December 21, 2012

American Clinical Laboratory Association

Ms. Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1590-FC
P.O. Box 8013
Baltimore, Maryland 21244-8013

Dear Ms. Tavenner:

The American Clinical Laboratory Association ("ACLA") appreciates the opportunity to comment on the "Medicare Program; Revision of Payment Policies Under the Physician Fee Schedule for CY 2013, Final Rule with Comment Period" (the "Final Rule").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies will be impacted directly by provisions of the Final Rule.

Our comments are focused primarily on three aspects of the Final Rule: the enormous cut in reimbursement for the anatomical pathology family of codes and, in particular, Current Procedural Terminology ("CPT") code 88305; the new description of the HCPCS G-code for prostate needle saturation biopsy procedures; and CMS's decision on payment for molecular pathology services.

I. CPT Code 88305

The majority of our comments focus on the draconian cuts made to payment for CPT code 88305 and related anatomic pathology codes, which represent tissue exam by a pathologist. We will focus our comments on CPT 88305, but the same comments apply to CPT codes 88300, 88302 and 88304. As of January 1, 2013, reimbursement for the technical component of CPT code 88305 will be reduced by approximately 52 percent (reimbursement for the global code will be reduced by approximately 33 percent). Cuts to the other anatomic pathology codes are also large, and all of the cuts will be extremely difficult for laboratories to absorb. It is possible that these cuts will limit the number of laboratories available to provide anatomic pathology services, which could affect patient access.

The Centers for Medicare and Medicaid Services ("CMS" or "the agency") apparently decided to make this drastic cut – amounting to hundreds of millions of dollars – based upon an analysis of one clinical application of the tissue biopsy services included in CPT code 88305. ACLA disputes the assertion that there exists a "typical" or "atypical" clinical case for CPT code 88305 on which to base pricing, since wide variations exist among patients and among

[1] 77 Fed. Reg. 68,892 (Nov. 16, 2012).

laboratories in the types of tissue being biopsied (*e.g.*, skin, breast, or prostate) and the way specimens are handled.

ACLA disagrees with CMS's rejection of several of the recommended cost inputs for CPT code 88305, with the disallowance of other inputs that are essential to preparing a tissue specimen for exam by a pathologist, and with CMS's characterization of the "direct" and "indirect" costs associated with this code. Taken together, we do not believe that the way CMS has valued CPT code 88305 accurately accounts for the true cost of providing this service to Medicare beneficiaries. Moreover, CMS has underestimated the labor costs associated with pathology services.

The potential revaluing of CPT code 88305 was not mentioned in the Medicare Physician Fee Schedule Proposed Rule for CY 2013,[2] and laboratories had no notice that this large a cut was imminent. While laboratories were aware that some reduction would be implemented, the significant cut included in the Physician Fee Schedule for CY 2013 took laboratories by surprise. It is extremely difficult for laboratories to adjust to and prepare for such a large reduction in such a short period of time. Additionally, this cut is coming on top of other large cuts sustained by the laboratory industry in recent years and additional cuts in 2013.

ACLA believes CMS's action with regard to the re-pricing of CPT code 88305 demonstrates some of the problems with the current pricing process. First, CMS relies heavily on the American Medical Association Relative Value Scale Update Committee ("RUC") evaluation process, which does an excellent job in many ways. However, the RUC process is closed to non-AMA members; thus, independent laboratories, which often are directly affected by the RUC's determinations on pathology codes, are totally excluded from the process. While we recognize that we could submit separate comments on the pricing of these codes, it is difficult to do so independently. We believe a more open and transparent RUC process would improve the pricing process overall.

ACLA also believes that the process by which CMS implements interim pricing changes is unfair and inappropriate. In this instance, there was no notice of the change in the Proposed Rule for CY 2013. Instead, a cut of more than 50 percent was announced on November 1, 2012 for implementation on January 1, 2013—a mere 60 days later. The process that led to such a significant cut without an opportunity to comment is unfortunate and puts all Medicare providers at a disadvantage.

We therefore ask CMS to refrain from implementing the cut or to phase it in over time. In addition, we urge CMS to reconsider its assumptions about the direct and indirect costs associated with CPT code 88305 and to acknowledge and account for the wide variation in the costs of the tissue specimen examinations that are encompassed by this code. We believe CMS should reflect these changes as soon as possible and certainly in the Medicare Physician fee Schedule Proposed Rule for 2014.

[2] *See* 77 Fed. Reg. 44,722 (July 30, 2012).

A. Background

CPT code 88305 is the most common code billed by laboratory pathologists. Its official descriptor is "Level IV - Surgical pathology, gross and microscopic examination," and it is used for examination of biopsies taken from the skin, breast, prostate, cervix, gastrointestinal tract, and lymph nodes, among other sites. The physician takes one or more biopsies from the site and puts each tissue sample (specimen) in a jar for transport to the histology laboratory. Each specimen represents a single claim to the Medicare program under CPT code 88305, but there is wide variation in the number of tissue blocks and the number of slides made from each tissue block, depending on the type and size of the tissue sample being tested and the patient's condition, among other factors.

In the Medicare Physician Fee Schedule Proposed Rule for CY 2012, CMS requested that the RUC review the practice expense ("PE") and physician work values for CPT code 88305 as soon as possible, based on the input from a single stakeholder that "the AMA RUC relied upon an atypical clinical vignette in identifying the direct PE inputs for the service associated with CPT code 88305."[3] The RUC commenced such a review.

In the Final Rule for CY 2013, one and a half years later, CMS revealed that the RUC recommended that several new PE costs should be incorporated into the Medicare reimbursement for CPT code 88305. CMS adopted some of these new supply and equipment costs on an interim basis, but it rejected others recommended by the RUC, which is exceedingly rare. It rejected the RUC's recommendation to include disposal costs and courier costs as direct PE costs. CMS said only: "We do not believe that specimen disposal or courier costs for transporting specimens are appropriately considered as disposable medical supplies. Instead, we believe the costs described by these recommendations are incorporated into the [Practice Expense Relative Value Units ("PE RVUs")] for these services through the indirect PE allocation."[4] The RUC also recommended that CMS recognize equipment maintenance costs and laboratory information system ("LIS") software and maintenance as direct PE inputs for CPT code 88305. CMS also rejected these recommendations.

The number of blocks the RUC assumed to be "typical" for CPT code 88305 was two. CMS did acknowledge in the Final Rule that "The number of blocks assumed to be used has a significant impact on the quantity of other supplies and the number of clinical labor and equipment minutes assigned as direct PE inputs to each code." CMS also said, "We are concerned that the number of blocks assumed for each code may be inaccurate."[5]

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[3] 76 Fed. Reg. 42,772, 42,795 (Jul. 19, 2011).
[4] 77 Fed. Reg. 69,074.
[5] *Id*. We note that in our comments on the Medicare Physician Fee Schedule Proposed Rule for CY 2012, ACLA made exactly these points: when billing using CPT code 88305, the number of blocks varies significantly from case to case, and there is no "typical" clinical vignette for this code.

B. There is not a "typical" or "atypical" clinical case for CPT code 88305, since wide variations exist among patients and among laboratories based on the types of tissue being biopsied.

We appreciate CMS's call for independent evidence regarding the appropriate number of blocks to assume as "typical" for all of the revalued pathology codes, including 88305. However, there is a wide variation in the number of blocks and slides used, depending on the site and size of the specimen being tested and the patient's condition. While many tissue biopsies may use an average of two blocks, the assumption on which the code revaluation is based does not account for the many kinds of biopsies that use more than two blocks. The following vignettes illustrate the variation among both blocks and slides per specimen:

- **Breast**: Two masses measuring approximately 4 cm^3 and 5 cm^3 are excised from patient's left breast. The first specimen is sliced for gross examination and 8 representative sections are fixed in formalin, embedded in paraffin to create eight blocks, from which one glass slide each is prepared for microscopic evaluation by the pathologist. The second specimen, due to its larger size, is sliced into 10 representative sections, creating 10 blocks, from which one glass slide each is prepared for microscopic evaluation.

  - Result: (2) 88305 billings: first with (8) blocks and (8) slides, second with (10) blocks and (10) slides

- **Cervical**: Endocervical polyp measuring approximately 3 cm in greatest dimension is removed. The specimen is sliced into three sections, fixed in formalin and embedded in paraffin to create three blocks, from which three glass slides each are prepared for microscopic evaluation by the pathologist.

  - Result: (1) 88305 billing; (3) blocks; (9) slides

- **Prostate**: Four biopsies are taken from male patient with enlarged prostate. Specimens fixed in formalin and embedded in paraffin to create four blocks, from which five glass slides each are prepared for microscopic evaluation by the pathologist.

  - Result: (4) 88305 billings; (4) blocks; (20) slides

- **Gastrointestinal**: Multiple rectal polyps and tissue fragments are submitted as a single specimen. Blocks are created for the following: (1) aggregate of tissue fragments; (2) polyp #1 (small); (3-4) polyp #2 (large, center section); (5-6) polyp #2 (large, side sections); (7) polyp #3 (large, center section); (8-9) polyp #3 (large, side sections); (10) two polypoid fragments; (11-16) polyp #4 (large, lobulated with margin of resection). Specimens are sectioned and embedded in paraffin to create a total of 16

blocks, from which 2-3 slides each are prepared for microscopic evaluation by the pathologist.[6]

- Result: (1) 88305 billing; (16) blocks; (33) slides

- **Bone marrow**: Core biopsy of patient's bone marrow is fixed in formalin, embedded in paraffin to create one block, from which two sections are cut and placed on glass slides for microscopic evaluation by the pathologist.

  - Result: (1) 88305 billing; (1) block; (2) slides

As these vignettes demonstrate, there is not a "typical" clinical case for CPT code 88305, since wide variations exist among patients and among laboratories in the types of tissue being biopsied. For reasons we expand upon below, we believe that the interim final value for CPT code 88305 is inadequate for a tissue exam with two blocks, and it certainly is inadequate for tissue exams that require many more blocks and slides than are accounted for in the RUC's assumption.

C. Courier costs, disposal costs, and LIS-related costs should be included as direct PE inputs.

We believe that CMS erred in rejecting the RUC's recommendations that disposal costs, equipment costs, and LIS-related costs should be included as direct PE inputs. Disposal and courier costs are attributable to a particular biopsy specimen and scale up or down based on the number of specimens. LIS-related costs also are variable direct costs for pathology services that fluctuate with specimen volume.

We ask CMS to provide a basis for its statement that disposal costs are accounted for adequately in the indirect PE allocation, and we ask the agency to reconsider its rejection of the RUC's recommendation that this cost should be a direct PE input. As the RUC recognized when it recommended that disposal of specimens, solvent, and formalin should be considered direct costs associated with CPT code 88305, these costs are attributable to individual specimens. Each tissue sample is fixed in formalin and embedded in paraffin. The number of specimens, tissue blocks, and slides made from the blocks determines the disposal costs. It is not possible to account for these costs in indirect PE costs because they are not encompassed by the general overhead costs of running a laboratory – they are separate hazardous waste costs that can be tied to a specific specimen. Therefore, they are properly characterized as direct PE inputs.

The same is true for courier costs, which are significant for laboratories. We do not believe that the indirect PE costs allocated to CPT code 88305 adequately account for this sizeable expense. In almost all circumstances, a patient is seen for a biopsy in a different location than the location where a pathologist examines that biopsy specimen. For a pathologist to examine a tissue biopsy in a timely manner so that a patient can receive appropriate care,

[6] This vignette provides an example of treatment of a specimen comprised of multiple tissue samples. Histology labs frequently receive specimens such as this in a single jar and must section the specimen appropriately to ensure the absence of malignancy throughout the specimen, often resulting in tens or dozens of tissue blocks.

specimens must travel rapidly and securely from the location where a biopsy is taken to the pathology lab by delivery services, couriers, and sometimes by airplane. Although more than one specimen may be included in a courier run, still there is a cost per specimen. The RUC acknowledged that courier costs are integral to the pathology service, and that they are attributable to a particular specimen. Courier costs typically are major costs for pathology laboratories, and we do not believe CMS adequately accounts for this through indirect PE costs.

Finally, we also believe that CMS was wrong to reject the RUC's recommendation to create distinct equipment items related to LISs as direct PE inputs for CPT code 88305 and other codes. The "CoPath" system referred to in the Final Rule is the brand name of a commonly-used component of a pathologist's LIS that is critical to tracking a patient's specimen from its procurement, through its transport to a pathology laboratory, to its block and slide preparation by a histotechnologist, to the specimen's examination by a pathologist, and finally to the report prepared by the pathologist. It also distinguishes between several specimens taken from one patient and stores information about the specimen for later use. Because patients' specimens are not procured at the pathology lab where the tissue examination takes place, tracking a specimen accurately and safely is essential, and it is a function that others specialists' computer systems do not require. CoPath systems (or systems with similar tracking and reporting functions) are not optional for pathology laboratories, and the software, equipment, and maintenance costs must be accounted for.

D. CMS's labor cost assumptions are inaccurate.

CMS has underestimated the labor costs for histotechnologists, whose services are integral to preparing tissue specimens for examination by pathologists. Histotechnologists are responsible for fixing specimens in formalin, embedding them in paraffin to create blocks, creating slides from each block, and staining specimens, all before a pathologist examines the specimen. CMS estimated a labor cost that amounts to 37 cents per minute. This is far below the most recent data available from the U.S. Bureau of Labor Statistics ("BLS"), which estimates a per-minute labor cost for histotechnologists of 47 cents per minute,[7] and even further below ACLA members' costs for histotechnologists, which is closer to 50 cents per minute. We understand that CMS's estimate is based on BLS data from 2007 and actually has remained unchanged for even longer. Qualifications for histotechnologists have increased in recent years: in general, five years ago, a histotechnologist would be required only to have high school diploma, but currently at least an associate's degree is necessary and some laboratories even require bachelor's degrees. Currently, there are approximately a third too few histotechnologists to service the current volume of specimens, and this shortage is likely to drive labor costs even higher in the future. CMS needs to account for the expanding skill set of histotechnologists and for the market dynamic, and it should update its data so that laboratories can cover these rising labor costs.

In sum, we believe CMS erred in rejecting the recommendations of the RUC concerning the expenses detailed above and in its failure to update the salaries paid to histotechnologists. This has resulted in a significant—and inappropriately large—cut to CPT code 88305.

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[7] Occupational Employment Statistics, May 2011, *available at* http://www.bls.gov/oes/.

E. It will difficult at best for laboratories to absorb this drastic cut in a very short timeframe.

CMS raised the specter of revaluing CPT code 88305 in July of 2011, in the Medicare Physician Fee Schedule proposed rule for CY 2012. However, it did not include any discussion of its plans in the proposed rule for CY 2013. While some laboratories may have anticipated some reduction in reimbursement for this code, no laboratory anticipated a 52 percent cut in the technical component of the code. CPT code 88305 is used to bill for the most commonly-performed laboratory services, and a cut of this magnitude will affect even the largest laboratory providers. Smaller and specialized laboratories will feel the cut even more acutely, especially as it comes on the heels of other significant cuts to laboratories in the recent years. The short period of time CMS has provided for laboratories to plan for this payment reduction makes the agency's choices to reject many of the RUC's recommendations even more disappointing.

II. Prostate Needle Saturation Biopsies

CMS implemented HCPCS code G0416 in the Medicare Physician Fee Schedule Final Rule for CY 2009 to be used for "surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens." At the time, CMS specified that "[u]nder the PFS, CPT code 88305 will continue to be recognized for those surgical pathology services unrelated to prostate needle saturation biopsy sampling."[8] In the Final Rule for CY 2013, CMS issued an interim final revision of the descriptor for HCPCS code G0416 to read "surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 10-20 specimens," (rather than 1 to 20 specimens, as it had been previously). The agency said little more than that it agrees with stakeholders that the description "should be revised to better reflect the interaction of this service, and associated RVUs, with billing for surgical pathology."[9] This time, CMS did not address the difference between examination of prostate needle saturation biopsies and prostate needle biopsies.

Despite CMS's clarification in the CY 2009 final rule, there has been some confusion about whether HCPCS code G0416 applies only to prostate needle saturation biopsies or to prostate needle biopsies, as well. At least one contractor had issued a policy (now withdrawn) that required laboratories to bill using the saturation biopsy codes when billing for more than five standard prostate biopsy samples from the same patient. As the agency is aware, a prostate needle saturation biopsy procedure is not the same as a standard prostate needle biopsy procedure, and they are used at different times for different reasons.

We understand from recent discussions with CMS representatives that HCPCS code G0416 is to be used only for prostate needle saturation biopsies and that CPT code 88305 is the correct code to use when billing for standard prostate needle biopsies, regardless of the number

[8] Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 73 Fed. Reg. 69,726, 69,751 (Nov. 19, 2008).
[9] 77 Fed. Reg. 69,059. This policy change was not included in the Medicare Physician Fee Schedule Proposed Rule.

of specimens procured. We appreciate this clarification and request that CMS memorialize its position in a written communication to Medicare contractors.

III. Payment for Molecular Pathology Services

CMS determined that payment for molecular pathology services should continue to be made under the Clinical Laboratory Fee Schedule ("CLFS"), rather than assigning the new CPT codes for these existing services to the Physician Fee Schedule, since the services *ordinarily* do not require the services of a physician. At the same time, it also established a new HCPCS code that can be used when a physician interpretation is requested by the ordering physician and when the service meets other requirements. ACLA applauds CMS's for its determination that these services should remain on the CLFS.

IV. Summary

In sum, we ask the agency to:

- Refrain from implementing the drastic cuts to reimbursement for CPT code 88305 and the other anatomic pathology codes, or to phase the cuts in over time; and

- Clarify in writing that HCPCS code G0416 is to be used only for prostate needle saturation biopsies, not for standard prostate biopsies.

Thank you for your consideration of our comments.

Sincerely,

Alan Mertz, President
American Clinical Laboratory Association