



The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) Heralds Passage of Physician Rating Legislation by the Ohio House

HB 122, introduced by Representative Barbara Boyd, Chair of the Ohio House Health Committee (D-9 – Cleveland) has successfully passed in the Ohio House of Representatives, after several months of working with AMCNO leadership and other interested parties including the Ohio Department of Insurance, the Ohio Attorney General, medical organizations, and the health insurance industry.

This legislation — meant to address the issue of physician ratings by insurance companies in Ohio will now move into the Senate for further debate. A companion bill — SB 98, sponsored by Senator Tom Patton (R-24 – North Royalton) is also under review by the Ohio Senate. The AMCNO worked with Senator Patton on the introduction of this

legislation as well and the AMCNO provided proponent testimony on the bill to the Senate Insurance, Commerce and Labor Committee.

Substitute HB 122 unanimously passed the House Health Committee on October 16th with no opposition testimony presented to

the committee. A substitute bill was introduced with the help and involvement of all interested parties. The substitute bill to HB 122 included changes to give the Ohio Department of Insurance rulemaking authority, to extend timelines and appeals, extend the scope of the bill to third party administrators, and have the Ohio Department of Insurance approve the appointment of the independent ratings examiner. It will ensure due process, transparency and accuracy, and accountability. Physician rankings should be based on quality, or quality and cost — but never cost alone.

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AMCNO Signs onto Amicus Brief Asking the Ohio Supreme Court to Block Diversion of Tobacco Funds

At the end of 2009 the 10th District Court overturned a trial judge's ruling from last August that blocked state leaders from liquidating the Ohio Tobacco Use Prevention and Control Endowment Fund. At stake in the litigation was use of money the state received from a settlement with national tobacco product manufacturers. Appellate judges said in their 3-0 opinion that the General Assembly retains its power to legislate with respect to custodial accounts such as the endowment fund unless the accounts have specifically been posted off-limits through a constitutional amendment.

The appellate panel said that while no Ohio court has directly addressed the issue, case law from at least one other jurisdiction confirms that a state legislature cannot create an irrevocable public trust. The General Assembly initially diverted the tobacco money in 2008 for high-tech industrial development as part of a \$1.57 billion state economic stimulus plan. The

money was subsequently earmarked for various health care initiatives in the current Medicaid budget. When state leaders agreed last year to move the money, the tobacco foundation tried to transfer about \$190 million to the American Legacy Foundation, a group that seeks to counter smoking and tobacco use. State officials responded by eliminating the

foundation and moving anti-smoking efforts to the Ohio Department of Health. The 10th District agreed with the trial judge that the contract between American Legacy and the state foundation was not valid or enforceable.

Brief Filed to Block Diversion of Funds

The American Legacy Foundation and other groups have asked the Ohio Supreme Court to block the state's diversion of \$258 million for

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In 2007, the New York Attorney General became active on the issue of insurance company doctor ranking programs. Pursuant to that New York activity, an agreement was reached by physician groups and health insurers to develop national standards that the companies will use to rate physician performance. That agreement protects the rights of health care consumers and has support from various medical groups, insurers and business groups.

Legislation was introduced and passed in Colorado that embraces many of these concepts. At the request of the Academy of Medicine of Cleveland & Northern Ohio, Rep. Boyd had the Colorado legislation drafted and introduced here in Ohio as HB 122. HB 122 provides that no designation or change in designation can be made without notification to the physician. Then, no publication can be made until at least 45 days has passed. That period of time is longer if the physician has indicated a desire to appeal. Once an appeal begins, it must be resolved within 90 days.

The legislation stresses that health plans must use risk-adjusted data, and base grades and

ratings at least in part on nationally recognized quality of care measures and not on cost alone. The legislation also provides physicians with the right to review and appeal their ratings.

"We're very interested in making certain that information regarding physician quality outcomes that are going to be used by patients and businesses is accurate, verifiable and that the process is as transparent as possible," said **Dr. John Bastulli**, Vice President of Legislative Affairs for the AMCNO. "We want to be certain that the public can understand the cost and why it may vary between health-care professionals. That way, those that are using this information can understand what went into the process." (For more information on this legislation see the legislative update on page 8 in this issue.)

Editor's Note: Listen to Dr. John Bastulli, Vice President of Legislative Affairs, discussing HB 122 on the award-winning AMCNO *Healthlines* radio program — go to www.amcnoma.org and click on the Healthlines link to locate the program recording. ■

NORTHERN OHIO PHYSICIAN

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AMCNO Signs onto Amicus Brief Asking the Ohio Supreme Court to Block Diversion of Tobacco Funds

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purposes other than smoking cessation and prevention. The American Legacy Foundation formally asked justices to review the ruling from the 10th District Court of Appeals which upheld the decision of Governor Ted Strickland and the General Assembly to spend the money on Medicaid and other health care programs. Joining the foundation in seeking Supreme Court review were former Attorney General Betty Montgomery, former Senate President Richard Finan, and former Director Nick Baird of the Department of Health. They were instrumental in the creation of the Ohio Tobacco Use Prevention and Control Endowment Fund (OTPF). They told the court that the General Assembly specifically intended it be permanently dedicated to tobacco use prevention and cessation programs. They were also part of a bipartisan committee created in 1999 to determine appropriate use of the \$10 billion Ohio was to receive as a result of a settlement between states and national tobacco product manufacturers.

Also filing a friend of the court brief in support of the American Legacy Foundation were the Academy of Medicine of Cleveland & Northern Ohio, the American Heart Association, the American Heart Association Great Rivers Affiliate, the American Lung

Association, the American Lung Association of Ohio, the American Cancer Society Ohio Division, the American Cancer Society Cancer Action Network, the Ohio State Medical Association, the Association of Ohio Health Commissioners, the Campaign For Tobacco-Free Kids, and the Ohio Public Health Association.

To recap, this action came in response to the New Year's Eve decision of the Ohio Court of Appeals of Franklin County, Tenth Appellate District. In that ruling, the appeals court reversed a lower court's order permanently enjoining the State from dissolving the Tobacco Use Prevention and Control Endowment Fund. The 1998 MSA provided more than \$200 billion to be paid to the states over 26 years in recognition of the lives and money lost to tobacco. To ensure that a substantial portion of its recovery was spent specifically on tobacco control, Ohio established OTPF and created an endowment for it.

Research shows that tobacco takes an enormous toll on Ohio — both in lives lost and dollars spent. Ohio's smoking rate is 20.1 percent, just below the national average of 20.6 percent, thanks in large measure to the work of Ohio Tobacco Prevention Fund.

Smoking costs Ohio more than \$4 billion annually in health care costs and another \$4.7 billion annually in smoking-related productivity loss (in 2004 dollars). A 2007 report by Legacy found that Ohio's Medicaid system could save \$550 million within five years if all Medicaid beneficiaries who smoke, quit. Ohio would reap the third-largest savings of all the states, making the case that despite this economic downturn in Ohio, keeping these funds focused on tobacco control is a wiser long-term investment, ultimately saving Ohioans' lives and money. The AMCNO will keep our members apprised of how this matter is resolved in the future.

Tobacco Advocacy Day In March

AMCNO senior staff and physician leadership will be participating in the Investing in Tobacco Free Youth Advocacy Day at the Ohio Statehouse on Wednesday, March 17th. Advocates from across Ohio will be in attendance at the event to get the word out to legislators that funding for all tobacco prevention in Ohio will end on June 30, 2010 unless something is done. Information on the outcome of this event will be included in the next issue of the Northern Ohio Physician. ■

The Proposed Pathway for Achieving “Meaningful Use” and EHR Stimulus Payments

By Amy S. Leopard, Walter & Haverfield, LLP

Physicians want to know how to qualify for Medicare and Medicaid incentive payments under the American Recovery and Reinvestment Act of 2009 (ARRA) stimulus legislation passed last year. Two new rules set the stage for how the U.S. Department of Health and Human Services (HHS) expects to roll out the eligibility, standards, and requirements for ARRA incentive payments for adopting and meaningfully using electronic health record (EHR) technologies.

On December 30, 2009, the Centers for Medicare and Medicaid Services (CMS) released proposed rules for what constitutes “meaningful use” of EHRs for hospitals and eligible professionals to qualify for extra Medicare and Medicaid payments. At the same time, the HHS Office of the National Coordinator (ONC) for Health Information Technology (Health IT) issued an interim final rule setting forth the initial set of standards and certification criteria that vendors must meet in order to have their EHR technology certified. Together, these rules set the stage for EHR adoption, use and exchange of health information to meet far-reaching federal health policy goals.

Background

Congress included the Health Information Technology for Economic and Clinical Health (HITECH) provisions in ARRA to establish a framework for HHS to regulate Health IT using objectives for healthcare quality, efficiency and patient safety. The stated goal is the adoption and use of EHR to improve healthcare delivery in a transformative way. ARRA requires CMS to make EHR incentive payments to eligible professionals and hospitals who adopt and begin to meaningfully use EHR technology meeting certification standards adopted by ONC.

Providers must demonstrate they are achieving “Meaningful Use” through three core concepts (1) using a certified EHR technology in a meaningful manner, including e-prescribing for physicians; (2) connecting the certified EHR technology to allow for electronic exchange of health information to improve quality and care coordination; and (3) submitting information, in a form and manner specified by HHS, on clinical quality and other measures selected by HHS.

Incentive payments begin as early as 2011 under Medicare Fee-for-Service, Medicare Advantage (MA) and Medicaid, and those

eligible professionals and hospitals who do not establish meaningful use by 2015 face reductions in their Medicare fee schedule. The two new regulations are designed to work together, with the EHR Technology Rule providing a pathway for the technology, closely linked to the Meaningful Use Rule proposing how eligible professionals and hospitals will use it.

Staged Approach

ARRA allows CMS to build up to a more robust definition of Meaningful Use as technology and provider capabilities ramp up over time. CMS has proposed a three-stage approach with the criteria for qualification becoming more stringent as the expectations rise to reduce the gap between today’s reality and the desired state of widespread use of EHR. Both rules contemplate that the state of the art of EHR technology and its adoption will evolve to move providers from the initial stages of capturing and using health information in a structured format to tracking clinical conditions and using health IT for order entry, result reporting and improving quality at the point of care to later stages where interoperability of EHR technology is possible and providers manage high priority conditions and improve population health with decision support.

The EHR Technology Rule

ARRA requires providers to use EHR technology certified by HHS and set December 31, 2009 as the statutory deadline for HHS to adopt an initial set of standards, implementation specifications and certification criteria for EHRs. ONC organized quickly and obtained input on what should constitute certified EHRs and how to address Meaningful Use in a way to advance HITECH health policies. HITECH federal advisory committees and stakeholders helped ONC craft a framework, definitions and timetables for the implementation of these core concepts

in public forums last summer. The initial deliverables focused on four outcome policy priorities and care goals and for the use of EHR technologies: (1) improving quality, safety, and efficiency and reducing health disparities; (2) engaging patients and families in their care; (3) improving care coordination; and (4) improving population and public health.

ONC met the statutory deadline for the initial set of EHR certification standards by publishing an Interim Final Rule. Those standards provide a roadmap for what vendors must do to have their technology certified, either as a complete EHR or as one or more EHR modules. ONC anticipates that vendors will offer a variety of software programs that alone or together with other certified modules will allow providers to assemble the capabilities required under the rule. The minimum standards for an EHR that qualifies for certification is one that (1) includes demographic and medical information such as a history and problem list, and (2) has the capacity to (a) provide clinical decision support, (b) support physician order entry; (c) capture query information relevant to quality; and (d) exchange and integrate health information with and from other sources. What is most important is that the EHR technology not only meet the certification criteria, but actually be certified. The certification process will be addressed in a forthcoming rule.

The Meaningful Use Rule

Medicare and Medicaid are separate and distinct programs with different eligibility requirements for both hospitals and eligible professionals. While hospitals may simultaneously participate in both the Medicare and Medicaid incentive programs, physicians must choose between the two (although that election can be changed once before 2015). This choice is strategic and will need to take into account the differences in eligibility, the different payment amounts, Medicaid volume criteria, and whether the physician has received any support payments (e.g., hospital EHR donations) under the rule as proposed.

Professionals eligible for the Medicare EHR

AMCNO ADVOCACY ACTIVITIES

program are doctors of medicine or osteopathy, dental surgery and medicine, podiatrists, optometrists, and chiropractors participating in Medicare. Under the Medicaid EHR program, physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants who practice predominantly in a federally qualified health center or rural health clinic led by PAs are eligible by meeting certain patient volume criteria. The Medicaid EHR program volume requirements are generally 30% of Medicaid patient encounters, although pediatricians with at least 20% of Medicaid patient encounters would qualify at a reduced level, and a special formula allows professionals who practice predominantly in FQHC and RHCs to meet the 30% threshold by considering needy individuals receiving Medicaid, SCHIP, or services at no cost or reduced cost based on payment ability.

Medicare EHR payments for eligible professions are 75% of Medicare allowable charges up to an annual cap for up to five years beginning in calendar year 2010. This means that eligible professionals can receive a total of up to \$44,000 over a five-year period, including \$18,000 in the first year for early adopters that qualify in calendar year 2011 or 2012. Eligible professionals furnishing more than 50% of Medicare covered services in a health professional shortage area (HPSA) earn an additional 10%.

Medicare carriers would pay out incentive payments in a single lump sum payment once determining that a physician demonstrated meaningful use for that annual period. CMS has proposed that the payments be made to the physician or to a single employer under a valid Medicare reassignment and would not allow physicians to allocate payments among multiple entities. Most hospitals and group practices will want to amend employment and professional contractor agreements to outline who is entitled to receive the payments.

Under the Medicaid EHR incentive program, the amount payable to eligible professionals is set at 85% of "net average allowable costs" capped by statute at \$25,000 for the first year and \$10,000 for five subsequent years. CMS proposes to set average allowable costs at \$54,000 per physician in the first year and \$10,000 per physician in annual maintenance costs for subsequent years. That amount for any particular professional would be reduced for any EHR

Caps on Medicare EHR Incentive Payments (HPSA add 10%)

| Calendar Year | First CY in which Physician receives Incentive Payment | | | | |
|---------------|--|----------|----------|----------|--------|
| | 2011 | 2012 | 2013 | 2014 | 2015 + |
| 2011 | \$18,000 | | | | |
| 2012 | \$12,000 | \$18,000 | | | |
| 2013 | \$8,000 | \$12,000 | \$15,000 | | |
| 2014 | \$4,000 | \$8,000 | \$12,000 | \$12,000 | |
| 2015 | \$2,000 | \$4,000 | \$8,000 | \$8,000 | \$0 |
| 2016 | | \$2,000 | \$4,000 | \$4,000 | \$0 |
| TOTAL | \$44,000 | \$44,000 | \$39,000 | \$24,000 | \$0 |

Medicaid Maximum Incentive Payment Amount for Eligible Professionals

| Net Avg. Allowable Costs, Cap | 85% EP Allowable | 6 yr Max |
|--|------------------|----------|
| \$25,000 in Year 1 for most professionals | \$21,250 | \$63,750 |
| \$10,000 in Years 2-6 for most professionals | \$8,500 | |
| \$16,667 in Year 1 for pediatricians with minimum 20% patient Medicaid volume, but < 30% | \$14,167 | \$42,500 |
| \$6,667 in Years 2-6 for pediatricians with minimum 20% patient Medicaid volume, but < 30% | \$5,667 | |

technology or support service payments received from sources other than state or local governments, so if the eligible professional received more than \$29,000 in the first year or \$10,610 in subsequent years from hospitals or private payors, those subsidies would be backed out. As a result, the maximum Medicaid incentive payment would be \$21,250 in the first payment year and \$8,500 annually in five subsequent years or \$63,750 over a six-year period for most physicians, with pediatricians in the 20-29% Medicaid patient volume corridor receiving one-third less.

Medicaid payments will be made through the states and states must prepare a health information technology plan to receive the CMS match for their EHR incentive programs. Unlike hospitals that are deemed to be meaningful users under Medicaid by meeting the Medicare criteria, eligible professionals seeking Medicaid incentive payments must meet the Medicare "floor" and additional state requirements that CMS approves. CMS would restrict states from adding required functionality to the EHR, but allow states to add additional objectives for eligible professionals and hospitals or measure their achievement in a different way.

Another distinctive provision of the Medicaid incentive program allows eligible professionals and hospitals to qualify for payments before achieving meaningful use during the first year only by adopting, implementing or upgrading EHR technologies. CMS would define this to mean that the EHR technology has at least been installed or use of it has begun, or for upgrades, that the available functionality of the certified EHR technology has been expanded at the practice site, including staffing, maintenance, and training.

The Hospital-based Exclusion

Hospital-based physicians are excluded from both programs. While the ARRA language contains this exclusion, CMS would define the term expansively to include not only pathologists, anesthesiologists and emergency physicians, but any other professional furnishing 90% or more of his or her professional services within a hospital inpatient, outpatient or emergency department setting. CMS proposes to use place of service codes on the professional claim form to determine who becomes ineligible under the 90% test.

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The Proposed Pathway for Achieving “Meaningful Use” and EHR Stimulus Payments

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CMS says it believes that since Medicare already pays hospitals for hospital outpatient and provider-based overhead, including an integrated medical record system, and physicians using these systems should not benefit under the new program. This despite the fact that throughout the Medicare rule, CMS makes clear the basis for incentive payments is not simply purchasing technology but going beyond EHR adoption to actually using it in a manner to support the HITECH health policy priorities. Medicare payments are not designed to be a reimbursement or pass through for software costs, rather incentive payments for using it as set forth in the statute.

While CMS acknowledges that there is an interest in assuring nearly all primary care physicians qualify for EHR incentive payments, it estimates that 27% of physicians would be considered hospital-based under this definition and ineligible for EHR incentive payments. For areas like northeast Ohio with several academic medical centers and integrated health systems, this proposal would have a devastating effect on the number of physicians eligible to participate in the program.

Fortunately, CMS seeks public comment on whether it should use a different method and any associated complexities and implementation issues resulting from including integrated health settings. **The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) is preparing comments on this particular proposal.**

Achieving Meaningful Use for Physicians

Physicians could be eligible for incentive payments as early as January 1, 2011. For the first payment year only, CMS proposes that physicians may demonstrate meaningful use of certified EHR technology over any continuous 90-day period within a calendar year. This flexibility would mean that a physician may begin using certified EHR technology in a meaningful manner as late as October 1, 2011 and still receive an incentive payment for 2011. However, after the first year, the physician would need to demonstrate meaningful use at all times. This requirement could pose challenges for physicians experiencing problems with a vendor keeping up with the EHR

certification standards or desiring to change EHR systems over the three stages of the incentive program. Expect commentators to request that CMS provide for some type of relief for these extraordinary or uncontrollable events. Eligible professionals and hospitals should be working with their vendors to confirm that the vendor can and will pursue certification of the technology under the initial standards and is committed to ramping up over the three stages.

Beginning in Stage 1, eligible professionals must demonstrate that they meet all of the Stage 1 objectives and associated measures. Examples of some of these initial measures for physicians include directly entering orders using CPOE for at least 80% of all orders, maintaining an active problem list in ICD-9 for at least 80% of unique patients, transmitting 75% of all permissible prescriptions electronically, and maintaining at least 80% of all active medications and medication allergies as structured data. Measures for hospitals to demonstrate meaningful use are separate and distinct but achievement obviously impacts or is dependent on physicians. For example, hospitals must demonstrate that 10% of all orders are entered directly by an authorizing provider on the inpatient EHR. In an effort to interface the physician with EHR decision support, CMS proposes that these orders be entered directly by the authorizing practitioner, triggering industry debate over the appropriate use of “scribes” or other members of the clinical team for order entry.

CMS will require substantiation through both data reporting and physician attestations as to the achievement of objectives. Surprisingly, CMS estimates only 9 hours for the physician burden in making these reports. Since many proposed measures require manual tracking and calculation of orders and encounters to compute percentages, one of the early criticisms of the rule has been the administrative burden in collecting and reporting performance.

Another big area of concern for physicians and hospitals is how they are to share health information with patients. Several of the measures address the care goal of patient information sharing and providing patients with health information, sometimes

electronically and sometimes on paper, at least initially. Hospitals and physicians would be required to provide patients an electronic copy of their health information (including diagnostic test results, problem list, medication lists and allergies) on request and within 48 hours at least 80% of the time. In addition, physicians would be required to provide patients with timely electronic access to that same set of health information within 96 hours of it being available to the physician for at least 10% of all unique patients. Hospitals would be required to provide patients with an electronic copy of discharge instructions and procedures at the time of discharge to at least 80% of patients requesting this information. Likewise, physicians would be required to provide clinical summaries for at least 80% of all office visits, although this information could be provided on paper.

There is also concern over the vast scope of the objectives and measures required under the rule. Many provider organizations have expressed concern that an “all or nothing” approach to qualification makes the programs unattractive, especially for those providers who have little or no experience with EHR adoption and are a bit overwhelmed with the breadth and depth of measures involved. Some of the quality measures for physician reporting follow PQRI and are in their infancy in terms of implementation guidance and acceptance by the medical community. Providers are also understandably concerned with making certifications to the government of compliance on technical criteria. Scaling these expectations and providing for the concept of substantial compliance and good faith certifications would help alleviate these concerns.

Comments are due March 15, 2010, and the AMCNO intends to comment on some of these challenging aspects of the rule. CMS does not anticipate publishing a final rule until after the first quarter of 2010, with an effective date 60 days thereafter. Stay tuned for further updates and join us at the AMCNO legal issues seminar in April for further discussion.

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AMCNO Board of Directors Welcomes State Medical Board Executive

Mr. Rick Whitehouse, the Executive Director of the State Medical Board of Ohio was in attendance at the January AMCNO Board meeting to present information about the work of the State Board. Under their Strategic Plan for 2011, the board has outlined three key strategies for furthering the agency's mission of public protection through effective medical regulation. These strategies include:

Strategy One – Culture – Create an Ethics Driven/High Performance Workplace

To accomplish this, the board is working to reshape their workforce specifically in staffing, training and technology. Another part of this strategy is to exhibit greater professionalism and adopt a customer service approach to dealing with stakeholders and others and to promote accountability and increase efficiency.

As a part of this strategy the State Board has been able to reduce its' licensing staff due to technological advances and the ability to streamline the licensure process. Technology has also enabled the board to obtain primary source documents electronically and to provide online licensure renewal.

Strategy Two – Competency – Develop a Holistic Approach to "Effective Medical Regulation" that helps maintain the competency of licensees and prevents adverse outcomes.

A key part of this strategy is for the state board to be proactive in dealing with at-risk licensees in order to protect the public and preserve stakeholder's interests in maintaining or restoring a licensee's ability to practice. Efforts include revamping current quality intervention efforts, developing tools to deal more effectively with minimal standards cases, and analyzing the need for specific areas of remediation. The board plans to provide stakeholders with information that reflects the Board's expectations regarding policies and rules involving professional conduct, minimal standards, best practices, and scope of practice.

Mr. Whitehouse noted that one of the goals of the board is to ensure that persons practicing medicine meet sufficient standards of education, training, competence and ethics. Everyone looks for the rankings of the state medical boards when they are published and the public tends to key in on how many disciplinary actions have been taken by each board during the course of a year; however, that is not all the state medical board does — they do a lot more than renew licenses and dole out disciplinary actions. For example, the board strives to identify someone who may have an issue or problems and provide them

with an educational intervention if warranted, and this is accomplished through the Quality Intervention Program (QIP).



Mr. Richard Whitehouse, Executive Director of the State Medical Board responds to a question from the AMCNO board.

QIP was designed and adopted into law to address quality of care complaints that do not appear to warrant intervention via formal disciplinary action. QIP focuses on cases in which poor practice patterns are beginning to emerge or the licensee has failed to keep up with changes in practice standards. An educational intervention may be all that is needed to bring the licensee up to current standards and practices. With a successful intervention, the licensee benefits by improving practice methods; patients benefit from having a better practitioner available to address their healthcare needs; and the Medical Board protects the public without an adverse impact on the availability of care in the community.

Strategy Three – Collaboration – Engage in partnerships with stakeholders and others in order to leverage available resources and improve healthcare in Ohio.

This strategy is meant to enhance the efforts of the board to instill a sense of ethics and professionalism in licensees and provide information on the Board's expectations as a regulatory body. Another part of this strategy is meant to protect the public by "building a better licensee" through public and private sector partnerships with the legislature,

professional schools, professional associations, media, state agencies, and others.

Medical Student Outreach

Mr. Whitehouse provided information on an educational project of the Board called "Partners in Professionalism." This project aims to promote professionalism and emphasize the ethical responsibilities of medical licensure to medical students. The goal is to educate students in how to avoid problematic behavior or practices, increase awareness of Medical Board functions, increase knowledge of state law and regulations related to medical practice, and enhance the relationship between the Medical Board and licensees. This is done by instilling professionalism and ethics into tomorrow's licensees by incorporating interaction with the Medical Board into the medical school curriculum. To date this project is underway at only one medical school in Ohio — Ohio University College of Osteopathic Medicine (OU-COM) but the Board would like to expand the project to other Ohio medical colleges.

Project activities include an interactive presentation provided by Mr. Whitehouse to the first-year medical students about the responsibilities of the Medical Board and a day spent at the State Medical Board for one of their monthly meetings. Prior to the Board meeting, the students are sent resource materials related to the disciplinary and policy matters on the Board's agenda and a videoconference is held between the State Board staff and the students. Staff members provide an overview of the Board agenda and answer student questions. At the Board meeting the students observe the Board's disciplinary actions and learn about situations involving licensees that result in disciplinary action by the Board. Students also learn about policy matters discussed and established by the Board. Students are provided with the opportunity to talk with the Board members following the meeting as well.

Students are then asked to reflect on their experience and anonymously submit their written comments about their experience to the OU-COM program coordinator to provide a qualitative review of their experience. The relationship continues with additional programs provided by the Board later in the student's academic career — designed to more intensely address impairment concerns, boundary issues, and the licensing process.

Mr. Whitehouse has asked to continue to meet with the AMCNO and our foundation regarding this program and other State Board projects in the future. ■

Legislative Update

By Connor Patton, AMCNO Lobbyist

Statewide Races

This will be a year of big decisions for the state of Ohio: the state will elect a governor, a United States senator, two Supreme Court justices and four other statewide officials. The filing date for candidates to run in the Democrat and Republican parties was February 18th and both parties have finalized who is going to be part of their slate with only two statewide campaigns having a primary.

Supreme Court Races

We have 2 candidates running for Chief Justice in the Ohio Supreme Court (OSC): Current Supreme Court Justice Maureen O'Connor who is the Republican candidate versus Eric Brown who is Probate Court Judge for Franklin County. O'Connor looks to be the stronger candidate having run statewide three times and running protected (she will remain on the court if she loses because her current term has not expired), but Brown is the strongest ballot name in Ohio history and will certainly have a lot of support because this position will control the court. Two other Supreme Court seats are also up with current Supreme Court Justice Judith Lanzinger running against Mary Jane Trapp who is the presiding judge for the 11th District Court of Appeals and the only Democrat statewide that is running from Northern Ohio. Current Supreme Court Justice Paul Pfeiffer is running unopposed. The AMCNO will be very active in the OSC races. Watch for more information in our publications, emails, and on our website.

Executive Branch Races

At the Executive level there is a lot at stake. First and foremost, the apportionment board, comprised of the Governor, Auditor, Secretary of State, and a member of the majority and minority party of the General Assembly, is an issue. The apportionment board is charged with drawing the House and Senate districts for the Ohio General Assembly and the party that has control usually is the predominant party for the next 10 years. In the Governor's race, Governor Ted Strickland chose as his running mate Yvette McGee Brown, a former Franklin County Juvenile Court Judge and current Vice President at Nationwide Children's Hospital. Governor Strickland has a war chest of \$6 million and will look to keep the office from opponent John Kasich who is not far

behind him with \$5 million raised. Kasich chose Mary Taylor, the current State Auditor, as his running mate. This move leaves the Auditor's office vulnerable and likely for a Democrat pick up as Hamilton County Commissioner David Pepper has been working hard and raising money. Pepper also has an advantage because the Taylor move created a primary for two GOP candidates that have raised little money and little statewide name recognition.

The Secretary of State's race also has a primary for the GOP with Jon Husted and Sandra O'Brien. O'Brien won the GOP primary for State Treasurer in 2006 and is the current Ashtabula County Auditor. The Democrats have chosen Franklin County Clerk of Courts Mary Ellen O'Shaughnessy as their candidate. O'Shaughnessy has been an active elected official in Columbus for over 10 years.

In the other statewide races we have Richard Cordray running for re-election to the Attorney General's Office against former United States Senator Mike DeWine. This will be an interesting race as both candidates will have strong financial backing and Cordray has done an effective job as AG. In the Treasurer's race Rep. Josh Mandel will look to upend current Treasurer Kevin Boyce. This race will be youth versus experience and will probably not get a lot of attention as the media focus will be on the higher profile races. One thing is for certain that the message will be on the economy which is the key issue shaping the voters mood. November 3rd is not that far off and a lot of what is happening at the federal level will certainly influence voters as well.

Legislative Activities

Sub HB 122 and SB 98

On the legislative side AMCNO has made great strides in being out in front of the legislature on the "Physician Ranking" issue which is HB 122 and SB 98. With the support of State Representative Barbara Boyd of Cleveland Hts. and Speaker of the House Armond Budish of Beachwood, AMCNO successfully lobbied the Ohio House of Representatives for passage of HB 122. HB 122 is balancing the rights of physicians to have accurate and relevant reporting of their practice and the desire of health insurers and consumers to have access to information about their treating physician. HB 122 passed

out of the Ohio House of Representatives on February 3rd with nearly a unanimous margin by a 97-1 vote. A lot of advocacy work was undertaken on behalf of AMCNO.

The physician ranking issue was introduced by the AMCNO in the former General Assembly and had only one hearing. AMCNO has been successful in introducing bills in both chambers of the Ohio General Assembly and has achieved passage in one chamber. The effort involved holding numerous stakeholder meetings with the Ohio Attorney General Richard Cordray, Governor Ted Strickland's Office, the Director's Office of the Ohio Department of Insurance, the Ohio State Medical Board, the Ohio Association of Health Plans, State Representative Barbara Boyd, Speaker of the House Armond Budish, and both Republican and Democrat members of the Ohio House of Representatives. Barbara Boyd viewed the bill as a common sense issue that would ensure transparency, due process, and fairness and deemed it necessary if insurance companies were going to use these practices. HB 122 passed out of the House Health Committee unanimously in October. It is not often that legislation moves along in the process with such support and acceptance. Also, with the partisan gridlock that has been occurring during this General Assembly this is quite an accomplishment. Speaker Budish and Rep. Boyd deserve our gratitude for their efforts with this issue.

The focus will now turn to the Ohio Senate where State Senator Tom Patton of Strongsville has held two hearings on his bill SB 98 and will either try to move his legislation or carry Barbara Boyd's bill HB 122. Once a bill is chosen as the vehicle for this issue, it should look to pass out of the General Assembly and make it to Governor Strickland's desk and signed into law.

House Bill 361

On April 7, 2005, Ohio's legal climate changed significantly when SB 80, a new tort reform law, became effective. This comprehensive piece of legislation made significant reforms to our legal system and ensures that both plaintiffs and defendants are treated fairly in the courts.

HB 361 sponsored by State Representative Dennis Murray and currently under review in the Ohio legislature would reverse the effect of a key provision of SB 80 related to the accuracy of evidence presented to a jury.

The Academy of Medicine of Cleveland & Northern Ohio has sent a letter of strong opposition on HB 361 to the sponsor of

LEGISLATIVE ACTIVITIES

the bill, the committee chairman and the members of the committee reviewing the legislation.

The letter notes that the AMCNO membership has an interest in the fair and forthright computation of damages, and in ensuring that jury awards are based on actual damages incurred, not on hypothetical or inflated "damages." Physicians, including those in the Northern Ohio community, are often litigants in a wide variety of civil litigation. Additionally, physicians play a critical role in the outcome of other litigation, even when they are neither plaintiffs nor defendants, but rather are serving as expert witnesses or testifying as treating physicians. Physicians are also directly involved by way of providing medical treatment for injuries sustained and by way of negotiating payments with health care insurers.

Under HB 361 any original billed charges for medical treatment would be presumed to be the reasonable value of those services. Furthermore, evidence of any reductions or waivers of those fees would not be admissible in court. In our opinion, this bill would perpetuate a misconception in jury trials — by preventing the jury from hearing that huge amounts of medical bills were written off or written down by doctors and hospitals, pursuant to pre-negotiated agreements. If an injured party receives the full amount billed rather than the actual amount paid, he/she would receive a windfall. The effect of HB 361 would result in economic damages awards in personal injury and wrongful death cases based upon billed medical charges that no party is obligated to pay, thereby allowing plaintiffs' attorneys and their clients to profit, based on false damages.

This bill could also have an effect on tort reform caps because these caps are calculated, in many cases, as a multiplier of the "economic damages" — which includes the amount of medical bills. Ohio Revised Code section 2315.18 limits the amount of non-economic damages in most tort cases to the greater of \$250,000 or three times the amount of economic damages up to \$350,000 per plaintiff and \$500,000 per occurrence. Thus, not only does HB 361 provide for windfall economic damages, it would also create higher non-economic damages due to falsely exaggerated economic damages.

In the *Robinson v. Bates* decision (112 Ohio St.3d 17, 2006-Ohio-6362) the Ohio

Supreme Court recognized that "because no one pays the write-off, it cannot possibly constitute payment of any benefit from a collateral source." According to the Court, both the original medical bill and the amount accepted as full payment are admissible to prove the reasonable value of the medical treatment. The Robinson court recognized that:

[B]ecause different insurance arrangements exist, the fairest approach is to make the defendant liable for the reasonable value of plaintiff's medical treatment. Due to the realities of today's insurance and reimbursement system, in any given case, that determination is not necessarily the amount of the original bill or the amount paid."

Also, under the present system set up by Robinson although the plaintiff's medical bills are admissible *prima facie* evidence of the reasonable value of charges for medical services, they can be rebutted by the defendant. This allows juries to review all of the information submitted as evidence of medical damages. HB 361 would prohibit juries from considering all of the relevant evidence when making a decision on damages, which would ultimately negatively impact defendants and case outcomes.

The AMCNO believes that because HB 361 would limit the evidence of medical damages in personal injury and wrongful death cases to only the amount of the original pre-write-off medical bill, it would allow plaintiff lawyers to provide inaccurate information to juries which would ultimately impact their determination of damages. The AMCNO believes that HB 361 would create a windfall for plaintiffs and would result in higher medical liability costs for physicians because plaintiffs could recover for costs that are higher than those that they actually incurred.

The AMCNO has been at the forefront in opposition to this issue by joining the Ohio Association of Civil Justice which was formed to oppose these kinds of issues and also by submitting an amicus brief now before the Ohio Supreme Court (see *Northern Ohio Physician* Jan/Feb 2010).

The AMCNO has a comprehensive tracking system of all health care related legislation in the General Assembly. If you are interested in receiving a copy of this document, please contact Elayne Biddlestone at (216) 520-1000. ■

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OHIP Receives Funding for Statewide Health Information Exchange (HIE) and Regional Extension Center (REC) Projects

The Ohio Health Information Partnership (OHIP), the state designated entity for health information exchange development, is pleased to announce more than \$50 million in funding to help make electronic health records more widely available in Ohio.

OHIP was awarded \$43.3 million as part of the HITECH provisions in the American Recovery and Reinvestment Act (ARRA) of 2009. The state's 2010-11 biennial budget also allocates \$8 million, in non-GRF funds, to the Ohio Department of Insurance to support efforts in health information technology (HIT). The AMCNO submitted a letter of strong support for the funding of the OHIP project.

More than one-third of the federal funds, \$14.8 million, will go toward development of a statewide health information exchange to allow for the sharing of electronic health records between authorized healthcare facilities and health care providers. In addition, \$28.5 million of these funds are designated to help with the creation of regional extension centers (REC), which will support hospitals and

health care providers in their adoption of electronic health records.

HealthBridge, a not-for-profit health information organization serving Greater Cincinnati and surrounding areas, has also been awarded a \$9.7 million Regional Extension Center grant from the federal government to serve a tri-state region, including portions of southern Ohio, northern Kentucky and southern Indiana.

In September 2009, Governor Strickland designated the OHIP as the non-profit entity that will lead the implementation and support of health IT throughout Ohio. OHIP subsequently applied for two HITECH grants — one to create a statewide HIE and the other for regional extension center development. OHIP will focus on working with healthcare providers to

lower the cost of acquiring and implementing electronic health records. Additionally, OHIP will assist providers in identifying qualified vendors to ensure electronic health records are properly integrated into the health care provider's individual environment.

The initial OHIP board includes representation from BioOhio, state medical associations, the state hospital association and state government. The partnership is expanding its board to include representation from health care payers, the business community, behavioral health providers, community health centers and consumers. **Dr. Lawrence Kent**, AMCNO board member, has been appointed to serve on the OHIP Health Information Exchange Committee. Other OHIP committees are being formed and the AMCNO will continue to keep our members apprised on the work of OHIP as this initiative moves forward. More information is available at <http://www.ohiponline.org>. ■

PalmettoGBA Comments on Comprehensive Error Rate Testing (CERT)

In recent months, Palmetto GBA has seen an escalating number of errors assessed by the Comprehensive Error Rate Testing (CERT) Review Contractor due to signature problems with practitioners' medical records, x-ray reports and laboratory/radiology orders.

The discovery of CERT errors may lead to increased scrutiny of future services billed to Medicare by the individual provider and/or the specialty practice that incurs the errors. To reduce the signature problems, PalmettoGBA plans to provide quarterly updates containing information on unacceptable documentation/signature issues, what is needed to resolve these issues, and suggestions on ways to share this information and improve claims submission/ documentation requirements.

Basically, The Centers for Medicare & Medicaid Services (CMS) has long-standing published requirements that a legible, valid signature (identifier) must be present on all substantiating documentation for claims

billed to Medicare. Palmetto GBA examined numerous examples of CERT signature denials and found in almost every instance, the basic documentation was acceptable. However, services that were denied due to one of four "not acceptable" signature reasons included:

- Illegible, unrecognizable handwritten signatures or initials
- Unsigned "typewritten" progress notes with a typed name only
- Unverified or unauthorized electronic signatures
- No indication of the rendering physician/practitioner

PalmettoGBA is sure that this current challenge is fixable and once achieved will prevent the delay in payments caused from claims being denied because documentation is not present to support payment. Important elements to remember:

- Be sure a handwritten signature is a mark or sign by an individual on a document to signify knowledge, approval, acceptance or obligation.
- Records should clearly indicate they have been "electronically signed by" and include a date/time. We strongly suggest adding verbiage to this effect for clarification and establishing a protocol to ensure valid signatures, are affixed to every order, record, or report within a reasonable time frame, i.e., customarily 48-72 hours after the encounter-but certainly before the claim is submitted to Medicare for payment consideration. ■

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AMCNO Member Discusses Diabetes Prevention with Seniors at Tri-C

AMCNO member **Karen Horowitz, MD**, of University Hospitals Case Medical Center spoke to participants in the Encore program at Cuyahoga Community College's Eastern campus at an AMCNO Speakers Bureau engagement this winter. Encore offers area seniors unique life enrichment opportunities for learning and Dr. Horowitz's talk about "Diabetes: Delaying Onset and Preventing Complications" earned high marks among audience members.

In her talk, Dr. Horowitz got back to basics by explaining how carbohydrates in foods are turned into glucose, the making of insulin and its role in allowing glucose to enter the body's cells to be used as fuel, and the difference between Diabetes Types 1 and 2. The audience learned about the risk factors for diabetes such as age, family history, hypertension, and obesity, and then went through a self-assessment screening exercise where they assigned points for applicable conditions/answers to a series of six questions.

According to Dr. Horowitz, the goal of treating diabetes is prevention of complications and she stressed to the audience that prevention works. Those

who have a prediabetes condition can delay or even prevent the onset of diabetes through diet and weight loss, exercise and sometimes medication. Dr. Horowitz explained that small changes can make a big difference and a weight loss of only 5-10 percent of one's body weight along with exercise of moderate activity for 30 minutes, five days a week is enough to make a notable difference.

Dr. Horowitz also noted that there were positive steps that those diagnosed with diabetes within the last 10 years can take to decrease some of the serious side effects. These include decreasing the chances of kidney failure, blindness and nerve damage by up to 66 percent through diabetes treatment and also the



Dr. Karen Horowitz greets a participant at the Tri-C Encore program.

10-year risk of heart attack by 25 percent through control of blood glucose levels. Dr. Horowitz reinforced that it is not too late to slow the progression of complications for those having diabetes longer than 10 years by treating the risk factors such as lowering glucose levels and cited the actions needed to attain excellent glucose levels.

Finally treatment for hypoglycemia, hypertension and hyperlipidemia was shared as well as goals for acceptable cholesterol levels. Dr. Horowitz left her audience with a final thought that diabetes management and prevention is about taking care of yourself and suggested they honestly consider what they are or are not doing right, what has or has not helped them succeed and what needs improvement. She encouraged audience members to seek the help of their doctor if needed to set individual goals for their diabetes management. After the formal presentation, Dr. Horowitz answered questions from the group.

The AMCNO wishes to thank Dr. Horowitz for committing her time to provide valuable information to this group. The AMCNO Speakers Bureau receives ongoing requests for speakers from organizations in our area. Anyone interested in participating in this worthwhile program should contact Debbie Blonski at (216) 520-1000 ext. 102. ■

A photograph of a female doctor in a white lab coat, smiling, holding a blue folder. She is standing in a clinical setting. The text "THE STRENGTH TO HEAL and protect the health of those who protect our country." is overlaid on the image.

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ARMY STRONG:

The Vulnerable Plaque and its Role in Coronary Artery Disease

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Although cardiovascular disease mortality has decreased over the past few decades, it remains the leading cause of death in the United States. Coronary artery atherosclerosis is the most common manifestation found in cardiovascular disease, with acute coronary syndrome as the most common complication.

Initially, coronary atherosclerosis begins as asymptomatic, non-occlusive plaques that progress to symptomatic, occlusive disease often related to atherothrombosis. Plaques prone to developing acute thrombosis are designated as vulnerable plaques. Although challenging, identifying patients with vulnerable plaques and localizing such plaques can offer an opportunity to target treatment in these patients and prevent acute myocardial infarction.

Vulnerable plaques are defined as non-obstructive silent coronary lesions which suddenly become obstructive and symptomatic. Several studies have estimated the incidence of vulnerable plaques to range from 11% to 22%, with 68% of these lesions presenting as acute coronary syndrome¹. Furthermore, studies have shown that the culprit lesion before myocardial infarction has usually less than 50% luminal narrowing on the angiogram². These plaques are typically comprised of a thin fibrous cap, form thrombus when disrupted or sustain a fissure, and are referred to as a thin-capped fibroatheroma. Less common are plaques that undergo erosion, with thrombus overlying an area of plaque with missing layer of endothelium. This particular type of plaque is more common in women less than 50 years of age¹.

Vulnerable plaques are comprised of inflammatory cells such as macrophages, T-cells, and neutrophils. Macrophages ingest modified LDL and transform into foam cells, thereby releasing inflammatory cytokines and proteases that induce fibrous cap thinning. Lipid-loaded foam cells eventually die, resulting in growth of the necrotic core⁴. Plaques with a thin fibrous cap containing a large lipid pool of cholesterol-rich necrotic core and plaques with greater than 50% necrotic core are at increased risk of rupture and thrombus formation. Within the necrotic core, macrophages secrete

Tissue Factor, and T-cells secrete enzymes such as plasminogen activators and matrix metalloproteinases (MMPs) which weaken the thin fibrous cap, predisposing it to rupture. Inflammatory changes within the plaque are a key characteristic of vulnerable plaques. These plaques are eccentric, undergo positive remodeling, and contain increased neovascularization via the vasa vasorum¹. Additionally, extravasation of RBCs into the plaque leads to intraplaque hemorrhage, causing oxidative tissue damage.

Currently, several diagnostic modalities have been developed to identify and evaluate vulnerable plaques. These include measuring inflammatory biomarkers, noninvasive imaging such as cardiac computed tomography (CT), invasive and noninvasive magnetic resonance imaging (MRI), intravascular ultrasound (IVUS), virtual histology (IVUS-VH), and ocular coherence tomography (OCT). Some of these modalities are under investigation and may soon play an important role in evaluation of patients with coronary artery disease.

Several inflammatory biomarkers are being evaluated as surrogate markers for presence of vulnerable plaques. Of note, high-sensitivity C-reactive protein (hs-CRP) and matrix metalloproteinase 9 (MMP-9) appear to be important biomarkers. MMP-9 is found in the macrophages and smooth muscle cells covering the shoulder region of atherosclerotic plaque. Studies have noted higher levels of MMP-9 in patients with ruptured plaques. High-sensitivity CRP is a very sensitive, although nonspecific, marker of inflammation. CRP levels are considered to reflect the severity and progression of the atherosclerotic process in the vessel and may constitute an independent risk factor for cardiovascular disease^{2,3}. Circulating inflammatory biomarkers provide valuable diagnostic and prognostic information, but do not provide any information regarding anatomic localization of the vulnerable plaque⁴.

IVUS is an invasive diagnostic tool utilized for assessing cross-sectional and linear imaging of atherosclerotic plaques in patients. It is useful in identifying hemodynamically significant lesions as well as assessing for proper apposition of stent struts after deployment. Furthermore, IVUS can be used to assess degree of calcification, plaque density, and arterial remodeling. Currently, IVUS with capability of measuring flow within the plaque to assess for neovascularization is under development¹. IVUS-VH is another form of imaging modality currently undergoing studies to further evaluate and characterize thin fibrous cap atheroma as well as the necrotic core. This imaging modality utilizes backscattered radiofrequency (RF) data from IVUS to generate a virtual histologic cross section of the plaque and evaluate for fibrotic tissue, fibrofatty tissue, calcific-necrotic core, and calcium. Recent trial utilizing IVUS-VH identified plaques with virtual histologic features that predict higher risk of coronary events. More trials are needed to establish diagnostic utility of this imaging modality and as well as correlation with adverse coronary events.

Cardiac CT allows for high-spatial resolution of the entire coronary arterial tree in a short period of time. The main drawback of CT is exposure to X-ray and iodinated contrast agents. With use of contrast agents and Hounsfield units, it is possible to characterize plaques and its components based on X-ray attenuation. At present time, CT is not selective for vulnerable plaques; however, macrophage-selective contrast agents are under development to improve identification of such plaques utilizing CT⁴.

MRI is useful for three-dimensional assessment of vascular structures and can assist in evaluation of various composition of the vulnerable plaques. MRI differentiates plaque components on the basis of chemical composition, water content, physical state, and molecular motion or diffusion⁵. At present, the ability of noninvasive MRI in the detection of vulnerable plaque is limited by multiple obstacles such as coronary artery and respiratory motion artifacts, small size of the plaque, and its central location. Intravascular MRI improves resolution and, therefore, characterization of coronary plaques compared to conventional MRI. Currently, MRI cannot quantify arterial remodeling; however, when combined with molecular imaging, intravascular MRI can image macrophages using multiple pathways.

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The Vulnerable Plaque and its Role in Coronary Artery Disease

(Continued from page 13)

Studies are ongoing regarding assessing degree of neovascularization as well as intraplaque hemorrhage using intravascular MRI. Another major drawback of MRI is the relatively long acquisition times to provide high-resolution images⁵.

OCT is an invasive imaging modality that utilizes back-reflected infrared light and provides the highest resolution of all invasive modalities. The major drawback to OCT is the need to displace blood in the vessel with saline flush, making this technique difficult in the evaluation of long segments. Due to excellent resolution of OCT, it can identify plaques with thin cap fibrous atheroma; however, necrotic core is poorly delineated with respect to surrounding tissue. Additionally, OCT can identify macrophages but lacks capability to assess for arterial remodeling due to limited penetration. Another promising utility of OCT is the capability to identify neovascularization in atherosclerotic plaques. Studies are lacking in this arena, though current studies are underway^{1,2,5}.

Currently, OCT is approved for use in Europe but still lacks FDA approval in United States. Several laboratories across the country are involved with studies evaluating usefulness of OCT in assessing and characterizing coronary plaques as well as apposition of stent struts after deployment. The Core Lab at the Harrington-McLaughlin Heart and Vascular Institute based at University Hospitals-Case Medical Center is the only FDA-approved laboratory at present and is heavily involved in research and development of OCT. It is anticipated that OCT will gain FDA approval in the next several months for routine use in clinical settings.

Among imaging modalities, CT and MRI hold promise given they are non-invasive studies. MRI provides excellent soft tissue contrast and an improved contrast resolution, though CT allows much shorter scanning times. IVUS-VH and OCT are invasive but offer excellent spatial resolution. The combinations of anatomical and biological imaging using hybrid techniques such as PET-CT or PET-MRI also appear to be useful. Utilizing imaging modalities that can measure inflammation offer the greatest promise to identify unstable plaques by providing

information on macrophages, adhesion molecules, proteases, and other matrix components⁴.

Systemic pharmacologic treatment is currently the mainstay therapy for management of coronary atherosclerosis and plaque stabilization. Aggressive statin therapy has been demonstrated to improve the lipid profile and decrease coronary syndromes. In addition to statins, adding angiotensin converting enzyme inhibitors, beta-blockers, and aspirin have significantly reduced acute coronary events; however, there is a still 22% recurrent event rate within two years after initial presentation. Even combined systemic medical therapy does not completely prevent plaque rupture, thrombosis, and myocardial infarction. Other forms of therapy are being evaluated in the form of regional and local therapy. Photodynamic therapy (PDT), endoluminal phototherapy, and cryotherapy are forms of regional therapy, of which PDT has gained the most attention. PDT is used most commonly in cancer treatment, involves photosensitizing (light-sensitive) drugs, light, and tissue oxygen to treat targeted diseases. Activation of the photosensitizer within tissue induces the production of free radicals, causing cell death via cytotoxic effects¹. Laboratory studies involving animal models have shown reduction in plaque size after treatment with PDT. Endoluminal phototherapy and cryotherapy are newer investigational techniques that are currently under development.

Coronary stents have been utilized as a form of local therapy, typically treating significant stenosis as well as ruptured plaques. However, it is possible that angioplasty and stents could play a role in treating plaques without significant stenosis in advance if vulnerable plaques could be identified. There are ongoing studies in animal models exploring this concept. Indeed, further studies are needed to adequately assess risk versus benefit in prophylactically treating vulnerable plaques with coronary stents. Nevertheless, atherosclerosis involves the entire coronary tree, and, by treating only one or two specific plaques with stents, may not be sufficient in eliminating future risks of acute coronary syndrome.

Diagnosis of coronary atherosclerosis, identification of vulnerable plaques via imaging and its treatment to prevent acute coronary syndrome continue to pose challenges to clinicians. It is unclear to what degree do vulnerable plaques have necrotic core, how thin the fibrous cap should be, or how much inflammation should be present to label it as high risk. Furthermore, the most vulnerable of plaques might be those that are already disrupted, with only small amounts of thrombus formation, yet are not clinically symptomatic. Characterizing vulnerable plaques with newer imaging modalities such as IVUS-VH and OCT, and treating invasively and noninvasively with novel agents will add to the armamentarium for diagnosis and management of coronary artery disease. With new methods and therapies being developed as well as current and future trials, more data will be available to hopefully shed light on prevention and management of patients with such widespread and devastating disease.

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Editor's note: The AMCNO welcomes article submissions from our members. The Northern Ohio Physician does not obtain medical reviews on articles submitted for publication.

AMCNO members interested in submitting an article for publication in the magazine may contact Ms. Debbie Blonski at the AMCNO offices at (216) 520-1000, ext. 102. ■

Retention by Providers of Overpayments by Medicare or Medicaid Now Constitutes A Violation of the Federal False Claims Act

John T. Mulligan

Physicians and health care providers throughout the country will shortly feel (and in many cases have already begun to feel) the effects of what has been referred to as a “game changer” and “gathering storm” of important recent federal fraud and abuse related developments. The primary components of this include:

- (1) Statements by various federal officials that the enforcement of fraud and abuse laws will be a high priority, and that the recovery of overpayments is viewed as a revenue source to help offset budget deficits;
- (2) Changes to the Federal False Claim Act made as part of the Fraud Enforcement and Recovery Act of 2009; and
- (3) The commencement of activities by Recovery Audit Contractors (“RAC”).

This article will focus primarily on the changes to the Federal False Claims Act, its implications for physician practices, and what physician practices should do to prevent problems.

1. Background.

The Fraud Enforcement and Recovery Act of 2009 (“FERA”) made significant changes to the Federal False Claims Act. Under FERA, it is illegal if the recipient of Medicare or Medicaid payments “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” An “obligation” is now defined to include, among other things, “the retention of an overpayment.” In terms of practical effect, FERA requires the refunds of Medicare or Medicaid overpayments because the knowing retention of an overpayment itself constitutes a false claim.

The terms “knowing” and “knowingly” mean that a person, with respect to information:

- “has actual knowledge of the information”; or
- “acts in deliberate ignorance of the truth or falsity of the information”; or
- “acts in reckless disregard of the truth or falsity of the information.”

No proof of specific intent to defraud is required.

There are certainly many situations in which the existence of an overpayment is clear, such as those involving routine billing errors. However, there are a host of situations that are less clear, and that will give rise to questions as to whether the “knowing” or “knowingly” standards are met. For example:

- (a) What if the practice conducts an internal self-audit and in reviewing a chart for a particular patient finds that certain of the notes necessary to support a particular billing are indecipherable?
- (b) What if the practice reviews a chart and discovers that the documentation fails to include an element that would justify billing at a particular code level, for example, in the case of a consult, where there is no documentation of the request for the consult?
- (c) What if a self-audit reveals (or it is simply “generally known” within the practice) that a particular physician uses a particular code at a frequency substantially higher than any other physician in the practice or sees an unusually high number of patients?

Concern has been expressed that many of the provisions of FERA are not sufficiently clear. It will likely take the development of case law to provide clearer guidance in certain areas. In addition there may be further legislative developments, or announcements by the federal government of how it will interpret various FERA provisions.

2. Risks to Physicians and Physician Groups.

The situations mentioned above have always presented issues for physician groups. That these situations give rise to possible False Claims Act violations increases the financial risk to physician practices. False Claims Act violations can result in criminal prosecution. Civil False Claims Act violations can also result in civil penalties, including treble damages, plus the civil penalty of \$5,000 – \$10,000 per claim. Simply put, a False Claims Act violation could have devastating results for a physician practice.

Significantly, liability under the False Claims Act extends to anyone who “conspires” to commit a violation. This raises the possibility of joint and several liability under which a group physician (or even a non-physician employee of the group) who was not directly involved in the false claim involving an overpayment could nonetheless be held personally liable if he or she had “knowledge” of it and failed to take steps to refund it. Exactly how government enforcement agencies or courts will interpret or apply this “conspiracy” liability in the context of the retention of overpayments remains to be seen.

Heightening the risk is the fact that a False Claims Act issue can arise not only through some form of payor audit, but also through a Qui Tam action brought by a person having knowledge of the false claim. A classic Qui Tam action is one brought by a disgruntled employee (particularly a disgruntled former employee) – a whistleblower. Compounding the problem is the fact that years may pass before the practice even becomes aware that a Qui Tam action had been filed.

False Claims Act violations can arise not only in the context of such things as documentation or upcoding problems, but can also arise due to a violation of the Stark law. Essentially, it is a false claim to submit a Medicare billing for services associated with a situation that gives rise to a Stark violation.

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Retention by Providers of Overpayments by Medicare or Medicaid Now Constitutes A Violation of the Federal False Claims Act

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3. Fostering a Culture of Compliance.

The best way to deal with these potential problems is to make sure that the false claim does not occur in the first place. To do this, practices must foster a culture of compliance in which every member of the practice's workforce (physicians and non-physicians alike) is sensitive to the need for compliance with all legal requirements, and is committed to making certain that problems are dealt with in a prompt and appropriate manner.

A critical component of a culture of compliance is a written compliance plan. While there is currently no federal mandate that providers maintain a written compliance plan, such requirements are contained in some of the health care reform proposals being debated in Washington. Many commentators believe that within the next year there will be a federal mandate for the adoption of a written compliance plan by any provider who provides services to Medicare or Medicaid beneficiaries.

While it is not the purpose of this article to identify all the specific elements of a written compliance plan, the following should be included:

- It needs to be in written form, and made available to all workforce personnel.

- All workforce personnel should be required to review the compliance plan at the commencement of employment, and certify in writing that they have read it and will comply with it.
- A Code of Conduct should be drafted and signed by each member of the workforce pursuant to which the workforce member commits himself or herself to abide by the compliance plan and support a culture of compliance within the practice.
- A high level member of the practice should be appointed as the compliance officer. In larger practices, there should be a compliance committee.
- Reporting mechanisms should be put in place under which workforce personnel can report instances of perceived noncompliance without fear of retaliation.
- All reports of compliance related issues should be fully investigated and written reports prepared.
- Regular training for all workforce personnel on compliance related matters should be provided.
- The compliance officer or compliance committee should, on at least an annual basis, make a written report to the practice's governing body (e.g., board of directors) with regard to what has occurred during the year and plans for compliance related activities during the upcoming year.
- Periodic self-audits should be conducted utilizing the services of a qualified consultant to identify problems or weaknesses.

It's Time For Your Portfolio Check-Up

In light of the recent market volatility, it may be a good time to let a professional review your current portfolio(s) and offer a second opinion. A professional opinion will offer you ideas on how to reallocate some of your portfolio and allow you to consider the addition of alternative investments to help remove some of the portfolio volatility. Second opinions are always helpful.

At Sagemark Consulting, we will help you build a financial plan that helps meet your needs and achieve your goals. We can help you discover the right financial strategies through our comprehensive financial planning services. We provide an unrestricted selection of products and services to help you meet your goals in:

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The risks to physician practices presented by improper billing activities, or presented by Stark law violations, have never been greater. As RAC contractors increase their activities, physician practices will be subjected to ever greater scrutiny. The new definition of what constitutes a "false claim" creates an additional significant financial risk for physician practices. Beyond that, the fact that large financial rewards are available to persons who bring successful Qui Tan actions will provide a strong incentive, especially for disgruntled former employees, to bring charges. Physician practices which do not have a compliance program, or have one but have not used it as a vehicle to develop a true culture of compliance, should do so at their earliest opportunity.

ATTENTION Academy Members:

Have you paid your 2010 dues? If not, this could be your last issue of the *Northern Ohio Physician*. Call the AMCNO's Membership Coordinator 216-520-1000 and renew your commitment to organized medicine today!

Willis Offers Insurance Programs for AMCNO Members

Mike Turney, Vice President, Human Capital Practice, Willis HRH

Willis offers an array of insurance programs for AMCNO members including individual and group health products through insurance carriers such as UnitedHealthCare, Anthem, Medical Mutual of Ohio, and Aetna. In conjunction with AMCNO, Willis now offers FormFire as a solution for physician's practices to reduce the hard work and frustration associated with shopping for combined medical insurance.

Getting real and confirmed pricing from multiple insurance carriers involves sharing employee and employee's dependents medical history on cumbersome paper applications. Rather than having each employee fill out multiple applications for multiple carriers, FormFire simplifies this process by taking it online. Employees complete an application through the FormFire website that is sent to all major medical carriers. Once completed, employers receive actual confirmed medical insurance rates from each carrier, not just best case scenarios. FormFire takes the guesswork out

of the application and renewal process.

FormFire is an interactive website, facilitating the application process through a personalized questionnaire for each employee based on their health history. Additionally, information is stored from year to year, making renewals quick and easy after updating employee profiles.

FormFire is highly secure and HIPAA compliant, and with the assistance of Willis, can transform the way your company shops for group health insurance.

Willis also offers group short- and long-term disability, group dental and group life insurance programs for physician's offices. Physicians on an individual basis also have access to disability and life insurance products at discounted association prices. Simplified underwriting is also available to members of AMCNO.

Willis is the third largest insurance broker in the United States and is a leader in providing insurance programs to physician's practices.

For more information on the insurance programs through Willis on behalf of AMCNO members, please contact Ms. Linda Hale at the AMCNO offices at 216-520-1000, ext. 101 and she can put you in touch with the AMCNO Willis representative.

MEDWORKS

MedWorks, Cleveland's new charitable healthcare organization, will join forces with the Free Clinic of Greater Cleveland, to provide free health services at a two-day event scheduled for May 1-2, 2010. MedWorks was formed to improve access to healthcare for Ohio's uninsured and underinsured populations by partnering with healthcare providers, corporate sponsors and other volunteers.

The event will take place at the Free Clinic located at 12201 Euclid Avenue in Cleveland. This is MedWorks' second free healthcare clinic. At the first event, held in July, MedWorks offered patients 1,600 medical, vision and dental appointments. Approximately 300 people received free new glasses, 130 women had pap tests, 50 people were HIV tested, 250 people had lab tests and another 120 had x-rays, with most patients provided instant results. The event was a rousing success, drawing healthcare providers from more than 20 medical specialties.

More than 300 lay volunteers, 100 doctors, 300 nurses and social workers volunteered in July and the interest in the upcoming clinic will undoubtedly bring as many or more volunteers to the table.

In addition to medical, vision and dental appointments, the MedWorks clinic will also include educational lectures and speakers on a wide array of topics ranging from nutrition, wellness, emergency preparedness and other topics. We will once again have a strong social work component on discharge. In fact, we plan to strengthen this piece to make sure we make some appropriate referrals.

We are delighted to once again partner with AMCNO as well as the Free Clinic and so many other local organizations to provide one-stop health and social services to our community. Our goal is to work with local health care providers to make medical services available all year round for our uninsured and underinsured population in order to improve the health of Clevelanders.

We will be scheduling two shifts each day, one from 6 a.m. – 12 p.m. and another from 12 p.m. – 6 p.m. If you are interested in joining our MedWorks volunteer team, please call our office at (216) 231-5350 or log on to our Web site: www.medworksusa.org.



amcno

THE ACADEMY OF MEDICINE OF
CLEVELAND & NORTHERN OHIO

Medical Records Fact Sheet Update Effective January 2010

Retention of Medical Records

Medical considerations are the key basis for deciding how long to retain medical records. Rules relating to the maintenance of patient records are to be found in the American Medical Association, Council on Ethical and Judicial Affairs, Code of Medical Ethics. Current Opinion **7.05**. Under Ohio Law (R.C. §4731.22 (B)(18)), violations of the AMA ethical rules can result in disciplinary action by the Ohio State Medical Board. Most states, including Ohio, do not have a general state law that requires records be kept for a minimum length of time. Ohio Revised Code §2913.40 (D) mandates the retention of records associated with Medicaid for a period of at least six (6) years after reimbursement for the claim is received by the physician. It is recommended that records relating to a Medicare patient be kept for at least six (6) years after the physician received payment for the service. Medicare's Conditions of Participation requires five (5) year retention. Managed care contracts should be consulted to see if they provide any specified period of retention of medical records. In all cases, medical records should be kept for the length of time of the statute of limitations for medical malpractice claims. Under Ohio Law an action for medical malpractice must be brought within one year after the cause of action "accrues" (R.C. §2305.113). However, there are various exceptions or special rules. For example, the statute of limitations in wrongful death cases is two years after the date of death. In the case of a minor, the statute of limitations does not begin to run until the minor has reached his or her 18th birthday. The statute can be "tolled" or otherwise extended in other situations, and the date on which a cause of action "accrues" can vary. As a practical matter, all of this makes it difficult to define the Ohio statute of limitations with absolute certainty. If you are discarding or destroying old records, patients should be given the opportunity to claim the records or have them sent to another physician. The AMCNO recommends that physicians keep medical records indefinitely, if feasible.

Update on Charging for Copies of Medical Records

A physician who treated a patient should not refuse for any reason to make records of that patient promptly available on request to another physician presently treating the patient, or, except in limited circumstances, refuse to make them available to the patient or a patient's representative (not an insurer). A written request signed by the patient or by what the law refers to, as a "personal representative or authorized person" is required. Ohio Revised Code §3701.74 obligates a physician to permit a patient or a patient's representative to examine a copy of all of the medical record. An exception arises when a physician who has treated the patient determines for clearly stated treatment reasons that disclosure of the requested record is likely to have an adverse effect on the patient, in which case the physician is to provide the record to a physician chosen by the patient. Medical records should not be withheld because of an unpaid bill for medical services. Ohio law establishes the maximum fees that may be charged by health care provider or medical records company that receives a request for a copy of a patient's medical record. Ohio law provides for certain limited situations in which copies of records must be provided without charge, for example, where the records are necessary to support a claim by the patient for Social Security disability benefits. EFFECTIVE JANUARY 2010, the maximum fees that may be charged, are as set forth below.

- (1) The following maximum fee applies when the request comes from a patient or the patient's representative.
 - a) No records search fee is allowed;
 - b) **For data recorded on paper:** \$2.73 per page for the first ten pages; \$0.57 per page for pages 11 through 50; \$0.23 per page for pages 51 and higher
For data recorded other than on paper: \$1.86 per page
 - c) Actual cost of postage may also be charged

- (2) The following maximum applies when the request comes from a person or entity other than a patient or patient's representative.
 - a) A \$16.78 records search fee is allowed;
 - b) **For data recorded on paper:** \$1.11 per page for the first ten pages; \$0.57 per page for pages 11 through 50; \$0.23 per page for pages 51 and higher
For data recorded other than on paper: \$1.86 per page
 - c) The actual cost of postage may also be charged

Ohio Law requires the Director of Health to adjust the fee schedule annually, with the adjustment to be not later than January 31st of each calendar year, to reflect an increase or decrease in the Consumer Price Index over the previous 12-month period. **Please note that the fees this year are lower than permitted in 2009 due to a negative CPI adjustment.** If you have any questions regarding this fact sheet or other practice management issues, please contact the AMCNO at (216) 520-1000 ext 102.

SAVE THE DATE

**The Academy of Medicine of Cleveland
& Northern Ohio (AMCNO)**
invites you to attend our 2010 Annual Meeting

Friday, April 23, 2010

Ritz-Carlton Cleveland • 1515 West Third Street
6 p.m. Reception • 7 p.m. Dinner
Black Tie Optional

Induction of the
2010-2011 AMCNO President,
Laura J. David, MD

Presentation of 50 Year Awardees and Academy
of Medicine Education Foundation (AMEF)
Scholarships to medical students from
Case School of Medicine, Cleveland Clinic Lerner
College of Medicine and
The Northeastern Ohio College of Medicine

AMCNO 2010 Honorees

John S. Collis, Jr., MD

John H. Budd, MD
Distinguished Membership Award

Joseph F. Hahn, MD

Charles L. Hudson, MD
Distinguished Service Award

Dale H. Cowan, MD, JD

Clinician of the Year Award

Pamela B. Davis, MD, PhD

Special Honors Award

Lawrence T. Kent, MD

Outstanding Service Award

The Honorable Barbara Boyd

Special Recognition Award

Bernie Rich and Jim Mathews

Honorary Membership Award

Edward E. Taber, Esq.

AMCNO Presidential Citation Award

Richard B. Fratianne, MD

Special Award with Portrait

*Please join us in congratulating our medical
scholarship recipients and awardees on April 23rd.*

AMCNO Physician Leadership Presents to Metro Medical Staff

In February, Dr. Anthony E. Bacevice, Jr., President of the AMCNO and Dr. Laura J. David, President-Elect, presented to over 100 physicians at Metro regarding the advocacy and community efforts of AMCNO. Drs. Bacevice and David stressed the importance of the AMCNO and our involvement at both the regional and state levels. ■



Dr. Laura David, AMCNO president-elect, provides the Metro medical staff with some key points regarding the activities of the AMCNO.



Members of the Metro medical staff listen to the AMCNO physician representatives discuss the activities of the AMCNO.

Constitution and Bylaw Amendments

In accordance with The Academy of Medicine of Cleveland & Northern Ohio's bylaws, the following changes to the Constitution and Bylaws of the organization are published to the membership. Comments on these changes (if any) should be sent to ebiddlestone@amcnoma.org.

The AMCNO mission statement is to be added to the Constitution and Bylaws under Article II – Purpose and Mission Statement:

"The mission of the AMCNO is to support physicians in being strong advocates for all patients and to promote the practice of the highest quality of medicine."

How to Manage Legal Issues Impacting the Practice Of Medicine

Wednesday, April 7, 2010 – Lakewood Country Club, or
Wednesday, April 14, 2010 – Mayfield Country Club
5:30 p.m. – 8:00 p.m.

Jointly Sponsored By:



PROGRAM FORMAT

5:30 p.m. – 6:00 p.m. — *Dinner*

6:00 p.m. – 6:30 p.m.

John Mulligan, Esq.

McDonald Hopkins, LLC

Recent and Pending Developments Involving the Privacy and Security of Patient Information.

Learn about new developments impacting the rights, responsibilities, and potential liabilities of health care providers and their business associates. Discuss the new notification requirements involving security breaches. Learn what health care providers should be doing now to minimize the likelihood of security breaches and detect and respond to them if they occur.

6:30 p.m. – 7:00 p.m.

David Valent, Esq.

Reminger, LLP

Are You RAC Ready?

Recovery Audit Contractors are private companies working on a contingency fee to identify and collect improper payments made to providers. The RACs have just begun conducting their audits here in Ohio.

What You Will Learn About Becoming RAC Ready:

Strategies for a Demand letter – how to reply, what you should and should not do.
Your Rights and Responsibilities
Steps you should take to limit your exposure to the RAC.

7:00 p.m. – 7:30 p.m.

Amy Leopard, Esq.

Walter & Haverfield LLP

Electronic Health Records and Meeting Meaningful Use

We will review how physicians may qualify for Medicare and Medicaid incentive payments for electronic health records (EHRs) under the American Recovery and Reinvestment Act (ARRA) and discuss definitions of who is eligible and why might 27% of physicians not qualify; how EHR incentive payments may affect hospital-physician relationships and medical staff expectations and changes you should consider in overseeing your vendor contracting process as the bar gets raised over the next 6 years.

7:30 p.m. – 8:00 p.m.

Panel Discussion/Question and Answer

Call (216) 520-1000 for more information and to register by phone,
or visit our Web site at www.amcnoma.org

MEET THE PRESENTERS

JOHN MULLIGAN is a member of the law firm of McDonald Hopkins, LLC. His practice focuses on the representation of physicians and physician groups, and he is a regular contributor to the Academy's publication *Northern Ohio Physician*. He is listed in the *Best Lawyers in America for health care*.

DAVID VALENT is a member of the law firm of Reminger Co., L.P.A. He focuses his legal practice in the areas of medical malpractice, health care law, transportation litigation and commercial premises liability. He is a member of various professional associations including the Ohio State Bar Association, the Cleveland Metropolitan Bar Association and the American Association for Justice.

AMY S. LEOPARD is a partner at Walter & Haverfield LLP and a member of its management committee. She counsels physicians, group practices, and entrepreneurs on licensing, payment, regulatory and technology issues.

REGISTRATION FORM

I will attend the following session:

— **April 7, 2010**
Lakewood Country Club
2613 Bradley Road
Westlake, Ohio 44145

— **April 14, 2010**
Mayfield Country Club
1545 Sheridan Road
S. Euclid, Ohio 44121

NAME _____

ADDRESS _____

CITY _____

STATE _____ ZIP _____

PHONE _____

FAX _____

FEES:

\$15.00 – Residents/Medical Students
\$35.00 – AMCNO Members
\$50.00 – Non-member Physicians/Staff

Return this form with your check made payable to The AMCNO and mail to:

AMCNO, 6100 Oak Tree Blvd, Ste. 440,
Independence, Ohio 44131

You may also fax back this form with a credit card payment. Fill in the information below and fax to (216) 520-0999.

MASTERCARD _____

VISA _____

AMEX _____

EXPIRATION DATE OF CARD _____

ID # _____

This program has been approved for two hours of Clinical Risk Management Education credit (1 hour live and 1 hour non-live) for those physicians participating in the UH Sponsored Physician Program.