

## Case Western Reserve University School of Medicine Chosen as One of Seven Regional Extension Centers in Ohio

### AMCNO to Work as a Stakeholder on the Project

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) president and executive staff were on hand at a media event hosted by the Cleveland Clinic when Governor Ted Strickland announced that seven regional sites across Ohio will receive a total of \$26.8 million in American Recovery and Reinvestment Act (ARRA) resources to assist in the implementation of the state's health information technology initiative.

These resources are a portion of Ohio's total \$43 million ARRA award for the Ohio Health Information Partnership (OHIP), the nonprofit entity designated by Strickland to lead the implementation of health information technology in Ohio.

OHIP will work with the selected regional partners to help more than 6,000 primary care providers install electronic health record (EHR) systems and connect to a statewide, secure health information exchange. OHIP regional partners will then work

with providers to get their systems connected to the secure statewide health information exchange. Through this exchange, physicians will be able to share information, if the patient has given permission to do so, with other providers such as hospitals, specialists, and laboratories. This will result in better coordination of care, reduced duplicative testing and safer prescribing.

The CWRU School of Medicine is one of seven REC's in Ohio established by OHIP and made possible by funding from ARRA. An eighth



*Dr. C. Martin Harris (second from left) and Dr. Pamela B. Davis, spend a moment with Governor Strickland (far left) and Mayor Frank Jackson at the REC media event.*

REC was awarded directly by the federal government to HealthBridge, a not-for-profit health information exchange serving Greater Cincinnati and surrounding areas.

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## AMCNO Submits Comments to CMS on Meaningful Use (MU)

On January 13, 2010, the Centers for Medicare and Medicaid Services (CMS) published the *Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs Notice of Proposed Rule Making (NPRM)*. Over the past two months, the physician leadership and staff of the AMCNO have been evaluating and reviewing the proposed rule. CMS is charged with ensuring that physicians are a key component of the effort under the American Recovery and Reinvestment Act of 2009 (ARRA) to promote health information technology and its use to transform medical practice and the health care delivery system. Our comments focus on our support for a program that allows as many eligible physicians as possible to participate and that creates trust and buy-in from physicians on the value of that participation and the fairness of the process.

After a detailed review and discussions with physicians and institutions from across the region, the AMCNO has prepared and submitted comments on the rule. The

Academy of Medicine of Cleveland & Northern Ohio made four key recommendations to CMS as follows:

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# AMCNO COMMUNITY ACTIVITIES

## Case Western Reserve University School of Medicine Chosen as One of Seven Regional Extension Centers in Ohio AMCNO to Work as a Stakeholder on the Project (Continued from page 1)

CWRU School of Medicine received \$7,942,500 in federal stimulus funds from OHIP. The funding will position CWRU School of Medicine as a regional extension center (REC) which allows it to help 1,765 health care providers in Lorain, Cuyahoga, Lake, Geauga and Ashtabula counties advance the use of health information technology (HIT) in their practices.



AMCNO president **Dr. Anthony E. Bacevice, Jr.**, (far left) and **Dr. Ronald A. Savrin**, talked with Governor Strickland following the presentations at the REC media event.

The REC endeavor, as directed by the federal government, is specifically targeted towards primary care providers, specifically, physicians — MDs or DOs who are family physicians, general internal, pediatric or OB/GYN (does not need to be board certified in these areas), and other primary care providers such as nurse practitioners, nurse midwives, or physician assistants with prescriptive privileges.

The CWRU School of Medicine will provide administration and management to multiple contractors whose roles will vary by expertise but overall will help providers select products and provide training on how to use the technology to its fullest potential in order to improve patient care. This includes providing workforce support, implementation and project management, practice and workflow design, vendor selection, privacy and security best practices, progress towards meaningful use, functional interoperability and health information exchange.

"The School of Medicine is committed to improving the health of our communities. We believe that HIT is a key tool in enhancing health care for patients and we look forward to partnering with independent healthcare providers to encourage quick adoption of health IT," said Pamela B. Davis, MD, PhD, dean of the School of Medicine and vice president for medical affairs at Case Western Reserve University. Dr. C. Martin Harris, of the Cleveland Clinic, represented the OHIP board at the event. He noted that improved technology is necessary

to integrate electronic medical records among hospitals and physician offices. "The ultimate goal, though, is not better technology, but rather better patient care," said Harris, chief information officer at the Cleveland Clinic. Harris further stated that "it's time to change our thinking about how and where health care should be delivered, while empowering patients to proactively manage their health care and connecting physicians across Ohio to improve access to patient data and information."

The CWRU REC has a number of stakeholders, including the Academy of Medicine of Cleveland & Northern Ohio (AMCNO) and the Academy of Medicine Education Foundation (AMEF). **The AMCNO immediate past-president, Dr. Anthony E. Bacevice, Jr., has been appointed to the CWRU Regional Extension Center (REC) Governance Committee.** The AMCNO will continue to be integrally involved in this project as it moves forward in our region.

In addition to CWRU the other regional partners include the Akron Regional Hospital Association which will receive \$3,928,500 to assist 873 primary care physicians, the Central Ohio Health Information Exchange (COHIE) which will receive \$6,084,000 to assist 1,352 primary care physicians, the Greater Dayton Area Health Information Network (GDAHA) which will receive \$2,898,000 to assist 644 primary care physicians, the Hospital Council of Northwest Ohio which will receive \$2,875,500 to assist 639 primary care physicians, the Northeast Ohio (NEO) HealthForce which will receive \$1,453,500 to assist 323 primary care physicians, and Ohio University which will receive \$1,818,000 to assist 404 primary care physicians. ■

## NORTHERN OHIO PHYSICIAN

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## AMCNO Submits Comments to CMS on Meaningful Use (MU)

(Continued from page 1)

- CMS should limit the definition of hospital-based professionals ineligible to participate in the EHR incentive programs to ensure broad physician participation in Meaningful Use.
- CMS should scale back the measures, make the thresholds for the objectives and quality metrics more realistic, and allow achievement of meaningful use on something less than an “all or nothing” basis.
- CMS should allow eligible professionals to demonstrate meaningful use through substantial compliance with the measures and objectives in Stage 1.
- CMS should streamline the administrative burden on physicians so that physicians can easily create the compliance documentation needed.

### 1. **CMS should limit the definition of hospital-based professionals ineligible to participate in the EHR Incentive programs to ensure broad physician participation.**

The NPRM definition of “hospital-based eligible professional” is too restrictive considering the statutory language and Congressional intent of the HITECH Act. This definition also is ambiguous given the current status of EHR technology in the ambulatory setting and inconsistent with the incentive payment rules for eligible hospitals. A restrictive approach to defining “hospital-based eligible professional” may delay or even curtail the development, implementation and meaningful use of ambulatory EHR systems. As a result, this definition may do more to thwart, rather than enhance, the meaningful use of EHR by physicians, despite the overall goals of the HITECH Act to expand physician use of EHRs and transform the existing health care delivery system.

The HITECH Act contains language intended to clarify the determination of “hospital-based eligible professional.” The HITECH Act defines a “hospital-based eligible professional” as:

an eligible professional, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of such services in a hospital setting (whether inpatient or outpatient) and through the use of the facilities and equipment, including qualified electronic health records, of the

hospital. The determination of whether an eligible professional is a hospital-based eligible professional *shall be made on the basis of site of service and without regard to any employment or billing arrangement between the eligible professional and any other provider.* HITECH Act at §4101 (emphasis added).

While the term “hospital setting” is not defined in the HITECH Act, Congress clearly intended that “hospital setting” have its plain and ordinary meaning, which simply is the traditional hospital setting (e.g., inpatient and ER) and not ambulatory care sites (e.g., clinics, provider-based outpatient settings, and care rendered by non-emergency physicians in observation units).

This concept of differentiating ambulatory care services from services rendered in the “hospital setting” is further supported by the various quality measures for “eligible professionals” in the NPRM. As to physicians, the plain and ordinary meaning of “hospital setting” should include only those physicians who base almost all their practice in the hospital *and* use the hospital’s qualified electronic health records, i.e., do not have or need an EHR for an ambulatory practice, regardless of the point of service codes reported by said physicians. The physician specialties referenced in the statutory definition (pathology, anesthesiology, or emergency medicine) are classic examples of physicians who practice in a hospital setting and do not generally maintain an ambulatory practice or have a need for an EHR separate and apart from the hospital EHR.

CMS assumed that, for purposes of the definition of “hospital-based eligible professionals,” physicians furnishing services in an inpatient or outpatient hospital setting are using the hospital EHR system(s). For inpatient hospital settings, this assumption may be valid. Physicians in certain specialties (e.g., cardiovascular surgery, neurosurgery) may provide their professional services primarily in a hospital setting but also use a separate ambulatory EHR for their practice. In many instances, however, physicians practicing in an integrated health system or academic medical center will primarily use a separate EHR system or module specifically developed for the provision of ambulatory care. An ambulatory EHR system is significantly different than an inpatient EHR system. Ambulatory EHR systems are designed and integrated differently and generally contain various add-on modules and components not found in inpatient EHR systems.

Applying the point of service rules proposed under the NPRM definition of “hospital-based eligible professional” will result in most, if not all, provider-based physicians of all specialties being deemed “hospital-based eligible professionals” and not eligible for the incentive payments. This is the case even though most provider-based physicians maintain an ambulatory practice and use a qualified ambulatory EHR despite reporting outpatient hospital point of service codes for billing purposes. We strongly believe that CMS must reconsider this proposal and interpret the term “hospital setting” in its plain and ordinary meaning to avoid such a restrictive result.

Physicians practicing in integrated health systems and academic medical centers have no financial incentive under the NPRM to partner with hospitals for meaningful use considering that the proposed point of service rule eliminates direct incentive payments to the physicians, which is neither justified nor desirable. There is no “double dipping,” considering that the meaningful use of an ambulatory EHR system by professionals furnishing services at outpatient facilities/departments (regardless if provider based for reimbursement purposes) will have little to no affect on hospital patient discharges, the variable component of the hospital EHR incentives. The hospital incentive programs for Medicare and Medicaid consider only the inpatient volumes in computing their applicable incentive payments.

The AMCNO advocated that CMS should limit the specialties included in the definition of hospital-based to those commonly and traditionally considered hospital-based (anesthesiology, pathology and emergency medicine). AMCNO recommends that CMS address the concerns over the definition of “hospital-based eligible professional” by eliminating from the point of service rules the point of service code for hospital outpatient (Point of Service Code 22). Elimination of this code will go a long way to cure any ambiguities and inconsistencies with the application of the definition of “hospital-based eligible professional” to those professionals that maintain and practice in an ambulatory setting. In addition or in the alternative, CMS should narrow the scope of the outpatient hospital point of service code so that it only applies to instances in which the otherwise eligible professional is strictly furnishing services through and using the inpatient EHR system of a hospital. This approach should be capable of easy implementation from a practical standpoint considering that

inpatient and ambulatory EHR systems are vastly different and physicians reporting a Point of Service Code 22 are highly unlikely to furnish services using an inpatient EHR system of a hospital.

**2. CMS should scale back the measures, make the thresholds for the objectives and quality metrics more realistic, and allow achievement of Meaningful Use on something less than an "all or nothing" basis.**

The AMCNO is also concerned that the breadth and number of measures and the requirement that core measures and specialty measures be met at 100% compliance will discourage physicians from participating in the EHR incentive programs.

AMCNO has members working solo, in smaller groups that have not adopted EHR systems, as well as some of the nation's most sophisticated institutions. Physicians in both settings desire to qualify for the EHR incentive programs. But making the achievement of Stage 1 objectives unrealistic for small physician practices will create a digital divide and serve to make healthcare delivery and referrals more disconnected and fragmented. AMCNO is a stakeholder in the Northeast Ohio Regional Extension Center to Ohio Health Information Partnership (OHIP) and will support that role in helping smaller physician practices adopt and meaningfully use certified EHR technologies. The reality is that those who are at the beginning of the adoption cycle still have a long way to go to implement the functional technology and develop the capabilities.

Given the tight timeframes, CMS should focus its priorities. We believe that at least in Stage 1, the laundry list of quality measures should be scaled back to an achievable level with only a few straightforward, achievable measures clearly identified for each specialty. Those measures should be evidence-based measures having full endorsement by the respective medical specialty societies **and** at the level of maturity where implementation specifications have already been developed. Maintaining and attaining achievement of dozens of measures is far too complex for each physician to administer. At most, physicians should be responsible for 3-5 quality measures in Stage 1.

The criteria for Meaningful Use also should be scaled back. We believe that requiring physicians to directly enter 80% of their orders for ancillaries is far too high. For Stage 1, a more flexible approach should be considered

for CPOE providing sufficient lead time for physicians to achieve the criteria. Obtaining 50% of all lab results in the EHR creates the need for many lab interfaces at this early juncture of HIT interoperability. Requiring e-prescribing for 75% of permissible prescriptions is too high given the various levels of adoption in the pharmacy world, the difficulties with the DEA restrictions on scheduled drugs and the other competing measures included in the NPRM.

**3. CMS should allow eligible professionals to demonstrate meaningful use through substantial compliance with the measures and objectives in Stage 1.**

The AMCNO believes that in addition to scaling back the thresholds and the number and variety of measures, CMS should reconsider the "all or nothing" approach to the measures and objectives. EHR implementations may experience delays or the need to change priorities based on legitimate and uncontrollable events, so flexibility in the roadmap to Meaningful Use should be designed into the incentive programs.

One solution for this problem would be to allow Eligible Professionals to achieve meaningful use through "substantial compliance" or in a quantitative approach, by allowing deferral of a set number of objectives and measures, as recommended by the federal Health IT Policy Committee. In addition, physicians need to be able to demonstrate meaningful use in something less than a full year if they experience uncontrollable events, vendor changes, and system upgrades.

**4. CMS should streamline the administrative burden on physicians so that physicians can easily create the compliance documentation needed.**

The AMCNO is also very concerned about the undue compliance burden for physicians. CMS estimates that Eligible Professionals will need to be directly involved in the reporting and submission of Meaningful Use objectives and measures and estimates eight hours for these tasks. An additional hour is estimated for quality measures and attestation. These estimates are low given the breadth and variety of measures and the difficulties expected in tracking and reporting data where manual computations are involved (e.g., if 80% of all orders must be placed through CPOE, the practice will need to manually track and count the orders placed outside the EHR). Physicians are also concerned about the scope of the attestation and hope that CMS can limit

the certification that physicians must make. Physicians should be able to rely on the ONC-designated EHR certification process for matters of technology and be protected from False Claims Act liability for good faith certifications.

Finally, the AMCNO asked CMS to consider a Medicare reconsideration process for reviews of contractor determinations of eligibility, similar to that established for Medicaid. Physicians need to know that the EHR incentive program will be administered fairly, and if mistakes are made or if additional documentation is needed from the physician, a process has been put in place to ensure fair and accurate determinations.

Members of the AMCNO board approved the points noted above and we await the final rule on this issue which should be due out sometime before June 2010. ■

## ***Breaking News:***

Congress responded to many comments from professional associations such as the AMCNO to expand the category of physicians eligible for EHR incentive payments under the ARRA/HITECH Act. On April 15, 2010, President Obama signed the Temporary Extension Act of 2010 to limit the definition of "hospital-based physicians" who are not eligible for EHR stimulus incentives. The amendment excludes hospital outpatient settings from this definition. As a result, physicians furnishing substantially all their Medicare services in a provider-based outpatient setting will now be eligible to participate by demonstrating they otherwise meet CMS requirements for "meaningfully using" a certified EHR technology. AMCNO thanks Sens. Brown and Voinovich for their swift action on this bill.

## AMCNO Legal Issues Seminar Offers Helpful Updates

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) and the Academy of Medicine Education Foundation (AMEF) co-sponsored their annual legal issues seminars in April that were well-attended by both physicians and physician office staff. Presenters included John Mulligan, Esq., from McDonald Hopkins, LLC, David Valent, Esq., from Reminger Co., L.P.A., and Amy Leopard, Esq., from Walter and Haverfield LLP with **President-Elect Dr. Laura David** facilitating both sessions. The presenters informed the audience of the legal issues currently impacting physicians in their practices.

### Privacy and Security Issues

During the first session, Mr. Mulligan talked about the evolution and change involving the privacy and security of patient information. Audience members were cautioned that while they may receive requests for the release of medical records that are deemed to be HIPAA compliant disclosures, in fact they may not be authorized. Building expertise internally and establishing an internal process to verify appropriate authorization before providing information will avoid problems with breaches in privacy of patient information. Routine review and sharing of things such as recent court decisions, their problems and pitfalls helps providers keep on top of compliance information and findings.

Physicians having the best intentions to comply with what they think is required can result in serious problems or claims and even law suits. HIPAA has strict requirements for authorization. Mr. Mulligan pointed out that while HIPAA permits certain disclosures, Ohio has its own state statute separate from HIPAA that also needs to be considered for compliance.

Mr. Mulligan also explained that this past year there have been significant developments regarding security of health information in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and cited some examples of breaches of security, including theft of company data, laptops and also carelessness in the handling of records. Regulations of the HITECH Act establish breach notification requirements when a breach is uncovered as well as penalties for breaches.

In 2009, the Centers for Medicare and Medicaid Services (CMS) summarized its findings from a compliance review the year prior.

### Common security shortcomings were of an administrative nature and included:

1. Lack of risk assessment and not analyzing one's own situation;
2. Failure to maintain current policies and procedures;
3. Inadequate security training;
4. Failure to assure workforce clearance;



Presenters from the AMCNO/AMEF legal issues seminar posed with several physicians that attended the meeting (left to right - Dr. Lawrence Kent, Ms. Amy Leopard, **Dr. Laura David**, Mr. John Mulligan, Dr. Patricia Kellner, and Mr. David Valent.)

5. Failure to monitor workstation security; and
6. Failure to encrypt information.

### Steps to strengthen security include:

1. Develop a process for employees to voice complaints or report violations and protect whistle blowers from retaliation;
2. Discipline personnel who fail to comply;
3. Assure ongoing training;
4. Do not require a waiver of rights as a condition of treatment;
5. Implement and modify policies as needed; and

6. Document all of the above; documentation can be critically important should you be called on to explain the actions of your practice.

In the event you are made aware of a breach, notice must be given to the patient and also the Department of Health and Human Services without unreasonable delay but not more than 60 days after the discovery. Where more than 500 individuals are involved, media notice is also required. Depending on the nature of the breach, HITECH Act monetary penalties can range from \$100 to \$50,000 per violation.

The last area of Mr. Mulligan's talk focused on the changes with business associates. What is a business associate?

- Not a member of your workforce.
- Provides services to a covered entity such

as a physician practice.

- The services involve the use or disclosure of protected health information.
- Examples include billing companies, attorneys, consultants and accountants.
- A physician can be a business associate, i.e. medical director services.

Mr. Mulligan explained that you should identify your business associates and confirm that you have up-to-date business associate agreements with each. He noted that you could have multiple agreements with the same business associate involving different services.

The HITECH Act expanded HIPAA standards to institute liability for business associates with breaches of privacy of health information. As a result, business associates:

- are now subject to certain HIPAA privacy and security requirements;
- will be required to implement security safeguards and adopt policies and procedures;
- will be directly liable for their breaches;
- become required to notify the covered entity of breaches; and
- both the business associate and the covered entity must take steps to cause a cure to the other's breach which can involve notifying the Department of Health and Human Services.

While not required, it would be a good practice to amend any business associate agreements due to the HITECH Act in order to deal with notification requirements, liability and indemnification issues, and mandatory insurance coverage. This will help to confirm the existence of written policies and procedures by the business associate. Seeking insurance to cover the risk was recommended and it was noted that a typical policy will not cover this area.



Ms. Amy Leopard provides the audience with background on the Meaningful Use rule.

Physician practices should confirm that their business associates have taken steps to comply with the new requirements under the HITECH Act. It was noted that some service providers will avoid business associate status by receiving only de-identified health information, i.e., when possible the removal of social security numbers, names, addresses before passing the information along makes the health information no longer protected under the Act.

## Recovery Audit Contractors

The next topic, "Are you RAC Ready?," was presented by Mr. David Valent and included



Mr. David Valent answers a question from the audience regarding recovery audit contractors.

an overview of the recovery audit contractor (RAC) process for Medicare reimbursements in order to assist audience members with becoming RAC ready. In 2007 with Medicare errors representing \$10 billion in lost monies, the government and congress enacted legislation that led to establishing the new RAC process to facilitate the recovery of payment for the most common billing errors, including incorrect payment amounts, duplicate claims/services, claims for non-covered services and incorrect coding.

A demo program started in 2005 in the states of New York, Florida and California, and in over three years this program recouped \$900M in improper payments collected. The RAC program in Ohio began in January, 2010, and to date has been fairly slow to get started. Currently inpatient hospitals and large facilities are being targeted for audits; however, everyone will eventually be targeted.

Mr. Valent talked about appeal rights and explained that just because you get a demand letter, it doesn't mean that you necessarily have to pay the money back. He stressed that a demand letter is the RAC's claim — in Ohio's case CGI's claim — of incorrect billing and providers should not be quick to write a check without a thorough investigation to ensure the determination is accurate.

There are 5 stages to the appeal process:

1. redetermination,
2. reconsideration,
3. appeal to an independent body,
4. appeal to a Medicare Department appeals board, and
5. Federal Court hearing.

Within the RAC process, there is a discussion period of 30 days where providers can call CGI and discuss their claims. Mr. Valent encouraged

providers to call CGI as many times as they feel are needed to get their questions or complaints answered; however, this discussion period is not an official appeal and should not be confused with such. It was noted that if necessary, providers should file an appeal by day 30 of the discussion period to start the process of disputing their claims and to stop recoupment and interest from accruing.

For a complex review:

- CGI sends a letter and requests records.
- Provider has 45 days to make available the requested records.
- Upon receipt of records, CGI has 60 days to advise the provider of any errors they have found.
- Provider then has 15 days to request a re-review, with no interest or recoupment of monies.
- On day 16, CGI will send provider a demand letter with a final determination of monies; at this point the 30-day clock starts (discussion period), etc.

For more information on the RAC process, see article *AMCNO Seminar on Recovery Audit Contractors – What You Need to Know* in the January/February 2010 issue of the *Northern Ohio Physician*.

The final presentation by Ms. Amy Leopard reviewed the framework for the new Medicare and Medicaid electronic health records (EHR) incentive programs and the new Centers for Medicare and Medicaid Services (CMS) proposal on Meaningful Use (MU) eligibility. Since CMS published the *Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs Notice of Proposed Rule Making (NPRM)*, the AMCNO physician and staff leadership have examined the ruling for problem areas and have prepared and submitted a letter to CMS identifying such (see the article pg. 1).

For complete information, see the article *The Proposed Pathway for Achieving "Meaningful Use" and EHR Stimulus Payments* in the March/April 2010 issue of the *Northern Ohio Physician*.

**Editor's note:** The AMCNO and AMEF wish to thank all of the presenters for their participation in these sessions. The AMCNO also wishes to thank UH for again approving this program for two hours of Clinical Risk Management Education credits for those physicians participating in the UH Sponsored Physician Program. ■

## Legislative Update

By Connor Patton, AMCNO Lobbyist

### State Legislative Schedule

You might think there are 9 months left in the year, but in terms of state government and the Ohio General Assembly there are only 4 months. Those months would be May, part of June, half of November and depending on the outcome of this fall's election a mad and frenzied lame duck session in the month of December. In those 4 months hopefully we will see the passage of the physician ranking bills (SB 98/ HB 122) sponsored by AMCNO, language to address Most Favored Nation clauses in hospital contracts, rules for the creation of casino gaming and a new gaming commission, a capital appropriations bill, and whatever legislation people can get done before sine die, which is the term used to describe the end of the General Assembly. The casino language must be done by June 3rd and the legislature will probably not return until after the November elections.

### Statewide Campaigns

On the campaign trail Ohioans have a fairly settled Democrat statewide ticket with the only primary being Lee Fisher against Jennifer Brunner for United States Senate. The rest of the Democratic candidates are Ted Strickland for re-election to Governor, David Pepper for Auditor of State, Richard Cordray for re-election to Attorney General, Mary Ellen O'Shaughnessy for Secretary of State, and Kevin Boyce for re-election to State Treasurer. Kevin Boyce is the youngest of the statewide candidates, but certainly has shown years of wisdom and experience as he has run a good office, providing savings of state dollars in a bad economic climate and acting as a great fiduciary on behalf of the State of Ohio. Also, Eric Brown and Mary Jane Trapp are running unopposed for Ohio Supreme Court.

On the Republican side there are a few contentious primaries. The Secretary of State primary is looking very heated as former Speaker of the Ohio House of Representatives Jon Husted runs against former Ashtabula County Auditor Sandra O'Brien. In the Auditor's race a freshman legislator Seth Morgan is pitted against Delaware County Prosecutor Dave Yost. Rob Portman for U.S. Senate, John Kasich

for Governor, and Mike DeWine for Attorney General are uncontested. In the Ohio Supreme Court races we have Maureen O'Connor who is the heavy favorite running for Chief Justice and Judith Lanzinger running for re-election.

### Most Favored Nation Joint Legislative Committee Releases Final Report

The AMCNO has been following the Joint Legislative Commission on Most Favored Nation Clauses in Health Care Contracts discussion that has taken place in Columbus over the past 13 months. House Bill 125 of the 127th General Assembly required the creation of this Commission. The Commission was charged with examining several aspects of the effect of MFN clauses on health care in Ohio. The scope of the Commission's work included studying the pro-competitive and anti-competitive aspects of MFN clauses; the impact of MFN clauses on health care costs and on the availability of and accessibility to quality health care; and the costs associated with the enforcement of MFN clauses.

The Commission consisted of members representing hospitals, insurers, providers, employers, antitrust attorneys, and the Ohio Department of Insurance. Members were appointed by the General Assembly.

In order to fulfill its charge, the Commission heard from two economists and an antitrust attorney with expertise in MFN clauses. The Commission also conducted two surveys of Ohio hospitals and insurers to collect Ohio specific information regarding the use of MFN clauses. While the surveys were not conducted using accepted statistical methods, they did provide information about the use of these clauses in Ohio.

After gathering the available information, the Commission came to unanimous consensus on a number of factual findings, which included the following:

- a) Whether an MFN clause is pro- or anti-competitive depends on the facts of the specific situation.
- b) The Commission is not aware of any information addressing whether or

not MFN clauses have a market-wide economic impact on health care costs in Ohio.

- c) The Commission is not aware of any information addressing whether or not MFN clauses have a market-wide impact on the availability of and accessibility to quality health care in Ohio.
- d) The Commission conducted a survey of hospitals and insurers as to their experience with MFN clauses.
- e) The surveys were not designed using accepted statistical methods. Responses were voluntary and blinded. Hospital respondents to the survey reported the following information:

1. Nine of the 13 large hospitals (which included hospital systems) and none of the six mid-sized hospitals with MFN clauses reported that they would have given a lower price to another insurer in the absence of an MFN clause.
2. Six large hospitals or hospital systems and three mid-sized hospitals reported that the existence of an MFN clause affected or discouraged them from entering into innovative payment methodologies with another insurer and six large hospitals or hospital systems and three mid-size hospitals reported that they did not.
3. 15 of 19 responding hospitals or hospital systems with MFN clauses use measures, such as price buffers, to ensure that an MFN clause is not violated.
4. There are costs to some insurers and hospitals associated with the enforcement of some MFN clauses.

The Commission also voted on the two recommendations required of it by the General Assembly. By a vote of 8 to 3, the Commission voted to recommend that the Ohio Legislature prohibit or restrict MFN clauses in health care contracts. Also, the Commission unanimously voted against recommending that the Ohio Legislature extend the two year moratorium on MFN clauses in health care contracts between hospitals and contracting entities. The AMCNO will provide our members with an update as this issue moves through the legislature in the coming months.

## **Health Care Reform Impact on Ohio Medicaid**

Ohio's Medicaid enrollment is expected to expand by 25% under the recently enacted health care overhaul, with more than half of the 554,000 new beneficiaries being citizens already eligible for coverage under the government-funded insurance system, an early analysis conducted by state official's shows. This will impact the state's bottom line starting in federal fiscal year 2014.

Those costs are expected to be significant given the annual entitlement spending in Ohio already exceeds \$15 billion across several state agencies.

About two million Ohioans currently benefit from Medicaid health coverage, according to the Ohio Department of Job and Family Services, which on its own accounts for about \$13 billion in yearly state and federal fund spending under the program. Ohio is expected to see Medicaid rolls expand by an estimated 275,000 people who will become newly eligible in four years. The bill, which requires states to have program expansions in place no later than 2014, includes 100% federal funding for that group during the first two years, and that scales down to 90% for 2020 and subsequent years.

Other changes and requirements in the federal health care bill include:

**Primary Care Physicians:** The state currently reimburses primary care physicians under Medicaid at 55-65% of what Medicare pays for office visits. The federal bill will require ODJFS to raise reimbursement rates for primary care physicians up to the Medicare rate.

**Medicaid Drug Rebates:** Ohio may have to rethink the way it handles drug rebates from manufacturers, as the program was changed effective February 1st to carve out pharmacy benefits from the Medicaid managed care program.

**Maintenance Of Effort:** While states have the option to expand Medicaid eligibility starting in 2011, the federal bill bars reductions in eligibility levels for children until 2019 and adults until 2014.

**Foster Children:** The federal bill requires Medicaid coverage to be extended to children who have aged out of foster care up to age 26. The Strickland administration previously extended that coverage in Ohio from age 18 to 21.

**Waiver Impacts:** The new law will allow states the option of expanding coverage to certain home- and community-based services now paid for under Medicaid waiver programs.

**Hospital Care Assurance Program:** Federal payments to hospitals for uncompensated care under HCAP are slated for reductions starting with \$500,000 nationally in 2014 and hitting \$4 billion in 2020.

## **Prescription Drug Abuse Task Force Formed**

Governor Strickland signed and created an Ohio Prescription Drug Abuse Task Force to, among other things, identify strategies for law enforcement and the General Assembly to pursue. Governor Strickland believes more Ohioans die from drug poisoning than from traffic accidents. Scioto County has the highest rate of prescription drug abuse and death in the state. The U.S. Drug Enforcement Administration (DEA) placed the county on its watch list of 10 areas nationally where the problem is most serious.

The Ohio Poison Action Group/New and Emerging Drug Trends Work Group sent a list of recommendations to the directors of the Ohio Department of Health (ODH) and the Ohio Department of Alcohol and Drug Addiction Services (ODADAS) aimed at reducing and preventing the abuse of prescription drugs.

The recommendations are expected to be used as a foundation by the Ohio Prescription Drug Abuse Task Force announced by Gov. Ted Strickland. The work group was formed in 2009 to make recommendations on stemming unintentional drug poisoning deaths. It was comprised of 150 members from state and local government, law enforcement, health care, education and mental health sectors.

Among the recommendations are:

- Increasing public awareness of the problem. This includes establishing local and regional task forces and funding social marketing campaigns by ODADAS, ODH, the Ohio Department of Mental Health, Ohio Department of Aging and the Ohio Department of Education.
- Provide health care professionals with information, training and materials to address the prevention and misuse/abuse of and unintentional deaths from prescription drugs. Among the sub-recommendations is developing a tool kit for use by health care providers to educate all patients who receive pain medication and requiring course work in substance use disorders for medical professional or allied health care degrees.
- Implement policy and legislative changes designed to prevent misuse/abuse and unintentional deaths from prescription drugs. The group urged legislation that would enact licensing standards for pain management clinics; to require all physicians and other prescribers to register with and use the Ohio Automated Rx Reporting System administered by the State Board of Pharmacy and to integrate an E-prescribing system with that system.
- Increase, improve and coordinate data collection related to the prevention of unintentional deaths from prescription drug overdoses. The recommendations urge collaborations between state agencies and other states, as well as the establishment of a Poison Death Review Committee.

**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. ■**

## AMCNO Participates in Tobacco Advocacy Day at the Statehouse

In March the AMCNO was pleased to be a participant in the Investing in Tobacco Free Youth Advocacy Day at the Ohio Statehouse. Joining the AMCNO were more than 200 anti-tobacco volunteers. The day began with an issue briefing prior to the participants meeting with their legislators from their respective districts.

The participants were asked to press legislators to consider equalizing the tobacco taxes and funding tobacco prevention and cessation noting that the use of non-cigarette forms of tobacco is rising, especially among youth since these products are candy flavored and cheap because of the low "other tobacco products" (OTP) tax rate. Equalizing the OTP tax to the current cigarette rate would generate \$50 million annually. This funding should be used to continue tobacco prevention and cessation programs which are scheduled to end as of June 30, 2010. In a recent poll, 74.9% of Ohioans supported taxing all tobacco products at the same rate and using the new funding for tobacco programs. Participants in the Advocacy Day reminded their legislators that for every thousand kids kept from smoking by tobacco prevention programs, future healthcare costs decline by roughly \$16 million and for every thousand adults prompted to quit, future health care costs drop by about \$8.5 million.

Legislators were also asked to consider increasing the cigarette tax by \$1.25 to \$2.50 per pack which would generate \$347.3 million annually. That money could be used as ongoing funding for healthcare shortfalls in the Ohio budget such as: Medicaid services, adults and protective services; healthcare for needy children, breast and cervical cancer screenings or other healthcare priorities.

During the event, a press conference was held where Beverly May, regional advocacy director for the Campaign for Tobacco-Free Kids, suggested legislation to increase tobacco taxes and thus save tobacco prevention services set to end July 1. Also speaking at the press conference was Rick Bender, who lost part of his tongue, half of his jaw and partial use of his right arm to oral cancer caused by tobacco use.

It remains to be seen if legislation will be introduced or if this issue will be handled

through other means. The AMCNO will continue to work with the coalition to push for changes in the cigarette and OTP taxes in an effort to continue to fund tobacco prevention and cessation programs in Ohio.

### The Ohio Supreme Court Agrees to Hear Tobacco Group Appeal

In other tobacco related news, The Ohio Supreme Court has agreed to hear the appeal of an anti-tobacco group that is trying to block the state's diversion of \$258 million for purposes other than smoking cessation and prevention. Justices unanimously accepted, without comment, a request from the American Legacy Foundation to review a December 2009 ruling from the 10th District Court of Appeals. The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), along with other organizations, has filed a friend of the court brief in support of the American Legacy Foundation.

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



*Ms. Shelly Kiser from the Ohio Chapter of the American Lung Association addressed the Advocacy Day participants during a legislative luncheon.*

Endowment Fund. The 1998 Master Settlement Agreement 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 the Ohio Tobacco Prevention Fund and created an endowment for it.

The appellate panel upheld a decision of Governor Strickland and the General Assembly to redirect money received from a settlement between states and national tobacco product manufacturers. Originally set aside to prevent smoking and to help consumers kick the habit, the state wanted to use the money instead for Medicaid and other health care programs. Justices are expected to schedule the matter for oral arguments later this year. ■

### **AMCNO Provides Comments on Health Care Reform Issues to CASE Law Students**

In March, **Dr. John Bastulli** the AMCNO Vice President of Legislative Affairs was invited to speak to fourth year law students at CASE on health care reform and other issues. Dr. Bastulli provided the students with an overview of the AMCNO position on health care reform as well as comments on the AMCNO backed physician ranking legislation.



*Dr. John Bastulli responds to a question from one of the law students in attendance at the CWRU Law School event.*

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## Health Care Reform Update

As noted in all the news media outlets President Obama has signed the \$938 billion Patient Protection and Affordable Care Act (the "Act") into law. On March 21, 2010 the House passed the Act along with the Reconciliation Bill, which is intended to amend the Act as passed. The Act contains extensive legislation that will be implemented throughout the next decade and will have significance for businesses as well as individuals.

The AMCNO Board of Directors has continued to evaluate the health care reform bill and legislation as it moved through Congress. The AMCNO believes that the current health care system is fragmented and unsustainable and does not meet the needs of our members and their patients. Our organization and the physicians we serve recognize the need for health care reform and have long advocated for change in the health care delivery system. The AMCNO has voiced its support regarding many of the aspects included in the legislation before Congress such as the funding of patient centered medical homes, enhanced access to care for all Americans, changes in health insurance company behavior, support for prevention and wellness programs, and support for changes in geographic variations to address both costs and care provided.

Specifically the AMCNO has advocated for Congress to pass legislation that would:

- Allow access to affordable health care for all Americans;
- Implement reform of Medicare physician payment methodologies;
- Not overburden or add costs to the Medicaid program;
- Enact meaningful medical liability reforms inclusive of alternative dispute resolution concepts and health courts;
- Provide for insurance market reforms that address the issue of physician profiling by health insurers, that enhance choice of affordable coverage and eliminate denials of care for certain conditions;
- Implement changes in geographic variations that affect costs and care provided;
- Require health care decision making by physicians and their patients, instead of by insurers or government entities;
- Provide for quality improvement as well as reductions in cost and waste;
- Provide for investments and incentives for public health and prevention and wellness initiatives;
- Standardize insurance claims processing requirements to eliminate unnecessary costs and administrative burdens;
- Provide for the implementation of health insurance exchange models versus a government-run public option;

- Remove restrictions on physician ownership of facilities;
- Provide appropriate avenues and funding for the growth of the physician workforce to meet demand.

The proposal that has been signed into law does address some of the points noted above; however it also creates a new health care entitlement program and expands an already underfunded Medicaid program. In addition, the legislation does not include changes to the Medicare SGR payment formula but it does create a new independent commission that could create more reductions in the Medicare physician payment system dependent upon how it operates in the future. The proposal also does not include meaningful measures to address medical liability reform.

**The AMCNO lobbyist Mr. Connor Patton and attorneys from the legal firm of McDonald Hopkins, LLC have prepared an overview of some of the items included in the Act. Here are some of the highlights:**

### *Creation of Health Benefit Exchanges*

The Act requires states to establish the American Health Benefit Exchanges and Small Business Health Options Program ("SHOP") Exchanges (collectively, "Exchanges") designed to assist individuals and qualified employers in purchasing coverage. Exchanges are required to:

1. Be a governmental agency or nonprofit entity established by a state;
2. Only offer qualified health plans;
3. Establish procedures for certification of health plans as qualified health plans; and
4. Require health plans seeking certification to submit a justification of any premium increase prior to implementation of such increase.

Additional information to know about the Exchanges:

- Exchanges will be required to keep an accurate accounting of all activities, receipts, and expenditures and annually submit a report concerning such accountings.
- The Exchanges will permit an employer to select a level of coverage for its

employees. Employees can then choose to enroll in any qualified health plan that offers that level of coverage. Initially, only individuals and employers with 100 or less employees will be eligible to participate in the Exchanges. Employers with 100 or more employees may join an Exchange after January 1, 2017.

- The Office of Personnel Management (which administers the Federal Employees Health Benefit Program) will be required to offer at least two multi-state plans in each Exchange. At least one plan must be provided through a nonprofit entity and one plan must not provide coverage for abortions except as permitted by federal law.
- Through the Exchanges, the Act will also provide funding for the Consumer Operated and Oriented Plan (CO-OP) program, a program to create nonprofit, member-run health insurance companies that will offer qualified health plans.

### *Impact on Employers*

The impact on your business depends on the size of your company:

- Beginning January 1, 2014, large employers (employers with 50 or more full-time employees) that do not offer qualified coverage to full-time employees will be subject to a penalty of \$750 per full-time employee. Employers that offer coverage but have at least one employee receiving a premium tax credit through an Exchange will be assessed a fee equal to the lesser of \$3,000 per employee receiving a tax credit or \$750 for each full-time employee. Employers that impose a waiting period on employees before permitting them to enroll in coverage will be assessed a fee per employee based on the length of the waiting period. The Act also prohibits employers from discriminating against or discharging any employee because the employee's actions subject the employer to penalties under the Act.
- Employers with more than 200 employees will be required to automatically enroll employees into the health insurance plans offered by the employer and provide notice to employees about Exchanges, the availability of a tax credit for premium assistance, and the loss of an employer's contribution to an employer-provided health benefit plan if the employee purchases a plan through an Exchange.
- Small employers (employers with no more than 25 employees and with average annual compensation levels not exceeding \$50,000) will be permitted to elect a tax credit of 35% of their employee health care coverage expenses beginning in 2010

and increasing to 50% of their expenses in 2014. The tax credit is phased out based on employer size and employee compensation levels.

- The Act requires the establishment of a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retirees prior to January 1, 2014.
- A new employee benefit cafeteria plan (Simple Cafeteria Plan) is established and defined as a plan that:
  1. Is established and maintained by an employer with an average of 100 or fewer employees during a two-year period;
  2. Requires employers to make contributions or match employee contributions to the plan;
  3. Requires participating employees to have at least 1,000 hours of service for the preceding plan year; and
  4. Allows such employees to elect any benefit available under the plan.
- Insurers of employer-sponsored health plans with an aggregate value that exceeds certain levels (generally \$8,500 for an individual or \$23,000 for a family) will be assessed a tax of 40% on the amount the plan exceeds those levels. The tax will be imposed on the issuer of the health insurance policy (in the case of self-insured plans, the plan administrator or the employer). The "aggregate value" of the plan includes healthcare FSAs, HRAs, employer contributions to HSAs, as well as coverage for dental, vision and other supplemental services (effective January 1, 2013.)

### **Impact on Hospitals and Nursing Facilities**

There are a variety of key provisions related to hospitals and nursing facilities:

- The Act imposes a penalty tax on charitable hospitals who fail to comply with the following requirements:
  1. Conduct a community health needs assessment every two years;
  2. Adopt a written financial assistance policy for patients who require financial assistance for hospital care; and
  3. Refrain from taking extraordinary collection actions against a patient until the hospital has determined whether the patient is eligible for financial assistance.
- Reduces state disproportionate share hospital ("DSH") allotments for most states by 50% or 35% (based on the state's most recent uninsurance rate).

- Supports a movement away from institutional long term care by authorizing states to offer home and community-based services and supports to Medicaid beneficiaries who would otherwise require care in an institution.
- Physician-owned hospitals that do not have a provider agreement in place by August 1, 2010, will be prohibited from participating in Medicare. Allows participation in Medicare under a rural provider and hospital exception if the hospital meets certain requirements addressing conflict of interest, bona fide investments, patient safety issues, and expansion limitations.
- Authorizes the establishment of pilot programs for specified hospitals and hospice programs, to test the implementation of a value-based purchasing program for payments to the provider.
- Authorizes appropriations to HHS for debt service on, or direct construction or renovation of, a health care facility that provides research, inpatient tertiary care, or outpatient clinical services, which meet certain requirements, including that the facility is critical for the provision of greater access to health care within the state.
- Establishes the availability of grants for:
  1. Nurse-managed health clinics;
  2. Enhancement of the nursing workforce through nurse retention programs;
  3. The establishment of new accredited or expanded primary care residency programs; and
  4. Activities that promote better care in long term care facilities.

### **Government Grants and Loan Opportunities**

The Act provides numerous grant and loan opportunities in a variety of areas, most notably for prevention and wellness initiatives and to increase and improve the healthcare workforce.

- Establishes grant programs focused on community preventative health activities and public health initiatives such as establishing programs to provide surveillance and response to infectious diseases and other public health concerns to be administered by the Director of the CDC.
- Establishes a healthcare workforce development grant program as well as various other grant programs to:
  1. Recruit students in social work and similar professions;
  2. Support training in cultural competency, reducing health disparities, and working with

individuals with disabilities; and

3. To support projects designed to provide low income individuals the opportunities to obtain education and training for healthcare occupations.

- Increases the maximum amount of loans made by nursing schools to students, expands student loan forgiveness to include allied health professionals employed in public health agencies and authorizes scholarships for mid-career professionals in the public health and allied health workforce for additional training.
- Authorizes appropriations for the National Health Service Corps Scholarship Program and the National Health Service Corps Loan Repayment Program.
- Establishes a Community Health Center Fund and appropriations to the fund to provide for expanded and sustained national investment in community health centers.

### **Prescription Drugs and Medical Equipment**

A few of the new requirements on the pharmaceutical and medical equipment industry are:

- Amends the Social Security Act to require drug, device, biological and medical supply manufacturers to report transfers of value made to providers, as well as information on physician ownership or investment interest in the manufacturer and it provides penalties for noncompliance.
- Further amends the Social Security Act to require a pharmacy benefit manager ("PBM") or a health benefits plan managing prescription drug coverage under a contract with a Medicare or Exchange health plan to report information regarding the generic dispensing rate, the rebates, discounts, or price concessions negotiated by the PBM, and the payment difference between health plans and PBMs and the PBMs and pharmacies.
- Imposes new taxes on manufacturers of pharmaceuticals (\$2.3 billion annually), medical device manufacturers (\$2 billion annually) and the health insurance sectors (\$2 billion in 2011; increasing to \$10 billion by 2016).

### **Medicare and Medicaid**

The Act expands Medicaid and the Children's Health Insurance Program ("CHIP") and includes many significant changes to both the Medicaid and Medicare programs. The changes are intended to improve access, delivery and quality of healthcare provided through the programs. In an effort to reduce

*(Continued on page 14)*

## Health Care Reform Update

(Continued from page 13)

costs, the Act also focuses on decreasing fraud, waste and abuse in the programs through integrity programs and initiatives.

### *Effect of Medicaid Expansion on State Budgets*

The Act expands Medicaid to all individuals under the age of 65 with incomes up to 133% of the federal poverty level. The expansion of Medicaid will be fully subsidized by the federal government from 2014 through 2016; however in 2017 financing for newly eligible individuals will be shared between the states and federal government. Even accounting for cost sharing, the Congressional Budget Office estimates that the Act will increase state spending on Medicaid/CHIP by \$26 billion as a result of the expanded coverage. As states look for ways to fund the increased cost, one option is to take funds that would otherwise be allocated for discretionary care and use those funds to finance the cost of newly eligible individuals. Medicaid providers providing discretionary care services could experience a reduction in coverage as the cost to states is fully phased in.

### *Impact on Private Insurance Industry*

The Act provides for many mandates to the insurance industry, such as prohibiting insurers from denying coverage based on preexisting conditions and discriminating against individuals based on health status or gender. The Act will prohibit plans from placing lifetime limits on coverage and beginning in 2014 annual limits on coverage will also be prohibited. Insurers will be required to provide dependent coverage for children up to 26 years of age. Insurers will be subject to certain reporting requirements, including information on how premium dollars are spent and justification for increases in premiums.

### *Individual Health Coverage Mandate*

Beginning in 2014, the Act will require all individuals (with limited exceptions) to obtain qualifying health coverage or pay a penalty. Enforcement of the full penalty (the greater of \$750 per person up to a maximum of \$2,250, or 2% of household income) will be phased in over the course of two years beginning in 2014. Individuals without coverage through their employer will be able to purchase coverage through Exchanges. The Exchanges

are established under the Act to provide access to coverage for individuals and small employers. Individuals who have coverage through their employer are permitted to keep their current coverage. Individuals purchasing coverage through the Exchanges with household incomes falling between 100%-400% of the federal poverty level will be eligible for tax credits related to their premiums and cost-sharing subsidies.

### *Individual Tax Matters*

- The Medicare Part A income tax rate will increase from 1.45% to 2.35% for individuals earning more than \$200,000 or couples earning more than \$250,000 (effective January 1, 2013).
- The Act also modifies current laws relating to HRAs and FSAs, such as increasing the tax on distributions from HRAs and FSAs that are not used for qualified medical expenses and capping contributions to FSAs under cafeteria plans to \$2,500 per year (effective January 1, 2011). ■

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## Current Treatments for Benign Prostatic Hyperplasia

*James C. Ulchaker MD FACS. Co-Director Prostate Center. Glickman Urological and Kidney Institute, Cleveland Clinic Foundation, Cleveland, Ohio.*

For numerous decades, transurethral resection of the prostate (TURP) has been considered as the gold standard treatment for benign prostatic hyperplasia (BPH). Although TURP significantly improves lower urinary tract symptoms (LUTS), complications associated with this procedure, such as TURP syndrome, operative bleeding requiring blood transfusion, and incontinence are still reported in up to 20% of operative cases.(1). Consequently, alternative minimally invasive modalities have been developed. Herein, we discuss the evaluation and initial treatments that can be performed in a general practitioner's office, and more invasive treatments for benign prostatic hyperplasia currently being performed by urologists.

The first key component to properly identifying those men who should be treated for benign prostatic hyperplasia includes a complete and thorough history and physical exam. Pertinent components in the history should include an American Urological Association Symptom Score (AUASS) and Quality of Life Score (QOL). This is a validated seven question score which takes into account both irritative and obstructive symptoms, as well as, how the negative effect of these symptoms affect a man's life. A digital rectal exam (DRE) is essential in an effort to grossly determine a man's prostate size and to palpate for prostate nodules which may indicate a prostate cancer. Both dip and microscopic urinalysis should be performed to screen for a multitude of metabolic problems, a serum creatinine should be obtained and the pros and cons of prostate specific antigen (PSA) should also be discussed. Most primary care doctors do not have the ability to measure a uroflow rate; however, many do have the ability to check a post void residual by a noninvasive bladder scan in their office.

The initial treatment for men with BPH is usually performed using watchful waiting, herbal therapy, or medical management. Watchful waiting is the preferred management strategy for patients with mild symptoms. It is also an appropriate option for men with moderate to severe symptoms who have not yet developed complications of BPH (e.g., renal insufficiency, urinary retention or recurrent infection). Watchful waiting is a management strategy in which the patient is monitored by his physician but receives no active intervention for BPH. The level of symptom distress that individual patients are able to tolerate is highly variable so that watchful waiting may be a patient's treatment of choice even if he has a high AUA symptom

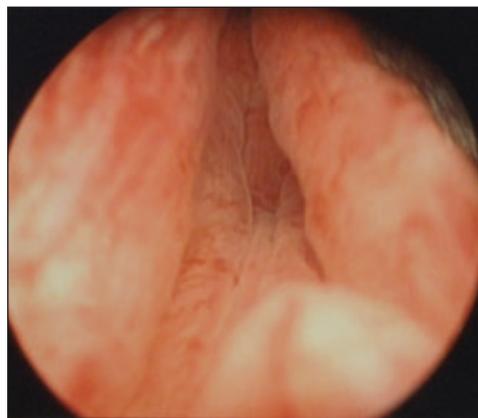


Figure 1: Obstructing prostate

score. Symptom distress may be reduced with such simple measures as decreasing fluid intake at bedtime and decreasing caffeine and alcohol intake. Watchful waiting patients usually are reexamined yearly, repeating the initial evaluation as previously outlined. Prostate volume is assessed by DRE and/or serum PSA. These may predict the natural history of symptoms, flow rate, and risk for acute urinary retention and surgery, patients may be advised as to their individual risk depending on the outcomes of these assessments. Measures to reduce the risk, such as herbal remedies and medical intervention, may be offered depending on the circumstances.

Common herbal modalities include Saw palmetto, Pygeum africanam, and pumpkin seed oil. These agents can be effective in men having mild cases of lower urinary tract symptoms. These substances are not regulated by the Food and Drug Administration, thus there is little data to support their clinical use.

Medical management usually involves the treatment of alpha blockers, 5-alpha reductase inhibitors, or a combination of the two forms of medications. Alpha blockers are effective by relaxing the smooth muscle of the prostate and bladder neck, thus decreasing overall lower urinary tone and therefore, allowing increased urine flow and improved emptying of the bladder. They usually have their effect within a couple weeks time, but have their limitations. Side effects may include orthostatic hypotension, lightheadedness, dizziness, fatigue, or retrograde ejaculation. The 5-alpha reductase inhibitors stop the conversion of testosterone to dihydrotestosterone and are effective by shrinking the overall size of the prostate, and lowering the PSA. They have also been shown to decrease the development of urinary retention and the need for surgical intervention. Side effects may include decreased libido, erectile dysfunction, and in rare cases, breast enlargement or tenderness. Of note, is that in two prospective randomized clinical trials that the combination of the two drugs increase the benefits for all of the above when compared to when either drug is used alone (2, 3).

When medical management fails, or men decide that they do not want to take medications, further urologic evaluation for these more complex patients, may involve more invasive evaluative procedures. Urodynamics have a utility in assessing bladder function and confirming bladder outlet obstruction in men with lower urinary tract symptoms (LUTS). However, pressure flow studies in the management of LUTS and BPH is controversial and is currently not recommended for routine use. We currently recommend the use of these studies for patients who demonstrate repeated elevations in PVR levels or have a known or likely component of having a neurogenic bladder.

Transrectal ultrasound can confirm prostate size, visualize prostate anatomy for invasive therapy, by assessing the presence of an intravesical component and size of the middle lobe, and diagnosing the presence of prostate cancer, if the PSA indicates, in concert with a prostate biopsy.

Endoscopic evaluation of the lower urinary tract is not recommended in an otherwise healthy male with an initial evaluation consistent with bladder outlet obstruction (BOO). However, cystoscopy is recommended if more invasive treatment alternatives are being contemplated, such as TURP or prostate

laser vaporization to determine the anatomical configuration of the prostate, or if hematuria is present.

Transurethral resection of the prostate (TURP) has long been considered the gold standard treatment in situations where medical management has failed. The TURP procedure uses electrical current through a wire loop to essentially whittle away the middle aspect of the prostate, thus coring its center. The prostatic chips are then flushed from the bladder at the end of the case. Postoperatively, a 24-48 hour hospital stay and Foley catheterization is usually required. The procedure yields excellent results; however, it also has many drawbacks. During the procedure an irrigant of fluid must be used to allow the surgeon the ability to visualize where the next piece of prostatic tissue needs to be resected. In the traditional TURP, this irrigant is usually composed of glycine. If excessively absorbed through the venous system, the life threatening complication of the TURP syndrome can occur. This syndrome consists of fluid intoxication, hyponatremia, myoglobinemia, and dialysis. Other potential complications of TURP include blood transfusion, incontinence, and erectile dysfunction. Newly developed bipolar electrical devices now allow saline to be used for TURP irrigation, however, most urologists that perform TURP still use traditional glycine irrigation.

Because of these major complications, a variety of minimally invasive treatment options have been developed. Some such as microwave therapy involve the use of heat to create an area of coagulative necrosis in the prostate. This eventually, over weeks to months, will lead to tissue resorption, alpha-adrenergic receptor destruction, and a subsequent improvement in urologic symptoms. One positive aspect of this procedure is that it only requires sedation in the office and that an anesthetic is not required. Its drawback, is that it does not produce the same long-term substantial benefits of urinary flow and symptom improvement that TURP does, and thus, this procedure is now used sparingly for those men who complain of moderate symptoms only.

When a more substantial long-term benefit is desired, prostate laser vaporization has become a much more frequently performed procedure. In this procedure, the prostate tissue is not resected, it is vaporized. The two most common laser wavelengths of energy are 532nm which is absorbed by oxyhemoglobin, and 980nm which is absorbed by both water

and oxyhemoglobin. Most commonly, these procedures are done under a spinal or general anesthetic. Intubation is often not necessary, but this decision should be made in conjunction with your anesthetic team.

These procedures produce a channel similar to TURP, but the severe complication profile is significantly reduced. Since normal saline can be used as the irrigant with light energy, the risk of TURP syndrome has been eliminated. Also, because this light energy is absorbed by hemoglobin, blood loss has been markedly decreased as well. Since visualization without the blood loss is much improved, the risk of damaging the urethral sphincter has lessened, and thus the urinary incontinence rate has also fallen. Because the depth of energy penetration into the prostatic tissue is significantly less than with traditional TURP, and no electrical energy damage is present to produce neurological injury, clinical trials have shown that the rate of erectile dysfunction using laser energy is essentially negligible (4). Patients with ongoing treatment of anticoagulants, such as aspirin, clopidogrel, and coumadin, can safely have laser vaporization performed (5). However, when possible, I prefer to remove these anticoagulants for 5-7 days. The patient is sent home the same day, usually 2-4 hours post op, and if the urine is clear the morning of postoperative day 1, the catheter is removed.

Laser vaporization of the prostate is not perfect and does have some minor, but irritating complications. Short term dysuria is common usually lasting 2-4 weeks. Urinary tract infections may develop postoperatively which may be secondary to small amounts of sloughed tissue which commonly occurs. Retrograde ejaculation rates of between 35-50% have also been reported.

For very large prostates, those greater than 150 grams in size, open simple prostatectomy may still have a role. This involves an incision from the umbilicus to the pubic bone; however, laparoscopic and more recently single port procedures have been reported. During all of these procedures, some type of incision is made in the prostatic capsule, and the prostatic adenoma is mobilized and expressed through this capsulotomy, then the capsulotomy is sutured closed. This is analogous to incising an orange peel, expressing the orange through the orange peel, and then suturing the peel closed. This procedure, compared to all prostatic procedures, yields the best functional result, however, it is the most substantially invasive, and thus is rarely performed in 2010.

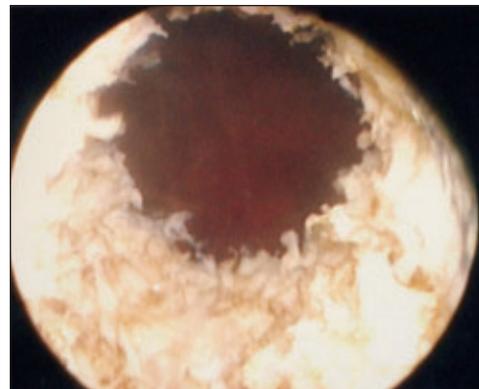


Figure 2: Prostate post treatment with 980nm laser

In conclusion, we continue to advance the treatments for BPH and now have numerous options for men to fit their short and long term needs. As physicians, we all must remember to treat the whole patient, and not just the prostate. Unlike twenty years ago, with the many different therapies currently available, one must take into account all aspects to a patient's quality and quantity of life issues, and choose the best individual treatment option for that particular patient.

**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. ■

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## AMCNO Speakers Bureau Talks Prevention with Seniors

The AMCNO Speakers Bureau is a favorite resource of the Encore Program for seniors at Cuyahoga Community College and Academy member **Gerard Isenberg, MD**, of University Hospitals assisted in March with an engagement at Tri C's Parma campus. The auditorium was filled with seniors who were eager to hear Dr. Isenberg's talk about prevention titled "Digestive Health — How to Live a Healthy Lifetime."

Dr. Isenberg's overall message was simple: if you want to prolong your life, improve your health through some lifestyle changes such as quit smoking, drink in moderation, get exercise at least 4 times per week, eat right, and see your doctor on a regular basis.

With March being National Nutrition Month, Dr. Isenberg noted that the food pyramid has changed and cited [www.mypyramid.gov](http://www.mypyramid.gov) as a great resource for "Steps to a healthier you."

The remainder of Dr. Isenberg's talk centered on various conditions associated with digestive health and the technology used to assist in diagnosis and treatment. He noted that sixty million Americans suffer from heartburn and that drinking coffee can

promote this condition. Complications include Barrett's esophagus, a pre-cancerous condition, esophageal ulcers and/or bleeding, and esophageal cancer.

He also illustrated for the group how ulcers can occur when excess acid is produced in the body; causes include use of nonsteroidal anti-inflammatory drugs (NSAID) such as ibuprofen and aspirin, *H pylori* bacterial infection, and smoking.

Dr. Isenberg further enlightened the audience regarding gallstones — a condition that occurs in women two times as often as men, women over 55 and people with a family history of gallstones. Eating fiber is a means of prevention as is drinking coffee, exercise and avoiding rapid weight loss.



*Dr. Gerard Isenberg listens to a question from a participant at the Tri-C Encore program.*

Dr. Isenberg wrapped up his presentation discussing colon cancer noting that this type of cancer is the second leading cause of cancer deaths, noting that ninety percent of all colon cancers can be prevented, yet only 40% of Ohio's population has been screened. Dr. Isenberg stressed to the group the need to get tested and discussed the various tests to diagnose the condition.

During his presentation, Dr. Isenberg provided the audience with an overview of some of the technologies used to aid in the diagnosis of the above as well.

The AMCNO wishes to thank Dr. Isenberg for committing his 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. ■

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## AMCNO Pollen Line Kicks Off Allergy Season

The AMCNO Pollen Line opened for business this year on April 1, with an immediately heavy call volume due to the quick rise in temperatures of early spring. Through the years of the AMCNO providing this important service, members of the Northeast Ohio community have come to depend upon the Pollen Line to help themselves better manage the allergy season.

In preparing for the allergy season this year, the AMCNO staff proactively reached out to both the local news media as well as the national weather channel in an effort to promote the Pollen Line and to offer this free service for their use in providing accurate pollen counts in our area. The only stipulation was that they include the AMCNO as the source of the data in their report. Staff fielded several calls from the media, including the *Plain Dealer* who once again was eager to promote this valuable AMCNO community service.

Allergists and AMCNO members **Robert Hostoffer, D.O., Theodore Sher, M.D., Haig Tcheurekdjian, M.D.** and **Amy L. Marks, D.O.**, of the Allergy/Immunology Associates Inc. again is providing daily pollen counts along with preventative methods to help allergy sufferers cope with the sniffing and sneezing brought on by the season through October 1. The Pollen Line is updated weekdays by 8:00 a.m. with the counts available either via the phone recording or online at [www.amcnoma.org](http://www.amcnoma.org). The public can call the free hotline at (216) 520-1050, accessible 24-hours a day, to hear this recorded report on the density of the allergens, probable effects on those sensitive to such agents, and what precautions to take.

Dr. Amy Marks recently was featured on the AMCNO *Healthlines* radio program discussing the pollen season and promoting the use of the Pollen Line. This taped interview can be heard at [www.amcnoma.org](http://www.amcnoma.org).



## SAVE THE DATE!

### The 7th Annual Marissa Rose Biddlestone Memorial Golf Outing



**Monday, August 9, 2010**

**KIRTLAND COUNTRY CLUB**

1 p.m. Shotgun Start  
1-2-3 Best Ball Format  
Raffle & Great Prizes

*Watch for details soon!*

## Roth IRA Conversion..... Is it Right for You?

The Tax Increase Prevention and Reconciliation Act of 2005 (TIPRA) eliminates income limits and allows all taxpayers to convert traditional IRAs to Roth IRAs beginning in 2010.

Roth IRAs can play an important role in retirement and legacy planning as they allow for tax-free growth and withdrawals that are not subject to required minimum distributions during the account owner's lifetime. If you have questions and wonder whether or not a conversion is right for you, we can help. Take advantage of the AMCNO member discount for a complimentary Roth conversion consultation.

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# AMCNO ACTIVITIES

## Medicare Cuts Delayed Again – COBRA Subsidies Continued – Definition of Hospital-Based Physician Corrected

Both the House and Senate have approved a package of short-term “extenders,” which includes a freeze on the Medicare payment formula used to reimburse doctors and continues a financial reprieve for the unemployed who rely on COBRA health benefits. The House passed the \$18 billion package 289-112. The Senate advanced the bill, 59-38. The votes came on the same day that a scheduled 21.2% pay cut officially went into effect.

The legislation extends until June 1 the current higher level of physician payment, but also extends federal assistance for COBRA premiums until May 1. It is possible that some claims for physician services were processed at rates reflecting the 21.3 percent cut. If that has occurred the Centers for Medicare and Medicaid Services have indicated that any such claims will be

reprocessed and payment adjustments made without physicians having to take any additional action.

The legislation also includes “EHR Clarification” language. Specifically, the legislation amends the definition of hospital-based eligible professional under ARRA. Instead of a hospital-based eligible professional pertaining

to a professional included in an “inpatient or outpatient” setting, the legislation amends the ARRA definition to include a professional in an “inpatient or emergency room setting.” As a result, physicians practicing in an outpatient setting can now be eligible for the Medicare/Medicaid incentive program under ARRA. The AMCNO sent a detailed letter to in response to the meaningful use rule indicating our concerns with this definition. This EHR clarification language is good news for the physicians in Northern Ohio. (See page 4 of this issue for more on this Congressional action and on Meaningful Use.)

Information concerning the Senate proceedings and the legislative language can be accessed at: [http://www.senate.gov/legislative/LIS/roll\\_call\\_lists/vote\\_menu\\_111\\_2.htm](http://www.senate.gov/legislative/LIS/roll_call_lists/vote_menu_111_2.htm).

## In Vino Veritas

AMCNO members, residents, medical students and spouses/guests attended this year’s wine tasting event on Sunday, February 21st at La Cave du Vin. Erich Lasher, wine guru at La Cave, reviewed the particular flavors and ingredients of each wine. The *San Felice II Grigio Chianti Classico 5L*, this big, full bodied Tuscan variety, was in the lead as the favorite until the *Domaine Paul Autard Chateauneuf du Pape 2006* was poured. This “massive” wine proved to be the perfect blend. Following that, the “Super Tuscan” *Podere Guado al Melo Bolgheri 2006*, aged in small French oak barrels got everyone sharing their excitement about wine.

The venue provided the perfect atmosphere to mingle with fellow AMCNO members and their guests...we will be doing it again next year, watch for information!

