Medi-Lab, Inc.
Leading the Way in Laboratory Testing Technology & Service
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Ms. Michelle Shortt
Director
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations and Regulatory Affairs
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-10193 and CMS-10133, Agency Information Collection Activities: Proposed Collection; Comment Request (Medicare Clinical Laboratory Competitive Bidding Demonstration)

Dear Ms. Shortt:

On behalf of my employer, Medi-Lab, Inc. of Lima, Ohio, I would like to thank you for the opportunity to submit written comments on the burden estimate and other aspects of the collection of information related to the Medicare Clinical Laboratory Competitive Bidding Demonstration Project.

I think that a properly designed application form would be the first place to begin in order to have a successful demonstration project. Detailed, accurate and complete information will be essential to ensure that the demonstration is consistent with the Medicare statute and the project's goal to maintain beneficiary access to clinical laboratory testing. Unfortunately, CMS's application falls short of this goal.

First, the application fails to ask any questions regarding the percentage of laboratory tests that are provided to residents of long term care facilities and skilled nursing facilities (SNFs). This is a particularly vulnerable and often times chronically ill population. These beneficiaries need a higher level of access and care than the current demonstration project design offers. The application does not ask such questions as:

What percent of laboratory testing is provided to skilled nursing facilities?
What is the geographic coverage your laboratory currently provides to these facilities?
How many skilled nursing facilities do you currently provide service to?
Do you provide 24/7/365 phlebotomy service?
How would you supply STAT services to skilled nursing facilities?
What is the Turnaround Time for STAT requests?

This is just a sample of some of the unique requirements of SNFs. In addition, these types of clients are more expensive and labor intensive to service than a typical physician office or drawing station. How will CMS prevent the winning laboratories from choosing to service only the easy, low-cost and high volume clients?

Second, the form includes a section for the applicant to list other labs that they will "subcontract" with. It is unclear if CMS has established any guidelines regarding the types of arrangements that bidders can have when developing consortiums. How will the DOJ and FTC monitor compliance to ensure fair competition and prevent violations of antitrust laws? What will prevent the bigger labs from bidding unreasonably low just to be one of the winners thus preventing smaller labs who serve the higher cost SNFs from being able to compete at such a low level of reimbursement? Once the smaller labs are driven out of business these large labs will have to come back to the government for an increase because it will be impossible to serve this segment of the population for much less than what is currently being reimbursed.

Third, there are questions regarding the applicant's CLIA status and Proficiency Testing programs but there is no initial measure of the quality of testing or service. How can you measure improvements or deterioration without this initial measurement? How will the increased volume affect quality?

Fourth, there are no the questions in the Capacity and Bid Price Information section that deal with the percentage of actual reimbursement versus submission. There should be some question that reflects the amount that providers must currently write off due to low reimbursement rates and failed medical necessity.

Fifth, I am concerned about the cost burden estimates provided by CMS. I feel these are greatly underestimated. The estimate of 100 hours is insufficient for a laboratory to gather all of the information required in the bidding application. The Supporting Statement For Paperwork Reduction Act Submissions states that the "estimate of annualized cost to respondents was based on the national average rate for Medical and Clinical Technologists from the Bureau of Labor (http://www.bls.gov/soc/home.htm) of $23.66 per hour. Medical Technologists are not the only people responsible for filling out this application and gathering the needed information. Others involved will include people from the billing department, medical records, accountants, lawyers, pathologists, laboratory directors, CEO's and physicians. Most of these individuals make significantly more than $23.66 per hour. The cost to obtain a reviewed financial statement alone is over $2,000.
The application asks for the Quality Assurance Contact which at first may be a current employee. However, as this project develops, this will evolve into a full time position resulting in an additional financial burden.

Sixth, the burden to bid on all 1,100 tests on the Medicare Fee Schedule could be reduced if the current HCPCS/CPT codes were revised and updated to reflect new technology and remove redundant codes. For example CPT code 80190 is Assay of Procainamide and in Ohio is reimbursed at $23.41 and CPT code 80192 is Assay of Procainamide with metabolites (e.g., n-acetyl procainamide). Both of these reimburse at the same rate so

why do we need two codes? It seems that one would be sufficient to cover both tests. Removing these duplicates would reduce the total number of tests on the fee schedule.

Finally, as a laboratory professional, I am deeply concerned with maintaining access to quality laboratory tests for all patients. I am happy to have the opportunity to contribute my comments and I hope they are a positive contribution to the demonstration project. I look forward to hearing your response to my questions and thank you for your consideration.

Sincerely,

Marcia Baggs

Marcia Baggs
Laboratory Manager

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North Memorial

Reference Laboratory Services
3300 Oakdale Avenue North
Robbinsdale, MN 55422

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern,

On behalf of **North Memorial Medical & Reference Laboratories** and as a laboratory professional, I am writing in response to the April 21 *Federal Register* notice, "Agency Information Collection Activities: Proposed Collection; Comment Request," regarding the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Bidding Form (CMS-10193, OMB#: 0938).

The burden estimates provided in the Supporting Statement are grossly underestimated and fail to account for the hourly rates necessary to complete the forms. The estimate of 100 hours to complete the application is unrealistic and will not be sufficient for most laboratories to assess whether their facility is required to bid based on Medicare revenue from the previous year, to assemble a complete financial statement, to negotiate subcontractor arrangements with other laboratories and provide signed agreements, and to determine capacity and bid price for all 1,100 tests on the clinical laboratory fee schedule. Furthermore, laboratories will need the services of individuals responsible for billing, collections, operations, and legal counsel to complete this information. None of these individuals' hourly rates were included in the calculation of the financial burden.

The application asks the wrong questions in order to ensure that quality laboratory services are maintained throughout the demonstration project, and there is little emphasis in the form on the collection of this information from bidding laboratories. The only information required is for a "Quality Assurance Contact," the laboratory's status under CLIA, and its Proficiency Testing program. These few measures oversimplify and fall short of determining a laboratory's capacity for quality.

The unresolved issues surrounding implementation of the competitive bidding demonstration project make accurate completion of the application form nearly impossible. For example, there is no clear definition of the terms "face-to-face encounter" or "nonpatient" in the application instructions or in the Supporting Statement. There is also no statement regarding whether a bidder can bid separately or form a consortia and also be a subcontractor listed by another primary bidder. These are crucial decisions that will affect how our facility will respond to the competitive bidding demonstration and price services within the demonstration. Finally, CMS requests proprietary information about our facility, which is worrisome, as while there is a statement regarding the protection of confidentiality of the information, there is no statements

regarding acceptance of liability if that information is released or disclosed to an unauthorized party.

In addition to the general comments provided above, as a member, I also support the detailed comments submitted by CLMA, the Clinical Laboratory Management Association, and refer you to those comments.

Thank you for the opportunity to comment on this important issue.

Sincerely,
Adam Grau, Marketing Representative

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American
Clinical Laboratory
Association

June 20, 2006

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Clinical Laboratory Services Competitive Bidding Demonstration Project

Dear Ms. Harkless:

The American Clinical Laboratory Association ("ACLA") is pleased to have this opportunity to submit our views with regard to the Clinical Laboratory Services Competitive Bidding Demonstration Project Notice ("the Notice") and the Proposed Form to be used by bidding laboratories ("the Form"). 71 Fed. Reg. 20697 (April 21, 2006). ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. The Notice in the Federal Register states that interested persons are invited to submit comments on the burden estimate included in the Notice or any other aspect of the collection of information. ACLA members would be affected by the Notice and are interested persons. As a result, reflecting the views of its members, ACLA is taking this opportunity to comment on various issues created by the Form and the basic assumptions that underlie it concerning how competitive bidding might work.

ACLA appreciates the opportunity to comment on the Form; however, because the basic rules and parameters for the competitive bidding demonstration have not yet been determined, or made public, it is difficult to comment fully or meaningfully on the Form. As a basic principle, it is logical to expect that the Form would have been the *last thing* to be drafted and that it would have waited until the requirements for the bidding process had been determined, so that the Form would actually reflect the bidding process. The current approach seems clearly to be putting the "cart before the horse" inasmuch as we are being asked to comment on a Form that is implementing a program that has yet to be formulated or subject to public comment by stakeholders.

Further, as discussed in greater detail below, the Form itself suggests that CMS has significantly underestimated the complexity of competitive bidding for laboratory services and the unique and serious issues that will be presented. Set out below, we discuss some of the general issues that are presented and then we discuss our specific concerns about the Form itself. In the Appendix, we have included numerous other questions that we believe must be considered as part of this demonstration.

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I. General Comments on the Form Itself

A. Commenting on the Form is Premature

First, it is important to note that prior to the release of the Form, the only public information about the model for laboratory competitive bidding was released last summer in a report by the Research Triangle Institute ("RTI"). The RTI report was no more than a proposal for implementing the demonstration project for the provision of clinical laboratory services and it included many, as yet, unanswered questions. While CMS submitted a report to Congress earlier this year, as required by the Medicare Modernization Act, that report contained even less detail than the proposal in the RTI report. Before and after the release of the RTI report, ACLA repeatedly requested the opportunity to provide input into the design of the model for competitive bidding for laboratory services, but was never afforded the opportunity to provide meaningful input. As such, ACLA members are sincerely concerned about having to comment on a Form that is integral to a plan that has yet to be finalized or even publicly set forth in its entirety for comment. By requesting comments on the development of a form for a process that is not completed, CMS has acted unreasonably and unfairly.

A review of the Form shows some of the difficulties laboratories would face being required to respond to the request for information at this early stage. For example, Question D.4 seeks information from the bidder for each type of test, including a "test weight" for each test. However, it is not clear what is meant by "test weight" or why it is included. According to the instructions, "the 'test weight' is the weight given to the test in determining an applicant's composite bid price." It seems likely that test weight is somehow related to volume of testing, but we would expect that the volume of testing covered by the bid would be information furnished by CMS, not the laboratory. However, the ambiguity of interpreting this requirement shows the difficulty of commenting on the Form, as drafted, at this early stage. We simply do not know what is meant by "test weight" because the model has not yet been finalized or, if finalized, it has not been publicly disclosed. As a result, prospective bidders do not know how to determine test weight, how test weight will be used in evaluating the bids, or even who is responsible for providing the information.

Similarly, while the Form also requests a bid price for each test, because the model is not yet final, it is also impossible to determine how a bidder will be able to respond even to this basic question. For example, when developing "weights" for CPTs that are often billed with multiple units, or quantities, how does the laboratory factor these quantities into the "weight" calculation and/or into the bid price? Additionally, it is impossible to estimate the volume and mix of tests because we do not know the volume of excluded tests, the volume and mix of tests provided by excluded laboratories, or the volume of testing performed by market segments that are so specialized and unique that they should be excluded from the demonstration (e.g., end-stage renal disease testing).

As discussed in greater detail below, it is impossible to actually submit a bid without knowing the geography, the approximate testing volume and mix, or the potential number of winners. As a result, it is difficult to comment on the Form, because the rules for the competitive bidding demonstration have yet to be established. Thus, CMS should finalize its plans for the demonstration project before seeking comments on the Form to implement that project.

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B. The Form Envisions an Unworkable One-Step Process

Based on the Form, CMS is anticipating a process that asks laboratories to submit both volume information and bids as part of a single process. Question D.1. asks laboratories to submit information on the total number of tests for residents of the Competitive Bidding Area ("CBA"), along with the percentage of tests performed for Medicare beneficiaries. It seeks similar information concerning revenue and "non-patient" test percentage. While we question why CMS needs information on the volume and revenues from non-Medicare testing at all, we assume the purpose of the request for Medicare information is to establish the universe of testing covered by the demonstration. However, as noted above, we are making that assumption in a vacuum, as the actual model for how the bidding will be carried out has yet to be decided.

Nonetheless, the requested information should not be part of the bidding process; an entity issuing a request for competitive bids to prospective bidders generally obtains that information from its own records *prior* to the bidding process. Prospective bidders cannot be expected to calculate a bid for an unknown volume of services. Similarly, bidders also need to have some idea how many likely winners there may be, because that will determine the likely volume any one laboratory receives, which will affect how it will calculate its bid. In fact, when commercial payors request bids, the request for the bid includes a database showing past utilization, a practice which allows the bidder to review, analyze and create a reasonable bid. Without that information, bidders simply do not have enough information to formulate a reasonable bid. Furthermore, bidders are responsible for and must bid for all services; however, tests vary in cost (including the cost of logistics) and not all laboratories provide all services. Furthermore, the award might be determined at the zip code level, according to the Form/Instructions. Therefore, it is incumbent upon CMS to provide data on the number of tests (by test type) by geographic areas, so that prospective bidders can accurately determine their costs.

C. CMS has Significantly Underestimated the Time and Cost of Completing the Form

The Supporting Statement provides that the estimated time for completing the application annually will be 100 hours for bidders. As proposed, clinical laboratories would need significantly more than 100 hours to complete the Form. The Form will require the calculation of an individual price to be bid for each of the over 1100 CPT codes for laboratory services. In addition, laboratories that do not perform all of the tests, or cover the entire geographic area, will have to contract or enter into arrangements with other laboratories – a time-consuming and resource intensive process that it is integral to the bid process and will add to the burden of completing the Form. Other issues that will increase the time and cost are discussed at various points in the comments that follow.

In addition, CMS states that the analysis will be completed by Medical and Clinical Technologists, who it estimates are paid a rate of $23.66 per hour. CMS is in error on this point. Medical Technologists are not likely to perform this analysis. The technologist's role is the vital and important job of performing and overseeing testing in the laboratory. The calculation of the bids typically is performed by other employees, with different and often more highly compensated skills, who are more familiar with contracting requirements. We point this out because we think it

suggests a gross misunderstanding of the functioning of a typical clinical laboratory and the amount and level of work that will be involved in responding to CMS' proposal.

Further, these projected costs do not include recognition of the additional expenses that laboratories necessarily will incur in modifying their business operations to comply with the requirements of the demonstration. For example, tests subject to the demonstration may have to be handled separately from tests performed for other Medicare beneficiaries, because of special requirements of the demonstration. Based on earlier descriptions of the competitive bidding model, demonstration tests may be subject to special quality reporting and auditing. This will require labs to establish special systems to track these tests as they move through the testing process. Moreover, because tests from a single physician often will include both demonstration tests and excluded tests (such as Pap smears), the laboratory will have to differentiate between the two, which also increases complexity for the bidder, and, as a result, must be figured into costs.

Finally, the Supporting Statement notes that the burden will be completed one time. However, since the demonstration will take place in two jurisdictions, some laboratories will have to complete the Form at least twice.

II. Comments on Specific Aspects of the Form

A. Bidding Status

CMS has set forth in the Form that non-bidders are required to complete only certain sections of the application. However, the instructions for completing the Form do not clearly define those clinical laboratories that would be considered non-bidders, except to provide that a non-bidder laboratory supplies less than $100,000 in demonstration tests during calendar year 2005 to Medicare beneficiaries residing in the CBA. The original RTI model proposed a number of other "non-bidders" including in-patient and outpatient hospital services and physician office laboratories. Again, it is not clear if the differences are significant or just an oversight, because the model has not been finalized. Nonetheless, CMS should further specify which clinical laboratories will be considered non-bidders and not include the volume of testing provided by these excluded laboratories in the volume of tests being let for bid. Likewise, CMS should clarify whether the $100,000 threshold will be determined based on the provider number or corporate entity and further define "corporate entity."

There are a number of other issues that relate to bidding status that have yet to be determined. For example, many laboratories do not furnish the full range of laboratory tests; rather, they specialize in certain types of testing, such as esoteric testing or testing related to specific conditions. Thus, those laboratories are likely only going to participate as subcontractors to another laboratory. However, if they have more than $100,000 in Medicare revenues, they are "required bidders," even though they are not likely to want to compete to provide the full range of services. The Form does not answer even the simplest questions. For example, if they do not intend to participate, do they have to submit a form as a "non-required bidder?" Can they still participate as subcontractors if they have not done so? Again, it is simply impossible for a prospective bidder to bid when the bid requirements are undefined because the actual model for the demonstration has never been finalized, or if finalized, it has never been disclosed.

B. Applicant Information

Section B.5 of the Form requires ownership information for the applicant laboratory. As part of this request, CMS asks clinical laboratories to indicate whether there is a "managing organization" for the laboratory. One can speculate that CMS' intent is to identify whether an outside entity has been hired to manage the laboratory; however, as defined, any person (e.g. the President of the clinical laboratory) could be considered a managing organization. CMS should clarify this definition.

Section B.7 of the Form requests the National Provider Identifier ("NPI") for the clinical laboratory furnishing the service. Many large entities may provide services through multiple subparts, all of which may have their own NPIs. Smaller entities are required to bid for the entire range of tests and therefore will have to retain other laboratories as independent contractors to provide the services the bidder does not itself perform. Thus, it will be necessary for a bidding entity to furnish information on numerous laboratories – a fact that may also affect the time involved in completing the Form. Furthermore, it will be important for CMS to establish payment procedures so that the payment goes not to the laboratory that furnished the service (the "rendering lab"), but to the headquarters of the laboratory (the "billing lab") that wins the bid. As such it is important to clinical laboratories that CMS makes clear in the Form that the laboratory furnishing the service is not necessarily the entity (or the NPI) that will be paid. Finally, when the bidding laboratory has both organizational and subpart NPIs, the Form should accommodate entry of both and clearly differentiate between them.

Section B.7 also requires information relating to the accreditation of the clinical laboratory. In that section, CMS asks whether it may contact the clinical laboratory's accrediting organization(s). This is an unusual, atypical question, and we are unclear as to its ramifications. Is there a penalty for not allowing CMS to contact the accrediting organization? If so, what is the penalty? We ask that CMS set forth its rationale for this question, the information that will be requested, and the ramifications of not allowing CMS to contact the accrediting organization.

Section B.9 requires clinical laboratories to provide credit information in the form of banking references and the line of credit that applies to the respective banking institutions. This information, however, seems unnecessary with regard to submitting a bid amount for the competitive bidding program. Thus, we ask that CMS provide its rationale for requiring such information. In addition, if clinical laboratories will be required to submit such credit information, CMS must ensure that the information will be considered confidential.

Section B.11 requires information relating to any adverse legal action that has been imposed on the applicant, the applicant's subcontractors, or the applicant's owners. The mention of the applicant's subcontractors, however, could suggest that clinical laboratories are required to provide information regarding adverse legal actions imposed on each and every subcontractor, at any time, including those that are not even engaged in the furnishing of laboratory services. CMS should clarify that such information would only be required with regard to the clinical laboratory's subcontractors that are engaged in the provision of services covered by the bid, and only for the previous three (3) years.

C. Geographic Coverage

Section C.1 requires information relating to the clinical laboratory's geographic coverage within the CBA. Specifically, CMS requests the ZIP codes of the areas the prospective bidder currently serves or plans to serve under the competitive bidding program. However, laboratories typically do not obtain the ZIP code of the patient's residence (which in fact may vary during the year).

This is an important aspect of laboratory testing that we are not sure has been adequately considered in the formulation of the demonstration. Applying the demonstration project to residents of a specific geography implicitly requires the lab to differentiate internal processes, both lab and billing, based on a patient residence. Today, patient residence is neither a primary nor a differentiating element employed in lab testing or billing processes. For example, lab testing systems and processes are designed to obtain specimens from and provide results to a physician or hospital location, *not* a patient address. Lab billing systems are designed to provide claims to specific Medicare carriers for tests provided to physicians and hospitals located in specific geographic areas, and *not* based on the patient's residence. Requiring labs to change their internal infrastructure, systems and processes to use patient residence as a differentiating factor will be an enormous and costly burden for labs, and should not even be considered for this demonstration project. CBAs for the demo project should be designed as they are today, based on the location of the ordering providers.

Another reason it does not make sense to say that the demonstration applies to all of the *residents* of a particular metropolitan area is because those residents may travel outside that area for testing and residents from outside the area may come into it. If a patient who is a resident of the CBA goes to Florida and has testing ordered there, it will be impossible for any laboratory to know that testing for that patient should be charged and reimbursed based on the demo price, rather than the usual price under the clinical laboratory fee schedule. Similarly, if a patient comes into the CBA, and sees a physician located there, the laboratory will not be able to determine that the patient should be charged and reimbursed based on the usual clinical laboratory fee schedule amount.

Section C.2 requires that prospective bidders provide a copy of the laboratory's current requisition or test form. However, for any given metropolitan statistical area ("MSA"), laboratories are likely to have many different test request forms ("TRFs"). In fact, clients may request customized TRFs, and there are often separate TRFs for particular categories of testing. Furthermore, because of tests that are excluded from the demonstration but still expected to be ordered on eligible beneficiaries (and therefore performed and billed on a separate track from tests included in the demonstration), laboratories will have to design entirely new test requisition forms to be used solely for the demonstration project. As a result, it is unclear whether clinical laboratories will be required to provide all TRFs that are potentially applicable to any test ordered for Medicare beneficiaries within the CBA, whether laboratories will be permitted to provide a representative sample of TRFs and explain that others are available upon request, or whether laboratories will have to design and provide new forms for what will actually be used during the demonstration. We ask that CMS address this issue so that laboratories can submit their forms accordingly.

Section C.5 requires signed letters of intent or agreements with a prospective clinical laboratory bidder's subcontractors. This requirement again illustrates the difficulty of the "one-step" bidding process as discussed above. Until the laboratory knows the anticipated volume and mix of testing, it may not know if it needs a subcontractor or how many different subcontractors it needs. Thus, the first step in the process should be to determine the volume and mix of testing. After that, the laboratory can determine whether or not it needs subcontractors and, if so, what types of subcontractors it needs. In addition, the requirement to submit all signed letters of intent or agreements for its subcontractors is a significant and intrusive burden that clinical laboratories should not be required to bear. So long as the bidding laboratory submits information on the identity of the subcontractors, the laboratory should not have to submit a copy of the actual agreement, which by its very nature will include confidential information, including how much the subcontractor is charging the bidder. In any event, we believe the fee schedule information should be redacted from subcontractor agreements, if it is required that those agreements be submitted to CMS. In the usual competitive bidding situation, the purchaser is not entitled to also know the winning bidder's acquisition cost and that should also be the case here for a variety of antitrust and competitive reasons. Finally, if signed letters of intent or agreements with subcontractors are required at all, the Form and instructions should specify that they are only required with respect to subcontractors expected to serve Medicare beneficiaries in the CBA during the demo.

D. <u>Capacity and Bid Price</u>

Section D.2 requires total revenue information relating to the provision of tests to residents of the CBA. First, as noted above, laboratories do not track information by the residence of the patient, so a bidder cannot comply with that request. This section also asks for the percentage of the total revenue that is collected from Medicare. Thus, this section requests both Medicare and non-Medicare revenue information. As the competitive bidding demonstration project only applies to Medicare beneficiaries, it is inappropriate to request non-Medicare revenue information in the application. We ask that CMS require only Medicare revenue information to be submitted, or clarify its rationale for requesting such information.

Section D.4, which requires certain capacity information to be included in a chart format for all demonstration tests, raises a number of concerns. First, the Form requires that bids be made based upon HCPCS codes; however, in many instances, one HCPCS or CPT code will cover several different tests. In those situations, laboratories often must submit different bid prices for a single HCPCS or CPT code reflecting the different tests that are billed using that single code; however, the Form provides no clear process for bidding different prices for the same HCPCS or CPT code. Second, as mentioned above, clinical laboratories cannot provide a bid price if the volume and mix of testing within the CBA has not been determined and disclosed to prospective bidders. It is impossible for a prospective bidder to calculate an appropriate bid amount for a test without knowing how many tests will be provided and how many laboratories will be providing such testing. Third, the Form requires that laboratories provide their own test weight, as noted above. However, as we pointed out, the weight associated with the test would be dependent on the volume of testing provided in the CBA, which is unknown to prospective bidders, and the weight is a calculation that should be determined by CMS. Finally, we are unclear as to the distinction between the terms "current annual capacity" and "maximum annual capacity." CMS uses these terms without providing clear definitions. As a result, before a prospective bidder can complete the Form,

CMS must define the terms in this section and explain the inconsistencies and issues that we have raised.

E. Quality

Section E requests that prospective bidders provide certain quality information. However, further supporting our concern that CMS has not adequately designed the bidding process, we must note that CMS does not require historical quality information, which is necessary to ensure a base line for providing quality clinical laboratory services.

F. "Gaming Behavior"

In several discussions of the proposed model, RTI and CMS have made references to "gaming behavior," although that term remains wholly undefined. To the extent that such behavior is used as a basis for determining the winners, as RTI and CMS have suggested, then the term must be more fully defined. We are especially concerned about one type of "gaming behavior" that has occurred in other contexts. In other bidding situations, laboratories sometimes submit exceptionally low bids for tests that they do not perform themselves, but contract out to other labs. These tests may be used as a "loss leader" or the laboratory may negotiate a special price with the performing laboratory. However, these bids can skew the overall results of the bidding procedure. Therefore, CMS should define the term, monitor, and have controls in place to watch for exceptionally low prices on send out tests.

G. Confidentiality

Under this proposal as published, laboratories would be required to submit a great deal of highly confidential and proprietary information concerning their business operations and testing. As a result, it is vital that this information be kept confidential and not subject to disclosure. The Supporting Statement notes that the contractor and the carrier are subject to confidentiality requirements, but it is not clear how this information would be handled under the Freedom of Information Act. As a result, the amount of confidential information required for the bidders (as opposed to the winners) should be kept to an absolute minimum and CMS should make it very clear that confidential information will not be subject to disclosure under FOIA or other requirements.

* * *

In closing, ACLA strongly believes CMS should first seek input on its plans for the demonstration project before seeking comments on the Form to implement the project. The errors and misconceptions in the bid Form and instructions are evidence of the underlying fundamental flaws in the current design of the demonstration project, which could prove fatal by preventing most bidders from being able to successfully implement the requirements as stated in the Form.

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ACLA is pleased to have the opportunity to respond to the Notice regarding the Form for the competitive bidding demonstration project. If you have any further questions or comments, do not hesitate to contact us.

Sincerely,

Alan Mertz/ ED

Alan Mertz
President

Appendix:

Issue	Questions
Potential requirement to split claims	1. Will claims for the same patient / same date of service have to be separated if the same accession includes tests covered by the demo and excluded tests (Pap smears, colorectal cancer screening tests, and new tests added to the Medicare Part B clinical laboratory fee schedule ("CLFS") during the demonstration)? 2. Will all claim forms go to the same carrier? 3. Will there be a different form for claims for the demonstration? 4. Will claims go to the same address / location of the carrier? 5. Will beneficiaries be confused by different notices of claims determinations?
Tests excluded	1. Will laboratories that are winning bidders be able to bill the beneficiary for tests that are <u>not</u> paid under the CLFS – such as RUO/IUO, various screening tests, etc.? Will laboratories that are losing bidders also be able to bill the beneficiary for these tests?
Coverage rules	1. What are the rules concerning limited coverage, including frequency denials? Are all rules suspended or do the claims under the competitive bid still go through the carrier's normal review process?
How are winning bidders determined?	1. What is the difference between composite bids, pivotal composite bids, and reservation bids? What criteria will be used to determine the pivotal composite bid, and how will it be calculated? 2. How do the factors of capacity, geographic coverage, quality, etc. impact the award of the bid? Are these factors only used to determine the "final winners" vs. a broader set of those that qualify as "not losers"? 3. CMS should define the term "gaming behavior."
Laboratory's usual charge	1. If a laboratory has a "usual charge" less than the demonstration price, would it be paid the lower of the demonstration price and the usual charge?
Bid price	1. Will the bid document indicate total volume and mix of tests included in the bid? Total volume and mix by ZIP code? The total volume has to exclude tests that are excluded as well as volume from laboratories that are excluded from bidding. We ask because the current form seems to contemplate that the bidder will submit ITS current volume and a price. Normally, one bids competitively with the goal of capturing a specified volume. 2. The bid indicates an expectation to pay contractors less than the aggregate amount that would otherwise be paid under the clinical laboratory fee schedule. Which "laboratory fee schedule" will be utilized for this determination – the local Medicare fee schedules or the NLA? 3. Is information submitted in connection with a bid subject to a FOIA request?
Demo Fee Schedule	How will the fee schedule for the demo be determined? The August 2005 RTI report included a proposed methodology for determining the new demo fee schedule which was not specifically referenced or elaborated upon in CMS's April 2006 report to Congress, so it is unclear whether CMS is adopting the RTI recommendation or whether it plans to use another methodology that has not yet been described.
Access	1. How will CMS establish a baseline for measuring the impact of the demo on beneficiary access to clinical laboratory services? 2. If tests per beneficiary and per clinical guideline will be the only measures of access during the demo, as CMS has suggested, how would a reduction in beneficiaries tested be reflected in an assessment of the demo's impact on access?

From: Glatzel, Edwin J. (CMS/OOM)
Sent: Thursday, September 29, 2005 1:19 PM
To: CMS - Central Office Executive Officers; CMS - Reg - Admin-Exec Officers
Subject: NEW Instructions for Training Funds Authorization

Effective October 1, 2005, the Office of Operations Management's (OOM) Learning Resources Group (LRG) will assume the responsibilities of reviewing and approving funds for all common expense training and for tracking all training activities, including discretionary and common expense training. LRG is required to provide information on employee training activities to the Department on a quarterly basis; therefore, we need your cooperation to assure we have the complete information needed to meet this requirement.

To meet the new reporting requirements, and to standardize training purchase practices throughout the Agency, the procedures for training purchases will change in several ways:

- By agreement with the Office of Financial Management (OFM), the Office of Acquisition and Grants Management (OAGM), and LRG, (and after consultation with several Executive Officers), **only the HHS-350** is to be used for **ALL** training purchases, unless the purchase requires the use of the HHS-393 (for custom designed training or purchases over $25,000). This includes both credit card and invoice driven transactions.

- Funds approval for ALL common expense training purchases will occur in LRG, not OFM.

- Components will continue to approve funds for training purchased using discretionary funds; however, you will need to enter into BUCS all required training information for each purchase, as BUCS will be used to compile Agency-wide training information for the quarterly reports.

- Components must also forward to LRG a copy of all training transactions (HHS-350s).

New Procedures for *DISCRETIONARY TRAINING FUNDS*

- Use only the HHS-350 Form for all training requests. (A sample form with the required fields highlighted, and instructions for completing the HHS-350 are attached.) The form can be found in the Forms Locator on the CMSNet.

- Please forward a hard copy of the HHS-350 to Sam Meagher at C2-15-26 or Fax Number at 410-786-1987.

- In addition to submitting the completed HHS-350, please enter **all information** from the HHS-350 form into BUCS including:
  - employee's name (First/Last),
  - organization,
  - pay plan-job series-grade (such as GS-107-13) (will fill in on new 11/9 BUCS rollout),

- course title,
- full vendor name,
- vendor employer identification number (EIN) (in Additional Data Field),
- dates of the course (in Date Area in Additional Data Area of BUCS),
- number of hours of the course (in Additional Data Area of BUCS), and
- cost of the course.

The detailed information is needed to help LRG to prepare tracking reports for the Department. We will be pulling reports from BUCS to provide this information and will use the hard copy HHS-350 as the backup information source.

New Procedures for *COMMON EXPENSE TRAINING FUNDS*

- Starting October 1, 2005, Mary Keogh and Rita Reinsel in OFM will no longer serve as funds approving officials for common expense training. LRG is taking over these responsibilities. Please forward all training requests and inquiries to Sam Meagher (410-786-4291) in LRG, C2-15-26, or fax 410-786-1987.

- Use only the HHS-350 Form when requesting training classes – please do NOT use the "Credit Card Form" or the "Training Worksheet (now obsolete)." To ensure each form is legible, please print the form after you have entered all the information for each request. Send the hard copy of the HHS-350 to Sam Meagher at C2-15-26 or Fax Number 410-786-1987 for funds approval. (Note: The PDF version of the HHS-350 Form, cannot be saved for future changes or use.)

- LRG will process the HHS-350 forms and will return the form to the component for registration in the class.

    - For training to be purchased with a Credit Card, LRG will return the original to the component, retaining a copy in LRG.

    - For training to be purchased through invoice to Accounting, LRG will forward the original to Accounting, and after Accounting commits the money and stamps the HHS-350, it will be returned to LRG. The original will be returned the component for registration, and a copy will be retained in LRG.

    - To purchase "custom designed" employee training, or training costing over $25,000, continue to use the HHS-393 form as you have in the past. When ready for funds approval, forward the completed form to Sam Meagher at C2-15-26 or Fax to 410-786-1987. If you have questions regarding when to use the HHS-393 rather than the HHS-350, please contact OAGM.

If you have any questions about this new process, please call Sam Meagher (6-4291) or Anna Barton-Thomas (6-4302).

If you plan to use a Credit Card for payment – it MUST be indicated at the top of HHS 350

CREDIT CARD

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

TRAINING NOMINATION AND AUTHORIZATION

IMPORTANT NOTICE

1. Form is to be typed or printed clearly.
2. Guidance for completion and code definitions are constrained on reverse of Parts 7 through 10.
3. Note Continued service Agreement on back of this page: sign if applicable.

1. Transaction Number (2-7)

SECTION A TRAINEE DATA

2. Social Sec. No. (8-16)	3. Last Name (17-32)	First (33-42)	Initial (43)	4. Organization *(Agency, Bureau, Off., Div., Br.)*
[redacted]	**Employee**	**CMS**	**A.**	**HHS/CMS/Center or Office/Group/Division**

5. Pay Plan-Series-Grade	6. Type Appointment	7. Position Title	8. Continuous Service		9. Hrs. of Prior Non-Gov't Training
			YEARS	MONTHS	
GS-107-??	**See Instructions**	**Written Per Position Description**			

10. Home Address: **Show Home Address To Insure Receipt of Mailed Pre-Work Materials**

11. Office Phone **(410) 555-5555**

SECTION B COURSE DATA

12. Training Hours: (52-55) A. Duty **0008** B. Non-Duty (56-59)

13. Training Period: From: (60-65) MMDDYY **12/01/05** To: MMDDYY **12/05/05**

14. Cost ($ only)	A. Tuition & Fees (72)	B. Books & Other (76)	C. Travel (80)	D. Per Diem (84)	E. Other Trans. (88)	F. Total (92)
	0450	**0250**	-	-	-	**0700**
Employee (97-121)	(97)	(104)	(105)	(109)	(113)	(117)

Privacy Act Statement Appears on Reverse of Part 1.

The training facility selected complies with Department Regulations regarding selection admission & treatment of students under Title VI of the Civil Rights Act of 1964.

15. Training Course Title (Do not exceed 45 letters) (122-166)
Learning To Communicate With Multiple Types of Audiences

16. Describe employee's training need and relate to official duties:
Employee is responsible for conducting Medicare Outreach sessions with beneficiaries and caregivers. Consequently he/she needs to communicate effectively with multiple organizations such as beneficiary groups. He/she also needs to effectively communicate with multiple types of audiences, from friendly to hostile, while maintaining a calm and professional composure fitting to CMS reputation.

17. Describe how course content relates to Item 16 above:
NOTE: The employee's justification for attending the training should clearly describe: 1. the employee's learning need, 2. how the course content will clearly satisfy that learning need, and 3. how the training will enhance the employee's performance in the workplace. For example:

The requested training will provide the employee with new techniques for analyzing the type of audience and to gear the presentation accordingly. The training will also help the employee effectively handle hostile questions without taking them personally and becoming frustrated and angry.

18. Name and Address to Send Payment ALSO Company Phone Number (167-201)
The Learning Organization Attn.: **EIN or TIN Here**
Address **7005 Hometown Avenue, Anytown US.** Zip (202-206) **11111**

19. Location of Training Name (207-241) **Center Training Sites** Attn.: **Name of Contact Person**
Address **5007 Homegrown Street, Trainingtown US** Zip (242-246) **22222**

20. Coding (See Instructions) A. Purpose B. Type C. Source D. Special Int. Program | 21. Self-sponsored | 22. Skill Code

SECTION C FISCAL DATA

23. Accounting Data *(Appropriation, Allotment, CAN, Class)*	24. SIBAC	25. Funds are available	Date
7560511/CAN/ Object Class (Tuition & Registration – 252W) (Training Attendance – 2140) (Conference Attendance – 2150)		**COMPONENT'S FUNDS CERTIFIER**	

SECTION D FISCAL DATA

TYPED NAME & TITLE (PHONE)	SIGNATURE	DATE	COMMENTS
26. Initiating Supervisor **1st Line Manager**			
27. Concurring Official **2nd. Line Manager**			
28. Concurring Official			
29. Approving Official **Manager with Delegated Approval Authority (Could Be Same as in #27)**			
30. Reviewing Emp. Dev. Spec.			
31. Authorizing Official			32. SPO CODE (283-261) (

SECTION E PROCUREMENT DATA

Reference your catalogue, please furnish the services mentioned in Item 15 above on the terms specified on both sides of the Vendor's Copy of this order, and on the attached sheets, if any, including delivery as indica purchase is negotiated under authority of 41 USC 252 © (3) or (5).

33. Send Invoice To:	34. Address Correspondence Regarding This Order To:
[redacted]	Name Title Phone
	Address
	35. Signature of Purchase Official

INSTRUCTIONS FOR COMPLETING FORM HHS 350

The form HHS 350 is to be completed for each training course requested. This requirement applies to all non-government training and all other training programs of eight hours or more.

NOTE: Effective October 1, 2005, the HHS-350 will be used to obligate payments for training made by government credit card and for payments via purchase order. To show that payment is via credit card and not purchase order, clearly write the words *CREDIT CARD PURCHASE* at the top of the HHS-350.

For the most part, the HHS-350 is self-explanatory. Items considered as self-explanatory are not shown under these instructions. Please note that ***Item Headings*** for the following major changes are shown in ***bold***:

Documentation Requirements for HHS-350s:
NOTE: There is specific documentation required with each HHS-350 (see below)

When preparing an HHS-350 for any training instance, you must attach a copy of:

1) **the course description,**
2) **the vendor registration form, and**
3) **any available information (such as found in a course catalog or on a course announcement) that shows the date, time, and cost of the requested training.**

HHS-350 Entry Changes:
The following information refers to specific entries and relates to the form by SECTION and / or ITEM NUMBER.

ITEM #1 TRANSACTION NUMBER – Transaction Numbering Process Change: Required by CMS Division of Accounting Operations (DAO)

Transaction Number is to be completed by component Budget Officer after determining that funds are available.

The transaction number in block 1 of the HHS-350 must be a 10-digit number in the following format:

Positions 1 through 3: first three letters of the employee's last name or the letters *GRO* if the HHS-350 is for group training

Position 4: one-digit fiscal year (e.g. 6 for FY 2006)

Positions 5 through 8: use 4-digit PROJECT number (formerly called FMIB number); if there is no specific PROJECT number for the training, cite the generic training PROJECT number 9113

Positions 9 and 10: two-digit sequence number (e.g. 01 for the first training class for a particular employee; 02, 03, etc. for each subsequent training class for that same employee)

ITEM #2 SOCIAL SECURITY NUMBER – Do Not Show Due to Privacy Concerns.

ITEM #6 TYPE APPOINTMENT – Show Career, Career Conditional, Excepted or other appointment as appropriate. For employees with time limited appointment, also show date of expiration of appointment.

ITEM #7 POSITION TITLE – Show position title as found on Position Description

ITEM #8 CONTINUOUS SERVICE - ***Does not need to be completed***

ITEM #9 HOURS OF PRIOR NON-GOVERNMENT TRAINING - ***Does not need to be completed.***

ITEM # 10 HOME ADDRESS – *Employees may show **either** their Home **or** Work Address. This block is needed in case the vendor sends out course materials prior to training. NOTE: Employees also MAY want to insert their work e-mail address in case vendor e-mails confirmations of attendance.*

ITEM #12 TRAINING HOURS - For part-time training insert the actual number of classroom hours as determined by the training facility. If course is an academic course, the following method of conversion must be used:
1 credit hour (semester) = 12 classroom hours
1 credit hour (quarter) = 8 classroom hours.

> ***Example:*** A 3 credit hour course = 36 classroom hours in a semester or 24 classroom hours in a quarter.
> NOTE: For full-time training multiply number of training days by eight. This must not exceed forty hours/week. ***Hours are shown with 4 digits: 40 hours is shown as 0040***

ITEM #13 TRAINING PERIOD – Show dates by month, day and year using 2 digit numbers only.
Example: **FROM:** ***02/02/05*** **TO:** ***02/04/05***

ITEMS #14A, B, and F. COSTS - Show dollars only, using 4 digits. Example: $132.00 – 0132.

ITEM #15 TRAINING COURSE TITLE - Show the exact course title. Do not use catalog number or designation. (Example: Show "Speaking Effectively to Large Audiences ", not "Public Speaking 506").

ITEMS #16 and 17 -These Items ***must be completed***. Approval and authorization of the training will be based upon the justification included in these Items. See details and examples below:

> **ITEM #16** – Clearly describe the employee's official duties and describe the employee's specific learning/ training need (***Learning Need definition – the aspect of the employee's work performance that needs improvement***).
>
> ***Example: "As I am responsible for beneficiary outreach, I am required to speak before large audiences of Medicare beneficiaries, their representatives, and various other large groups. As a representative of CMS, I must maintain a calm and professional speaking demeanor even when faced with hostile audiences. I need to enhance my ability to communicate clearly and effectively with these audiences to explain what they are entitled to under Medicare."***
>
> **ITEM #17** – The employee's justification for attending the training should describe how the course content will satisfy the employee's learning need, and how the training will enhance the employee's performance in the workplace.
>
> ***Example: "The requested will provide me with new, updated techniques for analyzing the audience so that I can gear the presentation accordingly. This training also will give additional insights on effectively handling hostile questions without becoming frustrated and angry."***

ITEM 18 Taxpayer Identification Number (TIN) or Employer Identification Number (EIN)

> **ITEM #18 – In addition to providing the requested information re: where to send payment; also include either the Taxpayer Identification Number (TIN) or the Employer Identification Number (EIN) as appropriate. NOTE: The nine-digit Taxpayer Identification Number (TIN), and the telephone number of the vendor providing the training should be shown on line 18 of the HHS-350 in the space after *"Attn."***

Taxpayer Identification Number (TIN) or Employer Identification Number (EIN) - defined

The TIN is a unique identifier that is assigned to all individuals and businesses that file tax returns in the United States. It also is known as the Vendor Tax ID Number. For individuals, the TIN is their social security number. For other businesses, the TIN is an Employer Identification Number (EIN) assigned by the Internal Revenue Service. The Division of Accounting Operations (DAO) is required by the Department of Treasury to associate a valid TIN with each payment issued by CMS.

NOTE: If the vendor's TIN and/or telephone number is not included or is incorrect, the HHS-350 will be returned by DAO unprocessed to the fund certification official.

Questions concerning the TIN/EIN should be directed to your component's Budget Officer.

ITEM #19 – This is the address of the location where the training will be held.

ITEMS #20 through 22 – ***Do not need to be completed***

ITEM #23 - ACCOUNTING DATA -To be completed for any training requiring an appropriation of funds.

Appropriation #: The number 7560511 always represents CMS, except for the 3rd digit which changes at the beginning of the current fiscal year.

Common Accounting Number (CAN) – See your component's budget officer for this information.

Object Class: See your component's budget officer for this information.

ITEM #25 – Must be signed and dated by the component's funds certifying officer. (Verifies sufficient funds are available).

NOTE: Signatures must be received/dated prior to the start date of the training. If not, the ratification process will be implemented with the Office of Acquisition and Grants Management (OAGM). If the training is approved but funds are not yet available, the 350 should be signed pending availability of funds and dated prior to the start date of training. Once funds become available, the 350 can be sent to DAO for processing.

ITEM #26 - INITIATING SUPERVISOR - To be signed by the Initiating Supervisor following review of the nomination for legal and regulatory compliance.

NOTE: Signatures must be received/dated prior to the start date of the training. If not, the ratification process will be implemented with the Office of Acquisition and Grants Management (OAGM). If the training is approved but funds are not yet available, the 350 should be signed pending availability of funds and dated prior to the start date of training. Once funds become available, the 350 can be sent to DAO for processing.

ITEMS 27, 28, 29 and 31: ***should be completed according to current policies within each CMS component. Original HHS-350 guidance also is shown for each Item.***

ITEM #27 and 28 -CONCURRING OFFICIAL - To be signed by Management Official(s) above the level of the initiating Supervisor whose concurrence in the initiation of the nomination is required by Agency instructions. Concurrence indicates the nomination meets legal and regulatory requirements.

NOTE: Signatures must be received/dated prior to the start date of the training. If not, the ratification process will be implemented with the Office of Acquisition and Grants Management (OAGM). If training is approved but funds are not yet available, the 350 should be signed pending availability of funds and dated prior to the start date of training. Once funds become available, the 350 can be sent to DAO for processing.

ITEM #29 -APPROVING OFFICIAL - To be completed by the Management Official delegated the specific authority to approve the type and length of training requested. This can be the same person who signed in Item 27 or 28. Signature indicates the nomination meets legal and regulatory requirements. **NOTE:** Signatures must be received/dated prior to the start date of the training. If not, the ratification process will be implemented with the Office of Acquisition and Grants Management (OAGM). If training is approved but funds are not yet available, the 350 should be signed pending availability of funds and dated prior to the start date of training. Once funds become available, the 350 can be sent to DAO for processing.

ITEM #30 -REVIEWING EDS – ***Does not need to be completed.***

ITEM #31 – AUTHORIZING OFFICIAL - To be completed by the official delegated the specific authority to authorize the type and/or length of training requested. Signature indicates the nomination meets legal and regulatory requirements.

NOTE: Signatures must be received/dated prior to the start date of the training. If not, the ratification process will be implemented with the Office of Acquisition and Grants Management (OAGM). If the training is approved but funds are not yet available, the 350 should be signed pending availability of funds and dated prior to the start date of training. Once funds become available, the 350 can be sent to DAO for processing.

ITEM #32 – ***Does not need to be completed.***

ITEM #33 – ***Send Invoice To: Include the following address:***

CMS/Division of Accounting Operations
P.O. Box 7520
Baltimore, MD 21207-0520

ITEM #34 – Address Correspondence Regarding This Order To: Complete as appropriate

ITEM #35 – Signature of Purchasing Official: Must be signed by component's designated Authorized Purchasing Official on all forms HHS 350 used as purchase documents.