories. Intermediaries use the same fee schedules as carriers when paying for outpatient laboratory tests performed by hospitals, nursing homes, and end-stage renal disease centers. Payment is only made to laboratories that are certified to perform laboratory services under the Clinical Laboratory Improvement Amendments (CLIA) under section 353 of the Public Health Service Act.

To enhance efficiencies in setting payment rates, we gather the carriers' local fee schedules into one data set referred to as the Clinical Laboratory Fee Schedule. By the 1st of November of each year, we update payments for inflation, when appropriate, and incorporate new payment codes into the data set, assign a payment rate to the new codes, and distribute the data set to the carriers and intermediaries electronically. In addition, we issue a corresponding Program Memorandum announcing the new codes and payment rates. The Program Memorandum lists an address for the public to send comments for the development of the following year's Clinical Laboratory Fee Schedule. We also make the data set and Program Memorandum available to the public through the Internet website at *http://www.hcfa.gov.* During the months of November and December, carriers, intermediaries, and laboratories upload the new data set, educate their customers, and test their claims systems in order to be ready for the new calendar year Clinical Laboratory Fee Schedule that will be effective on the 1st of January.

Payment Rates

Medicare pays the lesser of actual charges, the local carrier fee schedule amount, or a national limitation amount based on the local fee schedule amounts. The national limitation amount or maximum payment amount for each laboratory test is equal to a percentage specified by statute of the median of all carriers' local fee schedule

amounts. For calendar year 2002, section 1833(h) of the Act requires the national limitation amount for each test to be established at 74 percent of the median of all local laboratories' fee schedule amounts, or 100 percent of the median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established.

Payment Codes

The codes used on the Clinical Laboratory Fee Schedule are largely the CPT codes that are developed and published by the American Medical Association (AMA). The codes are a listing of descriptive terms for reporting clinical laboratory tests. The AMA publishes the updated codes (through books and magnetic tape) every year in October for use by payers and providers for the upcoming calendar year. Approximately 1,000 separate clinical laboratory codes are currently listed in the 80000–89399 CPT code series. In addition, the Clinical Laboratory Fee Schedule contains a small number (less than 50) of HCFA's Common Procedure Coding System (HCPCS) alpha-numeric codes that are developed by the Blue Cross and Blue Shield Association (BCBSA), the Health Insurance Association of America (HIAA), and HCFA. These codes were created to include clinical laboratory codes that are unique to the Medicare payment system. An example of this type of code is G0103, prostate cancer screening; prostate specific antigen blood test. This alphanumeric code was introduced effective January 1, 2000, to implement section 4103 of the Balanced Budget Act of 1997 that mandates additional coverage and tracking of expenditures for this type of test for Medicare beneficiaries.

The AMA's CPT Editorial Panel has procedures for receiving requests to change codes and conducts meetings to review the requests. The CPT codes are updated annually to reflect changes in the practice of medicine and provision of health care. A request for a code change may be submitted by any interested party. The CPT meetings occur several times a year and result in annual additions, deletions, and modifications of codes. By June of each year, the CPT Editorial Panel has largely completed its coding decisions for the upcoming calendar year. In the past, to accord with the AMA CPT publication schedule, we have not been able to make the new codes publicly available until October. This constraint did not permit us sufficient time to seek public input on the determination of pricing of new codes before we had to transmit the new fee schedule to our contractors. However, this year the AMA has agreed to make the codes available in draft during the summer so that we can proceed with this meeting to obtain public input.

Two methods for determining the payment rates for new codes are available, which may be summarized as follows:

• In the first method, called ''cross walking,'' we determine a new test to be similar to an existing test, multiple existing test codes, or a portion of an existing test code. The new test code is then assigned the related existing local fee schedule amounts and resulting national limitation amount. In some instances, we determine that a test may only equate to a portion of an existing test, and, in those instances, we specify payment at an appropriate percentage of the payment for the existing test.

• The second method, called ''gap filling,'' is used when no comparable, existing test is available. We then instruct each Medicare carrier to determine a payment amount for its area for use in the first year. Then, we use the carrier-specific amounts to establish a national limitation amount for the following year.

For each new code, we must determine whether it is appropriate to cross walk or to gap fill, and, if cross walking is appropriate, we need to know what tests to which to cross walk. These are the decisions on which we will seek public input at this meeting.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh)

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 22, 2001.

Thomas A. Scully,

Administrator, Health Care Financing Administration.

[FR Doc. 01–16370 Filed 6–28–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Structure Determination of Materials Using Electron Microscopy

Sriram Subramaniam (NCI)

[DHHS Reference No. E–187–01/0 filed 23 Apr 2001]

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a method for automating the acquisition of electron microscopic images from a desktop computer interface to provide for data collection by any user from any location. Automated low-dose image acquisition procedures are used to record high-resolution images on either film or CCD, at desired defocus values, and under conditions that satisfy user-specified limits for drift rates of the specimen stage. In a fully automated procedure of the invention, the determination of regions suitable for imaging are carried out automatically using spiral search algorithms. All steps subsequent to insertion of the specimen in the microscope can be carried out on a remote personal computer connected to the microscope computer via the Internet.

Lever Coil Sensor for Respiratory and Cardiac Motion

Kenneth W. Fishbein (NIA)

DHHS Reference No. E–134–01/0 filed 30 Mar 2001]

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a device that generates a signal for synchronizing an MRI scanner with a subject's respiratory and cardiac motion to prevent blurring of the image during the scan. This device uses a small electromagnetic pickup coil to simultaneously sense