



# MARIETTA MEMORIAL HOSPITAL

1

June 1, 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 Marietta Memorial Hospital Laboratory, Marietta, OH 45750 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,

Michael A. McGowan, MT(ASCP)  
Laboratory Director



2

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 Pathology 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).

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,

Frank P. Sipos, MBA, M.T.(ASCP)  
Director of Human Resources & Risk Management



**United  
Clinical  
Laboratories**

Cathedral Square, Dubuque, IA 52001  
Phone 563-556-2010

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

3

**CMS**

Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development-C  
Attention: Bonnie L. Harkless  
Room C4-28-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

To Whom It May Concern,

I am a clinical laboratory manager with over 25 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).

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,

Joyce Mueller  
Administrative Supervisor  
United Clinical Laboratories, Inc  
205 Bluff Street  
Dubuque IA 52001  
563-589-8168

joyce\_mueller@pa-ucl.com

joyce\_mueller@pa-ucl.com



**United  
Clinical  
Laboratories**

Cathedral Square, Dubuque, IA 52001  
Phone 563-556-2010

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

4

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 have worked in a clinical laboratory for over thirty years. 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,

**Ruth Schaefer**  
Education Specialist  
United Clinical Laboratories, Inc  
205 Bluff Street  
Dubuque IA 52001  
563-556-2010 #117

5

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 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).

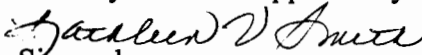
The burden estimates provided in the Supporting Statement are grossly underestimated and fail to account for the hourly rates necessary to complete the forms. The estimate of 100 hours to complete the application is unrealistic and will not be sufficient for most laboratories to assess whether their 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 "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 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,  
*Kathleen V Smith MT(ASCP)SBB*  
*Administrative Director, Laboratories.*