

# Navigating the Maze:

Challenges and Opportunities Facing  
Laboratories in the 21<sup>st</sup> Century



ACLA's 19<sup>th</sup> Annual Meeting • March 18-19, 2014



American  
Clinical Laboratory  
Association

## Welcome to ACLA's 19<sup>th</sup> Annual Meeting: "Navigating the Reimbursement Maze"

This is my 11<sup>th</sup> Annual Meeting at ACLA, and in previous years identifying a theme for the meeting was a challenge. Not so this year. Medicare reimbursement reduction proposals that have come at the laboratory industry from various institutions—the Centers for Medicare & Medicaid Services (CMS) to Congress—are unprecedented in both volume and intensity. **Successfully navigating this reimbursement maze is the top priority for ACLA.**

Last year, ACLA was engaged on a record number of advocacy issues, and was recognized as an industry leader on the frontlines of each debate. First, ACLA led an unprecedented advocacy coalition effort to stop a proposed CMS rule, which had it become final would have cut Medicare payments for some of the most common pathology diagnostic services—for breast, colon, prostate, skin, ovarian, leukemia and other cancers—by as much as 80% in some cases. Following an industry-wide education effort on the issues, CMS choose not to institute this so-called HOPPS rule in 2014. We are particularly proud of the engagement of not only our members and industry colleagues, but also the disease and patient groups who partnered with ACLA to oppose the proposed rule.

ACLA was also very active in navigating another reimbursement maze, the so-called "Gapfill" process for setting prices for many molecular test codes. As part of a coalition comprised of labs, patient advocacy organizations, and others, we made progress in some areas of code pricing that left to interim proposals, would have devastated smaller and specialized labs.

Labs faced the perennial threat of being a "pay for" for the extension of the Physician Fee Schedule Sustainable Growth Rate (SGR) last year, and ACLA was on the Hill all year advocating against another cut. In July 2013, CMS proposed a plan to begin a five year process of looking at all of the codes under the Clinical Laboratory Fee Schedule (CLFS) and determining adjustments test by test based on "technological changes." ACLA filed comments and has been in continuous dialogue with coalition partners with the objective of setting parameters on this process. ACLA has led a coalition of laboratory organizations in developing policy alternatives and is working with Congress to try to stop more across the board cuts while putting common sense limits on the CMS adjustment process.

ACLA has taken up another important advocacy cause to ensure that the military's Tricare beneficiaries have full access to important molecular tests, many of which are not now being covered. Our aggressive media outreach and Hill activities have helped shift some key perspectives in the decision-making corner. Finally, ACLA continues to engage on the issue of the oversight of Laboratory Developed Tests (LDTs), coding, and coverage issues.

ACLA's staff is one of the most experienced and talented in the association world. But even our terrific staff couldn't successfully "navigate the reimbursement maze" without the active participation of so many other industry leaders. Our efforts are multiplied many times over by the very active participation and help of ACLA's member companies, Board of Directors, our outside consultants and counsels, and our coalition partners.

The intense challenges we face on reimbursement have brought the lab industry together and given focus and consensus to our efforts such as I have not seen in my ten years here. As an industry, we provide the most critical information needed for 70% of physician decisions, we produce the critical results of common tests for chronic disease, that when caught early prevent years of increasing cost to the healthcare system, and we remain at the forefront of scientific advances in personalized medicine.

We have much to be proud of. Again, welcome to our meeting.



*Alan Mertz*  
Alan Mertz  
President, ACLA

TUESDAY, MARCH 18

8:00 - 11:00 am	<b>ACLA Board of Directors Meeting</b>	Cabin John/ Arlington Room, Level 3B
11:45 - 12:45 pm	<b>LUNCH:</b> All Registrants	Constitution D, E Level 3B
1:00 - 1:30 pm	<b>General Session</b> President's Welcome - ACLA Election of Board & Officers - ACLA 2014 Chairman's Welcome	Conference Theater, Level 1B
1:30 - 2:30 pm	<b>Keynote Address</b> The Political Outlook for 2014 and Beyond ▪ <b>Charlie Cook</b> , Editor & Publisher of The Cook Report, Political Analyst, National Journal and NBC News	Conference Theater, Level 1B
2:30 - 3:15 pm	<b>The View from CMS</b> ▪ <b>Marc Hartstein</b> , Director, Hospital and Ambulatory Policy Group, Centers for Medicare and Medicaid Ser- vices (CMS)	Conference Theater, Level 1B
3:15 - 3:30 pm	<b>BREAK</b>	
3:30 - 4:30 pm	<b>Commercial Versus Medicare Pricing for Lab Tests – It's Not What Policy Makers Thought</b> ▪ <b>Eric Hammelman</b> , Vice President, Avalere Health	Conference Theater, Level 1B
4:30 - 5:00 pm	<b>What Major Changes Are In Store for Medicare, Medicaid, and "Obamacare?"</b> ▪ <b>Tom Scully</b> , Senior Counsel, Alston & Bird L.L.P. and Former CMS Administrator	Conference Theater, Level 1B
5:30 - 7:30 pm	<b>Chairman's Reception</b>	Penn Quarter, Level 1B

WEDNESDAY, MARCH 19

7:00 - 8:00 am	<b>Buffet Breakfast</b>	Conference Theater, Level 1B
8:00 - 9:00 am	<b>View From Congress on Medicare, the SGR, and More</b> ▪ <b>Elizabeth Jurinka</b> , Chief Health Policy Advisor Assistant, US Senate, Finance Committee ▪ <b>Brian Sutter</b> , Staff Director of Health, US House of Representatives, Ways and Means Committee ▪ <b>Robert Horne</b> , Professional Staff Member, US House of Representatives, Energy and Commerce Committee	Conference Theater, Level 1B
9:00 - 9:45 am	<b>What Does the Future Hold for Molecular Diagnostic Reimbursement?</b> ▪ <b>Bruce Quinn, M.D., PhD.</b> , Senior Health Policy Advisor, Foley Hoag	Conference Theater, Level 1B
9:45 - 10:00 am	<b>BREAK</b>	Conference Theater, Level 1B
10:00 - 10:30 am	<b>Communicating the Laboratory Message Effectively</b> ▪ <b>John Schmidt</b> , President, Schmidt Public Affairs ▪ <b>Rebecca Reid</b> , Media Specialist, Schmidt Public Affairs ▪ <b>Erin Schmidt</b> , Digital Director, Schmidt Public Affairs	Conference Theater, Level 1B
10:30 - 11:30 am	<b>Regulatory Oversight of Lab Development Tests: A Discussion</b> ▪ <b>Ellen Flannery</b> , Partner, Covington & Burling, LLP ▪ <b>Lakshman Ramamurthy</b> , Director, Avalere Health	Conference Theater, Level 1B
11:30 - 12:00 pm	<b>Closing Remarks</b> Open Discussion   Closing Remarks	Conference Theater, Level 1B
1:00 - 4:00 pm	<b>Lobby Day Congressional Visits</b>	



## Alan Mertz

President  
ACLA

Alan Mertz became President of ACLA in 2003. During his tenure as President, ACLA's membership has grown, the organization has greater visibility in Congress and the Administration, and ACLA's advocacy programs have been successful.

During Mr. Mertz's tenure, ACLA has become a leader on advocacy issues dealing with laboratory reimbursement, regulation and coding. ACLA was instrumental in stopping legislation that would have instituted coinsurance for laboratory services in Medicare, in repealing the Medicare Competitive Bidding Demonstration program, and heading off a proposal for imposing a new federal tax on all laboratory revenue. In 2013, ACLA led a successful advocacy campaign in opposition to a CMS proposal that would have cut Medicare payments for common anatomic pathology services by as much as 80%. ACLA is in the forefront of advocacy with respect to reform alternatives for the Clinical Laboratory Fee Schedule.

ACLA is recognized as being in the forefront of advocacy efforts to ensure that regulatory changes do not stifle innovation in genetic and molecular testing. ACLA has also been a leader on molecular coding and reimbursement issues.

In 2007, ACLA launched the "Results for Life" educational campaign aimed at promoting the value of laboratory services. In 2009, ACLA started its Associate Member program for non-laboratory health care companies and organizations as a means of broadening education and communication with the laboratory industry's health partners.

From 1998-2003, Mertz was Executive Vice President of the Healthcare Leadership Council (HLC) and served as Acting President at HLC for one year. From 1980 to 1998, he served in three senior staff positions in the House and Senate, and was selected as a John C. Stennis Congressional Fellow in 1996. Mertz was an adjunct professor at George Washington University from 1997-99. He holds a Masters in American Politics from American University and a BA in Government from Monmouth College (IL).



## Steve Rusckowski

President and Chief Executive Officer  
Quest Diagnostics

Steve Rusckowski is President and Chief Executive Officer (CEO) of Quest Diagnostics.

Since joining Quest Diagnostics in May 2012, Mr. Rusckowski has focused on transforming the company, based on its compelling vision of "Empowering better health with diagnostic insights." Under his leadership, the company has refocused on its core diagnostic information services business, sold non-core assets, delivered disciplined deployment, including share repurchases and acquisitions, and simplified its organizational structure to better serve customers by removing complexity, speeding decision making and empowering employees.

Prior to joining Quest Diagnostics, Mr. Rusckowski was CEO of Philips Healthcare, which became the largest unit of Royal Philips Electronics under his leadership. He joined Philips in 2001 when it acquired the Healthcare Solutions Group he was leading at Hewlett-Packard/Agilent Technologies.

Mr. Rusckowski is a member of the Board of Directors of Covidien, a healthcare products provider, and Project Hope, a global health education and humanitarian assistance organization. He earned a Bachelor of Science degree in Mechanical Engineering from Worcester Polytechnic Institute and a Master of Science degree in Management from the Massachusetts Institute of Technology's Sloan School of Management.



## Charlie Cook

Editor & Publisher of The Cook Report, Political Analyst  
National Journal and NBC News

When Charlie Cook makes a pronouncement based on his analysis of the political scene in America, people who want to be “in the know” sit up and listen. For more than two decades he has been Washington’s most trusted—and most accurate—voice on all things political, whether it’s the outcome of a Congressional, gubernatorial, or presidential election.

As the editor and publisher of The Cook Political Report and a political analyst for the National Journal Group, his prodigious writing is a direct line to the heart of politics. He writes weekly for National Journal magazine and National Journal Daily, and he also pens a regular column for The Washington Quarterly. Once deemed “the Picasso of election analysis” by The Wall Street Journal and represented exclusively by Leading Authorities speakers bureau, Cook produces the sharpest political handicapping in the business, serving as the one-man, go-to-source for Americans who want to be truly informed.” For the spring semester of 2013, Charlie Cook was a resident fellow at the Institute of Politics at the Kennedy School of Government at Harvard.



## Marc Hartstein

Director, Hospital & Ambulatory Policy Group  
Centers for Medicare & Medicaid Services (CMS)

Marc Hartstein has been with the Centers for Medicare and Medicaid Services for more than 24 years. He worked on the original Medicare physician fee schedule and later as a hospital payment policy analyst where he assisted the Department of Justice in successfully defending the Department of Health and Human Services in *Regions Hospital v. Shalala* before the United States Supreme Court. From 2004 to 2007, Marc was Deputy Director of the Division of Acute Care where he led several IPPS reforms including development of the MS-DRGs. Marc was the Deputy Director of the Hospital and Ambulatory Policy Group from 2008 through 2012 and is currently the group’s Director. He manages four Divisions that set payments for over \$260 billion in Medicare expenditures that affect over 900,000 Medicare providers of hospital care, physician, laboratory and other services. He has a Masters Degree in public policy from the University of Minnesota’s Hubert H. Humphrey Institute of Public Affairs and a bachelor’s degree in political science and economics from the University of Vermont.



## Eric Hammelman

Vice President  
Avalere Health

Eric Hammelman, Vice President, provides data-driven analysis of the impact of payment policies on healthcare patterns. He helps clients across multiple sectors understand how data can better inform their business strategies, including responding to emerging trends such as medical homes and accountable care organizations, or shaping new payment policies including payment bundles. He also provides economic forecasts to meet different needs, including company-specific revenue and cost trends, industry-level expectations, or Congressional Budget Office-style legislative scores.

Prior to joining Avalere, Eric was an Associate Analyst with JPMorgan, where he analyzed healthcare service companies and provided investment advice to institutional investors.

Eric has a Bachelor's of Music Performance from the University of Illinois at Urbana-Champaign, an MBA from the Marshall School of Business (University of Southern California), and a Masters of Music Performance from the Mannes College of Music in New York, NY. Eric is a CFA Charterholder.



## Thomas Scully

Senior Counsel  
Alston & Bird, LLP

Tom Scully focuses his practice on health care regulatory and legislative matters. He is also a general partner with Welsh, Carson, Anderson & Stowe, a private equity firm in New York.

Mr. Scully was the administrator of the Centers for Medicare & Medicaid Services (CMS), from 2001 to 2004. CMS administers Medicare, Medicaid, SCHIP, and is the largest agency in the U.S. Government, spending more than \$1 trillion for fiscal year 2012.

At CMS, Mr. Scully had an instrumental role in designing and passing Medicare reform and Medicare Part D legislation and in making the vast agency more open and accountable to the public. He initiated the first public reporting and disclosure for comparative quality among hospitals, nursing homes, home health agencies and dialysis centers.

Before joining CMS, Tom served as president and CEO of the Federation of American Hospitals from 1995 to 2001. The FAH represents 1700 privately owned hospitals.

Mr. Scully was a partner in Washington, D.C., with Patton Boggs, LLP, 1993-95; deputy assistant to the president and counselor to the director OMB, 1992-93; and an associate director of OMB, 1989-92. In 1988, Tom worked on the Bush for President campaign; with Akin Gump from 1985-1988; and with US Senator Slade Gorton (WA), 1980-1985.

## Elizabeth Jurinka

Chief Health Policy Advisor  
U.S. Senate,  
Finance Committee

## Brian Sutter

Staff Director of Health  
U.S. House of Representatives,  
Ways and Means Committee

## Robert Horne

Professional Staff Member  
U.S. House of Representatives,  
Energy and Commerce Committee



## Bruce Quinn M.D., PhD.

Senior Health Policy Advisor  
Foley Hoag

Bruce Quinn, MD PhD, is a national expert on Medicare policy, the impact of health reform on innovation, and the crafting of successful business strategies within the US healthcare reimbursement system. Dr. Quinn has worked successfully with both large and small companies in overcoming hurdles to commercialization through negotiation, understanding insightful ways to use the existing system to advantage, and the mechanisms of policy change. Since 2008, Dr. Quinn has been a full time business strategist working with attorney and policy teams for healthcare and life sciences clients in the firm's Government Strategies practice.

Dr. Quinn travels nationwide to speak on health reform issues and publishes actively, recently writing two peer reviewed policy articles and an authoritative textbook chapter on advanced diagnostics. Dr. Quinn has also authored a series of white papers tracking federal molecular reimbursement reform 2011-2013. Before joining Foley Hoag LLP, he was the regional Medicare medical director for the California Part B program. Earlier in his career, Dr. Quinn was a physician executive in the Health & Life Sciences division of Accenture, working with the pharma, biotech, and genomics industries. Dr. Quinn is a board-certified pathologist. As a physician-scientist on the faculty of Northwestern University School of Medicine, he led pathology research for Northwestern's NIH-funded Alzheimer Research Center. Earlier, he also held academic positions at New York University School of Medicine and the UCLA Center for Health Sciences and is the author or co-author on 30 scientific publications. He also holds an MBA from the Kellogg School of Northwestern University.



## John Schmidt

President  
Schmidt Public Affairs

John Schmidt is a seasoned public affairs professional with more than 17 years experience in managing specialized public affairs campaigns for a wide range of corporate and association-related interests at the state and national levels. As President of Schmidt Public Affairs, he has successfully directed many large-scale public affairs and advertising campaigns focusing on government reimbursement programs, health care and provider issues, quality, branding and crises, among others.

John has served as lead communications counsel to several health care provider interests, where he has spearheaded award-winning public affairs initiatives, including grassroots, grass tops and earned media campaigns. His expertise in Medicare, Medicaid, tort reform, HIT, staffing issues, quality programs, regulatory and reimbursement reform and crises situations has resulted in billions of dollars in restored or new funding for his clients.

John has also led comprehensive public affairs initiatives for other health care groups including oncology, CKD and ESRD/dialysis, health information technology, imaging, biotechnology, oxygen providers, state health care organizations, pharmaceutical interests and patient advocacy groups. His strong command of legislative and public policy issues has garnered numerous top national awards from the public relations industry trade, including the top public affairs campaign in the country for three consecutive years.

Before founding Schmidt Public Affairs in early 2004, John was Senior Vice President for Edelman Public Relations' Healthcare and Sciences practice. His other roles prior included Group Manager for Ketchum Public Relations' Public Affairs practice, and Vice President of Ruder Finn.

A graduate of UNC-Chapel Hill with a B.A. in Advertising/Journalism, John is married with three children and three dogs. He resides in Alexandria, Virginia.



## Rebecca Reid

Media Specialist  
Schmidt Public Affairs

Ms. Reid has over twenty years experience in media relations and government affairs spanning local, state and national political and press arenas.

As a journalist in San Francisco, Reid began her career as a radio reporter/producer and a television news writer for network affiliate newscasts. As press secretary for members of Congress, she worked regularly with the national press corps on issues such as foreign aid, defense funding, Medicare and nuclear energy.

Following her tenure on Capitol Hill, including Press Secretary for Rep. Nancy Pelosi, she served as press secretary to County Executive Parris N. Glendening, prior to his election as Governor of Maryland. As director of Public Affairs for the Maryland Department of Transportation (DOT), Reid served as press secretary to the Secretary of Transportation, managed the Public Affairs Division for DOT headquarters, and acted as liaison to the Offices of the Secretary and the Governor for all DOT modal administration public information officers.

As chief consultant of her own public affairs firm, Reid provided a full range of media relations, government affairs and association management services to health care provider groups.

During her tenure at Edelman Worldwide in DC, she served as Vice President of Media Relations for the Healthcare Practice and played a key role in garnering earned media placements for several clients in The Washington Post, Wall Street Journal, CNN, network news and major dailies across the country. Other clients included pharmaceutical companies, The Joint Commission, quality improvement organizations, and organizations advocating on various issues such as cancer care and stem cell research.

For the last decade, Reid has managed national media outreach for SPA as well as written materials including, opinion-editorials, testimony before federal agencies and congressional committees and press conference scripts for various health-care clients.

In addition to her extensive media background, Reid has experience in local, state and congressional political campaigns and has managed national advocacy coalitions.





## Erin Schmidt

Digital Director  
Schmidt Public Affairs

Erin Schmidt is digital director at Schmidt, where she oversees digital and social media programs for our clients.

Since joining the Schmidt team in 2012, Erin has planned and executed digital and social media strategies for a range of client initiatives to support their advocacy, crisis management, government affairs, media relations, branding, and special events efforts. Her areas of expertise include social media plans and policies, digital content strategies, community management, online advocacy, crisis communications, web development, and production management.

Prior to joining Schmidt Public Affairs, Erin was chief operating officer and account supervisor at RB Oppenheim Associates, an integrated public relations firm in Tallahassee, Florida.

Erin holds a Master of Arts degree in media and communication studies from Florida State University and a Bachelor of Arts degree in communications from Luther College.

When she's not working, Erin enjoys performing with the 18th Street Singers, singing live band karaoke, and learning to play the drums.



## Ellen Flannery

Partner  
Covington & Burling, LLP

Ellen J. Flannery is a Partner in the law firm of Covington & Burling LLP and is co-chair of the firm's global food and drug law practice group. Ellen advises on regulatory requirements and strategies covering an array of medical device types, for clients including large companies, smaller companies with novel or breakthrough products, venture capital firms, and trade associations.

She is co-editor of the book entitled "In Vitro Diagnostics: The Comprehensive Regulatory Guide" (FDLI 2010), contributing author to the book "Medical Device Law and Regulation 2014" (PLI editions 2011-2014), and author of numerous published articles. She is Co-Editor-in-Chief of Covington's InsideMedicalDevices blog. She has taught food and drug law seminars at three law schools (Boston University, University of Maryland, and University of Virginia).

Ellen received her J.D. cum laude from Boston University School of Law, and A.B. cum laude from Mount Holyoke College.



## Lakshman Ramamurthy

Director

Avalere Health

Lakshman Ramamurthy, Director of FDA Strategy and Regulatory Policy, advises clients on medical device regulation and how to incorporate FDA regulatory strategy in business planning. He also aids clients on product life cycle management and evidence planning, including how best to leverage evidence generation for regulatory and reimbursement approval. Lakshman partners with device and diagnostics companies to anticipate evidentiary demands for product approval and real-world demands of purchasers and clinicians. He provides regulatory risk analysis and due diligence to private equity and venture capital companies investing in device/diagnostics companies.

Prior to joining Avalere, Lakshman worked at the FDA's Center for Devices and Radiological Health (CDRH) variously as a Senior Reviewer, Policy Advisor and Acting Associate Director; Office of Legislation in the Office of Commissioner, FDA; Bioinformatics Specialist at GlaxoSmithKline; and Genomics Manager at Almac Diagnostics, Inc.

Lakshman has a PhD in Molecular Biology from the University of North Carolina at Chapel Hill. He is a member of FDA's strategic team guiding the Entrepreneurs in Residence program at FDA CDRH, and a member of the Clinical Laboratory Standards Institute. Lakshman serves as faculty at the NCCN (National Comprehensive Cancer Network) Academy of Excellence and Leadership in Oncology.

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There is direct access to the Metro subway system from the hotel lobby. Fitness club, indoor pool, whirlpool, sauna and steam room as well as six restaurants and bars are available for all guests.

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