AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE

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June 19, 2006

Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
Division of Regulations Development-C
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: Bonnie L. Harkless

Re: CMS-10193 and CMS 10133

The American Society for Clinical Laboratory Science (ASCLS) is writing to comment on the April 21, 2006 *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 instructions to be used to complete the form and the Supporting Statement.

ASCLS is the nation's oldest and largest non-registry professional association for non-physician clinical laboratory professionals. The Society's mission includes promoting high standards of practice in the workplace and ensuring professional competence, while its ultimate goal is to ensure excellent, cost-effective laboratory services for consumers of health care. Our membership of nearly 11,000 includes clinical laboratory directors, managers, administrators, supervisors, and staff at all levels of practice in all disciplines.

ASCLS has a number of general questions about this process that we believe must be answered before this project commences:

- How will CMS handle the laboratory service needs of nursing homes if the small, local laboratories (either hospital outreach or privately owned) are not among the winners since these are the only laboratories that currently service this sector of health care?
- Physician office laboratories comprise the largest number of laboratories in this country with a 25-30% market share. How does their exemption impact the total savings anticipated from this demonstration project? How will those that are in the CBA be paid during the period of the project?
- How will quality of service be monitored during the project? ASCLS believes that the ombudsman role should be filled by a committee because the

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- complexities of laboratory services are beyond the expertise of any one person. Will the monitoring be done through a Medicare contractor? The contractor must then comprise both the fiscal intermediary and the carrier functions so the contractor is knowledgeable of all types of laboratories

Supporting Statement

#12. Burden Estimates (Hours & Wages)
The number of hours per bidder is grossly underestimated. Responding to this bid will require at least twice the upper limit of the estimate (i.e. twice the 100 hours).

The annualized cost is based on the salary of a staff scientist/techonologist. This is not the level of laboratorian needed to assemble the information for this bid. The laboratory will have to dedicate a management position and enlist aid from the legal, financial, and information technology departments. The salaries for individuals from each of these departments will exceed the $23.66 per hour CMS has factored into the cost of this burden.

#3. Use of Information Technology
We believe that this section needs clarification. What is the intent of the section? Is it supposed to explain how to submit the application electronically? What is meant by "collection"; is this supposed to be the application? Does CMS have the ability to accept an electronic signature?

Bidding Instructions

A. Bidding Status

Under the "Rules", the definition of "Required bidders" should include the exclusions (physicians' office laboratories, hospital outpatients, etc) as CMS cannot assume that every laboratory in the bidding area will already know about the exclusions.

ASCLS requests that CMS clarify in the instructions that laboratories that don't bid do not jeopardize hospital outpatient and physician office patient reimbursement.

CMS should explain the "pre-determined cap on total Medicare demonstration test revenue" for the non-required bidders. Is this different than the $100,000? What happens when the non-required bidder exceeds the cap - $100,000? If the annual cap is reached in year one of the project, is the lab able to participate the second year or is the lab excluded for both years two and three.

C. GEOGRAPHIC COVERAGE AND TEST MENU

#3 The instructions need to explicitly state how to add information for the all of the specimen collection locations if the application is submitted in hard copy or electronically.

The amount of information required to be submitted with the entire application will be volumes; in hard copy, for instance, it could fill multiple binders. The instructions do not standardize the organization of all of the material so that CMS can readily compare the submitted information. If the application can be submitted electronically, what software must be used, should the files be submitted on CD ROMs, or a different hardware?

#6 This question requests the types of expansion plans CMS expects a required bidder to provide if they are to win the contract. The announced start of the first demonstration project is April 2007. It will be impossible for most hospital laboratories who would qualify as required bidders to build and install the information system, construct specimen collection sites, etc. in the time left between now and the beginning of the project. This requirement effectively excludes this type of laboratory and restricts participation to laboratories that already have the infrastructure in place. Thus CMS has fewer bidders from which to choose.

Bidding Form

In 1998, CLSI (then NCCLS), published a guideline to follow when choosing a referral laboratory, *"Selecting and Evaluating a Referral Laboratory; Approved" GP9-A, ISBN 1-56238-357-4.* The criteria in this document outline the process that a laboratory conducts to choose such services. This document is the product of a CLSI consensus using input from laboratorians in government agencies, commercial and state referral laboratories, hospitals and accrediting bodies. ASCLS believes that CMS should use the same criteria to identify winners under the bidding competition. We are concerned that this form does not ensure that the winning laboratories are efficient and effective at delivering quality laboratory services. However, since CMS did not follow this document, ASCLS has the following questions and concerns:

A. BIDDING STATUS

The major question is whether this form will be filled out in an electronic format that will allow for the expansion of answers. ASCLS believes the form should be available in an electronic format.

B. APPLICANT INFORMATION

The financial information, business relations, etc that are being requested in this section will not be consistent from bidder to bidder. The information provided by Hospital outreach laboratories will not reflect the capitalization of the laboratory but rather that of the parent institution or system. This doesn't tell CMS whether the laboratory is viable enough to finish the demonstration project. The way these questions are crafted seems more focused on independent laboratories and possibly presents these laboratories with an unfair advantage.

C. GEOGRAPHIC COVERAGE AND TEST MENU

#5 Subcontracting

Most laboratories do not have letters of agreement with all of the reference laboratories that are used, with the exception of the major subcontractor. Will the lack of letters of agreement preclude the bidding laboratory from sending the tests from this project to a referring laboratory with which they have no letter of agreement?

It is not clear whether new agreements can be made during the demonstration project if, for example, a participating laboratory gets a request for a new test and needs to find a new referring laboratory.

#6 Expansion

Since CMS has not indicated the volume that a winning laboratory can anticipate, it is difficult to describe the degree to which additional staff, instrumentation, facilities, etc should be added. CMS must make it clear before the bidding takes place whether a laboratory can subcontract after the winning bids have been awarded if volume exceeds their capacity?

D. CAPACITY AND BID PRICE INFORMATION

#4 Test Capacity and Bid Price

We recommend that the application form comes pre-populated with the HCPCS codes and the test names to standardize the bid. A pre-populated list would remove ambiguity as to which tests were included in the bid. This is particularly important because many of the HCPCS and CPT codes are not analyte specific. They are general codes for a method, such as immunoassay,and the tests performed by this method can stand vary

dramatically in price. Therefore CMS will have to list what tests they want for these method codes.

We do not believe that CMS has made clear what is wanted in Column E – Test Weight in this section of the application. There needs to be a better description as to how to calculate the test weight if the bidding laboratory is supposed to do that. ASCLS suggests that CMS calculate the Test Weight since that would standardize the results and not leave the calculation to the interpretation of each bidder.

E. QUALITY

#2 Laboratory Registry
The question for this item asks for any affiliated laboratory. We urge CMS to define "affiliated" in the instructions. Does affiliated mean laboratories in your company or health system or the subcontractors of the bidding laboratory?

The only information in this section related to evaluating the quality of the laboratory is proficiency testing. The measurement of quality laboratory services is far more complex than proficiency testing results. Those results do not measure the laboratory's ability to provide the right information on the right patient at the right time. Therefore, ASCLS believes that CMS is not asking the appropriate questions to ensure that the winners can and do provide quality service. We again refer CMS to the CLSI document "Section 3 Criteria for Selection", which recommends that **before** entering into a contract for laboratory services, the purchaser of the services should have information about:

- 3.2.4 Turnaround times, including references from clients that document that laboratory's "compliance with its stated policy."
- 3.2.5 Communication systems that use "a standardized order entry or results reporting communication protocol.
- 3.2.6 Efficiency and timeliness of reporting results and the effectiveness of interpretations. Reports should include "age and sex adjusted reference ranges and/or other therapeutic and diagnostic reference ranges, where possible". The laboratory's turnaround time for reporting critical values, handling Stat tests, being available to answer questions about results, and responsive to handling "inappropriate/compromised" specimens are all criteria that should be queried before awarding any contracts.

The ASCLS recommends that CMS hold a working meeting soon to discuss the many open issues surrounding this process so they can be addressed in real time if this demonstration project is to move forward by the dates previously announced. ASCLS and its members thank you for your attention to these concerns and suggestions and reaffirm our willingness to work with you, your colleagues, the chosen contractor, and other stakeholders to ensure that the results of this demonstration project are as sound and definitive as possible.

Sincerely,

Bernadette Bekken, President
American Society for Clinical Laboratory Science

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June 19, 2006

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Ms. Michelle Shortt
Director
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Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L Harkless
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Baltimore, MD 21244-1850

RE: CMS-10193 Agency Information Collection Activities: Proposed Collections; Comment Requests (Medicare Clinical Laboratory Competitive Bidding Demonstration)

Dear Ms. Shortt:

Please accept the following comments regarding the application form CMS-10193 and the Medicare Clinical Laboratory Competitive Bidding Demonstration.

There are fundamental issues with the Competitive Bidding Demonstration that we believe need to be addressed, including the need to have a good method for tracking and documenting the demonstration's success or failure. The demonstration should be able to determine that the costs are not shifting to other health care entities. For example, as a result of perhaps saving laboratory costs through competitive bidding, the costs for pharmacy, hospital and ambulance increase because of poor turnaround time or access.

We would like for you to consider responses to the following questions.

1. How is CMS going to track those beneficiaries that reside in the winter months down south, and visit up north during holidays or summer months? Who's paying for the service under the competitive bidding demonstrations arrangement?

2. CMS will incur increased health care costs for beneficiaries, when a winning bidder cannot perform an ordered test timely, or when a beneficiary is transported to a hospital to obtain urgent test results because the winning lab is unable to perform the test timely. How is CMS going to track the increase costs for pharmacy, hospital and ambulances and its direct relationship to the demonstration?

3. How is CMS going to track State Agencies increase in costs, and survey deficiencies among nursing homes due to a bidder not being able to perform consistently for its contracted services?

4. How is CMS going to differentiate those bidders that perform blood draws in nursing homes and homebound patients with other laboratories that just pick up and transport specimens?

5. How is CMS going to communicate the volume in the demonstrations site and of each demonstration test the bidders will be bidding on? Volume is critical component to the quoting process.

6. Where in the application is the requirement for quality and turnaround testing questions?

Our specific comments to the application form, is as follows. Note that the colored and bold faced type is what we are recommending to be added or further explanation is required.

Application Form: Instructions for Completion Comments:

Section A. Bidding Status

Required bidders are defined as **laboratories certified under CLIA as moderate and/or high complexity testing facility** that supplied at least $100,000 in the demonstration tests during calendar year 2005 to Medicare beneficiaries residing in the CBA, Competitive Bidding Area. **(Is the draw and visit excluded from the $100,000 demonstration test since those prices are set by congress? If the CBA is the MSA (Metropolitan Statistical Area), and if a laboratory performs more that $100,000 in the area defined by CMS they are considered Required Bidders. So, it is not based upon the total business of the demonstration testing during the calendar year 2005, just those tests located in the MSA.)**

Rules:

(General Comment: The rules need to be more specific…like for example, is a late bidder still qualified to bid, and will it be accepted? Since specimen collection and visit are set by congress, including STAT services, how will they be considered versus a laboratory that just picks up specimens? Is the blood draw, STAT fee, and visit excluded from the total annual receipts?)

Section B. Applicant Information

10. Financial information regarding the applicant is required to understand and assess the applicant's financial viability. The following information should be included when the application is submitted.
    a. **Reviewed Financial Reports**….Small applicants are defined by the SBA as businesses having less than $6 million in annual receipts. **(Comment: According to SBA Website it states small business as defined as $12.5 million in receipts. Does the Women Business Enterprise under the Regulatory Flexibility Act and Enforcement Fairness Act come into consideration?)**
    b. **Audited Financial Reports…(Comment: This would be a hardship for those companies that fall slightly above what CMS is defining as a small business. The cost compared to what we are currently paying for outside Certified Public Accountant is currently $12,000 per year, and an audit would cost us an additional $25,000 per year.)**

Section C: Geographical Coverage and Test Menu

In first paragraph: define "Demonstration Tests"

1. Provide information regarding the acquisition and/or transportation of laboratory specimen. Attach a copy of your current requisition or test request form. **(Comment: These are two separate questions and should be separated as such; the acquisition of obtaining a specimen, and test request. The acquisition could be obtained in several methods to including drawing and transporting or just transporting the specimen. Also attaching a requisition form can be difficult because labs communicate with their clients via an electronic method, fax, or phone when communicating laboratory requests.)**
6. This question should be completed if the applicant plans to expand in-house after being awarded a bid contract. **(Comment: You should also ask the question that if you are not awarded the bid, what reduction in staff and facilities or possible closing of your business would take place.)**

Section D. Capacity and Bid Price Information

Section D collects information on the applicant's capacity **(Define capacity more and how will subcontracting be communicated when or included in capacity?)**

4. Complete the bid price table for all demonstration tests. A bid price must be provided for each Healthcare Common Procedure Coding System (HCPCS) **(Laboratory uses CPT Codes)**.

Clinical Health Laboratories services nursing home and homebound beneficiaries plus has some walk-in traffic at our Patient Service Centers. In the application, it does not address quality requirements, and access to care which includes travel, blood draws, STAT and time draws. Laboratory testing and result timeliness can be a matter of life or death. Our concern is will patients receive proper care under competitive bidding, and at what price or at what human cost? Unlike the Durable Medical Goods demonstration, which is product driven and has ample lead time, is not life or death. Laboratory Competitive Bidding should not restrict access, or eliminate beneficiaries and clients from the freedom of choice. Win-lose bidding will eliminate competition, which will raise prices in the long run.

Thank you for giving us this opportunity to comment on the contents of the application, and Competitive Bidding. We'd be happy to participate in adding any further comments, in order for the application process remains fair.

Sincerely,
Clinical Health Laboratories

Carol A. Kalina
CEO/President

CC: Kilbourne Medical Laboratory
Mark S. Birenbaum, Ph.D. American Association of Bioanalysts

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June 19, 2006

Centers for Medicare and Medicaid Services
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Division of Regulations Development—C
Attention: Bonnie L. Harkless
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To Whom It May Concern:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing in response to the April 21, 2006 *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).

AdvaMed is the world's largest association representing manufacturers that produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Our comments will focus on three areas: (i) the estimated burdens associated with the information collection; (ii) the utility of the form questions related to quality; and (iii) outstanding issues that will affect the ability of applicants to respond adequately.

I. Estimated Burden

In the "Supporting Statement for Paperwork Reduction Act Submissions" ("Supporting Statement") for the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project (the "Demonstration"), CMS assumes that the wage rate of a "Medical and Clinical Technologist" ($23.66 per hour) is an appropriate one for estimating the labor cost of completing the Demonstration forms. We are concerned that this may underestimate the true cost of completing such forms. Individuals from varying backgrounds, such as billing, collections, operations, and legal counsel, will likely be required to participate in submitting information in conjunction with the Demonstration's application process. The wage rates for individuals serving in these capacities may be higher than the rate assumed by CMS. As a result, we urge CMS to take this factor into consideration as it sets forth its burden estimate. In addition, we recommend that CMS consult with various laboratory community representatives in order to derive an accurate estimate of the total number of hours that will be involved in completing the form and submitting their bids.

On a separate note, we continue to have concerns with the administrative complexity and cost to the Federal government of implementing competitive bidding programs. While the Supporting Statement addresses "Cost to the Federal Government," this section addresses only the costs associated with developing and producing the "Bidders Package" for the Demonstration, and the costs of the contract with RTI. A thorough evaluation of the administrative cost and complexity involved in implementing competitive bidding for clinical laboratory services will ultimately be needed to evaluate the overall Demonstration.

II. Quality Issues

We recognize that clinical laboratories are subject to the regulatory requirements of the Clinical Laboratory Improvement Amendments (CLIA), which in turn affect the quality of lab services provided. However, in the context of the Demonstration, we are concerned that relying too heavily on the requirements of CLIA to ensure quality may result in a limited picture of the Demonstration's impact on patient care. To supplement the quality monitoring activities, we recommend that the Demonstration include patient-focused quality monitoring factors, such as patient satisfaction as it relates to specimen collection, and ease of access to phlebotomy or specimen collection centers. These factors will be important in evaluating the impact of clinical laboratory competitive bidding on patients.

III. Implementation Issues

We recognize that many implementation issues related to the Demonstration have yet to be addressed and resolved at this stage. However, the Demonstration form needs to be clear on its face for the Demonstration applicants. For example, the term "nonpatient" is

not defined in the form. This is an important term to define because we understand that some hospitals record their outreach lab business as "outpatient" rather than "nonpatient."

In addition, we recognize the importance of "subcontracting" relationships to the bidding process. However, given the potential antitrust issues that may be raised by such networks of bids, we urge CMS to provide guidelines for what kinds of networks will be considered appropriate and consistent with the antitrust laws.

Finally, we continue to be concerned about the impact competitive bidding will have on overall competition in the clinical lab services market. While initial savings may be gleaned through competitive bidding, in the long-run the market may suffer from lack of diversity as "losers" are unable to stay in business without Medicare as a payer. We hope that CMS will take into consideration the importance of numerous and diverse types of laboratory outlets in order to ensure patient access to high quality lab services.

* * * *

Thank you for the opportunity to comment. We look forward to working with CMS as the Demonstration is implemented.

Sincerely,

Ann-Marie Lynch
Executive Vice President

Cc: Linda Lebovic

INTERPATH
LABORATORY

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June 19, 2006

Ms. Michelle Shortt
Director
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Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attention: Bonnie L. Harkless
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Dear Ms. Shortt:

I am writing this letter to submit comments related to the Medicare Clinical Laboratory Competitive Bidding Demonstration. I am significantly opposed to competitively bidding clinical laboratory services. A clinical laboratory service is not a material product just transacted between two parties. It is a service that is complicated by many different entities and variables, not the least of which is continued reductions in reimbursement over the years. This is the first time I have been involved with an effort to request your department's consideration on new Medicare regulations being developed. The affect the proposed actions will have on my laboratory will be significant. We wish to remain an active participant in the delivery of healthcare and hope our input to this new proposal will help to develop the best process.

It is important to understand a bit about our laboratory so that you will understand why we are concerned enough to submit questions about the Bidding Demonstration. Interpath Laboratory has been providing laboratory services to Eastern Washington, Eastern Oregon and Idaho for over 40 years. We provide these services to mostly rural locations in those states where other larger, national laboratories and many hospital outreach laboratories won't go. We have emphasized quality and timely laboratory results, at the same time embracing new technology both in testing and information transfer. We are committed to providing the best laboratory services to Medicare patients and would like to see the demonstration project as comprehensive and the goals of the department acknowledged.

I have included below two general concerns regarding the competitive bidding project.

Application Form: A properly designed demonstration begins with an application form that is designed to illicit the information needed from bidders to ensure that the demonstration is consistent with the Medicare statute and ensures Medicare beneficiary access to clinical laboratory testing. Unfortunately, CMS's application form is not as comprehensive as it should be to capture such information.

First, while it asks a number of questions related to geographic coverage and the test menu, the form does not ask any questions that suggest how CMS plans to ensure access to testing for highly vulnerable patients, such as those residing in skilled nursing facilities (SNFs), or geographical locations where it is not profitable to provide clinical laboratory services. It is not

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clear from reading the form how CMS intends to prevent laboratories from using marketing and service strategies to target and serve only the easiest, low-cost, high-volume segments of the market.

Second, the form includes a "Subcontracting" section in which the applying laboratory would list any other laboratories with which it is establishing a subcontracting agreement. The form requires very little information to be provided under this section. Does CMS intend to provide bidders with a set of guidelines about the types of discussions they can have with other laboratories in developing a consortium? Has CMS identified specific individuals within the Department of Justice or the Federal Trade Commission assigned to monitor compliance with fair competition and antirust laws during this demonstration?

Third, the form does not adequately probe bidders for information about the quality of the clinical laboratory services they provide. The form merely asks the laboratory to designate a "quality assurance staff member to service as a point of contact", inquires as to the laboratory's status under the Clinical Laboratory Improvement Act program (CLIA), and request the laboratory to list the CLIA-approved Proficiency Testing programs in which it participates. It does not provide a mechanism by which to thoroughly assess the quality of the laboratories before the demonstration begins so that an accurate measure of quality improvement or deterioration can be made at the end of the demonstration.

Burden Estimates: In addition, Interpath is concerned that the burden estimates provided by CMS significantly underestimates the time and cost of completing the forms. The estimate of 100 hours is not sufficient for laboratories to assess whether the facility is required to bid based on Medicare revenue from the previous year; assemble a complete financial statement; negotiate subcontractor arrangements with other laboratories and provide signed agreements; and determine capacity and bid price for all 1,100 tests on the clinical laboratory fee schedule. Moreover, the individuals needed to complete the forms include those responsible for billing, collections, operations and legal counsel. None of the hourly rates for these individuals are included in the calculation of the financial burden.

As a partner in the delivery of rural healthcare, we are concerned about the quality and accuracy of laboratory testing, and we welcome the opportunity to contribute to the demonstration project. We look forward to hearing your response to our questions and concerns. Thank you for you consideration.

Sincerely,

Thomas M. Kennedy

Thomas M. Kennedy
President
Interpath Laboratory, Inc.

Medical Laboratory Diagnostics

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June 19, 2006

Ms. Michelle Shortt
Director
Centers for Medicare & Medicaid Services
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Division of Regulations Development C
Attention: Bonnie L. Harkless
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Baltimore, MD 21244-p1850

Dear Ms. Shortt:

This is in response to your solicitation of comments regarding the competitive bidding project and the demonstration projects application form.

We are a small (1500-2000 patients per week) independent community clinical laboratory serving north, central and a portion of southern New Jersey since 1951. We provide a personalized service to a segment of the clinical lab testing market that the large national labs have been unsuccessful in servicing or have avoided in servicing. We have over the years been in the position to establish a personal relationship with the Medicare covered patient and understanding of their unique needs.

The burden estimates that CMS proposes is significantly less than that estimated by our laboratory. As a small independent lab we would be required to retain legal council, and add significantly to the staffing costs in an effort to provide an accurate analysis and bid.

I am concerned about how you are taking into account access to certain services and assuring the quality of service is maintained analyzing both pre and post contract period. It does not appear to me to be based solely on a low fee schedule but also, however not limited to, access to quality services. An example of some of the segment that might be underserved is the following:

1) Provision of house call service. Currently our lab services approximately 150 patients per week. The large national labs have traditionally avoided servicing this population.

2) As a smaller lab we have been better able to respond to stat/emergency testing needs and same day reporting on select tests such as prothrombin time

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determinations, for monitoring coumadin therapy, a common analysis performed on Medicare covered patients. This has aided the physicians in providing accurate and timely care, as the results and accuracy on this particular test are affected by pre-analytic variables such as specimen stability and transport. Timely collection, analysis, and reporting on emergency requests routinely reduce the requirement of the patient to be referred to the local emergency room for evaluation. We do not see in the application process how such service will be monitored and guaranteed.

3) Providing service to nursing home patients and facilities that have predominantly Medicare covered patients. Some of these facilities were unable to establish service with the large national labs; however we are able to service this population. Does the application process evaluate both pre and post service expectations and goals?

As a laboratory director of an independent clinical lab that is concerned about the quality of lab services to our Medicare covered patients, I hope you find the above informative.

Sincerely Yours,

George N. Mitilenes Ph.D., HCLD (ABB)
President/Laboratory Director

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June 12, 2006

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To Whom It May Concern,

On behalf of **MARSHFIELD LABORATORIES**, 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.

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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, 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,

MARSHFIELD LABORATORIES

Gene R Shaw

By: Gene R. Shaw, M.D., Ph.D.
Its: Director

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To Whom It May Concern,

I am a clinical laboratory supervisor with over 30 years experience in the clinical laboratory. 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).

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In addition to the general comments provided above 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,

Rae Ann Maiers

Rae Ann Maiers
Site Supervisor
United Clinical Laboratories - Finley Site
350 North Grandview
Dubuque, Iowa 52001
563-589-2431
e-mail: raeann_maiers@pa-ucl.com

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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,

As a laboratory professional, I am writing in response to the April 21, 2006 *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).

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23

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,
Jerry W. Bennington, B.S.M.T. (AMT), CLC (AMT), MBA
Regional Laboratory Operations Manager
Marshfield Clinic
Marshfield, WI.

24

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

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24

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,
Susan A. Franks, MT(ASCP)
Laboratory Operations Lead
Franklin Medical Center
Greenfield, MA 01301
(413) 773-2536

25

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 **New Hanover Medical Group, P.A.** 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).

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25

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,
Cindy Young, Laboratory Manager

26

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

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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,
Lavonne Rodeffer, MT(ASCP)
Laboratory Director
El Dorado Hospital
Tucson, AZ 85712

United Clinical Laboratories
Cathedral Square, Dubuque, IA 52001
Phone 563-556-2010

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,

I am a clinical laboratory manager with over 30 years experience in the clinical laboratory. 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).

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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,

Mary Jo Bonifas

Mary Jo Bonifas
Manger of Laboratory Services
United Clinical Laboratories, Inc
205 Bluff Street
Dubuque IA 52001
563-556-2010 #127
mary_jo_bonifas@pa-ucl.com

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

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

Sincerely,

Nathalie Apke

Nathalie Apke, MT (ASCP).

29

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Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
Room C4-26-05
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Thank you for the opportunity to comment on this important issue.

Sincerely,
Walter T. Hayes
Administrative Director of Laboratory Services
Pocono Medical Center
206 E. Brown St.
East Stroudsburg, PA 18301

30

June 7, 2006

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

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

Sincerely,

Cristy Reynolds, MT(ASCP)

Cristy Reynolds, MT(ASCP)
Clinical Laboratory Consultant
1017 Jones Road
Irmo, SC 29063

31

June 7, 2006

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
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Thank you for the opportunity to comment on this important issue.

Sincerely,

Todd Proud

Todd A. Proud MT (ASCP)
Clinical Laboratory Consultant
719 Elmtree Lane
Claymont, DE 19703

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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

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

Sincerely,

Dr. Larry J Taylor M.T.

33

United Clinical Laboratories
Cathedral Square, Dubuque, IA 52001
Phone 563-556-2010

J.A. BRENNAN, MD
R.R. DUELAND, MD
T.T. EDMONDS, MD
P.G. ELLERBECK, MD
C.J. LEIGH, MD
J.C. O'CONNOR, MD
S.N. RAYMOND
J.R. SCHAEFER
O.D. SLAGEL, MD
R.J. THEOBALD
T.G. TIMMERMAN, MD

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

To Whom It May Concern,

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

Sincerely,

Sharon A Hosch

Sharon A. Hosch
Site Supervisor
United Clinical Laboratories, Inc
1111 3rd Street SW
Dyersville IA 52040
563-875-2949
sharon_hosch@pa-ucl.com

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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,

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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,

Anne T. Daley

Anne T. Daley, MS, MT(ASCP)DLM

35

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,

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.

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35

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,

Susan Cm Regional Manager

26

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

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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,

Kristine C Gregg

Kristine C. Gregg, MBA, MT(ASCP)
Director of Laboratory Services

37

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 Dean Health Systems 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).

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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,
John H. McAllister, Laboratory Supervisor

38

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 LaPorte Hospital and Health Services 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.

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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,
Robert C. Nelson MHA MT (ASCP)
Director of Laboratory Services

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 **Johnston Memorial Hospital, Abingdon, Virginia** 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.

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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,

Jim Romeo MT(ASCP)SM
Laboratory Director

40

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 **Johnston Memorial Hospital** 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).

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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,
Vicki Ward MLT ASCP Core Lab Supervisor

41

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,

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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,
Lisa Bailey
Johnston Memorial Hospital

47

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 Health Care Laboratory** 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.

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47

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,
Sharon Jackson
Director, Laboratory Services

PHYSICIANS REFERENCE LABORATORY, LLC
7800 West 110th Street
Overland Park, Kansas 66210
913-338-4070 or 800-821-3627

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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

June 8, 2006

To Whom It May Concern,

On behalf of Physicians Reference Laboratory, 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).

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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.

Best Regards,

Verlene Miller
Director Laboratory Operations
Physicians Reference Laboratory

44

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 Appleton Medical Center, Appleton, Wisconsin 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).

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44

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,

Jo Ann Lang, Laboratory Director
Appleton Medical Center
1818 North Meade Street
Appleton, WI 54911

PHYSICIANS REFERENCE LABORATORY, LLC
7800 West 110th Street
Overland Park, Kansas 66210
913-338-4070 or 800-821-3627

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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

June 8, 2006

To Whom It May Concern,

On behalf of Physicians Reference Laboratory, 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).

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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.

Best Regards,

Nancy Sheffer, BSMT (ASCP)
Supervisor, Microbiology Services
Physician Reference Laboratory
nancy.sheffer@prlnet.com

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 **Emerson Hospital** 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.

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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,
Barry Jones
Director, Lab & Rehab Services
Emerson Hospital
Concord, Massachusetts

41

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 Affiliated Community Medical Centers, P.A., 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 statement 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,

Phil Hansen
Laboratory Manager

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

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To Whom It May Concern,

On behalf of **Bon Secours Richmond HealthPartners 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! For non-profit hospital laboratories, this is an extra financial encumbrance that is detrimental to the institutions.

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. Large for-profit independent laboratories will be able to "outbid" hospital laboratories in their own communities.
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 are no statements regarding acceptance of liability by CMS 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,
Kay Creed BS MT (ASCP)
Direct Patient Care Director

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

49

To Whom It May Concern,

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.

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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 a facility will respond to the competitive bidding demonstration and price services within the demonstration. Finally, CMS requests proprietary information about a 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,

Debra Lial, CLS, ASCP

June 5, 2006

50

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 **Fairview Health Services (Minneapolis, MN)** and as the administrator for 8 hospital and 30+ clinic laboratories, employing over 900 laboratory professionals, 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.

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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,

Rick Panning, MBA, CLS (NCA)
President, Laboratory Services
Fairview Health Services
2450 Riverside Avenue
Minneapolis, MN 55454

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

51

To Whom It May Concern,

On behalf of Chambersburg Hospital, 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.

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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,
Anne Benedick M.T. (ASCP)
Administrative Laboratory Director
Chambersburg Hospital
Chambersburg, Pa 17201

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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 HealthEast Medical Laboratory 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.

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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 "non-patient" 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 are no statements regarding acceptance of liability if that information is released or disclosed to an unauthorized party.

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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,

Deb Rodahl, CLS, MBA
System Director
HealthEast Laboratories

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 St. James Mercy Health Systems of Hornell, NY 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.

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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,

Patricia Butray-Frey,Lab Manager St. James Mercy Health System

54

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 Murray Medical Center 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.

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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 statement 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.

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

Sincerely,

Jason Jackson, MT(ASCP)
Laboratory Manager
Murray Medical Center
707 Old Ellijay Rd
Chatsworth, GA 30705

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 Northwest Ohio Integrated 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.

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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,
Rhonda Perry
Manager, Laboratory Outreach Services
419-251-8270

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 **EXEMPLA LUTHERAN MEDICAL CENTER CLINICAL LABORATORY** 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.

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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,
Annette Danford, Director Laboratory Services

51

LAWRENCE MEDICAL CENTER
Integrity in Service to Others

Laboratory
202 Hospital Street
Moulton, Alabama 35650
Phone: 256-974-2228
Fax: 256-974-2284

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 **Lawrence Medical Center** 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.

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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"

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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,
Melba B. Seay BS, MT(ASCP)
Laboratory and Respiratory Director

56

Alta Bates Summit Medical Center

A Sutter Health Affiliate

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 **Alta** Bates Summit Medical Center 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.

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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,

Dorothy Mattingly
Clinical Laboratory Manager.

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 **the Department of Pathology and Clinical Laboratories at Rush North Shore Medical Center, Skokie, IL** 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.

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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,
Margaret Langguth
Administrative Director, Pathology and Clinical Laboratories
Rush North Shore Medical Center

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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 Murray-Calloway County Hospital in Murray, Ky. 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.

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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,
Linda J. Cavitt, B.S., M.T.(ASCP)
Director of Laboratory Services
Murray-Calloway County Hospital

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

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To Whom It May Concern,

On behalf of **Sunrise Medical Labs** 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.

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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,
Michael Zoebelein
Operations Manager
Sunrise Medical Labs
240 Motor Pkwy.
Hauppauge, NY 11788

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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 **Riverview Hospital Laboratory** 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.

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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,
Ronald Evan Reitenour, MT(ASCP)
Area Coordinator, Microbiology
HAZMAT Coordinator
Riverview Hospital
395 Westfield Road
Noblesville, IN 46060

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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 **Haywood Regional Medical Center** 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.

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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,
Mr. Terry M. Barnett MHS, MT(ASCP)
Administrative Director – Laboratory Services
Haywood Regional Medical Center
Clyde, North Carolina 28721

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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 Mercy Medical Center of Mt.Shasta, 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.

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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,

Nancy E. Shelton
Mercy Mt.Shasta Laboratory
914 Pine Street
Mt.Shasta, CA 96067

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 **Northern Montana Hospital** 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.

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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,
Jim Bennett
Laboratory Manager
Northern Montana Hospital
30 W 13th St.
Havre, MT 59501

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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 **Samaritan Hospital Clinical Laboratory** 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.

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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,

Gary King

Director of Diagnostic Services

Samaritan Hospital

Lexington, Kentucky

859-226-7026.

June 14, 2006

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 Mercy General Hospital 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.

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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,

Lin Kassouni, MHA, CLS, MT(ASCP)
Sr. Director, Regional Laboratory Services
Catholic Healthcare West
4001 J Street
Sacramento, CA 95819

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 **St. Catherine Hospital Laboratory** 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.

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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,
Mike Burkhart, BS MT (ASCP)
Director of Laboratory Services
St. Catherine Hospital
401 East Spruce St.
Garden City, KS, 67846-5679

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 Norman Regional Laboratory Service 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.

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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,

Danny K. Myers, MA, MT(ASCP)
Director, Laboratory, Outpatient Diagnostics, and Wound Care

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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 Brigham City Community Hospital 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.

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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,
Diane Wariner
Laboratory Manager
Brigham City Community Hospital
Brigham City, UT.

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 **(Sioux Valley Hospital Laboratory)** 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.

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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,
Allen Miller
Laboratory Director

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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 **University of Texas, M. D. Anderson Cancer Center** 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,
Louise Huck BS, MA
Laboratory Manager
Bone Marrow and Flow Cytometry Labs

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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 Jefferson Regional Medical Center Clinical Laboratory 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.

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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,
Michael R. Newton
Director, Laboratory Services

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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 **Paris Regional Medical Center Laboratory, Paris, Texas** 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.

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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,

Jack Gibson
Laboratory Director
Paris Regional Medical Center

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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 Arizona Chapter of CLMA 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.

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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,

Stephen A. Raymond

Stephen A. Raymond
Chapter President

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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 **AmeriPath Indiana** 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.

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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,
Theresa M. Topham, MT(ASCP), SH, MSHSA
Director of Operations
AmeriPath Indiana

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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 **Saint Francis Medical Center, Grand Island, NE** 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.

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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,
Mary Lou Emanuel MT(ASCP), MBA
Pathology Director
Saint Francis Medical Center
2620 W. Faidley Ave Box 9804
Grand Island, NE 68802-9804

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Abilene Diagnostic CLINIC

Abilene Diagnostic Clinic, PLLC
1150 North 18th Street, Suite 200
Abilene, Texas 79601
325-670-6481

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 Abilene Diagnostic Clinic Laboratory 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.

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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,

Vivian Denson, MBA, MT(ASCP)
Ancillary Service Director
Abilene Diagnostic Clinic, PLLC

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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

Silverton Hospital Laboratory
342 Fairview St.
Silverton, OR 97381

To Whom It May Concern,

On behalf of **Silverton Hospital Laboratory** 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.

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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,
James O. Sinn MA, MT(ASCP)
Laboratory Manager

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

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To Whom It May Concern,

On behalf of Rice Memorial Hospital 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.

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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,
Junell M. Petersen, MT,MS(ASCP)SH
Laboratory Outreach Coordinator, Rice Memorial Hospital, 301 Becker Ave. SW, Willmar, MN 56201

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 **Morgan Hospital and Medical Center** 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.

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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,
Deana Bowlds-Williams
Director of Clinical Laboratory Services.

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 Estes Park Medical Center 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).

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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,
Adina DeWitt
Laboratory Director

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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 **SWEDISH AMERICAN HEALTH SYSTEM in Rockford, Illinois** 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).

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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,
Beverly Arnold, MBA, MT(ASCP)
Laboratory Outreach Manager.

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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 (**CLINICAL DIAGNOSTICS lABS**) 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).

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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,
Sheela Puthumana, M.T.(ASCP)
Laboratory Manager

45

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 Metro Health Laboratory Grand Rapids MI 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.

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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,

Larry D. Ross
Laboratory Administrative Director

456

ESTES PARK MEDICAL CENTER

555 PROSPECT AVENUE • P.O. BOX 2740 • ESTES PARK, COLORADO 80517
PHONE 970/586-2317 • FAX 970/586-0109

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

May 30, 2006

To Whom It May Concern,

On behalf of Estes Park Medical Center, 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.

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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.

Best Regards,

Adina DeWitt

Adina DeWitt
Lab Director

47

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 Affiliated Laboratory, Inc. 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.

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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,

Carl Faulstick, M. Ed., MT (ASCP)
Corporate Compliance Officer
Affiliated Healthcare Systems
Bangor, ME 04401

68

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 Alegent Health Laboratory Services 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.

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60

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,

Kathy Nejezchleb

Kathy Nejezchleb
Compliance Specialist
Alegent Health Laboratory Services

49

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 Professional Laboratory Consultants 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.

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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,

Concepcion Gomez, M.B.A., CLS

6-2-2006

90

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 Virginia Commonwealth University Health System Pathology 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.

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40

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,

Johnetta W. Balk

Johnetta W. Balk, EMBA, MT(ASCP)SBB
Contract Administrator

9

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 **VCU Health Systems** 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.

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91

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,
Brenda Diffendal M.T. (ASCP)
Sales Representative Laboratory Outreach

97

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 Huron Regional Medical Center, Huron, South Dakota 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.

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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,

Owen Bain, MT(ASCP)
Laboratory Director .

HUNTSVILLE HOSPITAL

93

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 **the Huntsville Hospital Laboratory** 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.

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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,

Vicky McClain

Vicky McClain
Director, Laboratory Services
Huntsville Hospital

94

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 the University Suburban Health Center Laboratory 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.

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94

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,

Clive R. Hamlin

Clive R Hamlin,PhD, Laboratory Director
University Suburban Health Center
1611 S. Green Rd
S. Euclid, OH 44121

POUDRE VALLEY HOSPITAL
POUDRE VALLEY HEALTH SYSTEM

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

June 5, 2006

To Whom It May Concern,

On behalf of Poudre Valley Hospital, 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.

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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.

Best Regards,

Robert B Carpenter
Laboratory Director

96

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 the Vernon Memorial Hospital Laboratory 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.

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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,

Gary J Tricker

Gary J. Tricker MT (ASCP)
Laboratory Manager
Vernon Memorial Hospital
507 S. Main St.
Viroqua, WI 54665

250 Harrison Street, Suite 502
Syracuse, NY 13202

Business Office

Tel 315.464.6752
Fax 315.464.6749

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University**Pathologists**Laboratories,LLP

Laboratory Medicine At Its Best

Centers for Medicare and Medicaid Services
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

Dear Ms. Harkless:

On behalf of **University Pathologists Laboratories, LLP** 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.

Very truly yours,

Carol A. Barnett

Carol A. Barnett
Marketing Specialist

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YAMPA VALLEY MEDICAL CENTER

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

May 30, 2006

To Whom It May Concern,

On behalf of Yampa Valley Medical Center, 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.

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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.

Best Regards,

Mary Poskus-Fell MT(ASCP)
Laboratory Director
Yampa Valley Medical Center

Mary Poskus Fell

1024 Central Park Drive, Steamboat Springs, CO 80487
970-879-1322 • www.yvmc.org

UnitedHealth Services

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June 7, 2006

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,

United Health Services Hospitals

On behalf of **United Health Services Hospitals, Department of Laboratory Medicine** 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.

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Wilson Memorial Regional
Medical Center
33-57 Harrison Street
Johnson City, New York 13790
607.763.6000
www.uhs.net

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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,

John D Walters

John D. Walters
Manager
Department of Pathology/Laboratory Medicine

Penrose-St. Francis
Health Services

P.O. Box 7021
Colorado Springs, CO 80933
719.776.5000 Phone
www.penrosestfrancis.org

June 8, 2006

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 Penrose-St. Francis Health Services, 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 Service 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 1,000 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.

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

Best Regards,

Dianna Chestnut

Dianna Chestnut

DKC/dw

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16500 W. Indian Creek Parkway
Suite 102
Olathe, KS 66062
(913) 393-5312

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

June 07, 2006

To Whom It May Concern,

On behalf of (FILL IN YOUR FACILITY NAME), 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.

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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.

Best Regards,

Daniel L. Orr, MT (AMT)
Laboratory/Radiology Manager
Olathe Medical Services, Inc.
(913) 393-5312
dlorr@ohsi.com

Platte Valley Medical Center

1850 Egbert Street
Brighton, CO 80601
303.659.1531 fax 303.659.6401

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

June 8, 2006

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To Whom It May Concern,

On behalf of Platte Valley Medical Center 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.

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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.

Best Regards,

Rochelle Tisdale

Rochelle Tisdale

Children's Mercy
HOSPITALS & CLINICS
www.childrens-mercy.org

2401 Gillham Road
Kansas City, Missouri 64108
(816) 234-3000

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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

June 8, 2006

To Whom It May Concern,

On behalf of Children's Mercy Hospitals and Clinics, 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).

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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.

Best Regards,

Carol Freeland
Laboratory Special Projects Coordinator

Children's Mercy
HOSPITALS & CLINICS
www.childrens-mercy.org

2401 Gillham Road
Kansas City, Missouri 64108
(816) 234-3000

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CMS - Office of Strategic Operations and Regulatory Affairs
2006
Division of Regulations Development-C
Attention: Bonnie L. Harkless Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

June 8, 2006

To Whom It May Concern,

On behalf of Children's Mercy Hospitals and Clinics 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).

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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.

Best Regards,

Cynthia J. Kelley
Cynthia J. Kelley, Laboratory Services Manager

North Ottawa
Community Hospital
An Affiliate of North Ottawa Community Health System

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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

May 30, 2006

To Whom It May Concern,

On behalf of North Ottawa Community Health System, 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).

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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.

Best Regards,

James Hild BSMT (ASCP), MSA
Laboratory Manager

1309 Sheldon Road, Grand Haven, Michigan 49417 • (616) 842-3600
www.noch.org

WARREN HOSPITAL

185 Roseberry Street • Phillipsburg, New Jersey 08865
Telephone (908) 859-6700
Fax (908) 859-4546

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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 **Warren Hospital**, 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.

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WARREN HOSPITAL

185 Roseberry Street • Phillipsburg, New Jersey 08865
Telephone (908) 859-6700
Fax (908) 859-4546

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,

Joseph W. Henahan, MBA, MT(ASCP)
Administrative Director, Laboratory Services

Warren Hospital
185 Roseberry Street
Phillipsburg, NJ 08865

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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

June 6, 2006

To Whom It May Concern,

On behalf of St. Joseph and St. Mary's Medical Centers, 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).

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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.

Best Regards,

Lisa Muha, BSMT(ASCP)SBB
Regional Manager, Laboratory Services for Carondelet Health
St. Joseph and St. Mary's Medical Centers
Kansas City, Missouri

June 5, 2006

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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 **Lindsborg Community Hospital, Lindsborg, KS,** 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.

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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,

Terri Johnson

Terri Johnson
Laboratory Manager

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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 Highland District Hospital Laboratory 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.

109

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,

Larry Garner

Larry Garner BS,MT, ASCP
Laboratory Manager
Highland District Hospital
Hillsboro, Ohio 45133

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 Doylestown Hospital 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.

110

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,
Anne Boehringer
Adm Director Laboratories

Your Partner In Health For 20 Years

CompuNet®

CLINICAL LABORATORIES

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

June 16, 2006

To Whom It May Concern,

On behalf of CompuNet Clinical Laboratories, and as a laboratory professional, I am writing in response to the April 21, 2006 *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 for the persons necessary to complete the forms. The estimate of 100 hours to complete the application is not realistic and will not be sufficient for most laboratories to assess whether the 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. Further, the persons needed to complete this information will include persons responsible for billing, collections, operations and legal counsel. None of the hourly rates of these individuals were included in the calculation of the financial burden.

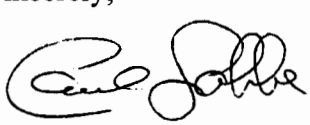
The application asks the wrong questions in order to ensure that quality laboratory services are maintained throughout the demonstration project, and there is little emphasis in the form on the collection of this information from bidding laboratories. The only information required is for a "Quality Assurance 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 still 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, 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 will price services under the demonstration. Finally, CMS requests proprietary information about our facility and there is only a statement regarding protecting confidentiality of the information but no statements regarding acceptance of liability if that information I 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,



Paul Labbe
V.P. Operations
CompuNet Clinical Laboratories
2308 Sandridge Drive
Dayton, OH 45439
937.297.8204
paul.r.labbe@questdiagnostics.com
www.compunetlab.com

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 Memorial Regional Medical Center Laboratory 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.

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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,
Deborah Ford, MT(ASCP)
Site Supervisor, MRMC Laboratory
804-764-6870

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 The Chambersburg Hospital 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,
Robin L. Barrows, MBA, MT(ASCP)
Assistant Director of Pathology

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 Rice Memorial Hospital 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 statement 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,
John Thon MA, MT(ASCP)
Laboratory Director
Rice Memorial Hospital
Willmar, MN 56201

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BOULDER COMMUNITY HOSPITAL
ESTES PARK MEDICAL CENTER
MAYO MEDICAL LABORATORIES
NORTH COLORADO MEDICAL CENTER
PLATTE VALLEY MEDICAL
REGIONAL WEST MEDICAL CENTER
THE CHILDRENS HOSPITAL

EAST MORGAN COUNTY HOSPITAL
LONGMONT UNITED HOSPITAL
MCKEE MEDICAL CENTER
PENROSE ST FRANCIS HEALTH SYSTEM
POUDRE VALLEY HOSPITAL
STERLING REGIONAL MEDCENTER
YAMPA VALLEY MEDICAL CENTER

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

May 30, 2006

To Whom It May Concern,

On behalf of Frontline Laboratory Network, a laboratory alliance in the states of Colorado, Nebraska, and Wyoming, 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.

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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 statement 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.

Best Regards,

Joe Miles, MT(ASCP), MHS
General Manager

5588 S. Parker Rd. #188, Centennial, CO 80015 (720) 876-0340 F(720) 876-0341 www.frontlinelabs.com

1116

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 Theda Clark Medical Center, Neenah, Wisconsin 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.

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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.

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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,

Thomas W. Jeske, Laboratory Business Unit Manager
Theda Clark Medical Center
130 Second Street
Neenah, WI 54956

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,

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.

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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,
Joyce Ludwick
Managing Consultant
Navigant Consulting Inc..

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 **Sacred Heart Hospital Laboratory** 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.

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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,

Susan Peiffer, MS MT(ASCP)

119

Committed to Serve; Compassion to Care

HUMBOLDT COUNTY MEMORIAL HOSPITAL
1000 N. 15TH STREET HUMBOLDT, IOWA 50548 (515)332-4200

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 **Humboldt County Memorial Hospital** 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.

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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,

Phil Rose, Laboratory Director
Humboldt County Memorial Hospital
1000 North 15th Street
Humboldt, IA 50548

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

120

To Whom It May Concern,

On behalf of Holy Family Memorial 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.

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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,
Vicki Wetenkamp
Administrative Director of Diagnostic Services

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 Avera St. Luke's Laboratory 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.

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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,
Dianne Dell
Laboratory Technical Director
Avera St. Luke's Laboratory

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 Crittenden Health Systems Laboratory 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).

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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,

Nancy Stedelin-Todd, M.A. MT(ASCP)DLM
Administrative Director Laboratory & Cardiopulmonary
Crittenden Healthcare Systems
520 W. Gum
Marion KY 42064

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

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To Whom It May Concern,

On behalf of **WPM Pathology Laboratory** 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.

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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,

Kirk Cates, MS, MT (ASCP)

Kirk Cates, MS, MT(ASCP)
Laboratory Consultant
WPM Pathology Laboratory
338 N. Front St.
Salina, KS 67401

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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 Susquehanna Health System 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.

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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,

Ruth Taddeo, MHA, MT (ASCP), Administrative Director, Laboratory Services

June 14, 2006

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 **The Presbyterian Hospital d/b/a Presbyterian Laboratory Services** 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.

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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,

Kathy M. Sloan

Kathy M. Sloan
Director of Presbyterian Reference Laboratory

MILFORD MEDICAL LABORATORY

Affiliated with Milford Hospital

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June 14, 2006

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 Milford Medical Laboratory, Inc. 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.

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2068 Bridgeport Avenue, Milford, Connecticut 06460 Tel 203 876 7745 Fax 203 877 8319

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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,

George T. Poole, BS, MS, MPH
Laboratory Manager
Milford Medical Laboratory, Inc.

June 14, 2006

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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,

As the Director of Laboratory Operations at Truman Medical Centers in Kansas City, Missouri 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.

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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.

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

Sincerely,

Charles E. Bartels

Charles E. Bartels
Sr. Director of Laboratory Operations
Truman Medical Centers
Kansas City, Missouri

Cancer Centers of North Carolina

Neeraj Agrawal, M.D.
William R. Berry, M.D.
Elizabeth E. Campbell, M.D.
Roy Cromartie, M.D.
Margaret A. Deutsch, M.D.
Maha A. Elkordy, M.D.
Alan D. Kritz, M.D.
John F. Reilly, Jr., M.D.
Virgil L. Rose, M.D.
Paramjeet Singh, M.D.
Stephen J. Tremont, M.D.
Robert S. Webbie, M.D.
Mark Yoffe, M.D.

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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 Cancer Centers of NC 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).

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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,

Jane Kirkeby

Jane Kirkeby, MT(ASCP)
Manager, Laboratory Services.

June 14, 2006

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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,

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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,

Charles E. Bartels

Charles E. Bartels
Sr. Director of Laboratory Operations
Truman Medical Centers
Kansas City, Missouri

Main Line Health

Bryn Mawr Hospital
Lankenau Hospital
Paoli Hospital
Bryn Mawr Rehab Hospital

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June 5, 2006

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 Main Line Pathology Associates and as a Pathologist, 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).

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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,

Gary S. Daum, M.D., President
Main Line Pathology Associates

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June 14, 2006

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 **Allina Medical 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).

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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,

Michael Dalager

Michael Dalager, MBA, MT(ASCP)
Operations Director

Allina Medical Laboratories
Administrative Offices
Internal Mail Route 10405
2925 Chicago Avenue
Minneapolis, MN 55407-1321

Main Line Health

Main Line Clinical Laboratories

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Main Line Health

Bryn Mawr Hospital

Lankenau Hospital

Paoli Hospital

Bryn Mawr Rehab Hospital

Great Valley Health

The Home Care Network

Lankenau Institute for Medical Research

Main Line Health Centers
- Exton
- Lawrence Park
- Shannondell
- Upper Providence

Main Line Health Adult Day Services

Main Line Clinical Laboratories

Wayne Center

June 5, 2006

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 Main Line Clinical 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).

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

Sincerely,

John C. Cardella

John C. Cardella, President and CEO
Main Line Clinical Laboratories

Main Line Health

Main Line Clinical Laboratories

1373

Main Line Health

Bryn Mawr Hospital

Lankenau Hospital

Paoli Hospital

Bryn Mawr Rehab Hospital

Great Valley Health

The Home Care Network

Lankenau Institute for Medical Research

Main Line Health Centers
- Exton
- Lawrence Park
- Shannondell
- Upper Providence

Main Line Health Adult Day Services

Main Line Clinical Laboratories

Wayne Center

June 5, 2006

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 Main Line Clinical 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.

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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,

Judyann Gilbert

Judyann Gilbert, Administrative Director
Main Line Clinical Laboratories

Main Line Health

Main Line Clinical Laboratories

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Main Line Health

Bryn Mawr Hospital

Lankenau Hospital

Paoli Hospital

Bryn Mawr Rehab Hospital

Great Valley Health

The Home Care Network

Lankenau Institute for Medical Research

Main Line Health Centers
Exton
Lawrence Park
Shannondell
Upper Providence

Main Line Health Adult Day Services

Main Line Clinical Laboratories

Wayne Center

June 5, 2006

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

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134

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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,

Glenn Bull, Administrative Director
Main Line Clinical Laboratories

Hackley
LakeshoreHospital
Personalized healthcare, close to home
72 South State St. · Shelby, MI · 49455 · 231.861.2156

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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

June 14, 2006

To Whom It May Concern,

On behalf of Hackley Lakeshore Hospital, 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).

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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 statement 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.

Best Regards,

Lori A. Stevens

Lori A. Stevens, MBA, MT (ASCP)
Laboratory Manager
Hackley Lakeshore Hospital

MOUNTAIN STATES
HEALTH ALLIANCE

1336

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 Mountain States Health Alliance 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).

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400 North State of Franklin Road Johnson City, Tennessee 37604-6094 Telephone 423.431.6111

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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,

Susan E. Williams

Susan E. Williams, MT, SH(ASCP), M.B.A.
System Services Director-Laboratory
Mountain States Health Alliance.

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Saint Luke's Hospital of Kansas City
SAINT LUKE'S HEALTH SYSTEM
saintlukeshealthsystem.org

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

June 10, 2006

To Whom It May Concern,

On behalf of Saint Luke's Regional Hospital of Kansas City 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.

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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.

Best Regards,

Barbara Young (MT)ASCP, SH
Manager, Hematology / Coag

Providence Health

Sisters of Charity of Leavenworth Health System

1378

June 8, 2006

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 Providence Medical Center, 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).

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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.

Best Regards,

Perpetua Akanigwo, MPA, MT(ASCP)PCCE

Providence Medical Center
- *Main Campus • 8929 Parallel Parkway • Kansas City, Kansas 66112-1689 • 913-596-4000*
- *Bethany Plaza Campus • 21 North 12th Street #105 • Kansas City, Kansas 66102-5172 • 913-596-4000*

Saint John Hospital
- *3500 South 4th Street • Leavenworth, Kansas 66048-5043 • 913-680-6000*

www.providence-health.org

Providence Health

Sisters of Charity of Leavenworth Health System

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June 8, 2006

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,

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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.

Best Regards,

James J. Schick, MSA, MT(ASCP)

Providence Medical Center
☒ *Main Campus • 8929 Parallel Parkway • Kansas City, Kansas 66112-1689 • 913-596-4000*
☐ *Bethany Plaza Campus • 21 North 12th Street #105 • Kansas City, Kansas 66102-5172 • 913-596-4000*
Saint John Hospital
☐ *3500 South 4th Street • Leavenworth, Kansas 66048-5043 • 913-680-6000*

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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 **(Midland Memorial Hospital)** 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).

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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,
Kerry Noormohamed, MT(ASCP)
Director, Laboratory Services.

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

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To Whom It May Concern,

On behalf of Wayne Hospital, Greenville, Ohio, 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).

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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,
Jane L. Tester

Jane L. Tester BSMT (ASCP)
Administrative Director of Laboratory Services
Wayne Hospital, Greenville, Ohio

Blount Memorial
Hospital

907 East Lamar Alexander Parkway
Maryville, TN 37804-5016
865-977-5595

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Division of Pathology and Laboratory Medicine

Pathologists

865-981-2335
865-977-5766 fax

David M. Gilliam, MD
Director of Laboratories

Robert M. Potter, MD

Harold E. Sightler, MD

Michael D. Teague, MD

Clinical Scientist

Ernest W. Fuson, PhD
865-977-5598

May 31, 2006

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 **Blount Memorial Hospital** 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).

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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,

John E. Bleazey,
Laboratory Manager

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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 **The Valley Hospital Laboratory** 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.

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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,

Lawrence J. Bologna
Director of Laboratory Services
The Valley Hospital
223 North Van Dien Ave
Ridgewood, NJ 07450.

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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 Southern Plains Medical Center 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).

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

Sincerely,

Sue Carter MT(ASCP)

Sue Carter, M.T.(ASCP)
Laboratory Manager
Southern Plains Medical Center
2222 Iowa
Chickasha, OK 73018

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PATHOLOGISTS' REGIONAL LABORATORY
Anatomical, Clinical, and Forensic Pathology

Directors:
R.W. CIHAK, MD.,FCAP
M. WILSON, MD., FCAP

LEWISTON • (208) 746-0516 • 415-6th Street, PO Box 956 • Lewiston, ID 83501 • FAX: (208) 746-4989 • Toll Free 800-443-5180
CLARKSTON • (509) 758-6576 • 1225 Highland Avenue • Clarkston, WA 99403 • FAX: (509) 758-3768 • Toll Free 800-443-5180
PULLMAN • (509) 332-6412 • 1205 SE Prof. Mall Blvd., Suite 107 • Pullman, WA 99163 • FAX: (509) 332-5980 • Toll Free 800-443-5180

December 8, 2005

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 **Pathologists' Regional Laboratory** 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"

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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,

Bruce Saunders

Bruce D. Saunders, MBA, MT(ASCP)
General Manager

146

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 **Portage Health System** 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).

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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,
Richard Kangas
Lab Director

Richard Kangas MT(ASCP) SC

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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 Alegent Health Laboratory 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).

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147

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,

Sheryl Wilson

Sheryl Wilson, MS, MT, DLM (ASCP)
Senior Executive, Alegent Health

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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 Forum Health Outreach 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).

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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,

Sallie Lepore 6/5/06

Sallie Lepore
Director Forum Health Outreach Laboratories

MARQUETTE GENERAL
HEALTH SYSTEM
MARQUETTE GENERAL HOSPITAL
1-888-818-3879 ✧ 1-906-225-3050
LABORATORY

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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 **Marquette General Health System Laboratory** 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.

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John Weiss, M.D., Medical Director ✧ CLIA #23D0038098 ✧ MGHS Hospital Lab (GL) 580 West College Ave. Marquette, MI 49855 ✧ MGHS Medical Center Lab (MC) 1414 W. Fair Ave. Marquette, MI 49855 ✧ MGHS Escanaba Lab (ES) 2500 7th Avenue South Escanaba, MI 49829 ✧ MGHS Gwinn Lab (GW) 135 East M-35 Gwinn, MI 49841 ✧

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HEALTH SYSTEM
MARQUETTE GENERAL HOSPITAL
1-888-818-3879 ✧ 1-906-225-3050
LABORATORY

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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,

John M. Rhoades
Laboratory Program Director
Marquette General Health System
Marquette, Michigan 49855

John Weiss, M.D., Medical Director
CLIA #23D0038098 ✧
MGHS Hospital Lab (GL)
580 West College Ave.
Marquette, MI 49855
MGHS Medical Center Lab (MC)
1414 W. Fair Ave.
Marquette, MI 49855
MGHS Escanaba Lab (ES)
2500 7th Avenue South
Escanaba, MI 49829
MGHS Gwinn Lab (GW)
135 East M-35
Gwinn, MI 49841 ✧

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 **Visalia Medical Clinic, Inc.** 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.

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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,
Allen K. Price, MT,MHL
Laboratory Manager.

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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 **Saint Francis Medical Center** 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).

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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,

Kim B Matthews

Kim B. Matthews MT(ASCP)
Laboratory Director

157

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 **Grande Ronde Hospital Laboratory** 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).

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157

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,

John Sanchez

John Sanchez, MT(ASCP)
Laboratory Manager
Grande Ronde Hospital
900 Sunset Drive
La Grande, Oregon 97850

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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 Falls Memorial Hospital 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).

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153

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,

Sam Segars, MT(ASCP)
Falls Memorial Hospital
1400 Highway 71
International Falls, MN 56649

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

154

June 15, 2006

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 Consultants Laboratory of Wisconsin, LLC, 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).

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

Sincerely,

Joseph Hayes

Joe Hayes
Blood Bank Supervisor

155

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

June 15, 2006

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
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Thank you for the opportunity to comment on this important issue.

Sincerely,

Kathra Clark

Kathra Clark
Cytology Supervisor

156

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

June 15, 2006

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
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Baltimore, MD 21244-1850

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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,

Barb Jacobs

Barb Jacobs
Histology Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

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 Consultants Laboratory of Wisconsin, LLC, 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).

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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,

Patty Birschbach, MLT(ASCP)

Patty Birschbach
Marketing/Sales Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

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

Donna Jost MT (ASCP)

Donna Jost
Client Services Director

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

154

June 15, 2006

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
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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,

Judy Miskov

Judy Miskov
Quality Assurance/Compliance Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

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

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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,

Linda A. Gustavus

Linda Gustavus
AP/Payroll Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

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 Consultants Laboratory of Wisconsin, LLC, 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).

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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,

Debbie Christian

Debbie Christian
Patients Accounts Supervisor

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 **St. Francis Hospital Laboratory** 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).

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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,

Lou Ellen Anderson

Lou Ellen Anderson
Laboratory Director

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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 **Frontline Laboratory Network** 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).

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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,

Diane Yaley North

Diane Yaley North
Outreach Program Manager

814 Bittersweet Lane, Longmont, CO 80503 . Phone (303) 772-3421 . Fax (303) 772-3381 . www.frontlinelabs.com

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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 The Everett Clinic in Everett, Washington, 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).

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It would be important to know prior to bidding, the total volume of Medicare testing for the given demographic area. Otherwise the bid would be a stab in the dark.

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,

Barbara Vogli

Barbara Vogli MT(ASCP)
The Everett Clinic Laboratory
Administrator

HI-DESERT MEDICAL CENTER
Your Partner for Life

165

June 15, 2006

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 Hi-Desert Medical Center Healthcare District 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 our facility, as a smaller laboratory and 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.

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6601 White Feather Road, Joshua Tree, California 92252 • 760/366-3711 • www.hdmc.org

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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,

Susan J. Shinaver, CLS, MT(ASCP), MS, CIDir
Administrative Director, Laboratory Services

760-366-6286
760-366-6279 fax

sshinaver@hdmc.org

LAKEVIEW
COMMUNITY HOSPITAL

408 HAZEN STREET • PAW PAW, MICHIGAN 49079-0209 • 269-657-3141 • FAX 269-657-1339

June 15, 2006

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 LakeView Community Hospital, 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).

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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.

Best Regards,

David N. Prudden, MT(ASCP)

David N. Prudden
Diagnostics Service Leader

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 Graham Massey Analytical Laboratories, Inc. 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).

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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,
TJ Tinghitella, Ph.D.

TJ. Tinghitella, Ph.D.(D)ABMLI
Medical Director: Graham Massey Analytical Laboratories

Associate Clinical Professor Laboratory Medicine
Yale University School of Medicine

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 Nephrology Hypertension Assoc. of CNY 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.

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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.

164

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,
Gail M. Higgins
Laboratory Manager

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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 **Katherine Shaw Bethea Hospital, Dixon, Illinois,** 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).

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

Sincerely,
Robin Jefford, HT, MLT (ASCP)
Histology Supervisor.

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 **Bon Secours HealthPartners Laboratory** 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).

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170

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

Sincerely,
Billie H. Vaughn

Billie H. Vaughn, MT (ASCP)
Administrative Director
Bon Secours HealthPartners Laboratory
Richmond, VA

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 Fletcher Allen Health Care, Department of Pathology and Laboratory Medicine 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).

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

Sincerely,

Janet Schroeter
Laboratory Compliance Specialist

KANABEC HOSPITAL

For Your Good Health!

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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 Kanabec Hospital Laboratory 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).

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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,

Karen Renaud

Karen Renaud
Manager Laboratory/Imaging
Kanabec Hospital

301 South Highway 65, Mora, MN 55051 • (320) 679-1212

ARKANSAS ONCOLOGY ASSOCIATES
An Affiliate Of US Oncology

UNIVERSITY AVENUE
1000 North University Ave.
Little Rock, AR 72207-6348
Tel: 501-661-0060
Fax: 501-661-1233

MEDICAL TOWERS II
9501 Lile Drive, Ste. 700
Little Rock, AR 72205
Tel: 501-223-8003
Fax: 501-223-8005

SPRINGHILL MEDICAL PLAZA
3401 Springhill Drive, Suite 490
North Little Rock, AR 72117
Tel: 501-945-3330
Fax: 501-945-8065

JACK J. STERNBERG, M.D.
THOMAS B. SNEED, M.D.
BILL TRANUM, M.D.
STACIE L. McCORD, M.D.
ANTHONY P. BUCOLO, M.D.
SYED AYUB MAZHER, M.D.
RAMAN DESIKAN, M.D.

Satellite Location: ST. MARY'S CANCER CENTER, 1808 West Main St., Russellville, AR 72801
Telephone: 479-967-6565 Fax: 479-967-4460

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 Arkansas Oncology Associates 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).

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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,

Pamela Powell,
Manager Laboratory Services

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

June 15, 2006

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,

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

Sincerely,

Dave Sehloff
Hematology Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

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

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

Sincerely,

Mary Laudolff

Mary Laudolff
Chemistry Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
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Thank you for the opportunity to comment on this important issue.

Sincerely,

Jodi L. Atkins

Jodi Atkins
Customer Service Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

176

June 15, 2006

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Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attention: Bonnie L. Harkless
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Thank you for the opportunity to comment on this important issue.

Sincerely,

Joyce Kovalaske

Joyce Kovalaske
Special Chemistry Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
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Thank you for the opportunity to comment on this important issue.

Sincerely,

Carol Hyland

Carol Hyland
President and CEO.

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

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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,

Amy Zipp
Laboratory Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

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June 15, 2006

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 Consultants Laboratory of Wisconsin, LLC, 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.

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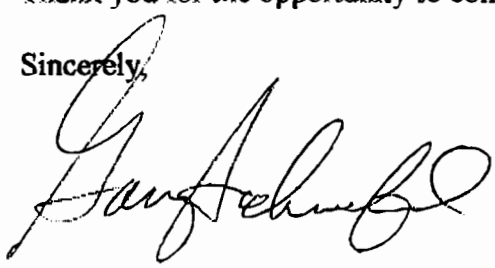

Gary Schwefel
Director of Technical Services

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

June 15, 2006

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

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

Sincerely,

Ruth Ausloos

Ruth Ausloos
LIS Supervisor

CONSULTANTS LABORATORY
A MEMBER OF AGNESIAN HEALTHCARE

430 E. Division Street ✦ Fond du Lac, WI 54935
Tel. 920.929.9300 ✦ Fax 920.929.9640

June 15, 2006

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

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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,

Ellen Wirtz
Microbiology Supervisor

Kettering Medical Center

Kettering Medical Center Network

NETWORK FACILITIES

Charles F. Kettering Memorial Hospital
3535 Southern Blvd.
Kettering, Ohio 45429
(937) 298-4331

Grandview Hospital
405 Grand Ave.
Dayton, Ohio 45405
(937) 226-3200

Sycamore Hospital
2150 Leiter Rd.
Miamisburg, Ohio 45342
(937) 866-0551

Southview Hospital
1997 Miamisburg-Centerville Rd.
Dayton, Ohio 45459
(937) 439-6000

Huber Health Center
8701 Old Troy Pike
Dayton, Ohio 45424
(937) 237-5777

Kettering Youth Services
5350 Lamme Rd.
Dayton, Ohio 45439
(937) 534-4600

Kettering College of Medical Arts
3737 Southern Blvd.
Kettering, Ohio 45429
(937) 395-8601

Sycamore Glen Retirement Community
317 Sycamore Glen Dr.
Miamisburg, Ohio 45342
(937) 866-2984

SERVICES

Wallace-Kettering Neuroscience Institute
3535 Southern Blvd.
Kettering, Ohio 45429
(937) 395-8002

Kettering Cardiovascular Institute
3535 Southern Blvd.
Kettering, Ohio 45429
(937) 395-8122

June 16, 2006

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 the Kettering Medical Center Network 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.

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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,

KETTERING MEDICAL CENTER

Thomas J. Foster
Director of Laboratories

MILTON HOSPITAL
AN AFFILIATE OF
Beth Israel Deaconess Medical Center

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June 15,2006

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 Milton Hospital's Clinical Laboratory 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.

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92 Highland Street Milton, MA 02186 TEL: 617 696 4600 WEB: www.miltonhospital.org

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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,

Martha Casassa, MS, CLD(NCA)
Laboratory Manager

LAWRENCE MEMORIAL HOSPITAL
Community Care—Community Pride

Main Campus
325 Maine
Lawrence, KS 66044
785-749-6100

LMH South
3500 Clinton Place
Lawrence, KS 66047

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

May 30, 2006

To Whom It May Concern.

On behalf of Lawrence Memorial Hospital, 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).

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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.

Best Regards,

Connie Broers MT (ASCP)

Connie Broers
Administrative Laboratory Director
Lawrence Memorial Hospital

SALEM HOSPITAL
REGIONAL LABORATORY SERVICES

CONFIDENTIAL

Laboratory Administration
Salem Hospital Regional Laboratories
P.O. Box 14001, Salem, OR 97309
Phone Number: 503.561.2864 Fax Number: 503.561.4706

To: Katharine I. Ayres
Date: 6-16-06
Fax #: 610-995-9568 **Pages:** 3 **, including this cover sheet**
From: Barb Nelson-Whitford
Regarding: CLMA 'Call to Action' Letter

If you do not receive the number of pages indicated, please call as soon as possible.

Pacific Health Horizons

SALEM HOSPITAL
REGIONAL LABORATORY SERVICES

Post Office Box 14001
Salem, Oregon 97309-5014
503.370.5350

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 **Salem Hospital Regional Laboratory Services** 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.

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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,

Barbara Nelson-Whitford
Administrative Director
Salem Hospital Regional Laboratory Services
PO Box 14001
Salem, OR 97309
503.561.5564
barbara.nelson-whitford@salemhospital.org

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

186

To Whom It May Concern,

On behalf of Bowling Green State University's Student Health Service 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).

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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,
Marilyn S. Mackay, MT(ASCP)SH.
Assistant Director and Laboratory Coordinator
BGSU Student Health Service
Bowling Green, OH. 43403