MARSHFIELD
LABORATORIES

1000 North Oak Avenue
Marshfield, WI 54449-5795

(11)

June 12, 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 **MARSHFIELD LABORATORIES** and as a laboratory professional, I am writing in response to the April 21 *Federal Register* notice, "Agency Information Collection Activities: Proposed Collection; Comment Request," regarding the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Bidding Form (CMS-10193, OMB#: 0938).

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

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

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

In addition to the general comments provided above, 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

By: Kurt D. Reed, M.D.
Its: Medical Director

1000 N. Oak Avenue
Marshfield, WI 54449
Phone: 715-387-9770
Fax: 715-387-7121

(12)

MARSHFIELD
LABORATORIES

1000 North Oak Avenue
Marshfield, WI 54449-5795

June 12, 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,

MARSHFIELD LABORATORIES

Mary Alice Kettrick Ph.D.

By: Mary Alice Kettrick, Ph.D.
Its: Director, Reference Labs

1000 N. Oak Avenue
Marshfield, WI 54449
Phone: 715-387-9770
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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 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

Dear Ms. Harkless:

On behalf of Main Line Health and as a healthcare 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,

John J. Lynch
President and CEO

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(14)

UniversityHospitals HealthSystem

University Hospitals of Cleveland

June 7, 2006

Centers for Medicare & 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

To Whom It May Concern,

On behalf of University Hospital of Cleveland Department of Pathology 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 information provided in the Supporting Statement in our opinion raises significant issues and concerns regarding the application process. There are at least 5 issues that are not addressed in the Supporting Statement that essentially make it impossible to responsibly complete the application. I have listed these issues below as bullet points with a brief explanatory description. Importantly I believe the estimations made concerning time and costs associated with completing the application are grossly underestimated. The estimate of 100 hours to complete the application process is unrealistic and will not be sufficient for most laboratories including ours. Most of the time will be spent retrieving the information and verifying its accuracy. This does not take into account the need for direct involvement and consideration of the application by hospital senior leadership, finance and legal departments.

Significant issues not addressed in the Supporting Document include but are not limited to:

- **QUALITY ISSUES**. 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 greatly oversimplify and fall short of determining a laboratory's capacity for quality.

11100 Euclid Avenue Cleveland, Ohio 44106
University Hospitals of Cleveland is the Primary Affiliate of Case Western Reserve University

- **EXPLANATION OF TERMS**. There is no clear definition of the terms "face-to-face encounter" or "nonpatient" in the application instructions or in the Supporting Statement. Indeed contradictory definitions of these terms are present in the Federal Register.

- **SUBCONTRACTOR LISTED BY ANOTHER PRIMARY BIDDER**. Can a bidder bid separately or form 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 process.

- **PROPRIETARY INFORMATION**. Proprietary information about our facility is required and frankly 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.

- **LETTERS OF AGREEMENT.** There is a total lack of information in the application instructions as to the content of information of the letters of agreement. The possibilities exist for commercial labs to use these letters to game the system assuring a favorable outcome for themselves.

  One of the potential unforeseen consequences of this initiative may be the empowerment of large commercial laboratories with a negative effect on the competitive environment and long term consequences that this may entail for quality and price structure of Medicare patients.

In addition to the general comments provided above, as a member of Clinical Laboratory Management Association, I support the detailed comments submitted by CLMA and encourage careful consideration of those points made by the CLMA.

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

Sincerely,

Don Landek

Don Landek
Administrative Director Department of Pathology
University Hospitals of Cleveland

(15)

AMERICAN ASSOCIATION OF BIOANALYSTS

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June 20, 2006

Ms. Michelle Shortt
Director
Centers for Medicare & 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

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

Dear Ms. Shortt:

On behalf of the American Association of Bioanalysts ("AAB"), I would like to thank the Centers for Medicare and Medicaid Services ("CMS") for the opportunity to submit written comments on the burden estimate and other aspects of the collection of information related to the Medicare Clinical Laboratory Competitive Bidding Demonstration. We appreciated the Open Door Forum that CMS held in Baltimore last August and were pleased that CMS incorporated a number of recommendations made by the laboratory community in its draft design, such as requiring bidders to bid on the full range of tests on the Medicare test menu and to submit multi-year bids.

As you know, AAB represents the owners, directors, supervisors, and technologists of community clinical laboratories. An improperly designed demonstration could irreparably disrupt existing laboratory markets and have a particularly negative impact on community-based clinical laboratories and the Medicare populations they serve. There are major segments of the laboratory market that are served almost exclusively by community laboratories. Nursing home patients are a leading example.

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). It is not

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 antitrust 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 serve as a point of contact," inquires as to the laboratory's status under the Clinical Laboratory Improvement Act program (CLIA), and requests 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, AAB members are concerned that the burden estimates provided by CMS significantly underestimate the time and cost of completing the forms. The estimate of 100 hours is not sufficient for most 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 professional association that cares deeply about the quality and accuracy of laboratory testing, AAB welcomes the opportunity to contribute to the success of the demonstration project. We look forward to hearing your responses to our questions and concerns. Thank you for your consideration.

Sincerely yours,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Administrator

cc: AAB Board of Directors