AMCNO Physician Leadership Meets with CGS Administrators

This spring, the Academy of Medicine of Cleveland & Northern Ohio (AMCNO) physician leadership and staff were pleased to welcome representatives from CGS at the AMCNO offices. The purpose of the meeting was to discuss recent issues that have arisen at both CGS and the Centers for Medicare and Medicaid Services (CMS). The CGS staff discussed claims processing issues, timely payment, customer service and other matters of importance to AMCNO members. On hand from CGS were Dr. Gary Oakes, Medical Director for CGS, Mr. Steve Smith President and COO of CGS, John Kimball, VP of Medicare Operations for CGS (via phone) and Vanessa Williams, CGS Provider Outreach.

The meeting was very productive with CGS representatives providing key updates and background information on how CGS and CMS have worked to resolve payment issues over the last few months. The AMCNO was pleased to learn that CGS plans to continue to work closely with us and meet with physician leadership and staff on a regular basis to discuss any problems or issues our members may be experiencing with CGS. Dr. Oakes also offered to prepare articles for upcoming issues of the Northern Ohio Physician magazine with an eye toward providing timely information on matters that could impact physicians and their practice.

The CGS representatives acknowledged that a strong relationship with the AMCNO is an important part of their success as a Medicare contractor and they also recognize the importance of establishing and cultivating relationships with key provider organizations like the AMCNO. To that end, the CGS Provider Outreach and Education team promised to continue to provide input to the AMCNO on

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AMCNO Submits Recommendations to the Ohio Supreme Court Urging Amendments to the Affidavit of Merit Provision

By: Bret Perry, Esq., Bonezzi, Switzer, Polito & Hupp Co., L.P.A.

Recently, the Academy of Medicine of Cleveland & Northern Ohio (AMCNO), submitted recommendations to the Ohio Supreme Court, Commission on the Rules of Practice & Procedure, on behalf of its 5,000 members, urging amendment of Ohio Civil Rule 10(D)(2), also known as the Affidavit of Merit provision. The recommendation was authored on behalf of the AMCNO Medical Legal Liaison Committee by Bret Perry, Esq. of Bonezzi Switzer Murphy Polito & Hupp Co. L.P.A. and Edward Taber of Tucker Ellis, LLP.

The Affidavit of Merit requirement in Ohio Civil Rule 10(D)(2), introduced in 2005, was designed to ensure that no healthcare provider was named in a medical negligence action unless a qualified expert had reviewed the case and determined, based on the available medical records, that the claims of medical negligence had merit. However, the Rule, in its current form, has failed in its intended purpose.

Under the Rule as currently enacted, a plaintiff prior to filing his or her Complaint must: (1) obtain the relevant medical records; (2) provide the records to a qualified expert pursuant to Evid.R. 601(D) and 702; and (3) if the expert determines that medical negligence may have occurred, obtain in writing the opinions of the expert as to each defendant thereby satisfying Civ.R. 10(D)(2). At the time of filing his or her Complaint, a plaintiff must attach an Affidavit of Merit or contemporaneously file a Motion for extension of time, up to 90 days, to obtain a sufficient Affidavit.

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AMCNO Submits Recommendations to the Ohio Supreme Court Urging Amendments to the Affidavit of Merit Provision (Continued from page 1)

Despite the straightforward requirements set forth in the Rule, Ohio trial courts are generally willing to grant repeated extensions of time to obtain the necessary expert review and Affidavit, well in excess of the 90 day limit, or are unwilling to dismiss the action when the Affidavit submitted does not comply with the Rule. The Rule as currently enacted has failed to prevent the filing of frivolous claims and the unnecessary naming of healthcare providers in actions involving medical negligence. The Rule as applied at the trial court level has failed to effectuate its intended purpose and as a result innumerable healthcare providers continue to be needlessly named in litigation, and forced to defend otherwise meritless claims.

For over two years, the AMCNO Medical Legal Liaison Committee has been proactive in reviewing these problematic issues. In conjunction, other associations, including the state medical association and The Doctors Company, referred issues and proposed changes concerning Civ.R. 10(D)(2) to the Ohio Supreme Court Rules Committee.

The state medical association suggested these proposed changes to the Rule: (1) a separate Affidavit of Merit be provided relative to each defendant named in the Complaint for whom expert testimony is necessary to establish liability; (2) a statement listing all the medical records reviewed, the source of the records and the dates of service; (3) a statement of the affiant’s qualifications, the familiarity with the standard of care and the medical specialty with which the affiant is familiar; and (4) a statement listing which defendant(s) proximately caused injury to the plaintiff.

The Doctors Company suggested that no extensions to file an Affidavit of Merit be granted beyond 180 days of the filing of the Complaint, and that the extension could only be granted “for good cause.” The reason for this suggestion is that Ohio law allows for a “180-day notice letter” regarding a plaintiff’s intent to sue and consequent extension of the statute of limitations by 180 days.

In accordance with Civ.R. 10(D)(2), AMCNO has proposed the following Rule amendments: (1) Affidavits of Merit shall be provided by an expert witness satisfying the requirements of Evid.R. 601(D) and 702 and R.C. 2743.43; (2) a separate Affidavit of Merit shall be provided relative to each defendant named in the Complaint for whom expert testimony is necessary to establish liability; (3) the expert must list his or her area of specialization and qualifications; (4) the expert must enumerate the records reviewed in reaching his or her conclusions; (5) any defendant named in an action alleging medical negligence is not required to answer or appear until 30 days after being served with an Affidavit satisfying all prerequisite requirements of Civ.R. 10(D)(2); and (6) the prerequisite requirements enumerated in Civ.R. 10(D)(2) are mandatory.

These proposed Rule amendments would remedy any ambiguity in the current version. In addition, the proposed Rule amendments would alleviate the unnecessary imposition on Ohio courts of matters alleging medical negligence. Finally, the Rule amendments would assist in alleviating the significant costs to the individual medical defendants, both financial and personal. Every medical defendant is faced with the personal cost of forever reporting any action in which he or she has been named as a defendant in a medical negligence action in addition to the financial costs associated with defending a claim, even those having an insufficient basis at the time of filing.

As it stands today, Civ.R. 10(D)(2) is not being followed by plaintiffs and the trial courts are not applying the Rule. This is not likely to change unless the Ohio Supreme Court Rules Committee applies the amendments to the Rule as urged by AMCNO.
Wage and Hour Compliance Necessary To Avoid Litigation Commonplace In Healthcare Industry
By Nicole J. Gray, Labor and Employment Attorney, McDonald Hopkins LLC

In 2010, the U.S. Department of Labor (DOL) announced that it was launching a mass wage and hour probe of the broadly-defined “healthcare” industry. The “healthcare” industry was not, however, limited to large hospital systems or nursing homes. Indeed, it includes independent physician practices, as well as home health agencies.

The DOL’s focus on the healthcare industry has steadily increased since 2010. Indeed, the DOL filed a lawsuit in December 2011 against an Ohio-based home health services agency seeking more than $84,000 in back wages and liquidated damages for 10 workers due to employee misclassification.

In addition to increased government enforcement, the healthcare industry has become an attractive target for private wage and hour litigants in part because employee pay is generally higher in healthcare than other industries. Wage and hour litigation continued in 2011 to out-pace other types of workplace class actions and has surged by more than 325% since the early 2000s. See Seyfarth Shaw LLP’s Annual Workplace Class Action Litigation Report: 2012 Edition. This trend is expected to continue in 2012 making wage and hour compliance essential for an employer to avoid becoming a defendant in the current surge of payroll practice litigation.

Wage and Hour Law:
The DOL administers and enforces the Fair Labor Standards Act (FLSA), the federal law that regulates the payment of minimum wage and overtime to non-exempt employees. In addition to the FLSA, many states have enacted statutes that provide greater protection to workers. Accordingly, employers must be aware of both federal and state overtime and minimum wage requirements.

The FLSA provides various exemptions to the general rule that employers must pay employees overtime rates of time and one-half the regular rate of pay for all hours worked in excess of 40 per workweek. Pursuant to the FLSA, employees are generally exempt from overtime laws if they fall into one of the following “white-collar worker” exemptions: (1) executive; (2) administrative; (3) professional; (4) computer; or (5) outside sales.

The FLSA regulations set forth three specific requirements for determining whether employees qualify for a white-collar worker exemption. The first criterion is a “salary-level” test, which requires an employer to pay an exempt employee a minimum of $455 per week. The second criterion, the “salary basis” test, requires that an exempt employee receive his or her full salary for any week in which he or she performs work, without reduction because of variations in the quality or quantity of work performed. The final criterion is a “duties” test, which requires that the job must have as its primary duty the job functions described under one of the exemptions (usually related to management, supervision, or authority).

Employees who do not meet the exemption classifications are deemed “non-exempt” and must be properly paid for all hours worked in a workweek. The failure to properly count and compensate an employee for all hours worked will likely result in an overtime violation because employers have not fully accounted for hours worked in excess of 40 during the workweek.

Common Wage and Hour Violations:
Wage and hour violations that plague many employers also occur in the healthcare industry, such as: misclassification of workers (as exempt from overtime pay), “off-the-clock” work, improper wage deductions, and failure to properly calculate overtime pay.

Misclassification:
Employees alleging misclassification are usually challenging an employer’s decision to classify them as “exempt” and assert that they were improperly denied overtime compensation due to such misclassification. When the FLSA was first enacted, an employer could fairly easily distinguish who in its workforce was a “manager” and who was a “worker,” such that it was clear which employees were exempt from the overtime regulations. However, as the economy has shifted from manufacturing to service industries and a more efficient economy eliminated multiple levels of middle management, the lines between exempt and non-exempt employees have been blurred.

Traditional misclassification of workers is a frequent problem in the healthcare industry and employers must avoid making classification decisions based on “exempt-sounding” job titles, such as Coordinator, Administrator, Analyst, or Specialist. Likewise, employers routinely misapply the learned professional exemption to questionable categories of workers, such as nurses and respiratory therapists. Moreover, some healthcare employees are misclassified under an executive exemption when their primary duties are really patient care, not management. Accordingly, proper determination of exempt or non-exempt status requires a close examination of each employee’s job duties measured against applicable regulations and case law.

Additionally, the healthcare industry is susceptible to misclassification claims based on an employer’s designation of an employee as an “independent contractor” rather than an “employee.” See McDonald Hopkins LLC, Worker Classification is Back in the IRS Spotlight, March 2010.

Calculation of “hours worked”: For years, among the most publicized and costly areas of wage and hour litigation for healthcare employers has concerned claims for failure to pay employees for off-schedule hours worked. In general, “hours worked” includes all time an employee must be on duty, on the employer premises, or at any other prescribed place of work. Also included, however, is any additional time the employee is “suffered or permitted” to work, even if the employer does not specifically authorize the work. If the employer knows or has reason to believe that the employee is continuing to work, the time is considered hours worked and must be compensated. For example, nurses who stay beyond their scheduled shift to work on patients’ charts (or take such work home to complete) must be compensated for the additional time worked, even if that additional time was not formally authorized.

Likewise, the employee who works through lunch due to a patient emergency must be compensated for the work performed even though it occurred during a designated meal period. “Bona fide” meal or break periods that are more than 20 minutes do not count towards hours worked under the FLSA, provided employees actually take the break and are completely relieved from duty during that time. Such breaks do have to be counted, however, to the extent that the meal period is used predominantly for the benefit of the employer. Accordingly, employers choosing to automatically deduct 30-minutes per shift must ensure that the employees are actually receiving the full meal break or the employer may be liable for a FLSA violation.

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Another common “hours worked” issue concerns travel time, which often arises with healthcare employees who are required to travel to different facilities within the same network during the workday or workweek. While ordinary travel to and from work is not compensable, time spent by an employee in travel as part of his or her principal activity must be considered hours worked. For example, if a licensed practical nurse who works at an assisted living facility, which has a sister facility 20 miles away, is asked to fill in for someone at the sister facility after she has begun her shift at her normal work site, her travel time must be paid.

**Calculation of overtime:**
A common error made by healthcare employers is the failure to include non-discretionary bonuses in calculating an employee’s regular rate of pay for purposes of calculating overtime. The FLSA requires that non-discretionary bonuses, such as bonuses announced to employees to encourage attendance or to sign-up for additional shifts, must be included in the regular rate of pay. Discretionary bonuses, however, that are determined at the sole discretion of the employer and are not made pursuant to any prior contract, agreement, policy, or promise which caused the employee to expect such payments regularly, may be properly excluded from the regular rate of pay.

Another potentially costly error may occur in an employer’s mathematical calculation of employee hours. Though the FLSA permits an employer to round employee time to the nearest quarter hour, a violation of minimum wage and overtime provisions may occur if the rounding is done in the employer’s favor. Rounding is acceptable where the practices average out so that the employees are fully compensated for all the time actually worked. Thus, employee time from 1 to 7 minutes of the quarter hour may be rounded down, and not counted as hours worked, but employee time from 8 to 14 minutes must be rounded up and counted as a quarter hour of work time.

Another increasingly litigated topic concerns the aggregation of hours worked at separate facilities for purposes of calculating overtime. The DOL may view time worked at two or three hospitals as time that should be aggregated if it believes that the hospitals function as “joint employers.” The DOL generally employs a fact-intensive approach to determining whether to aggregate work hours that primarily focuses on employee control issues.

**Conclusion:**
The potential risks to employers for improper payroll practices are severe and given the scope of the damages, a class action suit on FLSA grounds could be crippling for many employers. To ensure compliance with both federal and state wage and hour laws, particularly as wage and hour lawsuits continue to be an attractive target for both governmental audit and private litigation, employers should conduct periodic audits of employee classifications, review internal payroll practices, and educate managers about wage and hour policies. Employers are best served by pro-active planning to determine their wage and hour vulnerabilities and prepare strategies to avert future litigation.
AMCNO Legislative Update

Physician Immunity Legislation Update

In March, Dr. John Bastulli, AMCNO Vice President of Legislative Affairs and Mr. Edward Taber Co-Chair of the AMCNO Medical Legal Liaison Committee testified on behalf of the AMCNO in support of HB 421. This legislation, which was spearheaded by the Academy of Medicine of Cleveland & Northern Ohio (AMCNO) addresses a public and patient safety issue and is a modest attempt to close a loophole by modernizing existing law. The AMCNO Legislative and Medical Legal Liaison Committees have been working on this legislation and pushed for its introduction. The AMCNO wants to be certain that physicians have the ability to report information to the proper authorities or employers when necessary without fear of reprisal or disciplinary action.

Mr. Taber informed the members of the Ohio House Criminal Justice committee that this bill is not a major innovation. Rather, it modestly broadens and modernizes an existing statute – R.C. 2305.33 – to address a patient safety and public safety need relating to physician reporting of imminent dangers to two groups: (1) patients; and (2) the public at large.

He noted that the current statute needs to be amended because it has a glaring loophole – a loophole which has been exploited in litigation – and because its definition of “harm” has been rendered obsolete by developments in federal and state medical privacy law. As a result, the threat of medical privacy litigation is preventing physicians from being able to report imminent dangers.

He stated that when the current law, R.C. 2305.33, was originally passed, medical privacy litigation was not the prevalent liability risk that it is now. In fact, an independent tort for “unauthorized disclosure of medical information” did not exist in Ohio when this law was written. The law needs to be altered so as to broaden its scope, allowing physicians to do the right thing to protect patients and the public, without fear of liability.

Under the current law, physicians may warn certain people if a patient is operating a “commercial carrier,” such as a taxi cab, against the physician's advice. But, the physician may not report if the patient is disregarding the physician’s advice by operating other vehicles that could cause grievous injury to the patient or the public – such as a large truck, heavy machinery, or a car that is not a taxi cab.

Dr. Bastulli provided background to the committee on how the legislation could assist physicians in their practice. He noted that his practice provides anesthesia and pain management services at a number of healthcare facilities in the Cleveland area. These facilities have a policy that prohibits patients from driving until the day after their procedure in order to prevent them from operating a vehicle under the influence of hypnotics, sedatives and/or narcotics because these medications remain in their body for an extended period of time. He has had personal experiences with patients who have received anesthesia for procedures and then drove themselves home against medical advice and facility policies. Due to privacy concerns, he was unable to contact local authorities in order to protect the public at large. Furthermore, he noted that risk managers and hospital legal counsel have advised physicians that they are prohibited from contacting local authorities with respect to these types of cases and/or concerns.

After the hearing, the AMCNO worked with Rep. Slaby to prepare minor amendments to HB 421 that would clarify under what circumstances a physician could notify an employer if there was suspicion of drug or alcohol abuse and the patient's actions could endanger the driver or others. The amendment was adopted by the Criminal Justice committee and it was hoped that the bill would be voted out that same day. However, opposition testimony was provided by the trial lawyer association and the American Civil Liberties Union of Ohio. Both organizations testified that the legislation could have far-reaching ramifications and impact medical privacy laws. The state medical association testified in support of the measure and provided proponent testimony on the bill.

Going forward, the AMCNO will be working with another representative and new committee chairman on HB 421 since Rep. Slaby has been appointed to the PUCO board and has left the state legislature. The AMCNO plans to meet with the new committee chairman Rep. Kirk Schuring in the next few weeks to discuss the bill further.

Schools Across Ohio Continue to Opt out of BMI Screenings

The latest figures from the Department of Education show 545 traditional districts, community schools or nonpublic schools have already submitted waivers to a requirement they conduct BMI screenings for all students in kindergarten and grades 3, 5 and 9. That number makes up about 30% of all the education entities in the state, the remainder of which have until June 30 to submit a waiver if they choose not to comply. Last year 686 of the more than 1,800 education entities in the state opted out of the program that was enacted in “healthy schools” legislation from last session. For those that did participate, the data was submitted to the Department of Health for analysis, but submissions were so low it was not easy to come up with meaningful data. The bipartisan legislation creating the BMI screenings was the result of collaboration among hospitals, lawmakers, and physician associations including the AMCNO. The coalition of these groups backed the bill with the hope

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that there would be a greater focus on the health of Ohio students. The legislation allows parents to opt out of having their child screened or have the student's analysis conducted by a physician and then submitted to the school.

The Office of Health Transformation (OHT) Outlines Plan to Simplify Medicaid Eligibility
The Office of Health Transformation has proposed changes to Medicaid eligibility in an effort to prepare for the estimated 1 million Ohioans who could qualify for the program in 2014. OHT believes that the state's system for determining Medicaid eligibility is outdated and cannot support the amount of newly eligible Ohioans expected to apply. To counter this OHT has outlined a plan for simplifying the eligibility process and plans to take public comment on the proposal. The goal of the new approach is not only to improve the client experience but also to significantly reduce the cost of the eligibility system. OHT expects the new model would cover about the same number of individuals who would otherwise have been covered by Medicaid had no changes to the system been made. The new approach would make it easier for families to more easily see if they qualify for Medicaid. They would also be able to apply online under the proposal. To view the OHT concept paper on this topic go to: http://healthtransformation.ohio.gov/LinkClick.aspx?fileticket=OlqiSOVeb08%3d&tabid=117

Other Legislation Under Review

HB 438/SB297 – Clinical Research Faculty Certificate
The AMCNO actively supported this legislation and offered our assistance to the health care institutions around the state in their effort to get this legislation enacted. In addition, the AMCNO submitted written testimony in support of both HB 438 and SB 297 to the committee chairman, the sponsors of the legislation and to the Senate Health & Aging committee. The legislation allows for the renewal of a Clinical Research Faculty Certificate and implements certain requirements that must be met in order for a physician to obtain a certificate or renew their certificate. Once the legislation becomes law, Ohio has the ability to attract top-tier physicians to the state and then retain these physicians once they begin their work, keeping Ohio competitive in research and training. The legislation was spearheaded with the support of academic medical centers around Ohio, including the Cleveland Clinic and University Hospitals, as well as the strong support of the Governor's office.

Physician Assistants: HB 284
The Ohio Association of Physician Assistants (PAs) has introduced HB 284, which would make changes to the PA scope of practice. The legislation would give PAs the authority to make pronouncements of death, insert and remove chest tubes, prescribe physical therapy, write do not resuscitate orders and prescribe Schedule II controlled substances in specified health care settings. The AMCNO is neutral with technical assistance on this bill and we are monitoring the testimony on the legislation.

Payment for Health Care Services: SB 136
The AMCNO strongly supports this legislation which would modify laws on how physicians contract with health insurers, clarify prior authorization requirements, refine prompt pay timeframes, retrospective audits and outline how contracts with physicians could be changed. The AMCNO has sent letters of support to the legislature on this bill and we plan to testify on the bill when hearings are scheduled.

Prescriptive Authority: SB 83
Legislation that will allow Advanced Practice Nurses (APNs) to write Schedule II prescriptions has been enacted – APNs can now write Schedule II prescriptions, but only in certain settings such as hospitals, mental health or hospice facilities. The AMCNO sent letters to legislators asking that APNs be prohibited from prescribing Schedule II drugs in convenience care settings and this change was made to the bill. The AMCNO remained neutral with technical assistance on the bill throughout the debate. The legislation also had the support of both the Cleveland Clinic and University Hospitals of Cleveland.

CRNA Scope of Practice: SB 228/HB 485
The association representing the Certified Registered Nurse Anesthetists (CRNAs) and a number of hospitals are supporting legislation, SB 228 and HB 485, which would grant CRNAs the authority to independently prescribe medication in post-operative and intra-operative settings. The chairman of the AMCNO legislative committee has met with the sponsor of the legislation in the Senate and other interested parties on more than one occasion to address our concerns with this legislation. The main concern of the AMCNO with regard to this legislation is patient safety issues and the AMCNO continues to monitor the bill. At this time our position on this bill is neutral with technical assistance.

Youth Injuries: HB 143
This legislation will establish a statewide standard for a youth athlete's removal from the playing field if there is evidence of a concussion. The bill also requires an athlete who is removed from play due to a suspected brain injury to be cleared in writing by a physician or athletic trainer before returning to play.

The AMCNO strongly supports this legislation and we have written to the legislature offering our strong support. Our letter also expressed concern that there was discussion within the legislature to allow other healthcare providers such as APNs, physical therapists, PAs, optometrists, and chiropractors to clear an athlete for return to play. The AMCNO legislative committee has been following this legislation since it was introduced and we have notified the legislature that we believe that only those licensed health care providers whose scope of practice entails the diagnosis and management of brain injuries should have the authority to clear an athlete to play. At press time, a substitute bill had been drafted and accepted that addresses the AMCNO concerns. The AMCNO will continue to monitor this legislation as it moves through the legislature.

The AMCNO is currently tracking all of the health care related bills in the Ohio House and Senate. For more information about the AMCNO or our legislative initiatives please contact Ms. Elayne Biddlestone at 216-520-1000, ext. 100.
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Medicare Fraud Civil & Criminal Penalty: Pitfalls and Protections

By R. Mark Jones Partner, and Gregory L. Watkins, Associate, Roetzel & Andress, LPA.

Efforts to control the escalating costs of government paid health care are increasingly putting physicians, clinics and hospitals in the crosshairs of both criminal and civil investigations into allegations of Medicare fraud. Physicians and practice administrators must not conclude that because there was no intentional billing misrepresentation, that there is nothing to fear from such investigations. There are proactive measures available that will provide protections from the potentially devastating criminal and civil penalties that are authorized under the law.

Experts estimate that Medicare fraud costs taxpayers from 60 to 100 billion dollars each year. The Government is responding to this fraud in several ways. First, it is implementing fraud programs, such as the Health Care Fraud Prevention and Enforcement Action Team, that treat Medicare fraud as a cabinet-level priority. Second, it is utilizing financial penalties ranging between $5,500 to $11,000 per claim that can cost providers millions of dollars. A Miami physician was sentenced to 235 months in prison and ordered to pay $11.7 million in restitution for participating in a $23 million Medicare fraud scheme. The largest health care system in New Jersey paid $265 million to settle allegations that it fraudulently increased charges to Medicare patients. Finally, the US Department of Health and Human Services (“HHS”), working with the Office of Inspector General (“OIG”), has released plans to conduct investigations into services rendered by non-physicians under Medicare’s “incident-to” filing rules.

The first proactive step all providers must take is to review the adequacy of their Medicare and Medicaid billing compliance programs, and if no program is in place, providers need to immediately implement such programs after consulting with their attorneys. The compliance program is always requested in any investigation, and a properly implemented program is not only a defense, but the Attorney General’s guidelines require favorable consideration if a compliance program is in place, and an unfavorable consideration when there is no such program. Also, if a physician is criminally prosecuted, the U.S. Sentencing Guidelines allow for a reduction in sentence if there was a compliance program used prior to the alleged criminal activity.

The False Claims Act, 31 U.S.C. § 3729, imposes civil liability on any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” For example, a physician who charges for services not rendered or who “upcodes” a service (classifying a procedure as a more expensive one in an effort to obtain a larger reimbursement from Medicare), may be liable under the Act. A civil action brought under § 3729 can be initiated either by the Attorney General or by private persons on behalf of the U.S. Government (a qui tam action). When a private persons (referred to as a whistleblowers or a relators) initiate an action, they must first serve on the Government a copy of the complaint and a written disclosure of all material evidence and information. Next, the complaint is filed with the court under seal, meaning the complaint is kept secret from the potential defendant. The time from the filing of the complaint to the Court issuing an order unsealing the relator’s complaint so the provider can discover the allegations is no less than 60 days, but is more likely to be 18 to 24 months. Such actions require the Government to conduct investigations of the private citizen’s allegations of health care fraud and determine whether it will intervene and proceed with the action on behalf of the private citizen. However, because this process takes place while the complaint is under seal, there is a distinct possibility that the Government investigation will begin before the providers are ever aware of the complaint.

Unfortunately, providers who are the subject of these investigations often unknowingly expose themselves to additional liabilities and penalties while attempting to comply with the Government's requests for information. It is important that providers be proactive in dealing with the Government’s investigative process; educate themselves on the legal consequences associated with making a false claim, and involve their legal counsel at the beginning of the process.

If the Government decides to proceed with the action, it will begin an investigation using one of several government agencies (i.e., HHS or OIG) that issue subpoenas for simple pay disputes. The first indication that what is actually underway is a false claim investigation is a cover letter from the investigating U.S. Attorney. The letter includes Civil Investigation Demands (“CIDs”) stating the government is seeking information related to an investigation of either fraud or false claims. Unfortunately, providers who respond to either the subpoena or the CID without consulting an attorney may inadvertently disclose privileged information or expose themselves to additional liability.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) was pleased to co-sponsor a seminar with the law firm of Roetzel & Andress, LPA., covering the topic of the False Claims Act and how physicians can prepare for false claims enforcement. The seminar was moderated by Mr. Mark Jones with opening comments by the AMCNO president, Dr. Lawrence Kent. Presenters included Mr. Brian Dickerson, Esq., and Mr. Robert Graziano from Roetzel and Andress, LPA.

Attendees learned how to identify when they could be a target of an investigation and how to properly interact with the Department of Justice during their defense. The presenters provided an overview of the False Claims Act (FCA) and recent case decisions; the impact of recent settlements on criminal and investigative actions; new FCA enforcement initiatives in health care, and strategies in FCA cases and compliance techniques to reduce risks.

Please see the article on this page for more information on this important issue.
First, a provider may inadvertently reveal information protected by the attorney-client privilege. This privilege protects communications between clients and their attorney provided they are within the scope of representation. A provider who consults with an attorney after receiving a subpoena or CID is entitled to have those communications protected. However, those who fail to do so, and reveal information that would otherwise be protected, waive any future protection of those communications.

Second, a physician may inadvertently waive the Ohio physician-patient privilege when responding to a subpoena or CID. Under this privilege, a communication made to the physician by a patient, in relation to the physician’s advice to the patient, is privileged and the physician cannot be compelled to testify about such communications. However, a physician who willingly submits this information in responding has waived the privilege and can be compelled to testify regarding the communications. Therefore, a physician must always consult with an attorney to determine how to respond in a way that complies with the Government’s request and preserves the physician-patient privilege.

Third, providers may violate the Health Insurance Portability and Accountability Act (“HIPAA”) if they provide the Government with protected health information. HIPAA makes it a violation for certain health entities to reveal protected health information to third parties without the patient’s consent and imposes civil and criminal penalties. These penalties include fines up to $25,000 for multiple violations and fines up to $250,000 and/or imprisonment up to 10 years for knowing misuse of individually identifiable health information. Therefore, although providers may believe it is in their best interest to disclose as much information as possible to comply with a subpoena or CID, they may be harming themselves in the long run if the disclosed information is protected by HIPAA.

Also, physicians may face criminal sanctions if their responses to subpoenas or CIDs are false or misleading. Under Title 18 of the United States Code, a person who falsifies or covers up a material fact, or makes a false representation to the Government, with knowledge that the claim is false, is subject to imprisonment of up to five years. Additionally, an individual may face fines up to $250,000 for each offense that constitutes a felony and $100,000 for each misdemeanor. Organizations on the other hand may face fines up to $500,000 for each felony offense and $200,000 for each misdemeanor.

Finally, the Patient Protection and Affordable Care Act (PPACA) makes significant changes to the Medicare fraud provisions that will impact providers in the immediate future. To better understand these changes, providers should consult with an attorney to go over the new provisions and discuss strategies that providers can incorporate into their practices to deal with the new law.

As the Government continues its efforts to reduce the cost of Medicare fraud, providers need to take the appropriate steps to protect themselves from incurring any additional liabilities and penalties when dealing with these investigations. First, providers should consult an attorney and discuss strategies to proactively protect themselves from incurring additional penalties. Second, if ever presented with a CID or subpoena, a provider should seek counsel before responding in order to preserve any privileges and not incur criminal penalties. Finally, providers should contact an attorney to discuss the impact of the PPACA and determine which strategies need to be taken to better protect themselves from incurring liabilities.
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Disparity Created by Adult Vaccination Coverage Policies

By Rachael Hawthorn, M.D., Ph.D.
Preventive Medicine Resident
University Hospitals
Cleveland, Ohio

Shingles is a common illness. While 1 in 3 will develop it in their lifetime, 1 in 2 who reach age 85 will have had shingles.1 Incidence is on the rise, perhaps in part, due to the vaccination of children against chicken pox disease.2 Adults are benefiting less frequently from the immunologic reminder that they were afforded when caring for children infected with the varicella-zoster virus. The elderly are at increased risk for the illness as well as the complications that come with it, including post-herpetic neuralgia (PHN), which produces debilitating pain for potentially several years after the rash has resolved.1 Shingles and its sequelae can be disabling to the elderly, bringing a significant physical, social, emotional, and financial burden for its sufferers. Unfortunately, treatments aimed to alleviate the pain from either shingles or post-herpetic neuralgia frequently are not effective. In fact, shingles is the leading cause of pain-related suicide in the elderly.2

In economic terms, the costs to the health care system are substantial with hundreds of millions per year spent on care for shingles and its complications. Most of the care for those over age 65 is paid by Medicare or forked over by beneficiaries themselves.3

An intervention exists that can attenuate some of the burden of shingles. Zostavax, produced by Merck, is a vaccine against herpes zoster that has been approved by the FDA and on the market since 2006. In 2011, the FDA expanded its approval for use in those 50 years of age or older. However, The Advisory Committee on Immunization Practices (ACIP) maintains its recommendation for use in those 60 years of age and older. As with any live attenuated vaccine, certain contraindications to administration exist.4

Otherwise, it is a safe and relatively effective vaccine. Evidence compiled in the Shingles Prevention Study demonstrated that Zostavax had an overall efficacy in preventing shingles of 51%.5 This is comparable to other adult vaccines like pneumococcal and influenza vaccines which range in efficacy between 60-75% in preventing the strains of pathogens for which they are designed. While an estimate of 10 year efficacy is yet to be ascertained, evidence suggests that the Zostavax's efficacy wanes after year one but confers protection up to 7 years after vaccination.6 In addition, the vaccine lessens the severity of illness if a patient does get shingles after vaccination. Aside from preventing PHN through the prevention of the illness itself, it offers some protection against developing PHN in those who develop shingles after vaccination.5

While most primary care physicians will recommend the use of the vaccine to their patients, few seniors have actually been vaccinated.7 In fact, only around 10% of seniors over the age of 60 have received it.8 Why? There have been several barriers to the dissemination of the vaccine since it became available. Every year since its unveiling, there have been shortages of Zostavax. The same varicella virus stock used for Zostavax also goes into making Varivax, the chicken pox vaccine. When ACIP recommended a booster for children in 2006, the production of Zostavax was curtailed. National marketing campaigns by The Centers for Disease Control were cancelled when the vaccine was not available for purchase.9 Individual counseling by physicians with their patients does not occur either with a vaccine shortage.

Storage and transportation is an issue as the vaccine needs to be kept within a specific temperature range that is colder than many other vaccines. The typical dormitory style freezer is not sufficient to store it, and due to concerns about maintaining an adequate temperature range, special packaging has been engineered for transport. Obviously, there are substantial logistical and overhead issues in stockling a vaccine with these storage requirements. In addition, the cost of the vaccine makes keeping significant inventory prohibitive. Zostavax costs a smart $161.50 compared to Pneumovax (Merck) at about $50 and Fluluvax (GSK) at $7.50 a dose.10

As of this year, Zostavax is no longer back-ordered and Merck anticipates having a robust supply to meet demand. Does this mean that more seniors will obtain the vaccine? Probably not. The most cited barrier to getting the vaccine to Medicare beneficiaries has nothing to do with the rigors of manufacturing, storing, or transporting the vaccine. It has to do with cost and insurance coverage.11 You may ask, “Isn’t Medicare paying for preventive services with the passage of the Patient Protection and Affordable Care Act (PPACA)?” Not exactly. Although the PPACA requires that all private insurers cover ACIP recommended vaccinations (Zostavax is one of them) without cost-sharing to the beneficiary, the same is not true for Medicare. While adult influenza and pneumococcal vaccinations are benefits under Medicare Part B and are preventive services provided without cost sharing to beneficiaries, most other adult vaccines are covered under Medicare Part D which is the optional prescription benefit available to Medicare beneficiaries. The exceptions are those vaccines used as part of treatment. Examples are tetanus vaccine if the patient presents with a trauma to indicate its use or hepatitis A and B vaccines in those patients with high-risk conditions. In these cases, a beneficiary can obtain coverage for these vaccines under Part B instead of Part D.

This reimbursement scheme creates a significant barrier for physicians and patients who want to take care of vaccination at the point of care. While all Medicare Part D plans are covering the herpes zoster vaccine, they do so with different patient cost-sharing rates. Pharmacies bill under Medicare Part D, not physicians’ offices. If the patient would like to be vaccinated in the physician’s clinic, they will have to pay for the vaccine upfront and then submit their claim for reimbursement. The physician’s office fees and the amount reimbursed for the vaccine and its administration may not be the same. This potentially leaves patients with substantial out-of-pocket costs. A work-around solution to the law has been introduced by a private company for this problem. A web-based system can allow physicians to ascertain the rate of reimbursement for the patient as well as bill their Part D plan directly. However, not all Part D plans are currently engaged in this practice. While few physicians’ offices currently have this system in use, it is unclear how easily a system such as this can be integrated into a time and resource-constrained practice.

Alternatively, a physician can write a prescription for the vaccine to be obtained and administered by a local pharmacist. Ohio is one of the states that allows pharmacists to become certified to administer vaccines. There is a potential consequence of the loss of point-of-care intervention. The temporal proximity between the physician’s endorsement of the vaccine and its administration is lengthened. Patients may also have reservations about receiving interventions from a provider outside their physician-patient relationship. In addition, there are potential implications for the accuracy of immunization records. Accurate assessment of vaccine needs based on the physician’s medical record is crucial.

(Continued on page 14)
Disparity Created by Adult Vaccination Coverage Policies

(Mandated by the PPACA, the U.S. Government Accountability Office studied and compiled evidence regarding the barriers that Medicare beneficiaries face in obtaining adult immunizations covered under Part D plans rather than under Part B. Of the beneficiaries who had received herpes zoster vaccine, only about 5% had done so under Part D. In addition, less than 1% of beneficiaries used a Part D plan to cover payment of vaccination against tetanus, diphtheria, and pertussis (Td or Tdap vaccines). Authors of the report found that physicians do not tend to stock Zostavax due to the cost of the vaccine as well as the challenges of the reimbursement scheme. Medicare beneficiaries cited cost and challenges obtaining reimbursement as important barriers to obtaining the vaccine. The average amount of cost sharing in 2009 was $57 for shingles and $25 for Td/Tdap.\(^\text{11}\)"

Referral to a public health agency to obtain otherwise unaffordable vaccines, has been a frequently used solution to this predicament. The otherwise reliable safety net doesn’t work in this case. If a senior has insurance, any insurance (even Medicare Part B without Part D), the public health agencies hands are tied. Provision through Merck’s assistance program for Zostavax is only afforded to those without any insurance.

Clinicians are left not knowing how to counsel elders on obtaining ACIP recommended vaccines. The best bet may be to catch elders before they are enrolled in Medicare so they can obtain the vaccine without cost-sharing from their private insurance company. From a public health perspective, the current reimbursement scheme places the senior community in a vulnerable position and hinders the mission to achieve population health. Seniors remain at risk for diseases that can be prevented through vaccination.

The PPACA has created a disparity for vulnerable elders which may represent discrimination against the elderly pursuant to this preventive service. The herpes zoster vaccine has highlighted this issue with adult vaccination. The most vulnerable population for developing shingles, and the population that could benefit most from vaccination, has the most difficulty getting this protection.

References:
4) Harpaz R, Hale CM, Stephanie R, Blaisk SR. Update on herpes zoster vaccine: Licensure for persons age 50 through 59 years: CDC MMWR Weekly 2011 Nov; 60(44); 1528.

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. Julie Ferguson at the AMCNO offices at (216) 520-1000, ext. 102.
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Centers for Medicare and Medicaid Services (CMS) Releases Stage 2 Rules

CMS has released the proposed rules for Stage 2 for qualifying for the meaningful use of electronic health records incentives. The proposal raises the performance bar, and focuses on interoperability while delaying the state of Stage 2 from 2013 to 2014. The next stage of meaningful use will build on the criteria from Stage 1, requiring providers to exchange information in various transactions to work toward continuous quality improvement.

The Ohio Health Information Partnership has provided the AMCNO and other associations with the following information which outlines the changes that are proposed for eligible professionals (EPs):

- Regardless of when a physician meets MU, he/she will have two years of Stage 1 measures (those currently in effect) until needing to move to the increased Stage 2 standards. For those physicians meeting MU in 2011, they will not need to meet Stage 2 until 2014.

- Physicians will still be required to meet 20 MU measures: 17 Core and 3 Menu measures. Many of the menu measures from Stage 1 have been moved to Core measures for Stage 2. Physicians will still attest to meeting MU measures; however, starting in 2014, they will be required to submit the clinical quality measures (CQM) to CMS or other data registries as recognized in the rules. The rules have tried to realign the CQM reporting to match submission requirements for other programs, such as PQRS. CQM reporting will increase from 6 CQM measures in Stage 1 to 12 CQM measures in Stage 2. The proposed list of potential CQMs to select from for reporting is increased to 125 measures to accommodate specialists’ practices.

- Physicians will be required to provide patient portals for patient access to their medical records. The proposed rule requires the physician or other eligible professional (EP) to give access to at least 50% of their patients seen during the reporting period to results within four days of the report being available to the EP. Certain information may be withheld at the EP’s discretion. At least 10% of the patients need to view, download or transmit their information to a third party.

- Physicians meeting MU by 2013 will not be subject to any payment penalties. If they meet MU in 2014, they will need to attest to 90 days of MU by October 1, 2014 in order to avoid any penalty in 2015. This means that physicians will need to begin their 90 day reporting period for MU no later than July 2, 2014 to avoid payment penalties in 2015. Physicians not meeting MU by 2014 will be subject to a 1% decrease in Medicare Part B payments in 2015, 2016 and 2017 (for a total of 3%) until MU is met. Further payment penalties after 2017 will depend on the rate of adoption of MU nationally. Hardship exemptions will be reviewed on a case-by-case basis in the following circumstances: 1) no internet access for two years prior to the reporting period; 2) new physician practicing within the past two years; and 3) extreme circumstances (e.g., vendor going out of business, natural disasters).

- The computerized physician order entry (CPOE) measure has been expanded from just medication orders to include laboratory and radiology orders. The MU threshold for CPOE rises to 60% of all orders from 30%.

- Percentages for Stage 1 meaningful use measures have been increased to reflect greater activity by practices on EHR.

- Measures are now more responsive to specialists workflow issues: one of the menu measures includes online imaging results for one of the menu measures. Also, the vital signs measure is divided into blood pressure and height and weight, so if a physician’s scope of practice would include taking blood pressure but not height and weight, the physician can still meet that MU measure. The certification of EHR systems is more streamlined. The protocol for certifying systems (Certified EHR Technology, “CEHRT”) would be based upon the needs of the practice and would not require every element of certification in the system to be standard for all practices. This new level of certification, part of the permanent certification program ONC is adopting, will be effective in 2014 at the same time as the Stage 2 rules.

- Public health reporting: EPs are required to do ongoing public health reporting and not just test the connection. In Ohio, this would mean doing immunization reporting for EPs to the Ohio Department of Health’s Impact SIIS program.

The overall thrust of Stage 2 is actual exchange of clinical information. This definition requires the EPs’ practice to be engaged with some type of Health Information Exchange (HIE) so that the exchange of information can occur across different EHR systems and outside of one specific organization’s structure, be that a physician network or a hospital network. Emphasis is given to the electronic exchange of a continuity of care document (CCD) in at least 10% of the transitions of care or referrals.

The rules were filed in the Federal Register in March. The final rules should be released by late summer.

### Key Differences in Stage 2

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<td>Menu set measures</td>
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<td>Clinical quality measures</td>
<td>Report at least 6</td>
<td>Report at least 12</td>
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Source: CMS
AMCNO Provides Legislative Overview to the Cleveland Society of Obstetricians/Gynecologists

In March, Dr. John Bastulli, Vice President of Legislative Affairs for the AMCNO, was invited to provide a keynote address to the Cleveland OB/GYN Society outlining the work of the AMCNO with regard to legislative activities. Dr. Bastulli provided the group with detailed background on important legislation under review by the AMCNO, focusing on key legislation such as the physician immunity bill, the clinical research faculty bill, genetic counselors, and the physician ranking bill.

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All proceeds from the event benefit the Academy of Medicine Education Foundation.
CHAP Launches First Initiative

The Cuyahoga Health Access Partnership (CHAP) is a collaboration of organizations (including the Academy of Medicine of Cleveland & Northern Ohio) in Cuyahoga County dedicated to helping uninsured adults gain access to essential and preventative health care. This month, CHAP launched its first initiative, the Access Plan, to connect patients without health insurance to providers who offer discounted or free primary and specialty care.

CHAP is designed to simplify the process of obtaining health care for Cuyahoga County’s uninsured adults. By eliminating repetitive paperwork and establishing an interconnected referral process, the CHAP Access Plan allows members to establish a primary care provider or medical home at one of CHAP’s Primary Provider Partner locations. Their primary provider can then refer the patient to CHAP’s network of specialty care, if needed, without requiring an additional financial interview.

Potential CHAP members are 19 - 64 year old residents of Cuyahoga County that do not qualify for government-sponsored insurance or have insurance through their employer. CHAP member income must be at or below 200% of Federal Poverty Level, which is $46,100 for a family of four in 2012.

As the program begins, CHAP is focusing on enrolling patients in need of specialty care at its current Provider Partner locations. The next step for the Access Plan will be to reach out to individuals that aren’t yet connected to a primary care provider. Enrolling these patients will provide them access to the region’s robust healthcare system through a number of different partner channels.

Early in 2012, CHAP received its 501c3 status with the Internal Revenue Service, establishing the organization as a separate non-profit entity. With the support of three full-time employees, the donated time and resources of the founding partners, and a supportive community network, CHAP is advancing its mission to provide a system of health access for the adult uninsured population in Cuyahoga County.

CHAP Partner Organizations: The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), Care Alliance Health Center, CareSource, City of Cleveland, Cleveland Clinic, Cuyahoga County, Kaiser Permanente, MetroHealth, Neighborhood Family Practice, Northeast Ohio Neighborhood Health Services, North Coast Health Ministry, Saint Luke’s Foundation, Sisters of Charity Health System, The Free Medical Clinic of Greater Cleveland and University Hospitals. For more information about CHAP go to www.cuyahogahealthaccess.org

Attention Practice Managers:
The Spring 2012 Edition of “Practice Management Matters” is now available on the new AMCNO website at www.amcno.org/News and Publications. This publication will no longer be mailed out to our members or staff and will only be available online. Check our website periodically to view new issues of this publication or watch for callouts in email notifications to our members.

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AMCNO Launches New Website

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) is pleased to announce the launch of their new and improved website: www.amcno.org. The website features a new design with a fresh look, and is more focused on the needs of our members.

The new website offers a wealth of information and extensive background about the Academy of Medicine of Cleveland & Northern Ohio - including our rich history dating back to 1824 as well as information on current board members and committees. Take a moment to review the work of the AMCNO over the past year or learn more about the governance and mission of the organization.

Physicians now have the ability to join or renew their membership online – and learn more about the AMCNO member benefits including our advocacy and legislative activities. Our Advocacy page contains information outlining the legislation currently under review by the AMCNO, background on amicus briefs filed on behalf of our members with the Ohio Supreme Court, a detailed advocacy tool kit which provides information on how to contact and write your legislators, background on current Ohio legislation as well as details on how to donate to the AMCNO political action committee – NOMPAC.

The AMCNO Practice Resources page contains detailed information for physicians and practice managers such as insurance company contact information, how to deal with Medicare audits, coding information, tips on adopting electronic health records, information on HIPAA regulations, data and security issues and much more. Members will also find the AMCNO lawyer referral brochure online along with the AMCNO community resources list.

The website also provides details about the AMCNO’s work on regional and state issues along with information on the various community committees, boards and groups the AMCNO physician leadership and staff interacts with on a regular basis. In addition, members can now browse through past issues of the Northern Ohio Physician magazine, our Practice Management Matters newsletter and view more information on education and events supported by the AMCNO.

The website also provides detailed information about another important component of the AMCNO – the Academy of Medicine Education Foundation (AMEF). This foundation provides medical student scholarship funding and supports many other Northern Ohio community activities.

The website provides a plethora of information for the public – including links to recordings of the AMCNO award winning Healthlines radio program, Find a Physician look up which includes an online listing of all AMCNO active members, and daily AMCNO pollen counts. The public is also invited to follow us on Twitter where the AMCNO plans to “tweet” daily pollen counts, provide callouts when Healthlines programs are posted as well as other tidbits of importance to the community.

Members are also welcome to follow us on Facebook and Twitter where you can learn more about the activities of your regional organization – the Academy of Medicine of Cleveland & Northern Ohio (AMCNO).

AMCNO Announces Agency for Healthcare Research and Quality (AHRQ) Partnership

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) and the Agency for Healthcare Research and Quality (AHRQ) are pleased to announce that we are working together to share AHRQ’s patient-centered outcomes research, also known as comparative effectiveness research, with you and your patients. AHRQ is a Federal agency of the U.S. Department of Health and Human Services charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. The Academy of Medicine of Cleveland and Northern Ohio is an ideal partner to help disseminate this research, which is designed to inform health care decisions by providing unbiased comparisons of drugs, medical devices, tests, surgeries, or delivery methods for various health conditions.

As you may know, AHRQ conducts and translates patient-centered outcomes research into a number of valuable patient and professional materials. These evidence-based tools include plain language consumer and clinician guides, continuing medical education/continuing education (CME/CE) activities, faculty slide sets, web conferences, audio podcasts, and more. All of these tools are designed to encourage and support shared decision making between clinicians and patients, with a goal of better care and increased patient satisfaction.

As the AMCNO focuses on medical care grounded in evidence-based research, this new partnership with AHRQ ensures timely access to these valuable free resources and connects all of us with national efforts to improve health care outcomes. As part of the partnership, AHRQ links to the guides and CE modules will be available on our website, along with a link to the AHRQ website, www.effectivehealthcare.ahrq.gov, where you can learn more about AHRQ’s Effective Health Care Program. We hope you find these resources informative and helpful as you work to improve the quality of health care throughout Cleveland and Northern Ohio.

The AMCNO has also included several links to AHRQ educational materials on our new website at www.amcno.org/Education and Events. In addition, AHRQ authored articles will be published in upcoming issues of the Northern Ohio Physician magazine. Together we can increase awareness of this research to better aid you and your patients in making individual treatment decisions.
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