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AMCNO Meets with State Agencies Regarding Physician Ranking Legislation

AMCNO Spearheads Introduction of Physician Ranking Bills in the Ohio House and Senate

AMCNO representatives met recently with Ohio Attorney General Richard Cordray to discuss the AMCNO legislative initiative regarding physician ranking. AMCNO provided background on the issue to the Ohio AG and his legislative staff about the history of the bill noting that this legislation was introduced in the last General Assembly and there is now similar legislation under review in the current General Assembly.

The Ohio AG was interested to learn that the legislation was introduced in Ohio following a review of the actions taken by New York Attorney General Cuomo on the issue of physician ranking. The AMCNO outlined to AG Cordray that the purpose of this legislation is to provide patients with accurate information when selecting a physician. This legislation would prevent health insurance companies from ranking physicians

based solely on specific criteria to persuade a consumer to choose one physician over another. Under this legislation, the designations would be made based on cost efficiency, quality of care or clinical experience and it would establish standards for the physician designations. If passed, Ohio will be on the forefront of implementing important new policy that promotes accurate, safe and effective health care transparency for everyone.



AMCNO representatives meet with the Ohio Attorney General Richard Cordray (I to r) Dr. Raymond Scheetz, Jr., AMCNO president, the Ohio AG Richard Cordray, and Dr. John Bastulli, AMCNO Vice President of Legislative Affairs.

The legislation stresses that health plans must use risk-adjusted data, and base grades and ratings at least in part on nationally recognized quality of care measures and not on cost alone. The legislation also provides physicians with the right to review and appeal their ratings prior to the ratings being released to the public.

(Continued on page 2)

AMCNO Legal Issues Seminar Offers Helpful Updates

The Academy of Medicine of Cleveland and Northern Ohio (AMCNO) and the Academy of Medicine Education Foundation (AMEF) sponsored two legal seminars in April that were well attended by physicians and physician office staff. Presenters included Ed Taber, Esq., Kathleen Atkinson, Esq. and Anne Kordas, R.N., Esq. from Tucker, Ellis and West LLP, Amy Leopard, Esq. from Walter & Haverfield LLP, and R. Mark Jones, Esq. and Cheryl O'Brien, Esq. from Roetzel & Andress, LPA with AMCNO president-elect Dr. Anthony Bacevice, Jr. facilitating both sessions. The presenters informed the audience of the legal issues currently impacting physicians in their practices.

The first session focused on the top ten medical malpractice risks as Mr. Taber explained that malpractice litigation oftentimes is initiated by angry people due to perceived bad outcomes. Lawyers for plaintiffs build (Continued on page 3)



AMCNO president-elect Dr. Anthony Bacevice, Jr., provides the opening remarks at the legal issues seminar.

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AMCNO ADVOCACY

AMCNO Meets with State Agencies Regarding Physician Ranking Legislation (Continued from page 1)

The Ohio AG was aware that the New York Attorney General's office had reached a settlement agreement with CIGNA and the other major New York health insurers which provided guidelines for use by the insurers conducting physician profiling programs. The AMCNO also provided information to the Ohio AG regarding the physician profiling law that passed in Colorado in 2008 that required health plans to disclose all data and the methodology used upon which the provider's designation is based. This law requires that profiling be statistically valid, accurate and clearly attributable to the correct physician. Measures utilized in this law must be generally recognized guidelines for quality based on the physician's specialty. The law also includes a requirement that allows physicians to have both internal and external appeals if they believe a profiling decision is incorrect.

The AMCNO approached the Ohio AG to determine what role, if any, the AG may want to have relative to this initiative. Currently the legislation as drafted utilizes the unfair deception law as the enforcement mechanism with oversight of the law by the Ohio Department of Insurance (ODI). The AMCNO assured the Ohio AG that the legislation does not set up the ODI as the ranking service in the state and there is no appropriation to do that in the legislation. Rather, the intent is that the ODI would act as an overseer of the process. The AMCNO informed the Ohio AG that our representatives have met with the Director of the ODI and ODI is reviewing the legislation at this time.

It's Time For Your Portfolio Check-Up

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

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Drs. Bastulli and Scheetz spend a moment with ODI Director Mary Jo Hudson.

The Ohio AG's staff noted that the NY settlement with the insurers dealt with antitrust issues whereas the legislation deals with disclosure issues and setting up specific parameters for the insurers to conduct their ranking systems. AMCNO representatives agreed stating that the purpose of this legislation is to provide patients with accurate information when selecting a physician.

As a result of the meeting, Attorney General Cordray agreed to review the legislation with his staff to determine what level of involvement or support they may have in this process, noting that if the criteria addressed by the New York AG is included in the legislation it may get a favorable reaction. The representatives from the AMCNO were appreciative of his input and noted that we would be amenable to changes in the enforcement process or the providers that would be covered under the legislation based upon review by his office.

The AMCNO also met recently with the Director of the Ohio Department of Insurance, Mary Jo Hudson and several of her key staff members to discuss the legislation. The purpose of the meeting with ODI was for the AMCNO to obtain direction from them regarding what role ODI would consider relative to the oversight of the insurance companies in the physician ranking process. The Director noted that oversight for this type of activity would more than likely fall under the unfair deception law. The ODI would need to review their existing authority on a matter of this type and whether or not there would need to be changes outlining how the insurance companies conducted ranking and then determine whether or not non-compliance of these rules would constitute an unfair trade practice. The ODI noted that their primary concern is to assure that the consumer is getting accurate information from the company.

AMCNO Spearheads Introduction of Physician Ranking Bills

The AMCNO has been working on a draft of the physician ranking legislation for introduction in the 2009 legislature and we are pleased to inform our membership that legislation has been introduced in the Ohio House by Representative Barbara Boyd (D-9 – Cleveland), and in the Ohio Senate by Senator Tom Patton (R-24 – North Royalton). The bill numbers are HB 122 and SB 98. The AMCNO expects additional input from the Ohio AG and the Ohio Department of Insurance on the physician ranking legislation in the next few weeks. AMCNO members requiring additional information on this legislative initiative may contact the AMCNO EVP/CEO, Ms. Elayne Biddlestone at the AMCNO offices.

PRACTICE MANAGEMENT

AMCNO Legal Issues Seminar Offers Helpful Updates (Continued from page 1)

cases based on such things as poor care, incomplete charting or documentation, or bad testimony (i.e., physician is not well-prepped for a deposition by his/her lawyer).

According to statistics provided by the Ohio Department of Insurance (ODI) on medical malpractice claims, the top specialties involved in claims (for years 2005, 2006 and 2007) are internal and family medicine, general surgery and emergency room issues. The ODI data show the highest dollar amounts per case in these same years in the specialties of orthopedic surgery, gastrointestinal, neurology, pathology, anesthesiology, emergency room and OB/GYN.

The top ten medical situations appearing in lawsuits, examples, and ways to avoid them were cited by Mr. Taber. These top ten items included:

- Blood coagulation. (i.e., patients on Coumadin where someone is not carefully monitored or a failure to diagnose pulmonary embolism);
- (2) Medication errors/side effects. (i.e., when a patient is given a medication that sounds similar to another or a pharmacist incorrectly reads a prescription);
- (3) OB injured baby. (i.e., a newborn baby experiences lack of oxygen due to an incorrect charting of APGAR scores);
- (4) Decubitus ulcers. A problem develops when an ulcer goes deep into the fascia and becomes septic. Mr. Taber noted that it is important to appoint someone on the medical team to specifically watch for these issues;
- (5) Falls. A fall assessment should be completed on anyone prone to falls;
- (6) Surgical injury to surrounding tissue and organs. It is important to have signed consent forms, even if a general surgery, where the patient acknowledges there may be injury to a surrounding structure;
- (7) Infections. It is important to communicate with the patient on how to take antibiotics, to provide good documentation, and follow up with appropriate antibiotics;
- (8) Missed myocardial infarction (MI). Doctors should refer the patient to a cardiologist when warranted and document why an MI was ruled out along with any follow-up instructions given to the patient;

- (9) Post-discharge communication. If all the proper information is not available when a patient is discharged, follow up on any lab work ordered, schedule outpatient appointments and if on medication, determine which doctor is in charge of overseeing the medication and following up with the patient; and
- (10) Late cancer diagnosis. A lawsuit can originate for "loss of chance to live" at all levels. Since these cases do not only apply to oncology, physicians should document all findings, both positive and negative, and more carefully advise patients (and document) to seek routine screenings.

Mr. Taber noted that a positive bedside manner and complete and clear documentation are always most helpful.

During the next presentation on physician apology laws, Ms. Atkinson and Ms. Kordas explained that in 2004 an Ohio law passed known as the physician apology law, prohibiting the use of a physician's or staff member's statements of sympathy for an "unanticipated outcome" as evidence in a medical liability action. The law applies to civil actions and arbitrations, health care providers and their employees, statements made to the alleged victim, or a relative or representative of the alleged victim, and is inadmissible as evidence of an admission or liability.

considers writing off medical bills, the write off should be the portion used as a display of his/her apology only. Seeking advice and counsel in this instance was once again recommended.



Ms. Amy Leopard from the law firm of Walter & Haverfield, LLP emphasizes a point during her presentation on health information technology issues.

The next presentation by Ms. Amy Leopard explored the adoption of electronic health records (eHR) and health information technology (HIT) stimulus, updated attendees on the HIT donation rules and identified contractual issues with vendors. Ms. Leopard explained there is a lot happening around President Obama's commitment to invest in HIT and reduce red tape, prevent medical mistakes and save billions of dollars every year by making the system more efficient. For the full coverage of Ms. Leopard's presentation, go to page 5.

The final presentation by Mr. R. Mark Jones and Ms. Cheryl O'Brien focused on the source of "never events." The HHS created Centers for Medicare & Medicaid Services



Dr. Bacevice facilitates a panel discussion following the presentations. (I to r – Dr. Bacevice, Mr. Taber, Ms. Kordas, Ms. Leopard and Ms. O'Brien).

While to date there have been no cases in Ohio to test this new law, in many states around the country, protections are limited to expressions of sympathy, which are not statements acknowledging fault. It is always best to talk with the patient at the time there has been an error rather than waiting until a lawsuit situation. Attendees were encouraged to consult with their legal counsel or risk management department about requests by the patient or family to put something in writing. Too, if a physician

(CMS) to administer the Medicare and Medicaid programs with its mission being to ensure effective, up-to-date health care coverage and promote quality care for beneficiaries. The Deficit Reduction Act of 2005 directed the HHS to designate "at least two conditions" that result in a heavy financial burden to Medicare and Medicaid, changing the mission of CMS from care focus to expense focus. This Act directed that Medicare and Medicaid will not reimburse (Continued on page 4)

PRACTICE MANAGEMENT

AMCNO Legal Issues Seminar Offers Helpful Updates (Continued from page 3)



Mr. Mark Jones from the law firm of Roetzel & Andress, LPA responds to a question on the issue of never events.

hospitals for costs incurred to treat certain conditions after October 2008 if the conditions were not present at the time of admission.

The National Quality Forum (NQF) was created in 1998 with a mission to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs. The NQF identified 28 "never events" in 2002 that were defined as "adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers."

CMS also draws from the Leapfrog Group, which is a private employer organization that encourages transparency and easy access to health care information as well as rewards for hospitals that have a proven record of high quality care. In 2008 CMS designated eight conditions or "never events" deciding that it won't reimburse hospitals for the associated medical costs arising from these events which include: (1) retained surgical objects, (2) air embolism, (3) blood incompatibility, (4) catheter-associated UTI, (5) vascular catheter-associated infections, (6) pressure ulcers, (7) post-CABG mediastinal infections, and (8) hospital acquired injury (falls, burns, etc.).

Every year CMS is charged with finding more "never events" and for 2009 another nine potential conditions have been identified: (1) surgical site infections following certain elective procedures, (2) Legionnaires' disease, (3) extreme blood sugar derangement,

- (4) iatrogenic pneumothorax, (5) delirium,
- (6) ventilator-associated pneumonia,
- (7) deep vein thrombosis/pulmonary embolism,
- (8) staphylococcus aureus septicemia, and
- (9) clostridium difficle associated disease.

CMS is taking public comment (input from hospitals, doctors, and employees) on these nine items and a decision on whether or not they will become "never events" will be made by October 2009.

The consequences of "never events" have been financial pressure on hospitals from CMS and Leapfrog, care delivery pressure on doctors from hospitals, financial pressure from Leapfrog organizations to avoid "never events" as a means to improve quality of care and ensure reimbursements, and liability cost pressure on professional insurance carriers and doctors in underwriting and claims risk assessment. There can also be a trickle down effect with doctors from the hospitals with claims considered to be "never events."

For example, when providing evidentiary support of the plaintiff claims, plaintiff lawyers say there was a violation of the "never events." While there are regulations for hospitals and Ohio Law allows evidence of an administrative rule violation, there is no direct regulation of doctors and evidence of an administrative rule violation cannot be admitted into evidence against them. That said, if the hospital is a co-defendant in a never event occurrence there could be a "guilt by association" for doctors.

A word to the wise was to never underestimate the creative ingenuity of the plaintiff's medical malpractice bar. It was noted that they are always looking for ways to prevail. Also, never underestimate the receptiveness of the trial and appellate courts to new theories of liability. In essence the sitting judge may have a certain philosophy, and there are many seated judges that think tort reform is biased against the plaintiff. And last, don't assume that the Ohio Supreme Court will always protect the status quo. The pendulum could always swing back on the makeup of the court.

A complete legal insight into "never events" was included in an article published in the July/August issue of the *NOP*. AMCNO members who wish a reprint of this article may contact the AMCNO offices at (216) 520-1000, ext. 102.

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 approving this program for two hours of Clinical Risk Management Education credits for those physicians participating in the UH Sponsored Physician Program. ■

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LEGAL ISSUES

Stimulus Package Promotes Health IT Adoption

Amy S. Leopard Walter & Haverfield LLP

The Obama Administration clearly expects every American to have an electronic medical record by 2014. The American Recovery and Reinvestment Act of 2009 (ARRA) stimulus package will drive substantial funding for health information technology (HIT) adoption over the next seven years. ARRA appropriates billions for HIT infrastructure and provides significant incentives for health care providers to adopt electronic health records (EHR).

ARRA also includes the Health Information Technology for Economic and Clinical Health Act, also known as HITECH. HITECH sets forth a broad HIT agenda with concrete goals and objectives, significant changes to the HIPAA medical privacy and security rules, and criteria for how providers adopting EHR become eligible for bonus payments beginning in 2011. HITECH provides an enormous opportunity for those providers seriously interested in HIT adoption. At the same time, approaching EHR projects with the requisite planning and implementation tools these projects deserve is important.

HIT Promotion

President Obama's HIT agenda envisions HIT as a tool to drive efficiency and quality gains in the American health care system. In his inaugural address, President Obama promised that every physician office and hospital would have "cutting-edge technology and electronic medical records to cut red tape, prevent medical mistakes and help save billions of dollars each year." Congress responded within weeks by passing this historic legislation.

Section 3001 of HITECH codifies the U.S. Health and Human Services (HHS) Office of National Coordinator for Health Information Technology (ONC), which was established by executive order under the Bush administration. ONC has been given an extensive mission to develop a nationwide HIT infrastructure that:

- ensures health information is secure and protected
- improves health care quality, reduces medical errors and health disparities, and advances patient-centered medical care
- reduces health care costs from inefficiencies, medical errors, inappropriate care, duplicative care, and incomplete information
- provides appropriate information to help guide medical decisions at the point of service
- ensures the inclusion of meaningful public input in infrastructure development
- improves care coordination and health information sharing among physician offices, hospitals, labs, and others through an effective infrastructure for the secure and authorized exchange of health information
- improves public health and early identification and rapid response to public

health threats and emergencies (e.g., bioterror events and infectious disease outbreaks)

- facilitates health and clinical research and health care quality
- promotes early detection, prevention, and management of chronic diseases
- promotes a more effective marketplace, greater competition, increased consumer choice, and improved outcomes in health care services
- improves efforts to reduce health disparities

HITECH affords the ONC a great deal of flexibility in implementing the HIT agenda. President Obama appointed Dr. David Blumenthal, a primary care physician and Harvard Medical School professor, as the new National Coordinator for HIT. Dr. Blumenthal is expected to bring significant health policy considerations to the position as the Obama administration links HİT adoption with health reform efforts. He will be advised by members of the new HIT Policy Committee, many of whom bring broad health policy experience to update the federal Health IT Strategic Plan. A HIT Standards Committee of HIT experts is also being appointed to recommend uniform standards, technical specification and certification criteria for HIT technologies.

Federal and State Stimulus Funding

HITECH includes substantial stimulus funding to encourage HIT adoption. Federal funding will be available to invest in the infrastructure needed for the nationwide health information network, assist with provider education and medical informatics programs, fund HIT/EHR research and development programs, provide grants to states to facilitate HIT acquisition, and fund extension programs and regional HIT centers to assist providers with implementing, operating and maintaining HIT. ONC will control a significant portion of the stimulus funds by awarding federal planning and implementation grants to states and statedesignated entities (with broad stakeholder representation) to jump start HIT/EHR adoption. States are required to match at least 10% of any federal grants received from ONC. For example, by investing as much as \$15M in state funds for HIT implementation, Ohio may be eligible for as much as \$150M in matching federal funds. Rex Plouck, Governor Strickland's

point person for HIT, hopes to create a state-designated entity for Ohio to help fund EHR software for physician practices and regional HIT extension centers for training and implementation assistance. Plouck has pointed to health information exchange efforts as a forum for best practices to reduce duplicate tests, adverse drug interactions, and redundancies. Plouck envisions connecting physicians to results reporting for labs, medications, and imaging. The statewide organization could also serve as Ohio's central contact for a nationwide electronic health information network.

Incentive Payments to Providers

Additional funding will be available directly to providers to encourage HIT/EHR adoption. Much of this funding will be made available to providers in the form of incentive payments through Medicare and Medicaid reimbursement. Medicare incentive payments for hospitals and physicians will begin in 2011 for those who can establish "meaningful use" of certified EHR technology. Incentive payments will be made over five years and are weighted with higher payments for early adopters.

Medicare incentive payments can reach \$44,000 for eligible physicians and up to \$11 million for hospitals. For example, physicians demonstrating meaningful use by 2011 or 2012 will receive \$18,000 in the first year, and \$12,000, \$8,000, \$4,000, \$2,000 respectively over the following four years. Physicians practicing in a health professional shortage area (HPSA) can receive an additional amount of 10% in incentive payments. Hospital-based physicians (e.g., pathologists, anesthesiologists, or emergency physicians) would not be eligible for any incentive payments.

On the other hand, physicians choosing not to adopt HIT/EHR and engage in meaningful use by 2015 face reductions in their Medicare fee schedule — 1% in 2015, 2% in 2016, and 3% in 2017 (see page 6).

For hospitals, a formula for Medicare incentive payments begins in FY 2011 and similarly phases down over time. The base amount available is \$2M per year for eligible hospitals with add on payments to the DRG payment over a 4-year period based upon the quantity of annual discharges, Medicare payor mix, and a transition factor.

For providers with a high volume of Medicaid patients, Medicaid program incentive payments may be available for meaningful use of certified EHR technology. Providers eligible (Continued on page 6)

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Stimulus Package Promotes Health IT Adoption

(Continued from page 5)

for Medicaid program incentive payments include pediatricians, federally qualified health clinics (FQHCs), rural health clinics (RHCs), and physician assistants in physician assistant-led RHCs. Medicaid program incentive payments are an alternative to Medicare incentive payments, so eligible professionals must choose which incentive program carries the best benefits. Eligible Medicaid professionals could receive up to \$63,750 in federal contributions towards the adoption, implementation, upgrade, maintenance, and operation of certified EHR technology. Subject to a cap on average allowable costs, up to 85% of \$25,000, or \$21,250, will be provided to eligible Medicaid professionals for certified EHR adoption, implementation, or upgrading and up to 85% of \$10,000, or \$8,500, to eligible Medicaid professionals to operate and maintain certified EHR systems for up to 5 years.

High volume Medicaid hospitals and children's hospitals with little Medicare revenue have alternative Medicaid program incentive payments as well.

What Constitutes Meaningful Use?

The concept that provider incentives are not tied to tangible investments in HIT is a fascinating aspect of HITECH. Rather, the incentives are intended to flow to those providers that can demonstrate meaningful use of certified EHR technology.

Demonstrating that a provider is a meaningful user of certified EHR technology is difficult, at least for now. The demonstration should become easier when HHS develops a regulatory definition of meaningful use. HITECH requires that HHS base its definition of meaningful use on 3 core concepts: (1) the provider must demonstrate that it is using certified EHR technology in a meaningful manner, which shall include the use of appropriate e-prescribing; (2) the provider must demonstrate that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination; and (3) the provider must submit information, in a form and manner specified by HHS, on such clinical quality measures and such other measures as selected by HHS. The core concepts for hospitals are similar without the e-prescribing component. Many industry associations have already begun preparing comments as to the appropriate definition even in advance of HHS rule making.

A key component of meaningful use is the requirement that the provider use certified EHR technology. Under HITECH, certified EHR

First Pmt. Yr.	Incentive Payment per Payment Year						Non-Adoption Penalty
	1	2	3	4	5	Total	
2011	\$18,000	\$12,000	\$ 8,000	\$ 4,000	\$ 2,000	\$44,000	\$ —
2012	\$18,000	\$12,000	\$ 8,000	\$ 4,000	\$ 2,000	\$44,000	\$ —
2013	\$15,000	\$12,000	\$ 8,000	\$ 4,000	\$ —	\$39,000	\$ —
2014	\$12,000	\$ 8,000	\$ 4,000	\$ —	\$ —	\$24,000	\$ —
2015	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	-1% of Medicare fee
2016	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	-2% of Medicare fee
2017	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	-3% of Medicare fee

^{*}Courtesy of Dr. Brian Keaton

technology is qualified EHR technology that has been certified as meeting HHS standards for the type of record involved (e.g., ambulatory EHR for office-based physicians or inpatient hospital EHR for hospitals). Qualified EHR technology consists of electronic records of health-related information on an individual that include demographic and clinical information (e.g., medical history and problem lists) with functionality for clinical decision support, physician order entry, and quality information reporting. The technology also needs to exchange and integrate electronic health information with and from other sources.

HHS has not provided any indication as to the certification standards that it will use to certify qualified EHR technology. Nevertheless, some industry stakeholders believe that HHS will look towards CCHIT certification as the standard. A detailed explanation of the CCHIT certification standards and process, along with a comprehensive list of all CCHIT certified EHR technology is available at the CCHIT Web site (http://cchit.org) and CCHIT's EHR blog (http://ehrdecisions.com).

Now what?

Nationally, only 15-20% of physicians and 20-25% of hospitals have implemented HIT systems¹, although this adoption rate is thought to be higher in the metropolitan areas of Northeast Ohio. For these physicians and hospitals with significant investment in HIT, paying close attention to the HHS rulemaking efforts to ensure that their particular technology is certified for purpose of demonstrating "meaningful use" is a priority.

Most importantly, providers who have been considering the adoption of EHR technology will likely do so sooner now that the tipping point has been reached. The Medicare and Medicaid payment incentives are designed to do just that. The hope is that these incentives will ultimately off-set the start-up cost investment of a provider in HIT. This investment can be significant considering an initial license for an EHR system often ranges from \$25-45,000 per physician together with ongoing maintenance

and licensing fees ranging from \$3,000 to \$9,000 per physician annually².

Healthcare providers who have not yet thought about EHR technology should not run out and buy the first package without first considering their own requirements and incentive eligibility. In addition, hospitals, state and regional health information exchanges, IT vendors and financial institutions will likely be developing packages to assist those physicians who may not have the internal resources to evaluate and/or fund EHR technology solutions.

Since physicians have until January 2012 to establish "meaningful use" and receive full payments under the stimulus plan, prudence dictates that these decisions be made consistent with project management for the desired result with an eye toward incentive eligibility3. Most often, this begins with a requirements definition for the successful implementation of a solution. Whatever pathway chosen, it is clear that the investment and alignment of EHR technologies within the nationwide health information highway has now begun with full force. Stay tuned to Northern Ohio Physician as the robust HHS regulatory agenda and state level initiatives roll out.

References:

- "Accelerating Progress: Using Health Information Technology and Electronic Health Information Exchange to Improve Care," in First Annual Report and Recommendations from the State Alliance for e-Health (2008).
- 2. Id. These amounts may be lower for ASP model licenses not requiring significant investment in hardware or operating systems and higher for robust EHR systems with sophisticated decision support.
- 3. Physicians who wait until 2013 to establish meaningful use of a certified EHR technology are limited to \$27,000 over 3 years.

LEGAL ISSUES

Health Care Law: HIPAA Privacy And Security Rules

Stimulus Legislation Modifies HIPAA Rules For Protection Of PHI

Bernard J. Smith, Esq. Tucker Ellis & West LLP

On February 17, 2009, President Obama signed into law the "American Recovery and Reinvestment Act of 2009" (the "Act"), commonly referred to as the "stimulus bill." Most reports on this massive piece of legislation focus on its myriad of grant authorizations and sweeping changes to the tax laws. But make no mistake; the Act affects virtually every department and many regulatory functions of the Federal government. Included among its hundreds of pages are changes to the existing HIPAA rules governing the privacy and security of protected health information ("PHI"). These modifications appear driven, in large part, by the Act's support for the development of nationwide standards for and operability of electronic health records. Many of the new requirements will be of particular concern to business associates and might result in covered entities seeing increases in the cost of doing business with certain parties. At a minimum, covered entities will need to alter some practices and update existing business associate agreements.

Notification of Privacy or Security Breaches

The Act requires that under certain circumstances, either a covered entity or a business associate give notice to individuals of instances of a "breach" as to what the Act calls "unsecured protected health information." Unsecured protected health information means PHI that is not protected by new security standards designed to render PHI unusable, unreadable or indecipherable to unauthorized individuals. These new standards are to be issued within 60 days after the Act becomes effective. They may include new protective standards adopted in connection with the development and adoption of electronic health records. A "breach" is an unauthorized acquisition, access, use or disclosure of unsecured PHI. Certain inadvertent or unintentional acts are excluded from these new rules.

The Act requires delivery of notice by first class mail to each individual who is or might reasonably have been affected by a breach of unsecured PHI. Under certain scenarios, if notice by mail is not possible, other forms of notice, such as a Web site posting may be required. If more than 500 residents of a particular state are affected by a breach, notice through public media outlets is required. Notice must also be provided on an occurrence basis or at least annually to the Secretary of Health and Human Services. The Secretary must make information so received available publicly on the HHS Web site.

New Requirements for Business Associates

The Act imposes on business associates certain security and privacy requirements that under current law apply only to covered entities. These include the obligations to:

- implement administrative, physical and technical safeguards to protect the security of electronic PHI;
- adopt certain security policies and procedures; and
- comply with certain requirements of the privacy rules as if the business associate was itself a covered entity.

These new mandates should be reflected appropriately in a covered entity's standard form of business associate agreement.

The Act also subjects business associates to the same civil and criminal penalties that apply to covered entities in cases where a business associate violates certain of the Act's new rules.

Mandatory Disclosure Restrictions

The Act requires that a covered entity honor requests from individuals for restrictions on disclosure of information to health plans, for health care operations and payment purposes, if the PHI at issue pertains solely to a health care service or item for which the service provider "has been paid out of pocket in full." This is a significant modification to current law which allows a covered entity the discretion to accept or reject an individual's request for restrictions

on the disclosure of PHI. It presumably is meant to allow individuals who absorb the full cost of certain medical expenses to keep that information from being shared with health plans. It remains to be seen how this might affect health plans' clinical programs and underwriting.

Other Changes

There are numerous other changes in the almost fifty pages of the Act dealing with health information. These include:

- additional restrictions on the sale of PHI and its use for fundraising and marketing purposes;
- clarification of rules as to what constitutes a "minimum necessary" amount of PHI;
- treating certain organizations that provide data transmission to a covered entity in connection with electronic health records as a business associate of the covered entity and requiring that the service provider and covered entity enter into a business associate agreement; and
- provisions for improved enforcement of civil and criminal penalties for violations of HIPAA.

The above are just the highlights of the numerous provisions of the Act affecting HIPAA and the privacy and security of PHI. Covered entities are urged to familiarize themselves immediately with the Act's requirements and review their business associate and other relationships to determine how they and related agreements might be affected.

Bernard Smith is an attorney with the Cleveland office of Tucker Ellis & West LLP, practicing in the areas of Business Transactions & Securities, Nonprofit Organizations, Healthcare, Franchising, Tax Services and Information Technology. He can be reached at (216) 696-3952 or by email at bsmith@tuckerellis.com

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LEGISLATIVE ISSUES

Legislative Update

By: Connor Patton, AMCNO lobbyist

Ohio Budget Issues

Governor Ted Strickland's proposed \$55 billion dollar state operating budget (HB1), includes the key issues regarding healthcare, education funding, and the economic stimulus package. After some changes to the substitute bill, Speaker of the Ohio House of Representatives Armond Budish (Beachwood) may have the bill ready for passage in late April, where it will be sent over to the Ohio Senate for consideration. This will be guite an interesting task as the Ohio Senate is anticipated to make many changes to the bill, but will not have a lot of time because the bill must be enacted by July 1, 2009. The K-12 education portion of the bill alone had over 300 witnesses and provided over 50 hours of testimony.

After a tense negotiation over the \$8 billion Transportation budget (HB2) in late March between the Democratic controlled Governor's office and House and the Republican led Senate, this could be a sign of things to come for the state operating budget debate (HB1). When HB2 was sent over to the Senate many of the key items of the bill had been removed, but later reinserted after a conference committee was established. Key items on the Democratic agenda did not get reinserted into the bill. This is relevant because more than likely the Ohio Senate will make many changes to the budget bill, and the healthcare provisions, Medicaid funding, and board consolidation portions of the bill will be areas the Senate may decide to alter. Also, the Governor is required by law to have a balanced budget, making it more difficult with tax receipts and revenue having been below estimates for the last four months in a row.

The Strickland Administration's budget includes increases in fees that will generate a total of \$892 million over the biennium through the institution of a hospital franchise fee and an increase in the existing franchise fees for nursing homes and Intermediate Care Facilities for the Mentally Retarded (ICFs/MR), among other fee increases. State Medicaid Director John Corlett testified that the administration would have "very limited"

options" to make up the \$3 billion in Medicaid should the franchise fees not be enacted. Those are the elimination of optional services and "sharply reducing rates for all Medicaid providers," he said.

Several groups have appeared before the House Finance and Appropriations Committee in protest of these fee increases and have proposed a reduction in the fees or alternative sources of revenue be used or created to meet the Governor's budget estimates. The concept is to utilize the franchise fee hikes as a way to draw down matching federal Medicaid money to benefit the entire entitlement program and avoid rate hikes and other actions. The budget contains a Medicaid reimbursement rate of 5% for hospitals, but several witnesses have testified that this revenue hike is nothing compared to the anticipated impact of the franchise fee which several institutions have noted would result in staff cuts or increased costs for other non-Medicaid patients. The fee is designed to shore up Ohio's Medicaid budget, and would cost hospitals \$598 million over the next two years, but hospitals are also supposed to receive \$187 million in additional Medicaid reimbursement.

The Ohio Hospital Association noted that hospitals would lose \$411 million if they pay \$598 million in assessments and only receive \$187 million back over 18 months. Testimony was also provided by Northern Ohio hospital representatives from the Cleveland Clinic, St. Vincent Charity Hospital, Rainbow Babies & Children's Hospital and Summa Health System.

Some healthcare advocacy groups have even begun polling to see if Ohioans would be agreeable to an income tax increase in lieu of the new proposed fees.

At press time discussions were underway to make changes to the hospital franchise fee portion of the bill. The new bill includes increased hospital Medicaid fees to generate a higher return for the institutions, changes aimed to appease nursing home interests, including a return to Fiscal Year 2009

funding levels, and appropriations for other programs. Also of interest to AMCNO members is that the new bill contains a provision to extend the prompt pay law to apply to Medicaid managed care plans.

The AMCNO is monitoring the debate on this issue and will continue to provide updates to our members.

Another controversial portion of the budget bill seeks to consolidate the "back-office functions" of several state boards, including the State Medical Board of Ohio, into the Central Service Agency within the Department of Administrative Services.

The State Medical Board is concerned that this consolidation plan would remove the Board's "fiscal and oversight responsibilities as the Board would no longer make decisions related to finance, human resources, procurement, legal, policy and other unnamed functions." The board is of the opinion that their ability to direct resources and make operational decisions is a fundamental aspect of effectively licensing and regulating the practice of medicine. The plan also requires the Medical Board to pay unspecified service fees to Central Services for agency support functions currently provided in-house by the board. The Medical Board does not support the consolidation concept.

The AMCNO legislative committee has written to the Chairman of the House Finance and Appropriations Committee voicing our concern about this aspect of the budget proposal noting that we believe it does remove the Board's fiscal and oversight responsibilities and it could lead to increases in licensing fees for physicians in order to support the General Revenue Fund (GRF) and a reduction in the quality of physician licensure and regulatory services. The AMCNO further noted that the State Medical Board should remain autonomous and independent and we requested the removal of the State Board from the proposed consolidation plan. Discussions are underway with the administration regarding changes to the proposed consolidation plan and the AMCNO will provide additional information on this as the bill moves through the legislature.

(Continued on page 10)

LEGISLATIVE ISSUES

Legislative Update (Continued from page 9)

Healthcare Legislation currently introduced in the Ohio General Assembly

House Bill 8 - Autism - This bill prohibits health insurers from excluding coverage for specified autism services for individuals diagnosed with an autism spectrum disorder and creates the Commission on Autism Spectrum Disorders to investigate and recommend additional treatments or therapies for autism spectrum disorders to be covered by health insurers. Insurers are of the opinion that mandated coverage of these services will increase premiums and could impact small employers. There has been testimony from large institutions and organizations in support of the bill. The AMCNO legislative committee has recommended a neutral position at this time pending additional input and testimony as the bill moves through the legislature.

House Bill 74 – Nursing profession – This bill would require limits on mandatory nurse overtime, allow for tuition reimbursement for nursing education, tax credits for nursing professors, and tax deductions for nurse aides. The AMCNO legislative committee opposes any legislation that limits mandatory nurse overtime since this type of change could only exacerbate the nursing shortage problem for area hospitals.

HB 81 - Diabetes Coverage - This

legislation would require certain health care policies, contracts, agreements and plans to provide benefits for equipment, supplies and medication for the diagnosis, treatment and management of diabetes and for diabetes self-management and education. The AMCNO has supported this type of legislation in the past and the committee voted to support HB 81.

HB 93 – Bicycle Helmets – This bill would require bicycle operators and passengers under 18 years of age to wear protective helmets when the bicycle is operated on a roadway. The bill also establishes the Bicycle Safety Fund to be used by the Department of Public Safety to assist low-income families in the purchase of bicycle helmets. The AMCNO has supported this type of legislation

in the past and the committee voted to support HB 93.

SB 15 – Health Care Policies – This bill would prohibit discrimination in health care policies, contracts, and agreements in the coverage provided for the diagnosis and treatment of mental illnesses and substance abuse or addiction conditions. The committee decided to remain neutral with technical assistance pending additional information and testimony on this bill.

Senate Bill 34 - Health Insurance

<u>Programs</u> – This bill would create a health insurance program that allows municipal corporations, small employers, and nonprofit corporations or associations to purchase for their employees the same policies provided to state employees. The committee decided that until there was more information and testimony on this legislation the AMCNO would remain neutral with technical assistance.

Senate Bill 37 – Tobacco Tax – This bill would increase the tobacco products excise tax rate and credit some of the additional revenue to the Tobacco Use Prevention Fund. The AMCNO is a part of a tobacco coalition in Ohio that supports this legislation. The coalition strongly supports the increase in the tobacco products excise tax rate. The AMCNO committee voted to support SB 37 with technical assistance.

SB 69 – Student vaccinations – This bill would require that students living on-campus

housing at institutions of higher education be vaccinated for meningococcal meningitis and hepatitis B or obtain a waiver. The AMCNO committee voted to support this bill.

SB 86 - Emergency medical treatment -

This bill would grant qualified civil immunity to a physician who provides emergency medical services, first-aid treatment, or other emergency professional care in compliance with the Federal Emergency Medical Treatment and Active Labor Act (EMTALA) or as a result of a disaster.

The committee noted that this legislation appeared to grant immunity to a physician providing emergency care under EMTALA regulations as well as immunity in treating a patient in a disaster situation. The purpose of this bill is to encourage participation in emergency care and provide limited liability to medical providers who offer emergency care under EMTALA requirements. The intent of the legislation is to provide new limited liability protection to all physician health care providers in disaster and emergency situations. The AMCNO strongly supports this legislation and we plan to work with the sponsor of the bill and provide input on this bill as it moves through the legislature.

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. ■

NORTHERN OHIO PHYSICIAN

THE ACADEMY OF MEDICINE OF CLEVELAND & NORTHERN OHIO

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STATE LEGISLATIVE AND AGENCY UPDATES

Legislator Spotlight State Representative Barbara Boyd

State Representative Barbara Boyd (D-Cleveland) of the 9th District boasts a storied political career that now sees her serving the area of northeast Ohio that includes Cleveland Heights.

Rep. Boyd earned a bachelor's degree in education from St. Paul's College in Virginia in 1965. Her passion for public service, though, began with volunteer work on Jimmy Carter's Presidential campaign in 1976. Her activities there encouraged her to stay active in her community, and she began to volunteer in Cleveland Heights and in countywide political activities.

In 1983, Rep. Boyd became the first African-American elected to the Cleveland Heights City Council. During her tenure, she worked as a Community Relations Officer for the Cuyahoga County Juvenile Courts, undertaking countywide outreach activities for one of the oldest courts in the nation. She served on various Council committees before becoming Vice Mayor, and finally mayor of Cleveland Heights.

Her friends and colleagues convinced Rep. Boyd to run for State Representative, and in 1992, the voters in the 9th District sent her to the Ohio House for the first of four terms. She is most proud of the establishment of kinship care during her tenure.

Term limits forced her out of the House, but she continued her public service as an executive assistant to the Director of the Ohio Department of Job and Family Services. In 2005, Rep. Boyd joined the Children's Defense Fund as the Regional Manager for Northeast Ohio.

An overwhelming majority of 9th District voters returned Rep. Boyd to the Ohio House in 2006. She is keenly involved in legislation concerning health care, foster care, predatory lending, human services, children and families, kinship care. Alzheimer's disease and aging, schools and education funding reform, economic development and juvenile justice. She is also working to obtain a memorial statue or plaque in the Statehouse in honor of Ohio's Tuskegee Airmen.

Rep. Boyd chairs the Ohio House Health Committee, and serves as a member of the Finance Committee and its Human Services Subcommittee, as well as the Judiciary, Rules and Reference and Housing Urban Revitalization Committees.

She also serves on the House and Senate Cancer Caucus, the Joint Legislative Committee on Health Care Oversight, the Ohio Hepatitis C Advisory Commission, the Second Chance Trust Fund Advisory Committee and the Dentist Loan Repayment Advisory Board. She also has been reappointed to the Human Services Committee of the Midwestern Legislative Conference of The Council of State Governments.

Rep. Boyd is a founding member of the Black Women's PAC, and she is an active member of the League of Women Voters. Rep. Boyd is a member of Delta Sigma Theta Sorority, St. Andrews Episcopal Church, the Cleveland Heights Democratic Club and the 11th District Caucus. She



currently serves as President of the Black Women's Political Action Committee. She is also past Vice Chairperson of the Cuyahoga County Democratic Party.

Rep. Boyd has received numerous awards and recognitions for her contributions to the community, including Legislator of the Year and the Alzheimer's Award. Cleveland Magazine named her one of its 50 Most Interesting People in 1998. In 2007, Rep. Boyd received recognition for her commitment to and support of kinship caregivers in Ohio from the Ohio Grandparent/Kinship Coalition at the 1st Statewide Kinship Care Conference.

In her spare time, you can find Rep. Boyd at home in her kitchen with her husband Robert and daughter Janine, as family members and friends drop by for food, fun and a side dish of politics.

Editor's note: The AMCNO wishes to thank Rep. Boyd for sponsoring the physician ranking legislation which is strongly supported by our organization. HB 122 has been referred to Rep. Boyd's committee for review. Senator Tom Patton has introduced a companion bill in the Ohio Senate – SB 98 (see page 2). ■

State Medical Board of Ohio to Track **Demographic Physician Data**

The Medical Board is often asked how many Ohio physicians in a county practice a specific specialty. For example, the Medical Board would respond that 207 of the 6,194 physicians with active licenses in Cuyahoga County have indicated that OB/GYN is their primary practice specialty. Yet the Board cannot currently report how many of the 207 OB/GYN physicians are actually involved in clinical patient care, as the Medical Board has not had a way of capturing information about physician clinical activity or other physician workforce demographic data. However, this is about to change due to recently enacted legislation.

In 2006, the Ohio Board of Regents convened a group of policymakers, medical school the Physician Supply and Demand Consultation, educators, hospital administrators,

physicians and other interested parties. The group studied whether physician shortage is an issue for Ohio and considered what Ohio might do to respond if such a shortage occurs. Richard Whitehouse, Medical Board Executive Director, participated in the Physician Supply and Demand Consultation. Through its discussions, the group suggested that the Medical Board's license renewal process be used as a vehicle to collect physician workforce demographic data, and proposed model questions to be included in the renewal materials. Senate Bill 279,

(Continued on page 12)

STATE AGENCY UPDATES

State Medical Board of Ohio to Track Demographic Physician Data (Continued from page 11)

which went into effect on January 6, 2009, modified the biennial renewal procedures for physicians found in Section 4731.281, Ohio Revised Code, thereby allowing the Board to collect this information.

Board staff members are in the process of formatting the demographic questions into the renewal application. The revised application form will be implemented later this year. The additional renewal questions will ask:

- The average number of hours in clinical practice worked each week;
- If the physician's primary practice is located in Ohio;
- The licensee's type of practice such as: clinical; research; administration; education or medical volunteer, and the number of hours worked per week if licensee has more than one type of practice;

- The licensee's type of clinical practice setting such as office, hospital, emergency room, urgent care;
- The county and zip code of up to three locations where the licensee provides care;
- The licensee's practice arrangement such as solo practitioner; single-specialty group; multi-specialty group; full-time hospital employee;
- If the licensee holds certification recognized by the American Board of Medical Specialties or the American Osteopathic Association; if so, in what specialty; and
- Languages/dialects spoken and/or understood at the primary practice location.

It is anticipated that licensees will be able to answer many of the questions by selecting from a drop-down box on the electronic renewal form. Due to the staggered licensure renewal system used for physician license renewal, it will take two years for the Medical Board to collect baseline responses to the demographic questions. The data will quantify physician practice patterns throughout the state. This information will be a tool to help professional associations, hospitals, medical schools and other stakeholders identify and address physician workforce shortages in Ohio.

Editor's Note: The issue of having the State Medical Board track the physician workforce throughout the state was of great interest to the AMCNO board of directors and we discussed this concept with the Director of the Board at two of our board meetings. The AMCNO also participated in a statewide teleconference when this issue was first addressed. In previous issues of our magazine the AMCNO covered the content of these discussions along with background information on how this type of data was collected in other states by their respective State Boards.

The AMCNO is pleased that the State Medical Board of Ohio was able to codify into law the ability to track this information through physician licensure applications and our organization supported the bill in the legislature. We believe that the acquisition and dissemination of such information will clearly be useful for work involving specialty-specific data tracking, physician supply and demand issues, medical student enrollment needs and much more.

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THIRD PARTY PAYOR REVIEW FORM

The Practice Management Department of the Academy of Medicine of Cleveland & Northern Ohio (AMCNO) has been in existence for more than 20 years. When AMCNO members or their office staff has specific practice management issues, questions or concerns with the numerous insurance carriers, the practice management department is always available to address or investigate these and other issues. This third party payor review form is a tool physician offices may utilize when specific issues/problems with an insurance carrier arise.

Physician's Name:		Specialty:			
Address:					
City:	State:	Zip:			
Phone:		Fax:			
Contact Person:		Date Submitted:			
Name of insurance carrier: _					
Address of insurance carrier:					
Telephone number of insurar	nce carrier:				
CPT code in question:	Expec	ted amount of reimbursement:			
Patient First Name Only: (Please do not include the		**Insurance ID#:			
Date of Service					
Issue or Concern: (mark all Types of Denials Preauthorization Referral Claim Telephone Access Continuous busy signal Excessive hold time Numerous calls for a single	Payment Issues Delay in payment Late payment pattern Pre/Post payment review	Claim Patterns Down coding Recording of claims Lost claims Data entry errors by insurer Supporting documents missing Pertinent claim information mis	Documentation Requests Copy of medical record Operative report		
Other (specify)					
Attach a letter describing to	he problem and detailing the se	quence of events between your off	fice and the insurance		

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IMPORTANT: Please do not send confidential patient information without the proper patient consent. Remove all identifying information, such as patient's last name, from documentation prior to submitting to AMCNO. ***All claims must have a numeric identifier as a form of identification. If the patient does not have an insurance identification number, use the primary policyholder's social security number or the patient's social security number. Please be advised that the AMCNO may share this information with the insurance carrier, relevant state agencies, or other parties to expedite resolution of your problem. The submission of this form and any attached information is consent to release this form and information, as appropriate, by the AMCNO. Please mail or fax this completed form to the AMCNO, Practice Management Department, 6100 Oak Tree Blvd., #440, Cleveland, Ohio 44131 or fax (216) 520-0999. If you have any questions regarding this form and its use or additional issues or concerns, please contact the practice management department at (216) 520-1000 or e-mail concerns@amenoma.org

MEDICAL ISSUES

Immunization Benefits Far Outweigh Risks: Debunking Mythology

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Disclosure:

The authors report no conflicts of interest.

Introduction:

Immunizations are an integral part of preventative health care for infants, children, adolescents and adult patients. The immunization rates in the United States have been at record highs. Over the last several decades, the improvement in existing vaccines and development of several new vaccines have lead to reductions in occurrence and severity of a variety of once commonplace pediatric infections including: measles, mumps, pertussis, hepatitis B, polio, pertussis, and invasive Haemophilus influenza b to name but a few. In the last five years, vaccines have significantly reduced the rate of invasive bacterial disease from Streptococcus pneumoniae, the most common bacterial infection in pediatric patients. Adolescents are now being protected against most strains of Neisserial meningitidis. Vaccination against carcinogenic strains of human papilloma virus offers an exciting opportunity to prevent the development of cervical cancer. Yet, despite these exciting developments, physicians are increasingly being confronted by parents who do not want their children immunized because of fears of vaccine induced neurologic disease in an environment that they perceive to be low risk for their child acquiring a vaccine-preventable disease. In essence, they are espousing a free rider approach to immunization of their child while relying on herd immunity.

Recent media reports of both increasing rates of autism and suggesting links between autism and childhood vaccines can be alarming and confusing to both parents and physicians. Claims are based on perceived temporal relationships between both the increased numbers of recommended vaccines and increased incidence of autism and symptom presentation after vaccines in individual children. While the media coverage has certainly increased the public awareness of these disorders, the data demonstrating an

increased incidence of these disorders are less clear. In addition, parents are exposed to many Web sites, television reports and magazine articles that may describe families' perceptions of their children's altered development that began after their vaccinations. It is imperative the physicians who obtain consent from parents for vaccinations are knowledgeable about both the recent medical literature as well as any reports from the media.

Autism: Is the Incidence Really on the Rise?

Deciphering studies on the actual incidence of autism can be a daunting task. Many studies and media reports cite data collected from schools and other administrative programs to claim that the incidence of autism is rising. Passage of the Individuals with Disabilities Education Act (IDEA) in 1990 has led to increased screening and consequent diagnosis of this condition in public, primary schools. Many of the studies that report increasing prevalence include older children who are retro-diagnosed with autism; by definition, symptoms of autism must have onset prior to age 3 years. A more accurate measure would require the prospective collection of incidence data using standard criteria. The CDC published data from the Autism and Developmental Disabilities Monitoring Network¹ in 2007. This network used both health and psychosocial records of children at age 8. No increased prevalence was noted during the years 2000 through 2002. Further longitudinal studies will be necessary to accurately assess this question.

Prevalence data may also be flawed because many agencies and school districts do not use standard methodology to define autism. This variation in definition may result in the possibility of diagnostic substitution as a confounding factor in this data. Additionally,

economic pressures to categorize a child as autistic may influence diagnosis. For example, in the state of Ohio, children who are classified as "autism" by their school district are eligible for a large state scholarship if parents choose to forego any services from their local school districts. Many parents then use these funds to pay for private schooling, behavioral assistance as well as other therapies that may not be otherwise covered by insurance companies.

Autism and Vaccines: Is There a Link?

There are three postulated mechanisms of linkage between childhood immunization and autism; the MMR vaccine, thimerosal and excessive numbers of vaccines. MMR was identified as a possible etiologic agent in 1998 by Dr. Andrew Wakefield, a gastroenterologist. He published a case series of 8 patients with autism symptoms appearing within 1 month of their MMR immunization and gastrointestinal lymphoid hyperplasia². He theorized that this inflammation allowed usually non-permeable peptides to translocate into the blood and then into the brain, affecting development. Several subsequent studies explored this relationship and found no relationship between the vaccine and autism, including 2 prospective observational studies^{3,4}.

Thimerosal is an antibacterial preservative containing ethylmercury that has been used in multidose vaccines (not live virus vaccines such as MMR.) In 1999, the American Academy of Pediatrics recommended the removal of thimerosal from vaccines to prevent mercury exposure in young children. This act then raised public concern about a linkage between thimerosal and autism, despite symptomatic differences between autism and mercury poisoning. Multiple studies have failed to show any relationship between thimerosal and autism.

(Continued on page 16)

MEDICAL ISSUES

Immunization Benefits far Outweigh Risks: Debunking Mythology (Continued from page 15)

Another popular theory implicates the current vaccine schedule and claims that the recommended number of vaccines overwhelms the immune system and triggers autism in susceptible children via either a pathologic or autoimmune mechanism. The recent case of a 9-year-old with a mitochondrial enzyme deficiency and encephalopathy after immunizations was widely publicized by the media. The immunologic load from childhood vaccines represents only a small percentage of what a child's immune system routinely battles each year⁵. There has also been no plausible biological explanation of an autoimmune pathogenesis for autism. Despite sound scientific theories, further studies may be necessary to convince parents and the media that this is not a rationale reason for withholding vaccines.

In February 2009, the U.S. Court of Federal Claims ruled in favor of the Department of Health and Human Services in a case covering 5500 claims made to the Vaccine Injury Compensation Program. This ruling stated that there was no proven scientific link between vaccines and autism. It further stated that there was no evidence to suggest that thimerosal or the MMR vaccine altered the immune system or caused autism.

Herd Immunity: Don't Count on It

Herd immunity refers to the concept that if enough members of a population are immune, an infecting organism may not be sustainable in the population and, therefore, non-immune individuals would have a low risk of acquiring disease. Unfortunately, the immunity rate of the population required to achieve herd immunity is variable depending on the infection. The advent of international travel has also rendered the notion of discrete geographic populations somewhat obsolete.

What If We Don't Immunize?

Today's parents have grown up in an era where they would not likely know anyone who suffered from a vaccine preventable illness. In the pre-vaccine era in the United States, thousands of infants died annually from whooping cough, approximately 10,000 children a year suffered paralysis from polio, three thousand children would die from complications of measles, and twenty thousand infants a year were born with birth defects and mental retardation

from German measles. In areas of the world without access to routine vaccination, these illnesses are still causing significant morbidity and mortality. In 1999, the World Health Organization reported approximately 900,000 measles-related deaths in developing countries. There have been several small outbreaks of measles in the United States associated with international travel. Whether resulting from disruption in vaccine supply or parental refusal, there have been some recent outbreaks of diseases that had nearly become historical footnotes. In 2008, five children in Minnesota suffered invasive disease from the bacteria Haemophilus influenza b. One of these children died. In the late 1980s, this pathogen was the number one bacterial cause of meningitis and blood stream infection. The conjugate Hib vaccine has been universally recommended since the early 1990s. Very few United States physicians, including practitioners in infectious disease, who began training after 1992 have ever seen a case.

Don't Patronize

Vaccines, like any medication, do have some risks. Oral polio vaccine did carry a risk of vaccine associated paralysis. Smallpox vaccine could result in encephalitis. The first rotaviral vaccine was withdrawn from the market because of associated intussusception. To deny these things would cost credibility. There is constant federal surveillance of naturally occurring disease, monitoring of vaccine efficacy and collection of data about side effects. When the risk of vaccine associated disease from live-attenuated polio and smallpox outweighed the likelihood of children being

harmed by acquiring natural infection, these vaccines were no longer recommended. If there were to be a resurgence of small pox or polio, the benefit ratios would clearly tip in favor of reviving these immunizations. Vaccines, however, have not been shown to cause multiple sclerosis, autism, or immunodeficiency.

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

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



RULES AND REGULATIONS

The FTC's New "Red Flag" Rules: Do They Apply to Your Medical Practice?

By: Heather R. Baldwin Vlasuk Walter & Haverfield LLP Cleveland, Ohio

On May 1, 2009, the Federal Trade Commission (FTC) began enforcing its so-called "Red Flag Rules," which require creditors to create and implement a written Identity Theft Prevention Program. The Rules went into effect on January 1, 2008, but enforcement of the Rules had been postponed to allow entities time to come into compliance with the regulations. The goal of the Rules is to attempt to minimize the incidents and impact of identity theft.

In creating these Rules, as an expansion to the existing Fair And Accurate Credit Transaction Act (FACTA), the federal government continues to recognize that identity theft can have a real and lasting impact on its victims. In the realm of healthcare, when an individual's identity is stolen, more than financial repercussions can occur. For example, false and inaccurate medical histories may be created leading to inappropriate treatment and/or denial of health insurance claims or coverage.

Despite the admirable goal of the Rules, there has been some push in the medical community to seek an exemption from the Rules for healthcare providers. However, at the moment, the FTC has taken a firm stance that there is no industry-based exemption to the Red Flag Rules. Additionally, the FTC has clarified that HIPAA compliance and maintenance of ethical obligations to protect patient confidentiality do not relieve healthcare providers from compliance with the Red Flag Rules.

Because of the broad definition of "creditor" under the Rules, many healthcare providers, even those with small practices who do not seem to extend credit in the traditional sense, may still be subject to the Rules. Consequently, the enforcement date leaves many healthcare providers scrambling to find out what needs to be done to come into compliance with the Rules.

Are You Subject To The Rules?

The first step in faring your way through the Red Flag Rules is to determine if you, or your practice, extend "credit" for accounts used primarily for personal, family or household services; i.e. patient accounts for medical care. "Credit" is defined basically as deferring payment for products or services. But what does this mean for healthcare providers? In short, payment plans constitute deferral of payment and are, therefore, an extension of credit. And, according to the FTC, even deferring payment to allow a claim to be submitted to the patient's insurance and billing the patient later constitutes extending credit,

regardless of whether it is done as a courtesy to the patient or because it is required under contractual or state law. Therefore, if your practice utilizes payment plans or postpones payment in order to submit claims to insurance, it is likely that you must comply with the new Rules.

What Now?

Fortunately, the Red Flag Rules, and indeed the FTC, recognize that businesses, including medical practices, are not uniform. The Rules allow leeway for businesses to design and implement an identity theft protection program that is appropriate to its size, complexity, and the nature of their business. In fact, the FTC has stated that it expects that businesses for which the risks of identity theft are "minimal or non-existent will have a very low burden under the Rules." For example, a small medical practice with a well-known, limited patient base might have a lower risk of identity theft, and thus may adopt a more limited identity theft program than a clinic in a metropolitan setting that sees a high volume of new patients.

However, regardless of the size of your medical practice, basic steps need to be taken in order to comply with the Rules. You must assess the risk for identity theft in your practice, and create a written program that identifies warning signs of identity theft (so-called "red flags"), implements a procedure to detect the "red flags," sets forth a procedure to respond to "red flags" when they occur, and establishes a schedule for periodic review of the program, updates, and personnel training.

Creating A Program

As previously discussed, an Identity Theft Prevention Program may be tailored to each healthcare provider based on the size, nature and scope of the practice. Generally, the Program will identify "red flags" of identity theft that may arise. Examples of "red flags" are:

- Alerts, notifications, other warnings received from consumer reporting agencies;
- Presentation of suspicious documents (e.g., obvious forgeries or physical

- descriptions or photos not matching the person providing the document);
- Suspicious personally identifiable information (e.g., fictitious addresses, inconsistent personal information; lack of correlation between SSN range and date of birth);
- Other suspicious activity on the account (e.g., suspicious change of address); and
- Notices from patients, victims of identity theft, law enforcement, or other persons regarding the possibility of identity theft in connection with the account.

Once the "red flags" of identity theft are identified, the Program must set forth a plan to detect the "red flags." For example, a detection method may consist of checking photo identification at the time services are sought to ensure that individuals seeking medical treatment are who they represent themselves to be. Another approach may be to add a photo of the individual to the medical file upon the first visit and to compare such photo against subsequent persons seeking service under that name. Also, if patients provide their social security number, there are simple rules-of-thumb to detect SSNs that are invalid on their face based on the numbers composing the SSN. Larger practices may want to subscribe to commercial services that can screen for SSN validity.

Next, the Program must set forth an appropriate response procedure for when a "red flag" has been detected, so that the identify theft is prevented and/or its impact is mitigated. One starting point may be to ask patients to explain any discrepancies between conflicting personal information, such as when the address on the driver's license does not match the address given by the patient. Also, if it appears that a person seeking treatment is not the current patient for whom the personally identifying information corresponds, an appropriate response may be to notify the original patient and to refrain from commingling the medical information for the two individuals. Other responses may include changing security codes for external access to patient accounts and medical records, declining to open an account or closing and renumbering an existing account, and actively monitoring or notating specific accounts if the healthcare provider is notified by a patient of the potential for identity theft. Additionally, the Program should provide that collection on the account be stopped, if identify theft has actually occurred.

The Program should also provide for all detected "red flags" to be reported to a specific person, such as the chief practitioner, who would have the responsibility to take further action appropriate in the situation, such as thoroughly reviewing the circumstances and notifying law enforcement authorities if there is credible evidence that identity theft has occurred.

(Continued on page 18)

RULES AND REGULATIONS

The FTC's New "Red Flag" Rules (Continued from page 17)

Implementing the Program

After the Identity Theft Prevention Program is created, it must be approved, implemented, and administered. Under the Rules, the Program must be formally approved by the entity's board of directors. If there is no board, the approval should be made by the highest executive authority (i.e., the entity's president, management committee, or owner of a sole proprietorship). Also, the board of directors, an appropriate committee of the board, or a designated member of senior management must oversee, implement and administer the Identity Theft Prevention Program.

Furthermore, appropriate workforce training must occur, such as providing general training for all staff members and more extensive training on the Program for staff members charged with patient registration. It is recommended that the Identity Theft Prevention Program be made part of the initial training of all new staff members as well as part of annual training. Records that such training occurred should be kept by the employer.

The Program must also be periodically reviewed and updated based on the business' experience in encountering identity theft and based upon any changes to the size, nature and scope of practice. At least annually, staff should provide a written report to the board or designated senior management regarding significant incidents involving "red flags" and management's response, the effectiveness of the policy and procedures, and recommendations for change.

If a practice involves service provider arrangements allowing third-party access to patient accounts, such as outsourced billing, the healthcare provider must take some steps to ensure that the third-party complies with its own identify theft protection program. This oversight of service provider arrangements may be accomplished through mandating such requirements in service agreements.

Again, keep in mind that Identity Theft
Prevention Programs under the new Red Flag
Rules can and should be tailored to your
practices' specific size, complexity and nature.
Solo practitioners with minimal staff do not
need to create the same type of program as
would be required of hospitals or large clinics.
What is required, however, is that healthcare
providers follow each step listed above to
create, implement, oversee, and periodically
update an appropriate Program. Of course, if
you should have any concerns as to whether
the policy you are creating brings your practice
into full compliance with the Rules, you should
seek the advice of legal counsel.

To recap the Red Flag Rules:

Step 1: Assess whether your entity is subject to the regulation.

A healthcare provider is subject to the Red Flag Rules if the provider extends credit and maintains "covered accounts." Credit includes deferring payment for services to a later date. A "covered account" is defined as an account primarily for personal, family or household purposes that involves or is designed to permit multiple payments or transactions. Patient accounts are accounts for personal purposes and if multiple payments can be made on the account, the FTC considers it a "covered account" under the Red Flag Rules.

Step 2: Draft and Implement an Identity Theft Protection Program

Entities subject to the Red Flag Rules must design and implement an identity theft protection program which does the following:

- 1.) Identifies Covered Accounts.
- Identifies Red Flags "Red flags" are warning signs of identity theft. Some types of "red flags" are:
 - Alerts, notifications, other warning received from consumer reporting agencies;
 - Presentation of suspicious documents (e.g., obvious forgeries or physical descriptions or photos not matching the person providing the document);
 - Suspicious personally identifiable information (e.g., fictitious addresses, inconsistent personal information; lack of correlation between SSN range and date of birth); and
 - Other suspicious activity on the account (e.g., suspicious change of address).
- 3.) Detects Red Flags the Program must contain reasonable approaches to detecting the identified "red flags." One example would be instituting a policy to verify the patient's identity at time of registration.
- 4.) Responds to Red Flags the Program must set forth a process to prevent and mitigate the damaging effects of identity theft through appropriate responses to "red

flags." Examples of appropriate responses may be:

- monitoring covered accounts for evidence of identity theft;
- contacting the patient or account holder;
- changing security codes for external access to patient accounts and medical records;
- declining to open an account or closing an existing account; and
- notifying law enforcement.
- 5.) Provides for administration of the program, periodic updates, and employee training.

Step 3. Approve the Program

The entity's board of directors or other appropriate committee thereof must approve the Program. Also, either the board of directors or a senior level employee must be involved in the oversight, development, implementation, and administration of the program.

Further Information

Once again, it is recommended that entities consult with legal counsel to determine if they are subject to the Red Flag Rules and to create and implement a program in compliance with the Rules; therefore, physicians are encouraged to contact their legal counsel regarding this issue. If you have questions regarding the "Red Flag Rules," you may contact your own legal counsel or Ms. Heather R. Baldwin Vlasuk at the law firm that prepared this information for the AMCNO — Walter & Haverfield, LLP — (216) 781-1212. Additional information on the Red Flag Rules and identify theft may be viewed on the FTC Web site at http://www.ftc.gov/bcp/edu/microsites/idtheft// In addition, the FTC has prepared a guide for businesses — to view this guide go to http:// www.ftc.gov/bcp/edu/pubs/business/idtheft/ bus69.pdf. In addition, a sample policy and procedure form for implementing the Red Flag Rules in your offices may be obtained from the AMCNO office or you can download the form from the Practice Management link on the AMCNO Web site at www. amcnoma.org. This form was also included in the Spring 2009 issue of the AMCNO Practice Management Matters newsletter. ■



AMCNO ACTIVITIES

AMCNO Speakers Bureau Talks with Seniors

AMCNO member and past president William Seitz, Jr., MD, of the Cleveland Clinic, assisted with a Speakers Bureau engagement this winter at the Encore College at the eastern campus of Tri-C. The snow didn't keep this lively group of seniors away from coming to hear Dr. Seitz's talk about Joint Replacement in the Upper Extremity and Current Technology, an area of medicine that clearly impacts the elderly. Dr. Seitz explained the effects that aging and injury can have on our joints with inflammatory problems and the development of arthritis when the joints wear out or are fractured. Dr. Seitz also pointed out that there are many alternative treatment modalities and this type of surgery is usually a last resort.



Dr. William Seitz, Jr. speaks to the Tri-C Encore College group about "Joint Replacement of the Upper Extremities and Current Technology."

With current technology, physicians are able to replace parts of joints with custom implants that mimic the patient's own anatomy. Dr. Seitz explained that since these types of implants have now been manufactured

for over 20 years or more, they have become much more affordable. In addition, he can now submit a design to the manufacturer and receive the actual custom implant in five days.

According to Dr. Seitz, reconstructive surgery is being done more on younger patients such as professional athletes, which can put a tremendous amount of demand on the anatomic joint due to very active lifestyles. The anatomic joint can successfully restore motion, provide pain relief and improve function to a person disabled with limited motion or chronic pain. The physician's job is to advise any patient young or old of potential complications, the patient's responsibility post-surgery with rehabilitation



Dr. Seitz listens to a participant's question about joint replacement.

and ongoing restrictions, and re-injury and its impact on subsequent treatment. The good news is that if the patient follows these instructions and is careful, his new joint can last for a long time.

The AMCNO wishes to thank Dr. Seitz 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 call Debbie Blonski at (216) 520-1000 ext. 102. ■

AMCNO Wine Experience

AMCNO members and residents, medical students and their spouses attended this year's wine tasting event on Sunday, February 15th at La Cave du Vin. The evening began with the first pour of *Dibon Brut Reserve Cava N.V.* which was full of toasty, nutty qualities with notes of cinnamon and cornmeal. La Cave du Vin wine sommelier, Erich Lasher reviewed the particular flavors and ingredients of each wine as well as regional stories about each and recommended suitable food accompaniments. This year's focus was on some lesser known varietals.

This year's tasting included: *Bel Colle Favorita* 2006 Piedmont, Italy, rustic *Ammostus Monica di Sardegna* 2005 from Sardinia, Italy, and an earthy *Rocca delle Macie*, Morellino di Scansano 2005 Italy. From France, the *Vin de Pays De L'aude Carignan* 2007 brought forth some faint berry and spicy notes.

Black pepper? One of the favorites was a wine with dark, deep red and violet hues: *Terra Andina Carmenere* 2007 Valle Central, Chile. The subtle taste of black currant, blackberry, grilled red pepper and yes, black pepper was the surprise of the event.

The venue provided the perfect atmosphere to mingle with fellow AMCNO members and their guests...watch for information on the 2010 tasting!



Dr. and Mrs. Raymond Scheetz were on hand to enjoy the event.



AMCNO members spend a moment partaking of the varied appetizers provided at the event.



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