#6

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.

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,
Melba B. Seay BS, MT(ASCP)
Laboratory and Respiratory Director
Lawrence Medical Center
Moulton, Alabama 35650

ValleyHealth
Winchester
Medical Center

#7

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 Winchester 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.

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.

540-536-8000 • TDD 536-8483 • TDD Emergency 667-5200
P.O. Box 3340 • Winchester, Virginia 22604-2540

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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.

Barbara M Cowardin

Sincerely,
Barbara M. Cowardin M.S., M.T. (ASCP)
Corporate Laboratory Director
Valley Health
Winchester, Virginia 22601

#8

Rutland Regional Medical Center
AN AFFILIATE OF RUTLAND REGIONAL HEALTH SERVICES

160 Allen Street
Rutland, Vermont 05701

802.775.7111

June 6, 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 Rutland 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.

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,

Barbara M. Robinson
Administrative Director, Diagnostic Services

#9

WEST BUILDING
214 E. 23rd Street
Cheyenne, Wyoming 82001
307/634-CARE (307/634-2273)

UNITED MEDICAL CENTER
People Caring for People

EAST BUILDING
2600 E. 18th Street
Cheyenne, Wyoming 82001
307/632-6411

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 United Medical Center 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

#9

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,

Teresa Jarvis, MT (ASCP)
Laboratory Director
UMC Laboratories
2301 House Ave. # 105
Cheyenne, WY 82001

#10

"Quality care close to home"

Riverside Medical Center

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,

On behalf of Riverside Medical Center, Waupaca, 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 particularly our rural facility to assess whether our 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.

800 Riverside Drive • Waupaca, Wisconsin 54981 • 715-258-1000

#10

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 from 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.

Please bring a common sense approach to this issue. I don't believe that competitive bidding will do anything but hurt laboratories across the country but mostly small rural healthcare facilities such as ours. Thank you for the opportunity to comment on this important issue.

Sincerely,

Riverside Medical Center

Barry Osicka

Barry Osicka, B.S., MT(ASCP)
Laboratory Manager

Copy to: Craig Kantos, CEO
Dr. Richard Veiga, Medical Laboratory Director