



IAMERS Newsletter

Editor – Diana Upton

Technical Editor – Wayne Webster

May 9, 2011

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Amazing Fish Tanks at the Atlantis



Letter from the President

Dear Members,

We are back a week from our annual meeting in the Bahamas. It was paradise for kids, and kids at heart. What a beautiful facility.

Beyond paradise it was also, in my view, the best meeting we've ever had from a content perspective. On Page 2 and 3 you can read Wayne's and my take away on two of the talks.

As with all meetings, we ask the participants to fill out a survey at the end of the meeting. We were delighted by the positive responses we received. As well as finding out what you liked best, both socially and during the business sessions, we are also grateful for any ideas that you may have regarding future meetings.

By vote of the Board, the next Annual Meeting will return to Washington, D.C. The choice of Washington was influenced by our ongoing agenda with the FDA and Congress. This venue allows us to have great speakers at a reduced cost to IAMERS. It's also a great city in which to be a tourist.

In the meantime, we look forward to our next meeting in September in Munich, Germany. In early June, you'll receive detailed information on the meeting in Germany, as well as some great tours to occupy your free time.

This is a long Newsletter, yet I hope you take the time to read it and consider what we are pursuing on behalf of our members. We work for the benefit of our members. As such, it's important that you know what we're up to. It's also important that you give us your feedback.

Cheers,

Reviewing Our Favorite IAMERS Presentations at the Annual Meeting

Trends In Outpatient Imaging

A Review of a Talk by Ms. Maggie Sayre, Executive Director of AQ Imaging

Wayne Webster

Maggie Sayre of the Association for Quality Imaging (AQI) addressed the IAMERS annual meeting attendees. Her talk, Trends In Outpatient Imaging, focused on some of the important issues facing members of AQI and IAMERS. These trends range from reductions in reimbursement to legislative actions and will most likely reshape the medical imaging marketplace.

Formerly called the National Coalition for Quality Diagnostic Imaging Services (NCQDIS) the AQI has offices in Washington D.C. It represents and lobbies for its members, the independent imaging centers across the country. AQI officers and its board of Directors are drawn from well known medical imaging provider companies. AQI leadership positions are held by people from Shared Imaging Services, InSight Imaging, Alliance HealthCare Services, MedQuest Associates and RadNet.

Focusing on the uncertain climate in Washington after the passage of health care reform (the “Patient Protection and Affordable Care Act”) and the perceptions in Congress and at CMS (the “Centers for Medicare and Medicaid Services”) that medical imaging is the root cause of the expanding Medicare budget problem, she explained how vendors of services and equipment may be negatively affected. She warned that CMS along with MedPAC (the Medicare Payment Advisory Commission formed in 1997 as part of the Balanced Budget Act to advise Congress on issues affecting the Medicare program) and Congress are all taking aim at the medical imaging sector.

There’s more. Under the Deficit Reduction Act (the “DRA”) Medicare physician reimbursement was to be adjusted each year, over a 5-year period to result in an overall multi-billion dollar savings to the program. This legislated reduction never materialized as both Republican and Democratic Congresses deferred the mandate. Now CMS is planning to implement a reduction to recoup the unrealized savings.

To add to the misery the Medicare Physician Fee Schedule Rule as implemented by CMS in 2010, proposes to increase equipment utilization from the present 50% rate to 90%. The Rule’s not demanding increased patient imaging. It is lowering the payment per patient by artificially inflating the utilization rate.

For example: a CT scanner in 2010 has a mandated 50% utilization rate. Let’s say, on average, 10-patients are imaged daily at a reimbursement of \$100/patient. By increasing the utilization rate the provider maintains the same patient demand, 10/day, but with a mandated higher utilization rate it now receives \$55.55 per patient. With the change in utilization rate from 50% to 90%, an 80% increase, there is a corresponding decrease in reimbursement of 55%. Ms. Sayre suggested the free standing imaging market may not survive as we know it today if this inflation of the utilization rate is not adjusted more equitably.

There is a perception in Washington that from 1999-2005 there was exceptional growth in medical imaging services. I recall she used the words “*unbridled growth*”. It’s believed by CMS this gluttonous growth hurts Medicare and must be controlled by reigning in providers with reductions in reimbursement. This is done even when CMS is aware that these providers play no direct part in driving referrals.

With the role out of the DRA she explained there was a corresponding reduction in imaging services of 7%. At the same time CMS’s implementation of a multi-procedure payment reduction with CT for free standing centers, but not for hospitals, also negatively affected revenues. With the success of the bundled billing codes for CT, CMS plans to examine the entire medical imaging area and is expected to continue to offer up such changes in all modalities. If implemented, these changes/reductions will result in a further erosion of free standing center revenues, lowering their ROI.

Ms. Sayre pointed out in 2011 she expects to see MedPAC focus on imaging as its “*First Policy*”, first to be highlighted, first to be bundled and first to be cut, an ominous forecast for the medical imaging market space.

What can we expect in the immediate future? According to Ms. Sayre, “*a lot*”:

- Implementation of ADIS Accreditation for Medicare Part B providers (imaging centers). Without proper accreditation, in 2012 the provider will no longer be reimbursed by Medicare for services provided.
- Change in enrollment process for 2012. The imaging site must be accredited and on the list of Accredited Providers to receive reimbursement.
- CMS is proposing to address the missing 29% by reducing reimbursement to accomplish the same result. Without action by Congress to alter this course this reduction will pass through to the free standing centers.

- CMS is developing a Clinical Decision Support Criterion, another name for prior authorization approval, and plans to implement this in the future.
- MedPAC and CMS continue to evaluate the appropriateness of requiring prior authorization for all imaging services.
- The creation of the ACO (the “Accountable Care Organization”) most likely will have a substantive and negative impact on the use of imaging. A patient assigned to an ACO, something like an HMO, will arrive with an allocated amount for annual care. This may lead to rationing of services. Simply put, the less the ACO spends the more it keeps.

And in our immediate future:

1. the 2012 Medicare Physician Fee Schedule – Proposed Rule to be published in June in the Federal Register for public review and comment
2. Congressional discussions begin on the 29% reduction issue
3. Clinical Decision Support planning and proposals get underway
4. MedPAC presents its first report to Congress in June

I think Ms. Sayre’s take home message is clear. Medical Imaging is under the gun and nowhere is it more pronounced than at the free standing center. The changes, if implemented signal a possible return of medical imaging to the hospital and a change in the way medical imaging dollars are distributed. The effect on providers of services and vendors of equipment most likely will be profound.

Valuing Your Company for Sale A Panel Discussion by Brad Fleisher, Michael Oleksak and Michael Radin Diana Upton

There were so many good things in this presentation that I hope to repeat it at the next IAMERS Annual Meeting. My speculation is that even those who were present at the Atlantis will want to hear it again.

Not only was it excellent advice on how to prepare your company for sale, it was excellent advice on how to operate your company. In the process of running a company we consider several essential components that not only make for better performance but a better product at the time of sale.

One of our presenters, Michael Oleksak, wrote a book – *Intangible Capital*, which was given out to the attendees. Michael’s presentation focused on four key components within a business:

- Human capital – key competencies
- Structural capital – quality assurance, efficient operations, sales & marketing
- Relationship capital – reputation, supplier & customer relationships, FDA
- Strategic capital – your business model, healthcare industry pressures

These are keys to improve your current performance as well as long-term value.

To improve the performance and value your intangible capital, you must first know what you have and what your opportunities for improvement are. Do you value your employees? Do you see them as part of your long-range plans or simply people walking in and out the door to take your money? Do you have systems in place that you follow? What’s the state of your reputation within the industry?

All of the above issues need to be addressed when you sell your company. But they also come into play when you grow your company, or take on a new investor, or you seek additional financing.

Brad Fleisher is an attorney who helps people prepare to sell their business; a process that Brad says takes about three years. He defines it as the most important financial transaction of your life. Business owners are 2% of the population, and hold 80% of the wealth. Michael Radin, also an attorney, specializes in mergers and acquisitions within his law firm.

Brad and Michael get companies prepared for presentation to perspective buyers. During the preparation phase, you’ll need to examine: ownership & debt, human capital, production & distribution, branding, intellectual property, partnerships, your facilities, your equipment, regulatory compliance, litigation (past and present), and insurance. Above all, you must be ready to stand behind what you tell your buyer. If all of the above are day-to-day considerations, you’ll not only have a better product to sell; but a better company for the here and now.

IAMERS Welcomes New Member

Linde, LLC
Robert R. Van Kirk
Key Customers & Distributors
575 Mountain Avenue
Murray Hill, NJ 07974
Phone: +1.908.771.1564
Fax: +1.908.771.1764
Email: bob.vankirk@linde.com
Website: www.lindeus.com

Cryogen supplier



One of the many beautiful sights at Atlantis

IAMERS Membership Drive

In an effort to boost our revenue – and thus continue our efforts with the FDA, IAMERS sent a letter to members on December 2nd explaining the new membership drive. If you help us recruit qualified members, you'll be rewarded for your efforts.

If you bring three (3) new members to IAMERS within a 12-month period – any 12-month period, and they stay members for at least 13 months (in other words, they renew their membership), your dues will be free during the following year.

Please make sure the applying company lists you as their sponsor. A copy of the application to join IAMERS can be found on the website.

The drive started on December 1st and a few members are already on their way to free dues.

Currently, there is no scheduled end date for this membership drive.

The Fight Against Cerebral Palsy

Dear Friends and Colleagues,

The fight against Cerebral Palsy is long and hard and never-ending. The Children's Therapy Center is for those who respond to their heartfelt assistance and although slow, the results are rewarding.

You probably don't think that going outside and playing or riding a bike got s 4-year old is special, but for my grandson Sammy Leshin, it is a learning experience. By attending the children's Therapy Center, he is learning to walk with a walker, ride a bike with assistance, although he is still being fed by a tube.

I sincerely ask you for any contribution to this school so that they can continue this essential work.

Please refer any donations to Samuel Leshin.

Sincerely,
Dave Band

The Children's Therapy Center

Attn: Audra Hoffman

29-01 Berkshire Road

Fair Lawn, NJ 07410

Please refer donations to Samuel Leshin

Report of the Standards Committee

Wayne Webster

Introductory Statement

In 1995, the IAMERS Code of Ethics was approved. The Code specifically provided for the formation of a Professional Standards Committee, the purpose of which was to establish certain minimum standards expected of IAMERS' members.

["T]he IAMERS professional standards committee shall be responsible for the continuing process of establishing standards for the I.A.M.E.R.S. members in understanding ethics committee decisions with regard to enforcement of the Code of Ethics"¹ "The Professional Standards Committee is charged with the ongoing process of establishing ethical standards for the IAMERS' members (emphasis supplied)."

Since its inception, IAMERS has worked to establish appropriate standards. In 2010, it was decided at a business meeting that the Professional Standards Committee would formally be implemented for the purpose of establishing certain minimum standards or aspirations through which IAMERS' members would be encouraged to incorporate these concepts in their daily business practice. IAMERS' President, Diana Upton, appointed the undersigned to survey members, informally, and to thereafter make recommendations for ethical standards to be considered by the IAMERS' membership.

I have met and discussed with IAMERS' members, including stakeholders primarily engaged in service, selling, and original equipment manufacturers. They have graciously shared their time and, in certain instances, provided me with contracts, contractual provisions, and real life experiences to review as to this endeavor. Several key business concerns have been gleaned from the discussions. When a problem arises in a contract, members want to avoid the other party imposing "gotcha" clauses (where possible) and most wish to work with each other to bring about a resolution. Hence, the first recommended proposal is the adoption of an expressed covenant of good faith. This ought to be readily embraced as many states specifically incorporate the "good faith" provision found in 1-201 of the Uniform Commercial Code. Similarly, we encourage IAMERS members to adopt contract provisions which do not encourage the forfeiture of deposits for nonmonetary reasons. While it is difficult to establish exact circumstances, IAMERS members should not arbitrarily impose strict standards by which deposits are forfeited. Disputes should be resolved amicably. The Committee encourages the adoption of a provision by which the parties should turn to mediation in the first instance of a dispute. The Committee also wishes to encourage compliance with the FDA regulations pertaining to access to passwords, training and manuals. Finally, to avoid confusion, the Committee encourages the adoption of "integration clauses" or provisions which require that all of the terms of a contract be set forth in the contract (unless the parties wish for custom in the industry to be adopted). The following are some proposals to be considered for the formation of minimum standards. While we well recognize that these recommendations might not be adopted by all IAMERS' members (or be applicable to all business circumstances), we perceive that these recommendations are worthy of consideration.

Professional Standards Recommendations (for Adoption by IAMERS' Members)

1.) Covenant of Good Faith and Fair Dealing in Every Contract be Employed by IAMERS' Members. IAMERS' members recognize that while many contracts implement smoothly, there are times and circumstances where issues arise. As a practical matter, in many states this is codified expressly and an implied covenant, in these instances, means that the parties treat each other reasonably. Indeed, UCC section 1-201, the definition has been revised by the National Conference of Commissioners on Uniform State Laws to mean "honesty in fact and the observance of reasonable commercial standards of fair dealing". A similar concept is espoused in the Principles of European Contract Law. Accordingly, we recommend that IAMERS' members adopt expressly a covenant of good faith in their dealings and negotiations with IAMERS' members, and with all contracting parties.

2.) Equipment Deposits and Conditions where Forfeiture Permitted: Over the years, we are advised that some Ethics Complaints arise in connection with the withholding of deposits or the claim of "forfeiture" of deposits. In this regard, while there are circumstances which would warrant the forfeiture of a buyer's deposit as a general principle, the forfeiture of equipment deposits for non-monetary default violations is not recommended by IAMERS. While it is difficult to establish the exact circumstances, it seems appropriate not to permit forfeiture of deposits for violations of non-monetary covenants. It is not justifiable to cause equipment forfeiture to occur simply because of personality issues. The exceptions may exist in circumstances where a party is unable to undertake delivery of equipment and the time period by all reasonable expectations, and custom in the industry expires.

3.) Mediation: Mediation is becoming more and more adopted as a thoughtful and useful exercise, which companies regard as a more cost-effective solution to the resolution of disputes. IAMERS recommends the adoption of a mediation solution as a standard of exchange. One national mediation firm has offered clauses which provide for mediation in advance of arbitration. The mediation clauses may be found at www.jamsadr.com.

4.) Description of Equipment: When controversies occur, often they arise as to what is covered or not covered in the description of the equipment. Best practices seem to suggest that one attach a full and complete schedule of equipment rather than refer to it in a condensed or piecemeal fashion. In this way, parties may limit their potential controversies concerning the scope of equipment (i.e.: whether a table is included or some other item which one or the other parties may not actually have specified. Specificity and exactitude in a detailed description of the equipment work for the benefit of all parties).

5.) Compliance with FDA Regulations and Adherence to Quality Assurance Standards: The Professional Standards Committee expects all members to cooperate in providing access to assembly, installation, adjustment and testing information (including passwords, equipment manuals and training consistent with 21 CFR 820 and 21 CFR 1020). The Committee recommends the adoption of

standards which will require that access to passwords and equipment manuals be uniformly adopted consistent with existing FDA regulations. The Committee also recommends adoption of quality assurance standards including, whenever possible, compliance with ISO.

6.) Entire Agreement Clause

The Committee encourages that a clause be included, to avoid confusion, when agreements are being made between and among IAMERS members and other stakeholders by which the contracting parties declare the written agreement to be the complete and final agreement between the parties. No other representations (oral or otherwise) are to be permitted. The Committee remains concerned that equipment depictions on a Members website ought to be consistent with the description set forth in the agreement.

Please note:

During the Annual Meeting, the above report was adapted by the Board of Directors, with the approval of the general membership present at the meeting. As well, it was reviewed and approved by our General Counsel, Robert Kerwin. As such, the above will be considered a part of the IAMERS Code of Ethics; and it is anticipated that other professional standards will be adapted as a part of the IAMERS' by-laws.

FDA News & Information

Robert Kerwin, Esq.

On May 2, 2011, the U.S. Food and Drug Administration released a draft guidance for comment purposes pertaining to the Processing/Reprocessing of Medical Devices in Health Care Settings. Comments on the draft guidance may be made at www.fda.hhs.gov or addressed to Dr. Sheila Murphy at sheila.murphey@fda.hhs.gov. While the draft guidance appears not to relate to remarketers, refurbishers or remanufacturers of imaging equipment, it is not entirely clear that there may not be some calls from interested parties to expand the guidance to imaging modalities. A workshop will be held at the FDA White Oak Campus, Silver Springs Maryland on June 8-9, 2011. Among the issues to be discussed are: what are the nature, scope and impact of reusable medical device processing problems? What are the criteria to facilitate reprocessing and the validation protocols and how should problems with reusable medical device reprocessing be acted upon by industry users. The notice of the FDA public workshop signaled the FDA's focus: "FDA has received a number of reports of patient exposure to inadequately reprocessed medical devices and subsequent healthcare associated infections (HAIs). The FDA noted that "inadequate reprocessing may have been a contributing factor in microbial transmission and subsequent infection. The workshop is expected to cover improvements in device design reprocessing procedures and validation methodologies as well as healthcare facility quality assurance practices. See the specifics at www.fda.gov/reprocessingreusabledevices.

On April 7, 2011, the FDA held a public meeting also at its Silver Springs Campus to explore the development of a searchable medical device labeling repository which would be accessible to the public and to health care practitioners. The new on-line repository would not include equipment manuals or proprietary information. It would reportedly be searchable. It remains open as to how the FDA sponsored site with actually work. Comments are requested on or before May 10, 2011.

* * * * *

On April 13, 2011, the U.S. Government Accountability Office released testimony provided before the Special Committee on Aging, U.S. Senate updating its review of "FDA's Premarket Review and Postmarket Safety Efforts". In 2009, the GAO found that certain high-risk devices that are allowed to enter the U.S. market through the "less stringent 510 (k) process do not have adequate regulations which effectively enhance premarket safety e.g., for automated defibrillators and implantable hip joints. The GAO suggested that the FDA did not routinely analyze recall data which would identify trends and proactively identify risks in unsafe devices. It also suggested that the FDA did not adequately oversee recalls in certain instances. While the substance of the study did not pertain to imaging devices, it highlights the continued public focus on FDA and suggests that further safety measures should be undertaken. While it is difficult to extrapolate from GAO testimony, the testimony and the conclusions of the GAO seem consistent with a public trend by some stakeholders to suggest that current regulatory behavior increases the risk that unsafe medical devices remain on the market. See GAO-11-556T. This continued conservatism both inside FDA and with government watchdogs, suggests to this writer that the FDA is likely to be very conservative in its regulatory approach. The upcoming UDI draft regulation (due next month) may offer some further insight as to the FDA's use of the labeling requirements in UDI to impact IAMERS members.

2011 Annual Meeting @ Atlantis in the Bahamas

The 2011 Annual Meeting is now behind us. Everyone had a great time at the Atlantis. This place was paradise for kids. There are so many water activities to keep everyone busy. It's a wonder we could keep everyone in the meetings. For the vast majority, we were successful in keeping the participants in the room. It's a credit to the great speakers that we had and the wonderful program.

My favorite session was on selling your business. See Page 3 for a summary of that excellent presentation.

Many thanks to Bob Feldman for an excellent location, great food and a wonderful atmosphere. Thanks to Mary Band and Don Bogustski for the photos.

While most of the attendees filled out a survey, we would still like to hear any additional comments you may have regarding the meeting.



Dave Band, Barbara Poalise & Sandy Del Gozzo



Bob Feldman & Alan Pettenati



Joe & Kristin Sciarra



Karen Freund & Mary Band



Jeanna & Shelbe Simmons



Joan & James Dillard, Wayne Webster



Johnna Foscalina & Mark Bringolf



Karen & Tom Freund



Michael Radin & Maggie O'Mahoney



Emily, Lynn & Marc Regan



Diana Upton & Mike Schmit



Liz Fall, Kimberly & Liliana Bringolf



Traci & Christian Manetta



Liliana Bringolf & Denise Costa



Rob Manetta, Liz Cruz & Dave Band

Tom Freund Joins IAMERS Board of Directors



Tom Freund

We welcome Tom Freund, General Manager of Oxford Instruments Service, to the IAMERS' Board of Directors. Tom will replace Jeff Fall as the Chairman of Ethics. Should you need to discuss an ethics issue with Tom, please note his contact information.

Email: thomas.freund@oxinst.com
Phone: +1.732.850.9352

As this was an election year, please note additional changes to the Board of Directors.

2011/2012 Board of Directors

Dave Band	Founding President
Diana Upton	President
Jeff Fall	Vice President
Jim Goldner	Treasurer
Katie Moss-Solomon	Secretary
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Rob Manetta	Marketing Chairman
Rick Stockton	Membership Chairman
Tom Freund	Ethics Chairman
Anders Jensen	International Chairman
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Robert Kerwin, Esq. ●	Medical Advisor
	General Counsel

● Non-voting

Thanks to the 2011 Annual Meeting Sponsors

Advantage Medical Imaging
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Nationwide Imaging Services
Okon Metals
Platinum Medical Imaging
Diana Upton

Dunlee
International X-Ray Brokers
Medical Imaging Resources
MRN Resources
Northeast Electronics
Oxford Instruments Service
RSTI

Important Dates & IAMERS Events

April 2011						
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June 2011						
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August 2011						
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September 2011						
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October 2011						
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November 2011						
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28	29	30				

Religious/US/world holidays

♣ Member tickets are allocated based on company size in case of RSNA & ECR.
Companies with 15 employees or less receive 2 tickets.
15+ employees receive 4 tickets.

German Radiology Congress • 1 – 4 June 2011
Hamburg, Germany

SNM • 4 – 8 June 2011
San Antonio, TX

AAMI • 25 – 28 June 2011
Exhibits 25th – 27th
Henry B. Gonzalez Convention Center
San Antonio, TX
IAMERS Booth # 628

AHRA • 15 – 19 October 2011
Dallas, TX

IAMERS European Meeting • 7 – 9 September 2011
Bayerischerhof Hotel
Munich, Germany

EANM • 15 – 19 October 2011
Birmingham, UK

MD Expo • 20 – 23 October 2011
Hilton in Walt Disney World Resort
Orlando, FL

RSNA • 27 November – 1 December 2011
Booth # TBA

IAMERS Member Meeting • Sunday 27 Nov 2011
5:30 – 6:30 PM • InterContinental Hotel
IAMERS Annual RSNA Reception ♣
Monday, 28 November 2011
6:30 PM - ? • InterContinental Hotel
MEMBERS & THEIR GUESTS ONLY



Neuschwanstein – a.k.a. Ludwig's Castle
The inspiration for Walt Disney's Magic Kingdom

One of the many wonderful places to see if you come to the
IAMERS European Meeting in September

IAMERS News & Information

- IAMERS has established a Washington DC working group. During these meetings we exchange ideas on all issues pertaining to FDA and our legislative agenda. The next meeting will be held on May 12th starting at 11 am. As always, the meetings are held in our lobbyist's office. All members are welcome to join in – but you must let me know ahead of time. We bring in lunch so as to maximize our meeting time. Over the next few meetings, we would like to formalize a permanent group.
- Please visit the IAMERS website. We want you to be satisfied with your listing; and we welcome any ideas of suggestions that you might have.
- Please tell us if you can help on a committee. There's plenty to do in areas such as marketing. The more members that can help, the more we can accomplish. If there is something specific you would like to do for the association, let us know.
- Let us know what you think about our articles and our direction. If you don't communicate with us, we'll never know how best to improve. This is your trade association.
- Tell us what's important to you. What do you need from IAMERS on behalf of your business? If you don't tell us, we may not know.
- Is there something you would like to put in the Newsletter? Some news about your company? Let us know. We're happy to include it.
- IAMERS is grateful for the contributions of its sponsors – for all events.

Comments and opinions are welcome.

Diana Upton
201•357•5400

IAMERS has a unique opportunity to work with Hitachi for service and installations. This is the first OEM that has offered us this type of program. For more details on how you might benefit from this program, please contact Dave Band at info@dbicorp.com or +1.917.435.3100.

ISO Education for Members

We are planning an ISO seminar for early July. In order to not lose money for the association, we need to have a minimum of 10 participants @ \$300 pp. The price includes lunch and runs about four (4) hours. The meeting will be held in Washington, DC.

If you would like to attend this ISO education seminar, please let us know.

2011/2012 IAMERS Board of Directors

President – Diana Upton • dupton@optonline.net
Vice President – Jeff Fall • jfall@platinummi.com
Secretary – Catherine Moss-Solomon • katie@expertmedicalsysinc.com
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Technical Advisor – Wayne Webster • wayne@diagplus.com
Chairman Standards Committee – Wayne Webster
Medical Advisor – Steen Lindequist, M.D. • sl@agitomedical.com

IAMERS General Counsel
Robert Kerwin, Esq. • rkerwin@tbhr-law.com

Contact IAMERS @ 877•304•2637 or 201•833•1157