



THE FORUM

Sept/October 2012

Volume 11, No. 5

THE OFFICIAL MAGAZINE OF THE COLLIER COUNTY MEDICAL SOCIETY

***YOUR
VOICE
IN
ACTION!***



TICKETS ON SALE FOR
AN EVENING IN MONTE CARLO
details on page 5



WHAT'S INSIDE

CONSENT FOR
CLINICAL RESEARCH

WISE WORDS FROM
A LOCAL GERIATRICIAN

THE HC ACT AND
YOUR BOTTOM LINE



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CCMS MEMBER NEWS

Donald DiPasco, M.D., Internal Medicine, announces the opening of his new concierge practice, Personalized Physician Care, LLC, at 1865 Veterans Park Dr, Ste 202, Naples, FL 34109. Phone: 596-1111, Fax: 596-1659.

Florida Pain Center's new location as of August 6, 2012 is 12250 Tamiami Trail East, Suite 201, Naples, FL 34113. Phone: 659-6400.



Cataract and LASIK Specialist **Jonathan M. Frantz, M.D., FACS**, and General Ophthalmologist and Uveitis Specialist **Jeffrey L. Willig, M.D.**, have been selected for inclusion in the new 2012 Edition of the "Guide to America's Top Ophthalmologists."



Marianne Geraci, M.D., Ophthalmology, has relocated her practice to 5185 Castello Drive, Ste. 2, Naples, FL 34103. Phone: 963-9827 Fax: 963-9854.

Richard M. Kravis, M.D., Internal Medicine and a Concierge Physician, announces his new concierge office location at 606 9th Street North, Ste. 100, Naples, FL 34102. Phone: 262-6005.

Joseph Stafford, M.D., Internal Medicine, has relocated his practice to Physicians Regional Medical Group at their Bonita Springs location: 24231 Walden Center Drive, Ste. 100, Bonita Springs, FL 34134. Phone: 348-4170.

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CALENDAR OF EVENTS

Register for these events at (239) 435-7727 or info@ccmsonline.org

THURSDAY, SEPTEMBER 6, 2012 "The Future of Health Care in America"

6:00pm-8:30pm

Speaker: Jonathan Fleece, co-author of
"The New Health Age"

Gordon's on the River

475 North Street

Naples, FL 34104

Sponsor: Markham, Norton, Mosteller and Wright

SATURDAY, SEPTEMBER 29TH An Evening in Monte Carlo

6:30pm

A fundraising event to benefit PLAN

Naples Yacht Club

700 14th Avenue S.

Naples, FL 34102

details on page 5

THURSDAY, OCTOBER 11TH 16th Annual GI Symposium – 2.25 Hour CME

5:30pm-9:00pm

Presented by: The Gastroenterology Group of Naples

Kensington Country Club

2700 Pine Ridge Road

Naples, FL 34109

THURSDAY, NOVEMBER 1ST General Membership Meeting

6:00pm-9:00pm

"Contemporary Management of Aortic Aneurysms"

Presented by: Hiranya Rajasinghe M.D.

The Vascular Group of Naples

Kensington Country Club

2700 Pine Ridge Road

Naples, FL 34109

FRIDAY, NOVEMBER 16TH New Members Welcome Cocktail Party

6:30pm-8:30pm

Tiburon Golf Club

2620 Tiburon Drive

Naples, FL 34109

WHAT DO YOU WANT TO KNOW?

Help us make this magazine more valuable!

Send your topic ideas and letters to the editor or e-mail comments
to Dr. Richard Pagliara at rpagliara@hotmail.com.

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Naples, FL 34102
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General Surgery
The Vascular Group of Naples
2450 Goodlette Road N., Ste 102
Naples, FL 34103
643-8794 Fax: 430-7820
Board Certified: General Surgery

IN MEMORIAM

*Richard M. Glasser, M.D.
1960-2012*

It is with great sadness that we announce the passing of Ophthalmologist Dr. Richard Glasser, a CCMS member since 2006. We send our heartfelt condolences to his family and friends.



SUMMER WINE TASTING

CCMS members enjoyed an After 5 social at Ridgway Bar & Grill in July where they enjoyed over a dozen wines. Special thanks to First Citizens Bank for underwriting the great event.

Pictured are: (1) Dr. Michael Gloth & Dr. Lynn Byerly
(2) Dr. Tulay Darstek & her husband Jeremy
(3) Dr. Job Timeny
(4) Dr. Jaime Weaver and Dr. Rebecca Lambert with First Citizens Bank sponsors



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Naples Yacht Club

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MESSAGES FROM YOUR BOARD

SOUND YOUR VOICE

by Rolando Rivera, M.D., President,
Collier County Medical Society



The upcoming elections in November provide an opportunity for every CCMS member and their patients to make a difference in the way healthcare is delivered in our community. It is not withstanding that this opportunity brings with it many complex choices, some of which could gravely affect access to quality medical care because of unjust provider reimbursement. I encourage everyone to participate in the voting process and elect nominees that support fair reimbursement so we are not facing an industry that cannot fulfill its obligations.

HIE UPDATE

by Richard Pagliara, D.O., Vice President, CCMS,
and HIE Committee Chair

A meeting was held on August 15th at the Greater Naples Chamber of Commerce to discuss **health information exchange (HIE)** progress. Attendees included representatives from CCMS, CHP, NCH, PHO, PRHS and local health care. Both hospital systems outlined their processes for choosing HIE vendors, implementation plans, and ultimate connectivity goals.

Naples Community Hospital and Physicians Regional Health System are simultaneously developing separate HIEs. NCH is developing their platform with Cerner, and PRHS with Medcity. PRHS is piloting its HIE in Naples with eventual implementation at sister hospitals nationwide. Both HIE platforms will allow for the broad exchange of patient data, with different abilities and features unique to their systems. Both are planning to first enlist their own physicians and physician groups (October timeframe) and then market to the community at large in the following months. The cost structure was not discussed; however, it was stated that the ultimate physician cost should not prohibit participation.

Representing the interests of our physician members, the HIE committee will strongly encourage and support:

- Both HIEs interface directly at the local level or through an intermediary, such as the FHIN (Florida Health Information Network) at the state level.
- Exchanges be affordable and show real value to physicians, especially those not affiliated with either hospital system.
- Physician and office manager HIE education is imperative during the implementation/enrollment phase. Town hall meetings, hands-on demos, and webinars will be necessary.
- A well-balanced Governance Board to oversee the legal and security aspects of each exchange, creating trust and transparency; necessities for widespread physician enrollment and retention.

Our goal of bringing health information exchange to our community is soon approaching and we welcome this advantage in health care delivery. We will keep you posted.



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THE EFFECTS OF THE HEALTH CARE ACT ON HIGH INCOME INDIVIDUALS

by Karen Mosteller, CPA, CHBC, Markham Norton Mosteller Wright & Co, PA, a CCMS Preferred Vendor

As you are likely well aware, in June of this year, the U.S. Supreme Court upheld the “individual mandate” portion of the Patient Protection and Affordable Care Act, also known as the health care act. In doing so, the act’s provisions continue as scheduled with minimal modifications. To help offset its costs, the act contains several revenue raising provisions, including some tax increases on upper income taxpayers.

One of the key tax provisions of the health care act is a new Medicare surtax on net investment income for individuals, estates, and trusts. It is set to take effect for the 2013 tax year. The surtax is equal to 3.8% of the lesser of “net investment income” or the amount by which a taxpayer’s modified adjusted gross income (AGI) exceeds \$200,000 for single taxpayers and \$250,000 for married taxpayers. The types of **income that comprise net investment income include:** taxable interest, dividends, net capital gains, annuity income, passive royalties, and rents. The surtax does not apply to distributions from qualified retirement plans or IRA’s.

Here are two examples of how this surtax will work. Joe, a single taxpayer has modified AGI of \$250,000 of which \$75,000 is net investment income. The Medicare surtax will be 3.8% of \$50,000, the amount by which his modified AGI exceeds \$200,000. Tom and Mary file jointly and have modified AGI of \$380,000 of which \$115,000 is net investment income. Tom and Mary’s Medicare surtax is 3.8% of \$115,000, the full amount of their net investment income since it is less than the \$130,000 by which their modified AGI exceeds the \$250,000 threshold for married couples filing jointly.

Another key tax provision created by the health care act which takes effect in 2013 is the additional 0.9% Medicare tax on wages that exceed \$200,000 for single taxpayers and \$250,000 for couples filing jointly. Employers will be responsible to collect and remit this tax on wages exceeding \$200,000 without regard to the wages of a married employee’s spouse. Although they are required to withhold this additional tax from employee’s paychecks, the employer portion of the Medicare tax will remain the same. The additional 0.9% tax also applies to self-employment income above \$200,000.

Here is an example of how this would work. William earns \$225,000 at his job, and his wife, Sue, earns \$125,000 at hers. Their combined wages of \$350,000 are \$100,000 over the \$250,000 threshold for couples filing jointly so the amount of wages subject to the 0.9% tax is \$100,000. William’s employer withholds the 0.9% tax on \$25,000 of his wages, the amount in excess of \$200,000. Sue’s employer is not required to withhold the 0.9% tax on her wages since they are under \$200,000. However, William and Sue need to take into account the 0.9% tax on \$100,000 of wages when figuring their estimated taxes to avoid a shortfall on their income tax return.

There were a couple of other tax provisions of the health care act that take effect in 2013 which affect individuals. The first is an increased floor on the medical expense deduction for taxpayers who itemize from 7.5% AGI to 10%. The second is that individuals may only set aside \$2,500 in Flexible Spending Account (FSA) contributions annually via pre-tax cafeteria plans. Previously, employers were able to set their own limits.

Besides these changes, there is also the possibility that the Bush Era tax cuts will be allowed to expire at the end of 2012 for singles making over \$200,000 and couples making over \$250,000. So what can be done to plan for these changes? We highly recommend that you consult with your tax advisor on how these provisions will impact your specific tax situation, but here are a couple of tips to consider:

- Assess whether investment portfolios should be reallocated. It may make sense to shift assets between qualified and nonqualified accounts and rethink asset allocation (i.e., growth vs. income stocks, muni bonds, etc.). These changes would of course only be considered in light of your investment plan with your financial advisor.
- Consider accelerating income and/or deferring expenses based on what transpires at year end with the potential expiration of the Bush Era tax cuts. You may be able save a significant amount of tax if rates jump in 2013, coupled with the new 3.8% Medicare surtax on investment income. In this regard, consider a Roth-IRA conversion or security sales to accelerate gain recognition.

Karen Mosteller is a Certified Public Accountant and a Certified Healthcare Business Consultant. She has been recognized nationally for providing exceptional business solutions for medical practices. She was a presenter for the 2011 MGMA national conference in Las Vegas, where she educated physicians on the risks of employee fraud.

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CHANGING THE PARADIGM IN GERIATRIC CARE

by Mollie Page

If there's one thing Dr. Michael Gloth feels strongly about it's changing society's perception of the aging population.

"We no longer tolerate sexism or racism, so why is ageism still acceptable?" says the new Chief Medical Officer of Moorings Park Healthy Living system.

While working the nightshift as an orderly during college, Dr. Gloth noticed the sleeping patterns of older patients were different than younger patients.

"They'd wake up at 4:30am, just about the time I was losing steam," says Dr. Gloth. "Doctors on duty didn't show up until much later and these people were already starting their day."

Dr. Gloth says those morning hours spent in conversation with patients was a turning point in his life. Convinced he would become a doctor at age 8, the former member of the National Advisory Council on Aging for the National Institutes of Health as appointed by U.S. Secretary of Health Tommy Thompson, who also has 370 published articles and 17 books to his credit, is now focusing his attention on helping the senior population in Naples live much fuller and healthier lives.

Aside from raising four girls and running marathons, Dr. Gloth says he wants to help shift the paradigm that exists in aging from one that focuses on comfort to one that focuses on living.

"There's not much in the way of guidelines for us to follow when managing older patients with multiple diseases. What we know about things like Hemoglobin A1C levels does not apply to a patient over the age of 80," says Dr. Gloth, who adds that even research on the Shingles vaccine stops at age 79.

Set to open in late Spring of 2013, a 37,000 square-foot Healthy Living complex at Moorings Park will help the doctor, who sat on the panel that created the Beers Criteria, a reference addressing the safety of prescribing medications for older adults, forge a new path for better outcomes.

Admittedly, the aging demographic is shifting from patients in the Greatest Generation to Baby Boomers. Dr. Gloth says one major difference between the two is that he spends more time educating Boomer patients on why a certain treatment is not right for them.

"We're looking at a very engaged and health-conscious generation versus a generation that was more apt to not ask questions. This is not at all bad as these Boomer patients are more encouraged to make lifestyle habit changes in order to live better. Couple this with advancements in areas like cardiology or how we

treat osteoporosis, and we'll begin to see a more vital senior population."

The new Healthy Living facility will expand the outpatient clinic to provide more exam rooms and be outfitted with a dedicated rehabilitation suite, spa, and exercise and fitness room where he and a geriatric nurse practitioner with advanced training in geropsychiatry will be able to see more residents beyond the 200 they already serve.

Like most physicians, Dr. Gloth is concerned proposed reductions in Medicare reimbursements for 2013—by a third—will create a real challenge for physicians in Florida.

"It's important to collaborate as much as possible," says Dr. Gloth, who is the former Chair of the Information Technology Committee for the American Geriatric Society and has written extensively on the topic. "Given that we may be reimbursed solely on outcomes means we have to work as a team using the technology in front of us."

And even though he supports local efforts to implement an HIE (he was a collaborator of the HIE system used in Maryland), he fears it may take years to get off the ground in Florida since it's not a state-funded initiative that follows one set of standards.

Regardless, it's clear Dr. Gloth was brought to Naples to make improvements on how older patients are being treated. And participating in geriatric research is already on the radar.

"It's my hope that physicians in Collier County will help me make this paradigm shift. We have an opportunity to build a new set of guidelines and treatment plans for our elderly population that could one day be the foundation used across the nation."

Dr. Gloth encourages fellow members to utilize the current five clinic offices to see residents and hopes to meet more specialists in the coming months.



Dr. Michael Gloth stands beside a large greenhouse filled with orchids that are lovingly tended to by two Moorings Park residents.

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CROs MUST KNOW PATIENT CONSENT REQUIREMENTS

by Jeffrey L. Cohen, Esq., National Healthcare Law Firm

Clinical Research Organizations (CROs) in Florida have to be careful about ensuring compliance with state and federal patient consent requirements. To begin with, let's agree on the following language.

- a. Institutional Review Board ("**IRB**"): Empowered by FDA to oversee trials on human subjects. IRB oversees informed consent process.
- b. "**Investigator**" is person conducting the study. Often a physician but not always.
- c. "**Article**" is the drug, device or other item being tested.
- d. "**Subject**" is the human upon which the test is conducted.

FEDERAL LAW

Federal law contains the following for effective informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the Subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- Description of any reasonably foreseeable risks or discomforts to the Subject.
- A description of any benefits to the Subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the Subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the Subject will be maintained and that notes the possibility that the FDA may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research Subjects' rights, and whom to contact in the event of a research-related injury to the Subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the Subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances under which the Subject's participation may be terminated by the Investigator without regard to the Subject's consent. Non-specific statement that Subject's participation will be terminated for a failure to follow protocols is insufficient if Subject has not been apprised of all protocols.
- Any additional costs to the Subject that may result from participation.
- The consequences, to the Subject's health, of the Subject's decision to withdraw from the research, and procedures for orderly termination of participation by the Subject.
- A statement that significant new findings developed during the course of the research which may relate to the Subject's willingness to continue participation will be provided to the Subject.

Under federal law, informed consent is not required if, before the test is conducted, the Investigator and a physician who is not participating in the trial certify in writing:

- i. Subject is confronted by life-threatening condition necessitating use of the test article; AND
- ii. Informed consent is not possible due to inability to communicate with, or obtain legally effective consent from, the Subject; AND
- iii. There is not enough time to obtain consent from the Subject's legal representative; AND
- iv. There is available no alternative method of approved or generally recognized therapy that provides at least as good of a chance of saving the Subject's life.

If the Investigator feels that all items above are true, but the Investigator does not have time to obtain determination by an independent physician prior to administering the Article, the Investigator can obtain determination by an independent physician within five working days after administering the Article to the Subject. Certifications must be submitted to the IRB within five working days after administering the Article to the Subject.

When informed consent is required, it must be documented by

- A written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form. A "long form" or a "short form" of documentation may be used.
- A written "long form" embodies the elements of informed consent set forth above in section II. This form may be read to the Subject or the Subject's legally authorized representative. The Investigator shall give either the Subject or the representative adequate opportunity to read the form before it is signed.
- A written "short form" states that the elements of informed consent set forth in section II have been presented orally to the Subject or the Subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the Subject or the representative. Only the short form itself is to be signed by the Subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the Subject or the representative in addition to a copy of the short form.

IRB will sometimes waive the requirement that informed consent be documented for some or all Subjects. This waiver only concerns documentation. Informed consent must still be obtained. IRB itself can issue such a waiver if the trial presents a minimal risk of harm, and does not involve any procedures for which written consent customarily would be required in ordinary, non-trial, healthcare delivery, or if emergent circumstances justify such a waiver. If documentation is waived, informed consent must still be obtained verbally.

FLORIDA LAW

Current Florida law does not regulate the clinical trials research process. The investigational drug program and the Florida Drug Technical Review Panel were repealed by the Florida Legislature in 2000. Instead, clinical trials research is regulated entirely by federal law.

That said, clinical trials in Florida are subject to applicable state law, including the Florida Medical Consent Law (Section 766.103) and the health care surrogate provisions (Section 765).

The seminal law in Florida regarding patient consent is Section 766.103, F.S., the Florida Medical Consent Law. It precludes recovery in any court action based on a claim of failure to obtain informed consent, in essence, if:

1. The physician, ARNP or PA obtains the consent “in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community as that of the person treating, examining, or operating on the patient for whom the consent is obtained;” and
2. A reasonable person, based on the information provided above, would have a general understanding of the procedure, medically acceptable alternatives and the substantial risks in the proposed treatment; or
3. The patient would have reasonably undertaken the treatment had the patient been so advised; and
4. The consent is signed by a mentally and physically competent patient or other authorized person.

The failure to meet the above does not violate any law. Rather, meeting the above essentially precludes any successful lawsuit based on the claim that there was a failure to obtain informed consent.

Relatedly, Section 381.026, the Florida Patient’s Bill of Rights and Responsibilities state—**“Every individual has the basic human right to be informed about the medical treatment or procedure that is being proposed to them.”** Under this state law, the key principles that comprise Informed Consent are:

- The proposed Treatment
- The purpose of the treatment to be provided
- The common risks
- Benefits
- Side effects
- The specific dosage range for the medication, when applicable
- Alternative treatment modalities
- The approximate length of care
- The potential effects of stopping treatment
- How treatment will be monitored
- That any consent given for treatment may be revoked orally or in writing before or during the treatment period by the patient or by a person who is legally authorized to make health care decisions on behalf of the patient. (Section 394.459)

CROs have a lot of ground to cover to ensure patients understand the risks and benefits associated with participating in clinical research. They have to be particularly astute regarding not only federal law, but also the law of the state where the research is performed.

Mr. Cohen is board certified by The Florida Bar as a specialist in healthcare law and can be reached at www.floridahealthcarelawfirm.com and also by calling (888) 455-7702.

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MEMBER IN THE NEWS



The June edition of *D'Latinos* Magazine featured a nice cover story on our newly elected president **Rolando Rivera, M.D.**

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3838 Domestic Avenue
Mon.-Fri., 9am-4pm

MARCO ISLAND

Marco Island Police
Drop-Off Box
51 Bald Eagle Drive
Mon.-Fri., 8am-5pm

Marco Island
Recycling Center
(no controlled substances)
990 Chalmers Drive
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O. Villaverde, M.D., CPA

D. Ebaugh, ARNP
M. Gerrity, PA

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MEMBERS GET SOCIAL DURING THE SUMMER

Many CCMS members are taking advantage of the slow summer months by reconnecting with colleagues. Thanks to LeeAnn Kirwin and her team at Florida Community Bank for kindly sponsoring our August 23rd "After 5" event at Flemings Steak House; more than 40 guests enjoyed

networking and catching up with old friends. The very next day, our women physicians group enjoyed lunch at Seasons 52. The group has formed an official committee and is planning the next Womens Health Forum, which will take place on March 9, 2013.



Dr. Allan Weiss, Dr. Charles Montgomery, and Dr. Richard Pagliara at the After 5 at Flemings



Dr. Nena Korunda with Dr. Tami Kuhlman enjoy lunch at Seasons 52

Doris Lim with Dr. Catherine Kowal



Lee Ann Kirwin and Frank Salamone from Florida Community Bank

Dr. Holly Miller, Dr. Michon Floriani with Dr. Caroline Cederquist



Dr. Rebecca Lambert with Dr. Samantha Fisher







Dr. Charina Yango-Cadavos with Dr. Margaret Taha



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FMA DELEGATES ATTEND ANNUAL MEETING IN BOCA RATON

by Margaret Eadington, Executive Director, CCMS

Thank you to our delegation for taking time out of their “free-time” to represent CCMS at the Florida Medical Society Annual Meeting and House of Delegates, at the Boca Raton Resort at the end of July.

Dr. Joseph Gauta chaired the delegation, joined by delegates, Drs. James Talano, Brett Stanaland, Richard Pagliara, Mitchell Zeitler and Rafael Haciski. Drs. Talano, Zeitler and Haciski were appointed to serve on Reference committees, and Dr. Pagliara had the honor to represent CCMS during the Installation of FMA President Dr. Vincent DeGennaro.



Congratulations to Dr. Corey Howard as he continues his second year as Vice Speaker of the House and Chair of the AMA delegation. Also to Dr. Gauta for his appointment to the council on Ethical and Judicial Affairs Board, and to Dr. Talano to the Committee on Accreditation and CME.

(at left) **Your FMA Delegation:** Drs. Joseph Gauta, Richard Pagliara, Rafael Haciski, James Talano, Brett Stanaland, Corey Howard and Mitchell Zeitler.

On the front cover from top to bottom: (1) (l-r) Drs. Gauta, Pagliara, Haciski, Talano, Stanaland, Howard and Zeitler. (2) Dr. Howard officiates as Vice Speaker of the House. Dr. Zeitler (r) served on a reference committee. (3) The CCMS Delegation discusses the day's topics with Vice Speaker Dr. Howard. (4) Drs. Talano, Zeitler and Gauta seated in the House of Delegates.

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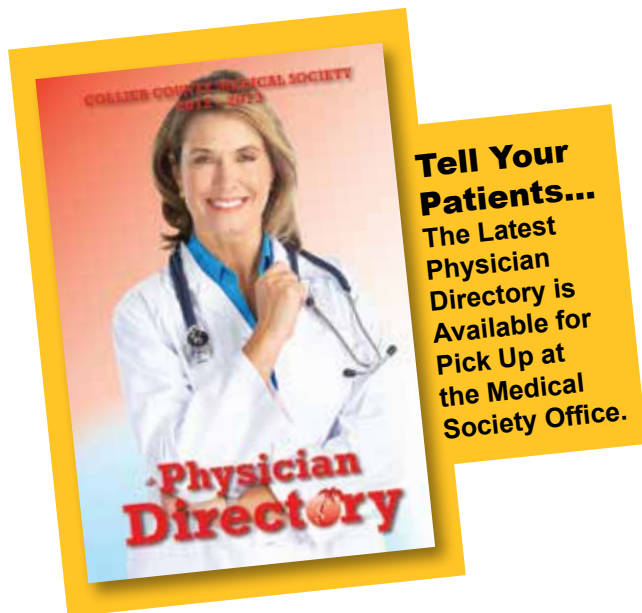
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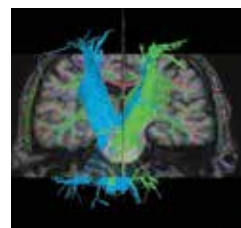
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