

THE FILTER

American Society for Clinical Laboratory Science-Nebraska
www.ascls-ne.org

ASCLS-NE President's Page

Submitted By Chelsea Reischl, MBA, MLS(ASCP)^{CM}

ASCLS-NE has been up to some great things!

We held a Leadership Board Meeting and Retreat on August 24th, 2013. It was a productive meeting as we were able to brainstorm ideas for membership recruitment and fundraising.

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November 16-17th, 2013 was the annual Region VI Fall Council Meeting. It was great to see the fellow Council Members and as always, was educational and productive. The main topic of discussion was ASCLS Membership. ASCLS is focusing on retaining members and recruiting new members, as we've seen a decline over the years. If you know of someone who used to be a member or someone who has never been a member, please let them know what a wonderful society ASCLS-NE is and the value of being a member. Visit ASCLS's Member page for more information on becoming a member: <http://www.ascls.org/join-ascls/join>.

Just a reminder of the upcoming Annual Spring Laboratory Meeting, which will be held in Lincoln, Nebraska April 9th - 11th, 2014. This year we are working on a joint meeting with CLMA Great Plains Chapter, ASCP, and PAMET USA-NE (Philippine Association of Medical Technologists). Be sure to mark your calendars and let your fellow laboratorians know! We will send out more information through the ASCLS-NE Members List Serve and our website soon. We look forward to seeing you there!

As it gets to be that time of year, I would like to wish everyone a safe and happy holiday season! Thank you for being a member of our society!

ASCLS–NE August 24, 2013, Retreat Minutes

Submitted by Donna Kruger

Members present: President–Chelsea Reischl, President Elect and Senior Board Member–Kevin McGuire, Treasurer–Marnie Imhoff, Secretary–Donna Kruger, Junior Board Member and GAC/PAC Chairman–Roxanne Alter, New Professional Committee Advisor–Ashley Collins, Membership Committee Chairman–Darlene Waters, Brad Hays.

1. **Board Meeting**–President Chelsea Reischl called the meeting to order.

a. **Board Leadership Reports:**

i. **Past–President**

- Lindsey had no report, concerns or requests for action.
- ASCLS Region IV reports reviewed.

ii. **President**

- Chelsea had no concerns or requests for action.

iii. **Treasurer**

- Marnie submitted the report–nothing adjusted. Noted that we need to be conscientious this year in regard to spending.
- Need to get financial information from 2013 Quad State meeting. Chelsea will contact Suzanne Campbell for the financials.
- We made \$8000 (minus the \$500 seed money) during the 2013 spring meeting. This was \$4000 less than the 2012 meeting.
- Roxanne addressed the \$100 budgeted for board meetings. She would like to leave this dollar amount in the budget but not have it used for food.
- New fundraiser for the 2013 Quad State meeting was the Order of Draw Charms. This was successful.

iv. **Secretary**

- No concerns or requests for action from the Past Secretary, Joyce.
- The minutes of the meeting from July 1, 2013 were emailed earlier. Chelsea submitted them at the retreat. Donna made a motion to accept the minutes as written, Kevin seconded. Motion passed.

v. **Senior Board Member/Spring Meeting Committee**

- Kevin had no concerns.
- Request for action: Need volunteers for the Spring Meeting planning committee. This meeting is April 9–11, 2014 at the Holiday Inn in downtown Lincoln, NE. Volunteers needed to be in charge of speakers, moderators, vendors, awards, etc.
- Question regarding whether CLMA and ASCP will be part of the meeting (waiting to hear back from them). This will be left to the planning committee to make decisions regarding their involvement, per Chelsea's suggestion.

vi. **Junior Board Member**

- Roxanne is committed to helping plan the spring meeting in Lincoln.

vii. **First Year Professional**

- No concerns or requests for action.

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viii. Student Forum President

- No concerns or requests for action.

b. Other Leadership Reports

i. Filter Editor

- No concerns or requests for action from Andrea.

ii. Membership

- No concerns or requests for action from Darlene.
- Only one membership from the membership booth at the Quad State Meeting.
- Article sent to the Filter challenging every member to get one person to join ASCLS-NE.
- Working on proposed future "Lunch & Learns".
- Working on cards asking "What can ASCLS-NE do for me?".

iii. LDC

- Chelsea reported for Lindsey. No concerns or requests.
- Lindsey wrote a blurb about one member getting one person to join ASCLS-NE which aligns with Darlene's goal.

iv. GAC/PAC

- Concerns: See Report submitted by Roxanne for 1) Budget line item for PAC need 2) Cost of handling campaign contributions by accounting firm hired by National office of ASCLS PAC.
- Our new legislative lobbyist is Patrick Cooney.
- Attendance at the National Meeting in Houston was up.
- Membership is down by about 2000 this year.

v. Website

- No concerns or requests for action from Ashley.
- Working on updates to the website and still trying to figure out templates.
- Wants to encourage people to use ASCLS emails.
- Marnie brought an issue she was having with spam with her email to Ashley's attention. Ashley will work on this.
- Roxanne proposes that the current person's name be displayed instead of just the office held for ASCLS emails. After discussion by the group it was decided to leave it as is.

vi. Bylaws

- No report from Anita Smith.

vii. PACE

- No report from Shana Jensen

c. Travel and Reimbursement Policy

Policy drafted past year and is finalized. Needs approval by board.

- Reference to page 3, section 4, paragraph 2 by Roxanne requesting that the wording needs to be redone. Roxanne will rewrite, send out to committee and send to Chelsea to post for an electronic vote.

*ASCLS-NE Retreat Minutes continued from page 3***d. Mentoring of New Leadership**

A listing of new leadership was read by Chelsea. This topic will be covered in the small group discussion later.

e. Annual Spring Meeting

See section above: "Senior Board Member/Spring Meeting Committee" for items already covered.

- Chelsea reiterated that a 2013 Quad State Meeting recap needs to happen. She offered to send out a doodle for a date and is willing to have this at her house.

f. Email accounts

All emails have been updated and this list will be sent out by Chelsea. The email listed is the one that should be used.

g. Time Commitment for Leadership

Estimated time commitments for all leadership roles can be found in the handbook (on ASCLS website). If you can't fulfill your commitment ask for help.

h. Filter Articles

There have not been very many submissions. Due to this lackluster response Chelsea will be assigning dates for submission of articles to leadership and/or committees in the future.

i. Fundraising

Wonderful fundraising at the Spring Meeting 2012-2013!

- Order of Draw Charms-Big thank you to Darlene for her donation of the materials and organizing making them.

Plans for fundraising for 2013-2014

- Order of Draw Charms again.
- Pampered Chef catalog show in the fall. Possible dates first 2 weeks in November. A request for someone who is an ASCLS-NE member who is a representative for Pampered Chef will be posted on the ASCLS Administration page. We would get 3% back of every \$1000 sold.
- Cups that can be purchased for \$3 and then can be sold for between \$5 and \$8.

Subcommittee formed to discuss combining the fundraising efforts of students and the ASCLS-NE society reported that their vote was unanimous not to combine the efforts of fundraising (see report of Fundraising Chair submitted for details). There was further discussion by board members regarding students' participation in "at large" fundraising. The expectation will be that students should participate. Marnie made a motion that the student forum does not receive money from the state society. Chelsea moved that the motion should be denied. Motion denied by the quorum.

ASCLS–NE Retreat Minutes continued from page 4

j. ASCLS National Meeting reports from those who attended

Ashley:

- Going for the second time was less overwhelming.
- Attended the President Elect session and has a lot of information from that session.
- The New Professional Committee has been given another year to become more active.
- Leadership Academy decided the 3 topics for future projects. This is the 7th year of this class.

Jasmine:

- No report submitted.

Roxanne:

- Region VI dinner was wonderful.
- Nebraska planned this dinner this year
- One issue was that Evite didn't work well for RSVPs so number was not accurate.

Chelsea motioned to adjourn at 1055.

Student Forum Update

Submitted by Ashley Collins

MLS and MLT students across Nebraska are already well into their fall semesters and the annual Husker Football ticket raffle has come to a close. A set of Husker football tickets for this year's fundraiser was donated by Linda Sykora and Kevin McGuire. A second set of tickets was donated by Dwayne Ball, husband of the late Shirley Noble. On behalf of the ASCLS–NE Student Forum, I thank each of you for helping with this year's successful fundraiser! University of Nebraska Medical Center, Methodist, and North Platte Community College students raised \$710 and the winner for that set of tickets along with a gift card to J's on Jackson was Amanda Juarez of North Platte. Southeast Community College students raised \$940.27 and the winner for that set of tickets along with a gift card to Applebee's was Levi Thomlison, a student in the welding program at SCC. In addition to the fall fundraiser, the ASCLS–NE Student Forum Representatives voted on leadership and this year's elected leaders have started to take on some of their responsibilities. This year's ASCLS–NE Student Forum President is Sara Ewing. She's a UNMC student currently in her clinical rotation in Scottsbluff. The ASCLS–NE Student Forum Treasurer is Laramie Lindgren and the Secretary is Rachel Monte de Ramos. They are both students at Methodist completing their clinical rotation in Omaha.

Yearly Treasurer's Report				
Statement of Cash Receipts and Disbursements, 1 July 2013- 30 Oct 2013				
Submitted by Marnie Imhoff, MBA, MLS(ASCP)^{CM}				
Money Market Balance 30 June 2013	\$ 17,963.99			
Cash Receipts				
Money Market Interest Income	\$ 3.99			
Spring Meeting Income	\$ 8,419.24			
ASCLS Membership	\$ 345.00			
Total Money Market Cash Receipts	\$ 8,768.23			
Disbursements				
Transfers to checking account		\$ -		
Total Money Market Disbursements		\$ -		
Money Market Account Balance 31 October 2012			\$ 26,732.22	
Checking Account Balance - 1 July 2013	\$ 3,544.78			
Cash Receipts				
Transfers from Money Market	\$ -			
Total Checking Account Cash Receipts	\$0.00			
Disbursements				
ASCLS National Meeting Attendance July 2013		\$ 1,544.32		
Website Maintenance		\$ 52.38		
PACE Providership		\$ 325.00		
ASCLS-NE Board Meeting		\$ 81.70		
ASCLS National Meeting Silent Auction Neb Donation		\$ 50.00		
Region VI Assessment		\$ 1,300.00		
Treasurer and President Bonding		\$ 99.00		
Total Checking Account Disbursements		\$ 3,452.40		
Checking Account Balance 31 October 2012			\$92.38	
ASCLS-NE SUMMARY OF ASSETS:				
Money Market Balance 31 October 2012			\$ 26,732.22	
Checking Account Balance 31 October 2012			\$92.38	
Scholarship CD Balance 31 October 2012			\$ 15,203.63	
Legislative CD Balance 31 October 2012			\$ 5,327.70	
Savings CD Balance 31 October 2012			\$ 11,689.41	
ASCLS-NE TOTAL ASSETS 31 October 2012			\$ 59,045.34	

Leadership Development

Submitted by Linsey Donner, MPH, CPH, MLS (ASCP)^{CM}, Leadership Development Chair

Have you ever thought to yourself:

- How can I make a difference in the clinical laboratory profession?
- How can I promote my profession?
- How can I network with other laboratory professionals in this state and nationally?
- How can I impact the changing world of laboratory medicine on a legislative level?
- How can I get the most recent information on key issues affecting the clinical laboratory?
- How can I make a contribution to my profession and fellow laboratorians (no matter how big or small)?

If you answered “yes” to any of these questions, ASCLS–NE is currently looking for new laboratory professionals to become active in ASCLS–NE Leadership!

Our current leadership (listed below) would like the opportunity to mentor you into a position you would enjoy and benefit professionally. We have many different positions including elected Board Members and Officers, appointed leadership, and committees to participate in. We need people to contribute their expertise no matter how small or large the contribution.

The ASCLS–NE Leadership recently published a leadership handbook which describes each position in detail. It is located on our website at www.ascls-ne.org under the Leadership link.

Please contact me at leadership@ascls-ne.org with any interests and questions you may have.

Elected Board and Officers

President: Chelsea Reischl
 President–Elect: Kevin McGuire
 Past President: Linsey Donner
 Treasurer: Marnie Imhoff
 Secretary: Donna Kruger
 Senior Board Member: Kevin McGuire
 Junior Board Member: Roxanne Alter
 First Year Professional: Jasmine Clarke

Appointed/Non–Voting Leadership

Membership Development Chair: Darlene Waters
 Leadership Development Chair: Linsey Donner
 Political and Government Action Committee Chair:
 Roxanne Alter
 Website Development: Martin Steinbeck and
 Ashley Collins
 FILTER Editor: Andrea Jones
 Scholarship and Loans Chair: Andrea Jones
 Student Forum President: Sara Ewing
 PACE Chair: Shana Jensen
 Bylaws Chair: Anita Smith
 New Professionals Advisor: Ashley Collins
 Historian: Nicole Meier
 Awards Chair: Lynnett Paneitz
 Fundraising Chair: Marnie Imhoff

Mark Your Calendars!!

The 2014 ASCLS-NE Spring meeting will be April 9-11, 2014 at Holiday Inn Downtown-Lincoln, Nebraska. A block of rooms has been reserved under “American Society for Clinical Lab Science-Nebraska” on Tuesday April 8th, Wednesday April 9th, and Thursday April 10th for the price of \$99.00 per night. The room reservation includes complimentary parking for all lodging guests and a complimentary manager’s reception from 4:30pm - 6:00pm. If interested in helping with the meeting, please contact Kevin McGuire at president-elect@ascls-ne.org

Plea For Speakers!

The ASCLS-NE spring meeting is in need of speakers for the 2014 Meeting that will be held in Lincoln, Nebraska on April 9, 10, and 11. If you are interested in speaking or know someone that is please have them send me and email at ralter@unmc.edu. Thanks Roxanne Alter

PACE Credit Available

Submitted by Shana Jensen

As a member centered organization ASCLS–Nebraska strives to provide services to grow individuals and the Clinical Laboratory Science profession. Providing Professional Acknowledgement for Continuing Education(PACE) is one way the organization strives to serve our members. ASCLS–NE has a PACE provider available to help attain PACE credit for educational presentations that fit any of the following criteria:

- a structured learning experience with an orderly time schedule providing credit for instructional time, including a quiz or exam if applicable, and evaluation time;
- time of instruction be at least 30 minutes in length;
- topic relates to clinical laboratory sciences or practice, and the rationale for programs not pertaining to management, education or supervision in the scope of practice of clinical laboratory science is to be clearly documented;
- written measurable learning objectives;
- instructor has the background and experience necessary to teach the subject.
- for Self Study material, inclusion of an evaluation or method of assessment to ensure that participants have achieved a specified level of performance.

Please consider developing your next educational offering to provide PACE credit as a benefit to your audience. Contact Shana Jensen at shana_jensen@hotmail.com for further information.

State Public Health Lab Celebrates 100 Years

Submitted by Karen Stiles

The State Public Health Laboratory in Nebraska: The First Hundred Years

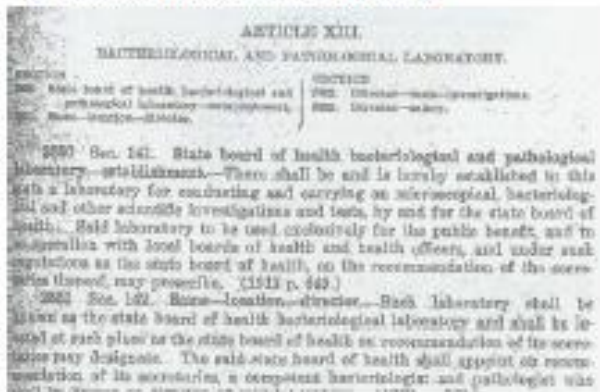
by Karen Stiles SM(ASCP)^{CM}
State Training Coordinator NPHL

The year 2013 has been highlighted with the 100th Anniversary celebration of the Nebraska Public Health Laboratory. A reception was held in the Durham Research Center in April, as part of the celebration for National Laboratory Week. This achievement was also recognized at the Annual Center for Preparedness Symposia held in Gering, Norfolk, Lincoln and Kearney. Through the years, the NPHL mission statement has been "Dedicated to protecting the health and safety of Nebraskans through diagnostic laboratory science, technology and education."



Dr. Peter Iwan, Dr. Steven Hinrichs and Anthony Sambol

Kristin Watkins, administrator in Regenerative Medicine, compiled historical documents to write the history of our public health laboratory. Dr. Iwan presented a timeline of events that brought the laboratory to what it is today. In 1909, there was mention of a "state laboratory" at UNL in the memoirs of Dr. Francis Long. Shortly after, Omaha and Lincoln experienced a typhoid fever outbreak. In Feb 1913, a "Health Train" promotion arrived in Lincoln, while local and state public health officials held a joint meeting. By April 1913, the "Bacteriological Laboratory" was approved.



Kristin Watkins Historical Timeline

- 1891: State Board of Health established
- 1913: State public Health Lab established - initially called the Bacteriological Lab
- 1918: the Great Influenza
- 1939: the State conducts major tuberculosis study
- 1943: the State first establishes local health departments
- 1952: Nebraska reports record cases of polio
- 1972: Nebraska closes state tuberculosis hospital
- 1997: Lab moves from Lincoln to Omaha - established the Nebraska Public Health Laboratory
- 2001: National anthrax outbreak
- 2003: West Nile virus invades Nebraska
- 2009: Influenza A virus H1N1 Pandemic
- 2013: Cyclosporiasis outbreak

Kristin's objective in writing the history of the NPHL was "not only centered around legacy knowledge for the laboratory, but also to provide important information of the history of how the public health laboratory grew and was enforced in Nebraska, especially concerning reportable diseases and specimen collection." She felt that tracing the laboratory's history was challenging. However, the knowledge obtained with her research provides insight into the importance of the role the laboratory played in the health of Nebraskans. With new diseases appearing and old ones emerging, the laboratory will continue to play a significant role in the future.



PAC and GAC Updates and Action Items

Submitted by Roxanne Alter

ACTIVITIES:

PURPOSE: Disseminates information about ASCLS national and regional legislative activity as well as legislative alerts to the our members of ASCLS-NE and other laboratorians who are interested what is happen in government.

Committee goals:

1. To keep members of the Region Council current on national legislative activities and state licensure activities within the state.
2. Bring Region concerns to the ASCLS GAC and to keep them apprised of any licensure activities within the Region.
3. communicate with the state GAC chairs on a regular basis.

Activities towards goals:

1. Attended Monthly ASCLS GAC Conference Calls.
2. Communicated with Region and State GAC Liasons concerning government activities.

Legislative Updates:

Although Don Levanty will still continue to have involvement with ASCLS, Patrick Cooney will take the lead as ASCLS Lobbyist in Washington DC.

- At the recent GAC Conference Call Patrick covered the recent government shutdown. A short-term budget is in place through mid-January 2014 and the debt ceiling until mid-February. Conferees from both houses of Congress have been selected to negotiate a longer term budget and are to have a proposal by mid-December 2013. We need to closely watch this process to follow what could potentially happen with Medicare, Medicaid and health spending in general.
- Patrick was able to meet with Representative Burgess (TX) and his staff to talk about the negotiated rulemaking strategy that we would like to pursue with legislation. Rep. Burgess is an OB-GYN physician. The House committees that will have jurisdiction are the Energy and Commerce Committee, chaired by Rep. Upton (MI), House Ways and Means (Rep. Camp-MI) and Health Subcommittee. We need to watch for potential cuts to the laboratory and how the SGR fix will be paid for. The last time there were budget discussions like this the laboratory community was not unified. Rep. Burgess is willing to take this forward as long as the laboratory community is unified and on-board. Patrick will be discussing this at the next CLC meeting. There is some evidence that ACLA, Quest and LabCorp may support the negotiated rulemaking strategy. When the timing is right we will need a strong grass roots effort with member of the above committees and the Senate Finance Committee (chaired by Senator Baucus from Montana).

A letter to all CLC members was circulated one month ago with the intent to sign on to Negotiated Rulemaking. That letter will be resent and during a conference call members will be asked if there is any opposition. With the previous negotiated rulemaking bill, there are still 6 co-sponsors that are still in Congress. These are all House members.

- Bishop (GA)
- Braley (IA)

PAC/GAC Updates continued from page 10

- Goodblatt (VA)
- Lathan (IA)
- Terry (NC)
- Upton (MI), chair of committee

We will wait for direction from Patrick to engage our grass roots to contact their members of Congress. We still, also will need a sponsor in the Senate.

- As far as the Accountable Care Act (ACA) it is believed that the approach will become one of “how can we fix” it as opposed to full repeal or “unfunding”. A bill has been proposed by a representative from Georgia that would fix the problems for small employers. It is believed this would have bi-partisan support. There will be significant pressure to make adjustments to the legislation.

Regulatory Updates:

Final rules are expected in November on the following. The government shutdown could impact the timing of the release of these rules but since many have impact in 2014, we cannot afford to have delays.

- OPSS bundling
- Updating CLFS for technology changes
- Anatomic Pathology technical fee cuts
- Proficiency testing

Definition of Negotiated rulemaking: is a process in American administrative law, used by federal agencies, in which representatives from a government agency and affected interest groups negotiate the terms of a proposed administrative rule. The agency publishes the proposed rule in the Federal Register and then follows the usual rulemaking procedure of soliciting public comments, which are evaluated for inclusion in the final rule.

Negotiated rulemaking, sometimes abbreviated as "reg neg," emerged most prominently in the early 1980s because of a concern that traditional rulemaking procedures had become too adversarial. John Dunlop, Secretary of Labor under President Gerald Ford, first introduced the idea of formally engaging affected interests in negotiations over federal regulations in the 1970s. In 1982 Phillip Harter, an administrative law expert, developed the idea of reg neg further in a report to the Administrative Conference of the United States and then a law review article, proposing negotiation as a means of alleviating the "malaise" that hindered the existing federal rulemaking process. The U.S. Environmental Protection Agency and the United States Department of Transportation were the first agencies to experiment with negotiated rulemaking. Other agencies were more reluctant to try it, out of concern about its legality. Those questions were answered when the United States Congress enacted the Negotiated Rulemaking Act of 1990 (Reg Neg Act), "to encourage agencies to use negotiated rulemaking when it enhances the informal rulemaking process. The Reg Neg Act was reauthorized in 1996 and is now incorporated into the Administrative Procedure Act, at 5 U.S.C. §§ 561–570.

PAC/GAC Updates continued from page 11

A believer in the effectiveness of reg neg, President Clinton encouraged agencies to use the approach in Executive Order #12866 and in a subsequent Presidential Memorandum.

Although only a small fraction of all regulations have been developed through negotiated rulemaking, a variety of federal government agencies have used the procedure, including the U.S. Departments of Education, Housing and Urban Development, Health and Human Services, the Interior, Labor, and Transportation, and the U.S. Environmental Protection Agency. Negotiated rulemaking is currently required under the Higher Education Act and the Native American Housing Assistance and Self-Determination Act.

Clinical Laboratory Community Supports Negotiated Rulemaking to Reform the Clinical Diagnostic Laboratory Fee Schedule

November 11, 2013

The Honorable Dave Camp
Chairman
House Ways & Means Committee
Washington, DC 20515

The Honorable Sander Levin
Ranking Member
House Ways & Means Committee
Washington, DC 20515

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
House Energy & Commerce Committee
Washington, DC 20515

The Honorable Max Baucus
Chairman
Senate Finance Committee
Washington, DC 20510

The Honorable Orrin Hatch
Ranking Member
Senate Finance Committee
Washington, DC 20510

Subject: Clinical Laboratory Community Supports Negotiated Rulemaking to Reform the Clinical Diagnostic Laboratory Fee Schedule

Dear Chairmen and Ranking Members:

We are writing on behalf of the clinical laboratory community to strongly urge the Congress to consider legislation requiring the Centers for Medicare and Medicaid Services (CMS) to enter into negotiated rulemaking with stakeholders in the clinical laboratory community to refine and develop an updated clinical laboratory fee schedule.

Action is warranted by Congress to establish such a negotiated rulemaking process. The fee schedule for clinical diagnostic laboratory tests under Part B of the Medicare program was developed in 1984 based on the local prevailing fees charged in 1983. The cost of clinical diagnostic laboratory tests, laboratory equipment, supplies, and medical professional staff has increased exponentially in recent years. Clinical laboratories are currently reimbursed at levels below those provided in 1984 when adjusted for inflation. The fee schedule for clinical diagnostic laboratory tests is the last Medicare fee schedule that has not been made reliant on prospective payment or relative value as the primary payment methodology. Clinical laboratories provide vital information that influences all major diagnostic, treatment and prognostic patient-care decisions.

As CMS considers reform of the clinical laboratory fee schedule, the agency must take into consideration the impact changes will have on access by all individuals enrolled in Part B to quality laboratory services in all settings. In addition, the agency must establish a mechanism to periodically revise the fee schedule for years subsequent to the first year in which the updated fee schedule is implemented. It should also establish a mechanism to provide for annual inflationary updates to the fee schedule for each year after the first year for which the updated fee schedule is implemented. The complexities of these tasks require the input of stakeholders representing the beneficiary, the clinical laboratory community, clinicians and the agency to achieve an efficient, cost-effective, accessible, quality process.

Letter Supporting Neg/Reg continued from page 12

We realize that other proposals outline across the board reductions to the fee schedule. While such reductions might be handled by many of the large laboratory service companies which rely on Medicare clinical laboratory test reimbursement for only about 15% of their revenue, hospital and community laboratory services which care for 45-55% of Medicare beneficiaries will not be able to absorb arbitrary cuts such as the one being proposed.

The need to modernize the clinical laboratory fee schedule is apparent. Now is the time for Congress to instruct CMS to engage stakeholders in the process of negotiated rulemaking. For more information on this issue, please contact Patrick Cooney at 202-347-0034 x101 or via email at patrick@federalgrp.com. Thank you for your consideration.

Sincerely,

American Society for Clinical Laboratory Science
American Medical Technologists
American Society for Clinical Pathology
American Society for Microbiology
Clinical Laboratory Management Association

Section-by-Section Establishing Negotiated Rulemaking Authority for the Clinical Laboratory Fee Schedule

SEC. ___. PROCESS FOR THE MODERNIZATION OF THE FEE SCHEDULE FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

IN GENERAL.—

The Secretary of Health and Human Services shall—

- (1) establish a negotiated rulemaking committee to negotiate and develop a proposed rule for a modernized Medicare clinical diagnostic laboratory fee schedule; and
- (2) establish an annual update process for the clinical diagnostic laboratory fee schedule;
- (3) not later than 24 months after the date of the enactment of this Act and pursuant to such negotiated rulemaking process, submit to Congress a report relating to such modernized Medicare clinical diagnostic fee schedule; and
- (4) promulgate regulations establishing such Medicare modernized clinical diagnostic fee laboratory schedule if the Committee reaches consensus.

ELEMENTS FOR INCLUSION.—

The negotiated rulemaking committee established shall consider the following elements and include them in the proposed rule for a modernized Medicare clinical diagnostic laboratory fee schedule:

- (A) Access, to the greatest extent possible, by all individuals enrolled in part B of title XVIII of the Social Security Act to quality laboratory services in all settings.
- (B) Establishment of a single, rational, and national fee schedule for clinical diagnostic laboratory tests.
- (C) A mechanism to periodically revise the fee schedule for years subsequent to the first year in which the fee schedule is implemented that includes the following components:

- The mechanism is sufficiently adaptable to incorporate new clinical laboratory tests and technology into the fee schedule in a timely manner and to provide appropriate reimbursement for these tests.
- The mechanism periodically and appropriately revises clinical laboratory reimbursement to reflect the evolution of costs, value, and utilization of such tests.
- The mechanism is not based on an arbitrary cap.
- The mechanism provides for revisions to the fee schedule at least once every five years, but not more frequently than annually.
- The mechanism provides for input from relevant stakeholders, including patients, health care providers, and clinical laboratories.

(D) Budget neutrality for the first year for which the updated fee schedule is implemented taking into account annual adjustments, the annual addition of new tests, and any other utilization increases that would have been recognized.

(E) A mechanism to provide for automatic annual inflationary updates to the fee schedule for each year after the first year for which the fee schedule is implemented.

(F) A transition period to phase in the application of the payment rates under the fee schedule based on blended payment rates between such fee schedule and the fee schedule in effect on the day before the date of the enactment.

(G) A fee schedule that does not utilize beneficiary cost sharing.

ELEMENTS FOR CONSIDERATION.—

Such negotiated rulemaking committee shall consider whether to include the following elements in the Medicare modernized clinical diagnostic laboratory fee schedule:

(A) A fee schedule that provides for greater administrative simplicity and efficiency by eliminating or reducing the number of differential payment rates for clinical diagnostic laboratory tests.

(B) A fee schedule that addresses the unique reimbursement problems laboratories face as indirect providers, including requirements that laboratories must rely on diagnosis codes provided by ordering providers.

SEC. __. ESTABLISHMENT AND DUTIES OF NEGOTIATED RULEMAKING COMMITTEE. ESTABLISHMENT.—

Not later than 30 days after the date of the enactment of this Act, the Secretary shall publish a notice in the Federal Register of intent to establish a negotiated rulemaking committee to negotiate and develop a proposed rule for a Medicare modernized clinical diagnostic laboratory fee schedule. Not later than 60 days after the day on which such notice of intent is published, the Secretary shall appoint members to the Committee.

COMPOSITION.—

(1) **IN GENERAL.—** The Committee shall be composed of 19 voting members appointed and 2 nonvoting members.

(2) **VOTING MEMBERS.—**The Secretary shall appoint as voting members of the Committee individuals as follows:

- (A) One individual from an organization primarily representing independent clinical laboratories operating on a national basis.
 - (B) One individual from an organization primarily representing independent clinical laboratories operating on a regional or local basis.
 - (C) One individual from an organization representing hospitals that perform clinical diagnostic laboratory tests.
 - (D) Two individuals from organizations representing physicians with expertise in clinical diagnostic laboratory tests.
 - (E) Three individuals from organizations representing non-physicians with expertise in clinical diagnostic laboratory tests.
 - (F) One individual from an organization representing manufacturers of equipment designed for clinical diagnostic laboratory tests.
 - (G) One individual from an organization representing individuals enrolled under part B of title XVIII of the [Social Security Act](#).
 - (H) One individual from an organization representing private payers for clinical diagnostic laboratory tests.
 - (I) One individual with expertise in measuring resource utilization by clinical diagnostic laboratories in performing tests.
 - (J) One individual with a background in health economics and the ability to quantify the value of clinical diagnostic laboratory tests.
 - (K) Two individuals from organizations representing generalist non-physicians with expertise in clinical diagnostic laboratory tests.
 - (L) One individual who is a physician or clinician who prescribes clinical diagnostic laboratory tests.
 - (M) One individual who is a physician or clinician who performs point-of-care tests in the physician's or clinician's office.
 - (N) One individual from an organization representing individuals with scientific background and experience in clinical laboratory health care services.
 - (O) One individual from an organization representing managers or supervisors of clinical laboratories.
- (3) NONVOTING MEMBERS.—The Secretary shall appoint one nonvoting member to the Committee. The Chairman of the Medicare Payment Advisory Commission shall appoint one nonvoting member to the Committee.

DUTIES.—

The Committee shall negotiate and attempt to reach a consensus concerning a proposed rule with respect to establishing a Medicare modernized clinical diagnostic laboratory fee schedule.

TERM. —

Each member of the Committee shall be appointed for the life of the Committee

TEN REASONS TO SUPPORT P.A.C.:

- ♦ PROFESSIONALS
ADVOCATING FOR
COMMON SENSE (PACS)

What seems like common sense to us is a mystery to Congress. Through P.A.C. donations we are able to inform our members of Congress about what does/ does not make sense.

- ♦ PERSISTENCE AMIDST
CHALLENGES:

Even though it might be easier to give up; we continue on. Together we can conquer all.

- ♦ PERSONAL ACCOUNTS
& CONCERNS:

SHARING PERSONAL EXPERIENCES AND CONCERNS HELPS OTHERS UNDERSTAND THE SITUATION BETTER.

- ⇒ PROFESSIONAL ALERT
COMMITTEE:

"THIS IS NOT A DRILL... THIS IS OUR LIVELIHOOD!!!"

- ⇒ PERPETUAL ADVOCACY
COALITION:

Our work is never done. We must be vigilant at all times to ensure members of Congress understand the importance of the work we do.

- ⇒ POLICY AND CHANGE:

Influencing and shaping new policies; using our voices for change. When we unite our voices we are STRONG!

- ⇒ PROMOTE AND
CHALLENGE:

Letting members of Congress know how essential our profession is for patient care; 70% + of a clinician's treatment approach is based on the results we provide. Challenging members to image healthcare without the laboratory...

- ♦ PRO ACTIVE
COMMUNICATION:
**No More Sitting on the
Sidelines: We Came To Play!!**

- ♦ PROMOTE AND CHALLENGE:
Challenging the "Black Box"
laboratory idea and making
ourselves visible!

- ♦ PUBLIC AWARENESS
CAMPAIGN:
**A vast majority of people
don't know what we
do; in order to be heard we
need to make sure the general
population understands our
importance!**