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Usage of Tamper-Proof Rx Pads Delayed for Six Months

Strong advocacy by the AMCNO and other organizations, in particular the Ohio Pharmacy Association, helped secure a six-month delay of a federal requirement that handwritten Medicaid prescriptions must be written on tamper-resistant prescription pads. Efforts included a letter, signed by the AMCNO president to Congressional representatives urging the passage of legislation to delay the mandate, which originally was to have taken effect Oct. 1, 2007. The new deadline for usage of the tamper-resistant prescription pads is April 1, 2008.

Sens. Sherrod Brown, D-Ohio, and George V. Voinovich, R-Ohio, sponsored this measure in the Senate and Rep. Charlie Wilson, D-Ohio, sponsored the bill in the House. The bill allows six more months before prescriptions for patients on Medicaid must be tamper-proof. The Ohio lawmakers say they hope the six-month delay will give doctors and pharmacists time to learn how to comply with the law without it posing problems for them or their patients.

The AMCNO has been monitoring the development of this issue and how it could impact a physician practice. Physician offices and staff should be aware that even though there is a six-month delay now in effect, offices should start now to get acquainted with what the new rule will require once implemented. Listed below is a short synopsis of what physicians and their staff may expect once this requirement is in full effect on April 1, 2008:

Overview of tamper-resistant prescription pad law (to become effective on April 1, 2008)
In order for Medicaid outpatient drugs to be reimbursable by the federal government, all written, nonelectronic prescriptions must be executed on tamper-resistant pads.

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Another Successful Year for the AMCNO Pollen Line – 2007 Recap

By Arthur Varner, MD

The 2007 pollen season was like the weather this summer, all over the place. A nice March led to an early start to the trees pollinating but the Easter snowstorm not only knocked the Indians to Milwaukee but wiped out the maple pollen season entirely. So the tree pollen season for 2007 was nothing like 2006 when we experienced some of the highest counts ever.

Grass pollen season started out normally but never reached very high counts due to the drought of late May, June, and July. The heavy week of rain in August brought the grass back to life and we saw a mild second grass pollen season in September, which has not occurred for some years.

Ragweed, aided by earthworms, was probably the worst of all the pollen seasons this year. We had two Fridays in a row in August with perfect conditions for high ragweed counts — hot weather with a strong wind from the south prior to a storm front moving in later that night. In fact, the count on September 1st was 118 grains/m^3, the second highest recorded level in Cleveland in over thirty years. But as usual, Cleveland had the lowest ragweed counts of any major city in the Midwest.

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Usage of Tamper-Proof Rx Pads Delayed for Six Months

(Continued from page 1)

To be considered tamper-resistant a prescription pad must contain at least one of the following:

- one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or
- one or more industry-recognized features designed to present the use of counterfeit prescription forms.

In addition, at a point one year after the implementation date, in order for prescriptions pads to be considered tamper-resistant, a prescription pad must contain all three of the above characteristics.

The requirement, once implemented, will apply to:

- All written prescriptions presented at the pharmacy on or after the published implementation date regardless of when the prescription was written;
- Written prescriptions for all outpatient drugs, including controlled, non-controlled, and over-the-counter drugs;
- Written prescriptions for drugs provided in a long-term care facility;
- Written prescriptions when Medicaid pays any part of the claim, including when Medicaid is not the primary payer, and
- Written prescriptions billed to Medicaid after the date of service due to retroactive eligibility.

The requirement, once implemented, DOES NOT apply to:

- Orders for medications administered in a provider setting (e.g., physician office or hospital outpatient or emergency department) and billed by the administering provider;
- Refills of written prescriptions presented at a pharmacy before the implementation date;
- Electronic, faxed or telephoned prescriptions; and
- Prescriptions for which payment will be made by a Medicaid managed care entity (i.e., this requirement applies only to prescriptions written for patients who receive a monthly paper Ohio Medicaid card, not to prescriptions written for patients enrolled in a Medicaid managed health care organization).

Remember, physician offices are not exempt and, in addition, prescriptions will be covered if the physician provides the pharmacy with a verbal, faxed, electronic, or tamper-resistant written prescription within 72 hours of the date the prescription was filled.

Physicians interested in obtaining compliant prescription pads prior to the revised implementation date may want to contact the following vendors for more information:

- MediScripts can provide pads for individual physicians in all specialties, except surgery, where special group requirements apply. They do NOT provide individual pads for APNs or PAs. Call them at (800) 387-3636 for more information.
- For those physicians who are used to printing their own prescriptions and prefer customized, noncommercial pads, another possible source is Rx Pads, Inc. This company has the tamper-proof "security" pads that meet all the standards and offer pads in varying quantities with greater discounts the more you order. For example, they charge $33.95 plus shipping for 10 pads. For more information check their Web site at www.rxpads.com/2007/Index.aspx or call (800) 307-7717.
- ScriptShield is offering a 10% discount for its HologramRx scripts and 5% off of National RxSecurity script prices for pads ordered between now and the end of the year. To receive an order form, call either HologramRx at (866) 356-1050 or (800) 510-1050, or visit their Web site at www.scriptshield.com or www.nationalrx.net.

The AMCNO will continue to provide our members with input on this issue as information becomes available. ■

Another Successful Year for the AMCNO Pollen Line – 2007 Recap

(Continued from page 1)

The mold season was also unusual. The drought in early summer with the grass browning early led to an early increase in the dry summer molds (such as *Alternaria* which can cause hay fever and asthma) in July and August. The heavy rains then brought all the plants back to life and we only see high mold counts when the vegetation is dying and decaying. The leaves seemed late to fall as well so the mold counts in September were lower than usual but we can expect to trend upward till the frost.

Late summer and fall is also when we see a surge in dust mite levels in the home due to an increase in indoor air humidity. These patients are usually diagnosed with colds or sinus infections and the cause is rarely found unless allergy testing is performed. Patients have more nasal (sneezing, congestion) than eye symptoms but we did see some rashes and hives due to dust mites this season.

This time of year is also when patients are likely to be stung by stinging insects such as yellow jackets, bees, wasps and hornets. If a patient experiences anaphylaxis from a sting they should carry an Epipen but also see an allergist and be tested. Immunotherapy, allergy shots, for venom hypersensitivity is very effective. It is estimated that 40 U.S. Americans die every year from these reactions.

In conclusion, the pollen season of 2007 was at times severe but overall mild. It has been a pleasure doing the Pollen Line for my third year and look forward to next year. Go Indians!

Arthur Varner, MD

Dr. Arthur Varner is a Board Certified Allergist with Allergy Diagnostic and is a longstanding member of the AMCNO. The AMCNO gratefully acknowledges the hard work and dedication of Dr. Varner in providing the pollen counts and background information for the AMCNO Pollen Line.

Editor's Note: The AMCNO Pollen Line was the first of its kind in this community and has been in existence for over forty years, and it continues to be a highly reliable resource for physicians and their patients. ■

Adapting to Changes in Physician Relationships with Hospitals and Industry

By Amy S. Leopard, Esq., Walter & Haverfield LLP

Physician relationships with hospitals, healthcare systems and others in the healthcare industry have been under intense scrutiny by federal regulators during the past year. The feds are revitalizing efforts to restrict the financial relationships physicians have with hospitals, device manufacturers and entities to which physicians make referrals. The Centers for Medicare and Medicaid Services (CMS) has tweaked the Stark II physician self-referral rule and is proposing extensive changes for the future. At the same time, the U.S. Department of Justice and the Health and Human Services (HHS) Office of Inspector General (OIG) recently executed consent agreements with orthopedic device manufacturers that will single-handedly restructure compensation relationships between these surgeons and device companies.

Physicians can expect increased emphasis on both the disclosure of these relationships as well as the documentation required to pass muster. Physicians and their affiliated organizations need to study and understand what CMS and the OIG consider to be either problematic or flat out prohibited and use this learning to inform both short- and long-term planning.

Immediate Stark Law changes — Stark III

CMS published a new Stark rule in September that will take effect on December 4, 2007. The Stark law prohibits a physician referral to an entity for certain "designated health services" covered by Medicare if a financial relationship exists between the referring physician (or an immediate family member) and the entity unless the arrangement meets an exception. Thus, the following changes demand immediate analysis and action if noncompliance is identified.

Probably the biggest change CMS is implementing is what is referred to as the new "stand-in-the-shoes" rule. *Under this provision, financial arrangements between entities that bill Medicare and physician organizations such as group practices will now be deemed to create a financial relationship with each of the referring physicians in the group on the same terms as the arrangement with the physician organization itself.* By collapsing the physician into the financial relationship, this rule now regulates indirect financial relationships previously outside the purview of the Stark law and requires a specific exception, rather than the current more lenient approach. A grandfathering provision will allow certain existing arrangements to comply with the rules in effect on September 5, 2007.

What this means is that outside an employment relationship, almost all financial relationships with a referring physician, whether direct or indirect through a group practice, will require a writing in advance of any compensation being paid. This remarkable change occurred without much industry comment and without CMS thinking through possible unintended consequences of such a broad sweep. Indeed, this change may be a trap for the unwary, or at the minimum, require wholesale record-keeping changes between entities that bill Medicare and their referring physicians.

On the other hand, another upcoming change helps parties involved in compensation arrangements when technical noncompliance issues arise, such as when parties properly enter an agreement that lapses without renewal and the physician continues to perform services without a written agreement. In such an instance, CMS will allow a six-month holdover period on the same terms and conditions. Thus, when payments should continue to be made at fair market value for legitimate services rendered, this provision will reduce the risk that the failure to execute a renewal document timely will subject the parties to liability.

Finally, CMS has liberalized the circumstances under which physician recruitment and retention payments can be made and the criteria for what constitutes an appropriate "relocation" to be eligible for hospital subsidies. Of significant interest to group practices receiving hospital payments to assist with physician recruitment is CMS' stated intention to expand the ability of practices to impose certain types of restrictive covenants, such as a non-compete, on a recruited physician if the restrictions are deemed to be reasonable. How this provision will be interpreted is anybody's guess.

Stark IV: The Final Frontier?

Under proposed Stark regulations pitched this summer, CMS put forth for consideration several bold initiatives that would have far-reaching and dire consequences if adopted. These broad proposals range from increased restrictions on the types of ancillaries than can be provided within group practices to changes that would quash many current hospital-physician alignment initiatives.

For physician groups, CMS is seeking comment on the type and scope of services to diagnose and treat patients that a group practice may provide. CMS is concerned about the proliferation of expensive imaging technologies and other in-office ancillary services. The July notice seeks public comment on whether CMS should restrict groups from furnishing (1) ancillaries other than at the time of an office visit, (2) ancillaries provided through "turnkey" arrangements, (3) physical therapy provided by independent therapists within the group, and (4) high-ticket items generally. CMS appears to be questioning any arrangement with outside suppliers construed as a markup of the professional or technical component.

CMS also proposes some other technical changes to expand the types of entities that are regulated by the Stark law to go beyond those entities which bill Medicare directly. This broad brush would expand the Stark law to directly regulate entities not billing Medicare which are not currently regulated, including leasing companies and staffing companies owned by physicians.

CMS is considering a reversal in the course it took in 2001 when it outlined how leases and services could be provided either on a "per-click" basis or "under arrangements." An "under arrangements" alignment model is a structure under which referring physicians provide goods and services to a hospital directly, or through a joint venture with the hospital, and the hospital then bills Medicare for the services (e.g., imaging, outpatient services, cardiac cath labs). The CMS proposal considers whether the Stark rule should prohibit these arrangements. This area must be watched closely over the coming months and may cause transactions for services furnished 'under arrangements' to be restructured or postponed.

CMS also asked for comment on whether it should continue to allow equipment rentals to be based on a "per click" basis; i.e., lease payments based on a per-use or per-service fee. CMS's concern here is that physicians will be

rewarded for each referral made for services covered by Medicare. CMS would strictly prohibit any lease payments from fluctuating on the basis of referrals or other business generated between the parties, i.e., where the rental charges reflect services provided to patients referred by the lessor physician to the lessee even if the payment was at fair market value.

Another area in which CMS seeks comment is compensation to physicians and physician organizations involving percentage-based arrangements. CMS would change its current policy allowing percentage compensation methodologies that meet fair market value standards by prohibiting percentage-based compensation unless the formula is based only on revenues generated from services that the referring physician personally performs.

These proposals reveal an about-face from regulations that expressly permitted "under arrangements" models and percentage and service-based payments even if the physician received a payment generated through a referral from the physician. If adopted, these proposals would entail restructuring of most leasing arrangements not based on a set, fixed in advance rental payment.

It is not altogether clear whether CMS will adopt these provisions or simply regulate them differently, and industry commentators certainly will provide policy and statutory authority contrary to the CMS proposals. Nonetheless, the fact that CMS is asking these questions reveals a change in course and at a minimum it can be anticipated that these types of arrangements will be subject to additional safeguards and stricter scrutiny. Stay tuned.

Orthopedic Settlement Agreements

While CMS tightens the Stark rule, the OIG has focused on device manufacturers and surgeons with whom the device companies have consulting relationships. In an area distinguished by a lack of hard and fast rules and nuances in industry views on how to appropriately manage and disclose conflicts of interest, stakeholders grappling with these issues have issued a wide range of guideposts for compliance. Many of these are voluntary industry compliance practices or institutional codes of conduct adopted within the past year.

Now, the Justice Department has announced that five companies comprising 95 percent of the U.S. market for hip and knee implants have agreed to resolve allegations that their compensation arrangements with orthopods violated the federal anti-kickback law. The anti-kickback law prohibits anyone from offering, paying, soliciting or receiving anything of value in return for (a) referring or arranging for the referral of patients to receive services covered by Medicare, Medicaid and TRICARE or state health care programs, and (b) purchasing, ordering, or arranging for the purchase or order of items covered under these programs.

The orthopedic companies must overhaul physician compensation practices and adopt ongoing compliance monitoring and auditing. Four of the companies (Biomet, DePuy, Smith & Nephew, and Zimmer) also paid significant fines and penalties and entered five-year corporate integrity agreements with the OIG. A fifth company, Stryker, entered a non-prosecution agreement requiring 18 months of monitoring based on its early cooperation. These agreements anticipate significant internal and external monitoring and reporting and periodic certification of compliance to the government.

Of particular interest are some of the terms and conditions in the deferred prosecution agreements. These agreements defer prosecution of criminal conspiracy charges under the anti-kickback statute for 18 months based upon compliance program initiatives and remedial actions. The agreements make mandatory the AdvaMed Code of Ethics on Interactions with Healthcare Professionals. Specific safeguards are required to be monitored by outside independent monitors. A required safeguard will be the preparation of a "needs assessment" by 2007 year-end to reflect expected consulting service needs in the areas of medical and clinical training, educational, and R&D areas. An advance budget for the total amount of payments made to consultants for consulting, honoraria, scholarships, gifts, contributions, donations, etc. must be approved by the outside monitor.

Once the need is set, it will be used as a basis for all physician hiring beyond January 1, 2008. Payments for all consulting agreements are limited to the fair market value hourly rate and cannot exceed $500 per hour for time expended. Anything not approved within the plan will require an independent fair market value analysis (e.g., if outside of certain ranges). Royalty payments for intellectual property contributions will require an analysis of the physician's individual contributions and cannot be paid in advance or in anticipation of product sales.

All consulting agreements must be in writing and executed by numerous company officials. Product development and research agreements must be specifically approved by the head of research and development, whereas clinical service agreements (for clinical trials, clinical studies, etc.) must be specifically approved by the Clinical/Regulatory Vice President. The company President, General Counsel and Compliance Officer each must execute all consulting agreements. The physician must provide a summary of the services provided and the company must independently verify in writing that consulting services were actually rendered and the length of service. Except for data collection, travel and prep time, a company representative must be present.

Finally, the government has focused on the disclosure aspects of these types of arrangements. New consulting agreements and renewals will require physicians to disclose their engagement both to their patients as well as any affiliated hospitals. Likewise, the orthopedic companies must prominently feature on their Web sites the names of retained consultants and disclose payments within $25,000 increments. It is not entirely clear how these formalities will be implemented, but certainly the contracting process has now become complex, the planning process elaborate, and the financial terms transparent for the entire orthopedic industry.

Conclusion

Many of these changes will complicate, sometimes unnecessarily, legitimate and beneficial arrangements within the industry. As is always anticipated when CMS and the OIG begin to tinker with these rules, unintended consequences and unforeseen regulatory burdens often take months, if not years, to identify and resolve.

For the foreseeable future, one thing is clear — the regulatory environment within which physicians have financial relationships and make referrals is undergoing a marked transformation. As Stark III rolls out by year end, it is a good time to review 2008 compensation arrangements and consider the effects of these rules to determine whether restructuring is necessary and what compliance documentation will be required to protect both the physician and the organizations with whom the physician has financial relationships.

Amy S. Leopard is a partner at Walter & Haverfield LLP representing health care clients on business and transactional issues, regulatory compliance and government investigations. She may be reached at aleopard@walterhav.com.

This article presents general information regarding legal developments and does not constitute legal advice for a particular set of facts. ■

LEGISLATIVE UPDATE

By Michael Wise, JD, AMCNO Lobbyist
McDonald Hopkins, LLC

TESTIMONY PROVIDED BY AMCNO ON SB 59
The Academy of Medicine of Cleveland and Northern Ohio ("AMCNO") has been the leader in pursuing Alternative Dispute Resolution ("ADR") in the State of Ohio. AMCNO's legislation, SB 59, is sponsored by Senator Coughlin and mandates arbitration for all medical malpractice claims. To insure the constitutionality of the Bill, parties may proceed to Court after the arbitration but they must pay the attorney fees of the other side if the party loses at arbitration and then loses again at trial. This Bill had stalled in the Senate Insurance Committee but is now receiving additional hearings. In October, Dr. John Bastulli and myself testified on behalf of the Bill. At that time, the Committee accepted a Substitute Bill. The Substitute Bill, which the AMCNO helped write, contains five changes, which are outlined below.

CHANGES TO SB 59 ACCEPTED
Historically, a party to an arbitration could purposely not put forward their best case and then rely on an inflammatory dissenting opinion from their chosen panel member to protect them in a subsequent court proceeding. Therefore, we clarify that dissenting arbitration opinions are not admissible in a subsequent court proceeding. Second, we addressed a constitutional concern about selection of the pilot counties by choosing our pilot counties using a concept found elsewhere in the Ohio Revised Code. The constitutional argument is typically an equal protection argument. With the Amendment, the counties shall be selected by the Director of the Director of the Department of Insurance, after consultation with the Ohio Supreme Court. In addition, three counties must have populations of 250,000 or more, one additional county must have population of one million or more, all counties must be in the top 25th percentile for medical malpractice premiums as determined by ODI, and the Director of ODI may choose other counties at her discretion (limit of 7 total). Third, the applicability of the Bill is expanded. The Bill now covers individuals who are agents or employees of the covered doctor. Fourth, the current SB 59 allows a respondent/defendant to just not respond to the arbitration and force the matter into Court. The Substitute Bill provides for appointment of an additional panel member and an order against the respondent for failure to reply and participate in the arbitration proceeding. Last, the Substitute Bill adds a Unity of Provisions Clause.

In addition to strong support from the AMCNO, SB 59 has garnered additional support from the Ohio Hospital Association, the Ohio Podiatric Medical Association, the Ohio Chapter of the American College of Obstetricians and Gynecologists, the Ohio Osteopathic Association and the Ohio Orthopaedic Society. The AMCNO has been actively working to garner support from other specialty societies around the state. To date, the state medical association has yet to voice their support of the bill. In fact, the state medical association has written to at least one specialty society stating in part "in the state of Ohio medical liability rates are starting to move in a very positive direction for physicians, therefore we (the OSMA) want to be very cautious about potentially upsetting this downward trend in premiums." In addition the state medical association provided input that, in our opinion, did not clearly outline the process and purpose of the legislation. Contrary to the opinion of the state medical association, the AMCNO cannot agree that there is anything positive about the direction of the current medical liability climate in Northeastern Ohio and we will continue to advocate for passage of SB 59. (See pullout box on next page for AMCNO letter in response to the Ohio Dermatological Society.)

HOUSE BILL 125 –
THE HEALTHCARE SIMPLIFICATION ACT
One other Bill that AMCNO has been directly involved with is HB 125 – the Healthcare Simplification Act. The Ohio House of Representatives passed HB 125 by a vote of 91-5. We attended the interested party hearings on this legislation — a Bill that was designed to provide remedies for many of the excessive administrative demands faced by doctors in their interactions with health plans. The intent of the Bill was to implement reforms that would provide for ease in the health insurance contracting process, fairness in contracting, a standardized credentialing process and Web-based eligibility verification. However, after many hearings and interested party meetings, the bill has been changed radically since it was first introduced.

Several amendments added to the legislation by the insurance lobby now provide for additional flexibility for insurers regarding the way in which providers access the Web-based eligibility system and insurers may also continue to use existing codes based on Social Security numbers or birth dates to avoid the cost of creating a new method. Other amendments dealt with health insurance industry concerns over definitions, the contract amendment process, the credentialing time line, applicability of the bill to programs of the Department of Job and Family Services and physician groups, summary disclosure forms, and other issues.

Interestingly, HB 125 specifies that disputes that only concern the enforcement of the contract rights conferred by certain provisions in the bill are subject to a mutually agreed upon arbitration mechanism that is binding on all parties. The Bill then authorizes an arbitrator to award to the prevailing party reasonable attorney's fees and arbitration costs, and prevents a party from simultaneously maintaining an arbitration proceeding and pursuing a complaint with the Superintendent of Insurance to investigate the subject matter of the arbitration proceeding. This provision may have positive implications for AMCNO's efforts with Sub. SB 59.

HB 125 also creates a 15-member Joint Legislative Study Commission on Most Favored Nation Clauses in Health Care Contracts, chaired by the Superintendent of Insurance, and charged with studying specified areas pertaining to most favored nation clauses in health care contracts, and requires the Commission to submit a final report of its findings and recommendations to the General Assembly.

The AMCNO, although still supportive of the intent of the bill, has some reservations about the latest version and we have contacted the bill's sponsor and sent additional comments on the Substitute Bill to the Chairman of the Senate Judiciary and Civil Justice Committee. The AMCNO is concerned that the latest version of the legislation does not go far enough in that the insurance companies are not completely prohibited from using an all products clause, and that the bill does not completely prohibit insurers from including a most favored nation clause in contracts. Instead, at the present time the latest version of the bill calls for a two-year moratorium on the usage of a most favored nation clause while a joint legislative review committee reviews the matter, and the bill would "restrict" the use of all products clauses. Other states have already prohibited the use of such clauses and we feel that Ohio should follow suit. In addition, the Department of Justice has begun to investigate the use of these clauses in the insurance field. These clauses are unfair and would never be allowed in other business practices.

The AMCNO would also have preferred that language were included in this bill that addressed the definition of what constitutes "medical necessity." Often insurance companies make decisions relative to medical necessity matters that are inappropriate and not in the best interest of patients. Insurance companies routinely deny access to benefits guaranteed by their contracts, and this denial of payment for medical care can result in a patient receiving inadequate or delayed treatment. Physicians should be in control of what is deemed medically necessary for a patient — not an insurance company. The AMCNO would favor inclusion of a definition of medical necessity in this legislation along with an amendment requesting that the Ohio Department of Insurance create a healthcare panel inclusive of physician representation that would review and comment on health insurance company practices.

Legislative Update

In addition, the AMCNO is still a proponent of allowing physicians to jointly negotiate with insurance companies with regard to their contracts. Without the ability to jointly negotiate it will be difficult for physicians to have any real impact in their negotiations with the large insurance companies in Ohio.

The AMCNO will continue to advocate for passage of HB 125, however, if there were an opportunity to revise the legislation to include some of the points outlined above, the legislation would be much stronger and have a greater impact on physicians and their practice. The AMCNO will continue to monitor this legislation as it moves through the Ohio Senate.

OTHER LEGISLATIVE ACTIVITY
Both the House and the Senate have seen the introduction of a number of health care-related bills. Bills of specific interest include:

HB 149 Optometry – Modifies the scope of practice of an optometrist holding a therapeutic pharmaceutical agents certificate or topical ocular pharmaceutical agents certificate. Requires the State Board of Optometry to adopt rules governing the authority of optometrists to administer and prescribe controlled substances. The AMCNO is concerned that this legislation will alter the scope of practice of optometrists in the state, however, amendments are under consideration that may change the direction of the intent of the bill. Additionally, there is discussion underway about adding an amendment to the bill that would outlaw the sale of decorative contact lenses at retail stores in Ohio, where these lenses may be obtained without a prescription or a fitting — which can lead to severe eye problems. The AMCNO will continue to evaluate this legislation.

HB 185 – Nursing Overtime – Prohibits hospitals from requiring registered nurses and licensed practical nurses to work overtime as a condition of continued employment. Permits a nurse to work overtime voluntarily. Establishes a $10,000 per violation civil penalty for violating the overtime prohibition, to be imposed by the Ohio Department of Health. The AMCNO opposes this legislation because of concerns that passage of this bill could escalate the nursing shortage problem in Ohio.

HB 238 – Prescriptive Authority – This Bill would amend the Ohio Revised Code to allow advanced practice nurses, who have completed additional required education, to prescribe Schedule II controlled substances in certain circumstances and with certain limitations.

While the AMCNO supports amending the Ohio Revised Code (ORC) to allow advanced practice nurses, who have completed additional required education, to prescribe Schedule II controlled substances in certain circumstances and with certain limitations, we do have some reservations about allowing this prescribing practice under certain conditions.

Currently the AMCNO supports this legislation with technical assistance, which means that the AMCNO believes that there is a need for changes to the Bill before the AMCNO can fully support the legislation. The AMCNO has notified the nurse practitioners that while the AMCNO has no problem with APNs prescribing Schedule II controlled substances it has to be done only while they are under a collaborative agreement with a physician and only if both the collaborating physician's name and DEA number is included on the prescription along with the name and DEA number of the APN. The AMCNO has also voiced concerns if the prescription for Schedule II drugs were to be provided to a patient in certain outpatient settings such as in a retail or minute clinic where the collaborating physician is not always readily available — the AMCNO would question that type of prescriptive authority.

The AMCNO has chosen to wait until we have had a chance to review an amended version of HB 253 before voicing our full support of the bill.

Senate Bill 152 – Bicycle Helmets – To require bicycle operators and passengers under 18 years of age to wear protective helmets when the bicycle is operated on a roadway and to establish 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 supports this legislation.

Senate Bill 186 – Cancer Trials – To prohibit insurers, public employee benefit plans, and multiple employer welfare arrangements from excluding coverage for routine patient care administered as part of a cancer clinical trial. The AMCNO supports this legislation.

We are still less than half way into a two-year legislative cycle yet, as you can see, there is considerable activity on the health care front in the General Assembly. AMCNO has a comprehensive tracking system of all health care-related legislation in the General Assembly. If you are interested in receiving a copy of this document, please contact Elayne Biddlestone at (216) 520-1000. ■

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Letter sent to the President-Elect of the Ohio Dermatological Association by the AMCNO in response to comments sent to ODA by the state medical association concerning SB 59.

I write to take issue with many of the statements made by OSMA in their July letter. I am somewhat encouraged that the OSMA is not opposing this legislation. However, I am sure that the Academy of Medicine of Cleveland & Northern Ohio (AMCNO) would certainly welcome the OSMA moving from neutral to supportive of SB 59.

First of all, malpractice premiums in Northern Ohio are NOT decreasing. The rate of growth in these premiums is decreasing but the premiums themselves are still at record highs and increasing. We are losing both physicians and medical school applicants to other jurisdictions. These are the reasons that the AMCNO is pursuing SB 59.

Second, the AMCNO is in agreement with the OSMA that the current and historical arbitration provisions in Ohio have not been effective. The hope at the AMCNO would be that this common ground could be the basis for proactive reform of this type of Alternative Dispute Resolution in Ohio. SB 59 would allow arbitration to effectively resolve medical malpractice claims.

Third, I will not debate the constitutionality of the loser pay provision here. The AMCNO believes that the provision is constitutional for a number of reasons. However, the only opinion that ultimately matters will be that of the Ohio Supreme Court. That said, if the loser pay provision is struck down the entire Bill WILL be struck down. The only way that the legislation would survive such a ruling would be if there was a severability clause and this Bill DOES NOT contain such a clause.

Finally, a reference was made to trying a case twice. SB 59 utilizes a bifurcated process. The arbitration panel only rules on liability and a jury then rules on damages. The purpose of this approach is to reduce "loss costs" not to increase such costs. The arbitration process in SB 59 is designed to be less expensive than a jury trial and the loser pay provision will provide a mechanism to protect the integrity of the arbitration process.

Best regards,
James S. Taylor, MD, President, AMCNO

The Voice of Physicians in Northern Ohio

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MEET YOUR LEGISLATOR


Matthew Dolan

Representative Matthew Dolan serves as the State Representative for the 98th House District, which consists of Geauga County as well as Gates Mills, Highland Heights, Mayfield Village and parts of Mayfield Heights in Cuyahoga County. He is currently serving his second term in the Ohio House.

Representative Dolan obtained a bachelor's degree in history from Boston College and is an alumnus of the Case Western Reserve University School of Law. Dolan began his career in 1990 an Assistant Attorney General for the State of Ohio and later became an Assistant Geauga County Prosecutor in 1993. He then joined the firm of Thrasher, Dinsmore and Dolan, where he has been a principal since 2001, specializing in Municipal Law, Real Estate and Criminal Law.

Dolan currently chairs the House Finance and Appropriations Committee. He is also serves on the House Judiciary Committee. As Chairman of the House Finance and Appropriations Committee, Representative Dolan sponsored House Bill 119, Ohio's $52 billion operating budget for the 2008-2009 biennium. The operating budget is responsible for funding all aspects of the Executive, Legislative and Judicial branches of government. Among the issues covered in the operating budget include funding for primary and secondary education, higher education, tax reform, economic development, environment issues and a homestead exemption that provides a property tax relief for senior citizens.

In the area of Medicaid and health related issues, House Bill 119 increased the Medicaid reimbursement rate for physicians by 3% per year; increased eligibility for children services from 200% to 300% of poverty levels as well as increasing the eligibility for pregnant women from 150% to 200% of poverty. The bill also provides the necessary funding for children's hospitals that serve a vast number of covered children. The budget passed both the House of Representatives and the Senate with unanimous bi-partisan votes, the first time this had happened in more than 50 years.

Representative Dolan supports the provisions in House Bill 125 that will establish certain uniform contract provisions between health care providers and third-party payers, standardize credentialing, and require third-party payers to provide health care providers with specified information concerning enrollees. House Bill 125 will relieve much of the paperwork burden and allow doctors more time to spend with patients. He continues to work towards a solution to give Ohioans more access to critical healthcare.

Outside of the legislature, Representative Dolan is also an active member of his community. Dolan is currently a Board Member of the American Red Cross, Greater Cleveland Chapter, where previously he was the Chairman of the Advisory Board. He is also a Board Member of Kent State University-Geauga Campus, as well as the Geauga YMCA Wellness Center and the Chardon Community Day Care Center. Additionally, he serves as a member of the Geauga Library Foundation. ■

Overview of UnitedHealthCare (UHC) Physician Advisory Council Fall Meeting

UnitedHealthCare (UHC) Rolls Out Advance Notification Program
UnitedHealthCare recently sent out correspondence to physicians and hospitals concerning UHC's advance notification program. AMCNO leadership has discussed this program with the medical director of UHC and have learned that, under the program, physicians, health care professionals and non-facility providers rendering services are still required to provide notification for all admissions. However, in order to promote administrative simplification, as of December 3, 2007, UHC is reducing the number of inpatient admissions that would require advance notification. Failure to notify for specific elective procedures will impact reimbursement.

Physicians are responsible for advance notification for inpatient services involving orthopaedic surgeries (spinal surgeries, total knee replacements and total hip replacements); transplants; reconstructive/potentially cosmetic procedures, and bariatric surgeries. The new rules for these specific inpatient services will require advance notification of at least 5 business days prior to planned admissions (or as soon as the admission is scheduled if it is scheduled less than 5 business days in advance). Advance notification from the physician has to occur before the patient is admitted to the hospital.

Reimbursement reductions will occur only if the advance notification is not received. Reimbursement reductions will only impact the party who fails to meet their specific obligation under the program (i.e., physicians, health care professionals, non-facility providers and hospitals will no longer be impacted by another party's failure to provide required notification). However, if a physician does not meet the obligations for advance notification when billing for a service on the advance notification list they will be subject to reductions off the contracted rate BEFORE member benefits.

Hospitals will be required to notify UHC within 24 hours of the patient's admission to the hospital. UHC will have 24-hour availability for hospital contacts. Reductions for late admission notification will apply equally to hospitals of ALL contracted types. If the hospital fails to provide admission notification or admission notification is received more than 72 hours after admission UHC will apply a 50% reduction off the contracted rate for the entire admission before enrollee benefits (this applies only to hospitals related to any inpatient admission). If the hospital provides a late admission notification (i.e., received more than 24 hours but within 72 hours after admission) they will be subject to a 50% reduction based on the computed average of the daily contracted payment rate for the days preceding notification (applies only to hospitals related to any inpatient admissions.) Additional information may be obtained at the UHC Web site at www.uhc.com.

UnitedHealthCare Premium Designation Letters Mailed to Physician Offices
Letters went out in September informing physicians of their Premium Designation status with UHC. There was a six-week "reconsideration period" after receipt of the letters. Physicians had from 9/7/07 to 10/31/07 to provide self-reported, additional information on patient cases. Physicians who meet the quality and efficiency guidelines will receive a two-star designation, and physicians who meet the quality guidelines will receive a one-star designation. There could be several reasons why a physician would not meet either of the guidelines. There may be no record with UHC that they are board certified, or it could be they did not have a sufficient number of claim volume. If a physician does not meet either of the guidelines, the physician may go to the UHC portal and check their cases to see if they can provide additional data. The physicians who receive only the quality rating but not the efficiency rating may also want to check and verify their data.

Patient Centered Medical Home
UnitedHealth Group, the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP) and the American College of Physicians (ACP) have announced a pilot program to accelerate the implementation of a primary care model, called the patient-centered medical home, designed to improve patients' total health and care delivery. UnitedHealth Group, with the support of the professional societies, will provide enhanced payment to reward primary care doctors whose care is based on this model, and who demonstrate measurable improvements in the overall health of their patients.

In this model, each patient will have the choice to select a personal physician, or "medical home," who knows his or her medical and family history and coordinates their medical care. The physician will be responsible not only for treating a specific ailment or condition, but also for working with the patient to better manage his or her health care needs and arranging care as appropriate with other professionals. The patient-centered medical home model places special emphasis on preventing disease and improving the care of chronic conditions. It emphasizes behavioral health support and patient education as well as the diagnosis and treatment of acute illnesses. The pilot program will be launched in Florida with approximately six specially chosen primary care practices that will employ the model. The concept is to implement a patient-centered, systems-based approach to care delivery, which has been shown to improve quality, reduce cost, and improve patient satisfaction. The idea is to launch a new model of primary care that restructures payment to align with the value of care provided by primary care physicians. Participants will be exempt from UHC notification requirements (i.e., radiology) and will be provided an enhanced service model to streamline administrative functions. A survey will be the basis as to how practices are selected. Mathematica has been retained as well to help with sample size and evaluation tools.

The study is to be undertaken in up to 2-3 different geographic locations and takes place over a 24-month time frame to allow behavioral changes to have measurable impact. At press time the other pilot sites had not yet been chosen. ■

Concerns with the National Practitioner Data Bank

By Michael J. Jordan, Walter & Haverfield LLP

When the National Practitioner Data Bank ("NPDB") was created by the Health Care Quality Improvement Act of 1986 (the "HCQIA" or "Act"), Congress made specific findings which, it believed, justified increasing the protection given to peer review activities.[i]

These findings included a "national need to restrict the ability of incompetent physicians to move from state to state without disclosure or discovery of the physician's previous damaging or incompetent performance.[ii] Although the congressional goals are certainly laudable, the past twenty-one years have proven that the practical implementation of the Act, particularly of the NPDB, may pose career-ending problems for physicians who are far from incompetent.

Overview of the Act

The NPDB receives reports which may be grouped in five different categories:

1. Malpractice payments made for the benefit of physicians or other practitioners;
2. Actions taken by state medical boards adversely affecting physician licensing;
3. Professional review actions taken by health care entities, including hospitals, which are adverse to physicians;
4. Drug enforcement agency actions; and
5. Exclusions from the Medicare and Medicaid programs.

As an authorized healthcare entity under the statute, hospitals are specifically authorized to obtain information on file with the NPDB. Hospitals are, essentially, required to query the NPDB when a physician applies for clinical privileges and every two years that a physician is on the medical staff or holds privileges. Indeed, failure to submit a query may be used against a hospital in a medical malpractice action and will substantially weaken a hospital's position taken in any claim of negligent credentialing.[iii]

While there are many significant issues raised by the broad scope of the statute, and its applicability to physician assistants, residents, nurses, dentists, and other licensed health care practitioners, this article will focus on issues between physicians and hospitals. In that respect, there are two major areas of concern resulting from reports which hospitals are required to make to the NPDB. First, a hospital must make a report to the NPDB whenever a physician's clinical privileges have been adversely affected by a professional review action for a time period of greater than thirty (30) days. Second, a hospital is required to submit a report if a physician has surrendered clinical privileges while under an investigation relating to incompetence or improper professional conduct, or if such surrender was in exchange for the hospital not conducting such an investigation.

If a hospital makes a report under either situation set forth above, a physician may, but is not required to, add a personal statement which will also be disclosed to any entity which submits a query. A practitioner can also challenge the accuracy of a report by requesting that the Secretary of Health and Human Services review the information. Practically, however, the Secretary's review is concerned with whether the submitted report is accurately completed, not with the merits of the underlying dispute. Reports are rarely changed.

Mistakes Physicians Make

The effect of the NPDB reporting requirement upon the ability to settle medical malpractice litigation is well known by attorneys, physicians, and judges. Less well understood is the difficulty the Act creates with respect to hospital professional review actions.

First, it is essential that any physician faced with the possibility of an adverse peer review action address the situation immediately. All too often, physicians believe that they will receive a "fair shake" in a peer review hearing and that the matter can be resolved amicably. Unfortunately, it is often difficult for anyone to remain objective in such a situation. If the hospital's peer review action in any way restricts a physician's clinical privileges, the physician must take steps to address the matter before thirty (30) days have expired. Because the hospital is required to make a report whenever a restriction on privileges exists for greater than thirty (30) days, the only flexibility a hospital can possibly have in terms of whether and what to report is if the matter is reviewed before the expiration of the thirty-day period. It may be possible, during that window, to recast the action in a manner that will make it non-reportable. A physician whose privileges are restricted and who allows that thirty-day period to lapse does so at his peril.

A second mistake physicians make is to relinquish their privileges while under investigation. A common situation involves a physician who holds medical staff privileges at more than one hospital. If a peer review matter arises at one institution, the physician may become disgruntled with the hospital and simply relinquish medical staff privileges in the belief that he can maintain his practice at other hospitals where he is credentialed. The flaw in that approach is that the hospital conducting the peer review must then make a report to the NPDB, of which all other hospitals will learn, and likely much sooner than the next recredentialing period. Medical staff bylaws commonly require physicians to voluntarily notify the institution of any adverse action taken by another hospital.

A third error results when physicians attempt to negotiate a peer review matter by agreeing to some resolution which they believe will not have an adverse impact on their careers. However, if that resolution requires an NPDB report, little if anything will have been achieved. It is critical to understand what must be reported and what need not be reported prior to entering into any agreement.

Finally, an error physicians make is failing to understand that the peer review process may be used to retaliate against or stifle the opinion of a physician who is outspoken in his criticism of other medical staff members or the hospital administration. Because of the strong immunity afforded the peer review proceedings by the Health Care Quality Improvement Act and state statute,[iv] the peer review process may be used to target an outspoken physician on the basis of "misconduct." Virtually all medical staff bylaws classify "misconduct," or similar acts, as a basis for the initiation of disciplinary action. While this use of the peer review process was clearly not contemplated by

the drafters of the HCQIA, it is a practical fact which physicians must evaluate in deciding how to address the actions of other medical staff members or hospital administrators with whom they disagree.

Finality of Hospital Action

Although there have been successful challenges to peer review proceedings, these almost always involved situations where the hospital disregarded the procedural requirements of the HCQIA or a similar state statute.[v] Unless a court finds that a hospital failed to comply with the standards set forth in the statute, it is extremely unlikely that there will be judicial redress for an adverse peer review determination even if there was a substantive error in evaluating the physician's conduct. Courts are extremely reluctant to "second guess" a peer review panel or board of directors' decision which restricts or revokes a physician's medical staff privileges. While this may make sense in a case involving an evaluation of a physician's medical care and treatment, courts have demonstrated a similar reluctance to interfere with a board or panel's decision predicated on nonmedical actions, such as revocation due to physician "misconduct." Note that this reluctance to interfere with a hospital's decision extends even to cases where a board of directors disagrees with the decision of a peer review hearing. For example, there are cases where a physician was exonerated by a peer review panel, only to have a revocation of privileges reinstated by the hospital board. Most bylaws specify that the hospital board may approve, reverse, or modify the decision of the peer reviewing panel. That may happen, for example, if the hospital claims that a physician's conduct was so detrimental to the hospital's mission in the community that his privileges should be revoked even if a peer review panel found in favor of the physician. Even in cases of this nature, judicial challenges are difficult at best.

Conclusion

Any physician confronted with the possibility of an NPDB report must: (1) act quickly, (2) not agree to resolve the matter or resign from the medical staff without fully evaluating the consequences of such action, and (3) be cautious not to lay the basis for allegations of misconduct. While it is difficult to quarrel with the congressional intent giving rise to the National Practitioner Data Bank, the practical consequences of an adverse report mandates extreme caution for a physician confronted with the possibility of an adverse report. ■

i 42 U.S.C. § 11101, et seq.

ii 42 U.S.C. § 11101(2).

iii See O.R.C. § 2305.251.

iv O.R.C. § 2305.251.

v *Poliner v. Texas Health System,* 2006 U.S. Dist. LEXIS 13125; *Ahmed v. University Hospitals Health System,* 2002 Ohio App. LEXIS 1843.

AMCNO Offers Workers' Compensation Group Rating Plan for Members

As a member benefit, The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) offers a Workers' Compensation group-rating plan to our members that can help save money on premiums. This savings is made possible through our partnership with CompManagement, Inc. (CMI), a Sedgwick CMS Company, our third-party administrator, and alliance with the North American Employers Council. CMI was founded in 1984 to provide employers with professional and personalized cost control services in the areas of workers' compensation and unemployment compensation, and has grown to providing administrative service to over 21,000 employers in Ohio.

By grouping several companies together, CMI can offer a group-rating discount. Even if an organization already pays a *small* premium, they may qualify for a CMI group program to get *an even lower* rate.

In a letter sent earlier this year, AMCNO informed its members that CMI has begun the review process for 2008 group participation, which means that your practice can find out just how much you can save. Whether you are currently in another group or did not qualify in the past, we strongly urge you to participate in the AMCNO group-rating review.

Though this is a *no-cost, no-obligation, no-risk* review, should you decide to take advantage of the significant savings, *all of the physicians in your group* will need to become members of AMCNO. Bear in mind, however, that if you are currently enrolled in a group plan with another medical association in a state other than the AMCNO plan, you are probably paying higher dues. AMCNO's dues are substantially less per member and we provide discounts for groups with over 10 members. This enables our physician members to take advantage of the Workers' Compensation group-rating program along with other AMCNO benefits and services. To find out more about the plan or AMCNO membership dues, please contact BobbiJo Christensen at CMI, (800) 825-6755, ext. 3074, or Elayne Biddlestone at AMCNO, (216) 520-1000, ext. 100. ■

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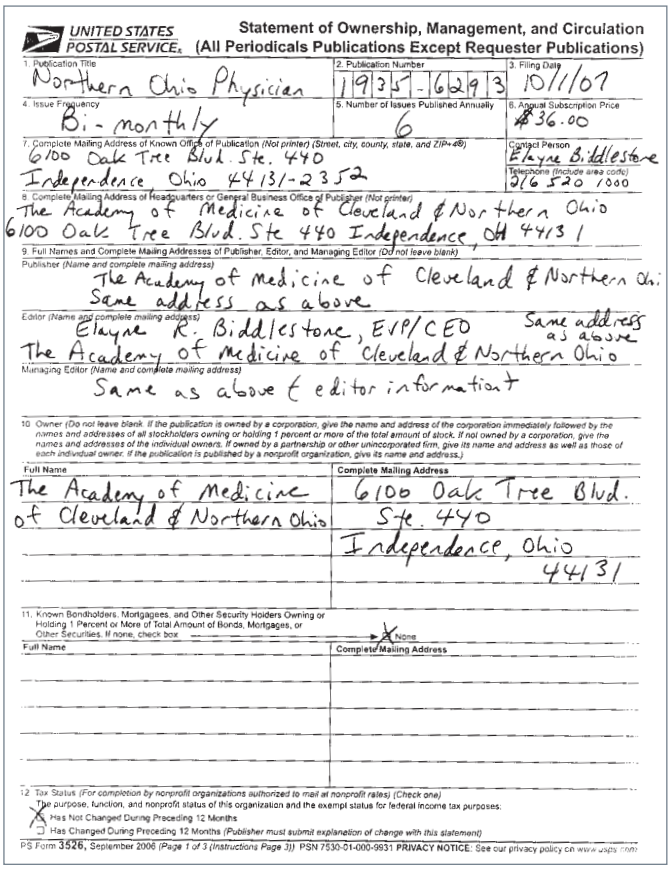

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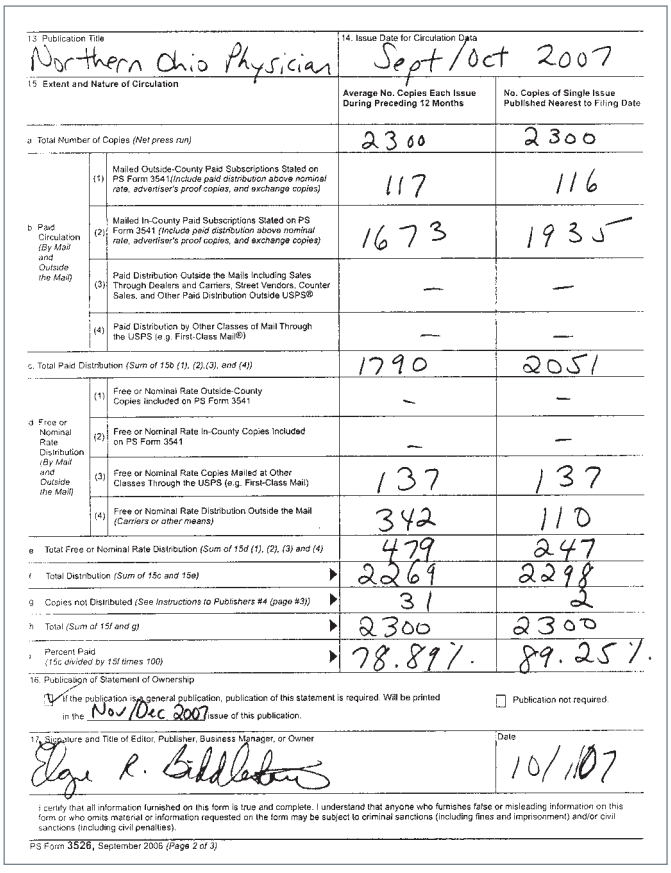

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Retail Clinic Concept Continues to Raise Concerns

Recent acquisitions of retail health clinics by major pharmacy chains have sparked a debate concerning the ethics and economics of providing health care in the same location where drugs are dispensed. Recently, the American Medical Association (AMA), which emphasizes that it is not opposed to retail health clinics, has called for regulation of the clinics and new principles to make sure there are no unfair incentives for patients to choose care at the clinics over physician practices. Among the regulations sought by the AMA are investigations of the connection between retail clinics and pharmacy chains with an eye toward possible conflicts of interest and development of guidelines for model legislation that regulates the operation of store-based clinics. In addition, the AMA is questioning the concept of co-payment reductions and waivers, which some insurers are allowing retail clinics to offer. The AMA is of the opinion that these provide an unfair incentive for patients to choose a retail clinic for care versus physicians.

AMCNO Activity

Of note is the fact that the AMCNO has had this issue on our radar screen for more than two years and physician leadership from the AMCNO have already voiced concern to state agencies and the administrators of these clinics in Ohio. Among our concerns were the amount of supervision provided in these clinics by a licensed physician, privacy issues associated with HIPAA, self-referral implications, and public health concerns among others. AMCNO leadership believes that this concept further fragments health care and steers patients away from their medical home. The "convenience care" offered is no substitute for the relationship between a patient and a primary care physician.

Responses received by the AMCNO board from our state regulators outlined that the clinics located in our state were operating under appropriate laws, however, if physicians in the community were to become aware of any healthcare-related risks or lack of appropriate referrals, these matters should be referred to the appropriate state agency. The AMCNO board determined it would be prudent to have a policy in place regarding these store-based clinics as they continue to proliferate in our area and elsewhere.

A policy was adopted in September 2006 and published in AMCNO publications. In brief, the AMCNO policy calls for store-based health clinics to have a well-defined and limited scope of clinical services, consistent with state scope of practice laws; must use standardized medical protocols derived from evidence-based practice guidelines; must establish arrangements by which their health care practitioners have direct access to and supervision by MDs/DOs consistent with Ohio law; have protocols for ensuring continuity of care with the practicing physicians within the local community; inclusive of encouraging patients to establish care with a primary care physician (PCP) to ensure continuity of care; clearly outline their policy on payment for services including types of health care coverage accepted by the clinic; inform patients in advance of the qualifications of the health care practitioners who are providing care, as well as the limitation in the types of illnesses that can be diagnosed and treated; and establish appropriate sanitation and hygienic guidelines and for these facilities to ensure the safety of patients.

At the September 2007 AMCNO board of directors meeting, another item was added to the above referenced policy which states: *Health insurers and other third-party payors should be prohibited from waiving and/or lowering co-payments for patients who receive services at store-based health clinics.*

The AMCNO plans to review the model legislation developed by the AMA when it becomes available. In the interim, the AMCNO plans to continue to monitor the effects of store-based clinics on the healthcare community in Northern Ohio. The AMCNO would like our members to keep us apprised of how the presence of these clinics in our community has affected your patients and/or your practice. Please send in any comments/concerns you may have directly to our EVP/CEO, Ms. Elayne Biddlestone at ebiddlestone@amcnoma.org. ■

AMCNO Board Responds to Bill Introduced with Intent to Revise Medicare QIO System

Max Baucus (D-Mont.) and Chuck Grassley (R-Iowa) have introduced a bill (S1947) under which Medicare quality improvement organizations (QIOs) could not conduct investigations of beneficiary complaints about health care providers when they serve as consultants for those providers. The Centers for Medicare and Medicaid Services pays about $300 million annually to contract with 53 QIOs — organizations that operate in all 50 states to improve the quality of care provided to Medicare beneficiaries. The bill would establish new Medicare Provider Review Organizations (MPROs) to investigate complaints from beneficiaries. Under the legislation, CMS could contract with current QIOs to serve as MPROs, although not for the same states in which QIOs serve as consultants for health care providers. The bill also would allow other organizations to compete with current QIOs and would prohibit the renewal of noncompetitive contracts.

AMCNO RESPONSE: The AMCNO has written to the Northeastern Ohio members of Congress outlining our concerns noting that change in the beneficiary review process as provided for in S1947 would "turn back the clock to the 1980s, when Medicare's PROs responded to our members' quality shortcomings with threats and sanctions, rather than assistance." The AMCNO also noted in our letter that case review must be linked to quality of care assistance to physicians stating that most quality problems are best addressed by finding their root cause and changing the way care is provided, not by threatening regulatory action. The AMCNO agrees that medical review duties should remain within the state QIO's scope of work and should be performed by physicians who deliver patient care.

Editor's Note: The AMCNO will continue to monitor this legislation and provide updates to our members.

AMCNO Joins National, State and Local Organizations Endorsing the Family Smoking Prevention and Tobacco Control Act

The AMCNO has joined the hundreds of other medically related organizations endorsing S.625/HR 1108, the Family Smoking Prevention and Tobacco Control Act. This legislation would give the U.S. Food and Drug Administration the authority to regulate tobacco products. Despite being responsible for more than 438,000 deaths each year, tobacco products are virtually unregulated by the federal government.

Led by the American Lung Association, American Cancer Society-Cancer Action Network, American Heart Association, and Campaign for Tobacco-Free Kids, the AMCNO joined organizations across the country committed to reducing and preventing the staggering death and disease caused by tobacco use. Tobacco-caused disease is the number one preventable cause of death in the United States. In 2004, the U.S. Senate voted overwhelmingly, 78-15 to grant the FDA effective authority to regulate tobacco products, but the legislation ultimately died in a conference committee. Forty-three years have passed since the U.S. Surgeon General reported on the unquestionable dangers of smoking. Since that time, tobacco products have become the largest single preventable cause of death in America while Congress has yet to take meaningful action.

This legislation meets the standards long established by the public health community for a strong FDA tobacco regulation bill that protects the public health. It would give the FDA the necessary tools and resources to effectively regulate the manufacturing, marketing, labeling, distribution and sale of tobacco products. The FDA would have the authority to:

- Stop illegal sales of tobacco products to children and adolescents.
- Require changes in tobacco products, such as the reduction or elimination of harmful chemicals, to make them less harmful and less addictive.
- Restrict advertising and promotions that appeal to children and adolescents.
- Prohibit unsubstantiated health claims about so-called "reduced risk" tobacco products that discourage current tobacco users from quitting or encourage new users to start.
- Require the disclosure of tobacco product content and tobacco industry research about the health effects of their products.
- Require larger and more informative health warnings on tobacco products.

The AMCNO has written to Northeastern Ohio Congressional Representatives and Senators asking for their strong support of this legislation. ■

The Ohio Hospital Association and the Northeastern Ohio Quality Collaborative Project

At the September 2007 board meeting, Dr. David Engler, the Vice President for Data Services from the Ohio Hospital Association (OHA) provided a presentation regarding the Northeastern Ohio Quality Collaborative.

Dr. Engler noted that there are five separate quality collaboratives around the state of Ohio — located in Columbus, Cincinnati, Dayton and now Northeast Ohio. The fifth collaborative involves six children's hospitals around the state. The collaborative are intended to operate as community-based quality improvement programs focusing on improving the health of the community. The collaborative model is meant to be a proactive approach to quality improvement with actionable measures that identify clear opportunities for change.

The purpose and principles of the collaborative are:

- To support the sharing of hospital specific outcomes of care in ways that promote learning and the adoption of best practices across all institutions;
- To manage reporting initiatives and methodologies at the local level;
- To use the measures and indicators as a guide to continuous quality improvement;
- To establish a forum for peer review protected discussions across institutions;
- To use the state in a nonpunitive fashion;
- To use the data in a noncompetitive manner; and
- To use this collaborative as a starting point for further examination of health care delivery within the community.

Currently there are 33 hospitals in Northeastern Ohio participating in the collaborative and the cost to participate is the same across hospitals. Participating hospitals in the NE Ohio Collaborative receive a yearly summary of hospital specific outcomes of care, mortality rates and length of stay, as well as quarterly reports for each of the nine clinical services that OHA measures. The nine clinical services measured are: acute myocardial infarction, coronary artery bypass graft; congestive heart failure, chronic obstructive pulmonary disease, community acquired pneumonia, GI hemorrhage, laminectomy, major joint replacement and stroke. The yearly outcome reports contain comparisons to selected regions throughout the state, allowing hospitals to not only compare hospital outcomes of care but also compare to community-wide outcomes. The quarterly reports are provided to each hospital and contain run charts showing individual hospital outcomes versus predicted-based on the models. Each hospital receives a quarterly report showing case listings with scored outcomes of care for each patient —

(Continued on page 16)

AMCNO BOARD ACTIVITIES

The Ohio Hospital Association and the Northeastern Ohio Quality Collaborative Project

(Continued from page 15)

this allows hospitals to drill down on their data. The risk adjustment system is built into the OHA database employing clinician judgment and empirical modeling of data for each clinical entity. The determinants of outcomes include effectiveness of treatments, patient risk factors, random chance and quality of care. The models are recalibrated on a yearly basis with changes to patient selection (parallel to the Joint Commission and the Agency for Healthcare Research and Quality) along with changes to the risk adjustment elements. The key results have been an improved learning curve, a sharing of results and comparisons across cities.

Each of the collaboratives has a minimum of three committees, which meet on a quarterly basis. The Quality Council governs the project and is made up primarily of hospital medical directors and CEOs, the Medical Directors Committee directs the various projects, and the Steering Committee validates the reports and ensures the quality of the data, reports, and information fed to each of the member hospitals. During these meetings, OHA shares the progress and results of the other collaboratives; and participants have found this information quite useful in setting their agendas. The collaboratives are set up to be peer review protected organizations and each participant agrees to abide by the confidentiality of the data. Dr. Engler stressed that this is not a pay-for-performance program or a program similar to the Cleveland Health Quality Choice program, which was operating in Cleveland in the 1990s. One of the differences in this project is that hospitals cannot say they are the "highest ranked hospital" in the program and at this time the business community is not involved in NE Ohio or Columbus — however, they are at the table in Cincinnati and Dayton.

The collaborative concept offers the ability for the groups to move into other value added projects based upon identified opportunities for quality improvement. For example in Columbus they are moving into a patient safety initiative and a citywide patient safety conference in addition to working on a stroke initiative and public reporting. In Dayton they are working on pneumonia results and conducting a cost analysis while in Cincinnati they are working on a congestive heart failure conference in conjunction with the Columbus collaborative.

Editor's note: The AMCNO board of directors is interested in having the AMCNO involved in the Northeastern Ohio Quality Collaborative. The AMCNO board has asked the OHA to consider what role, if any, the AMCNO might have in this project. ■

NORTHERN OHIO
PHYSICIAN

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Call for 2008 AMCNO Honorees

The AMCNO invites you to nominate an individual who is a member of the AMCNO that you believe is deserving of special recognition by the AMCNO. Any physician who wishes to nominate an individual for one or more of these awards should complete the form below and mail it to me at the AMCNO, 6100 Oak Tree Blvd., Suite 440, Cleveland, Ohio, 44131. You may also FAX your nominations to Elayne Biddlestone at (216) 520-0999 OR you may call her at (216) 520-1000, ext. 100 to provide your honoree nominations over the phone. Deadline for submission:12/31/07.

- JOHN H. BUDD, M.D. DISTINGUISHED MEMBERSHIP – This award is bestowed upon a member of the AMCNO who has brought special distinction and honor to the medical profession, to our community and to our physician association as a result of his or her outstanding accomplishments in biomedical research, clinical practice or professional leadership. Often, such an individual has already gained national and/or international recognition because of the importance of his or her contributions to medicine.
- CHARLES L. HUDSON, M.D. DISTINGUISHED SERVICE – Awarded to a physician whom the AMCNO deems worthy of special honor because of notable service to and long activity in the interest of organized medicine.
- CLINICIAN OF THE YEAR – Awarded to a physician whose primary contribution is in clinical medicine and whose service to his/her patients over many years has reflected the highest ideals and ethics of, and personal devotion to, the medical profession.
- Your Name: _____
- Your Nomination: _____
- Nominated for the following award:

_____

Please include an explanation as to why you are nominating this individual

_____

_____

Are you Interested in Running for the AMCNO Board of Directors in 2008
Directors are elected to represent their district, which is determined by primary hospital affiliation or at large for a two-year term. Members of the Board are responsible for addressing issues of importance to physicians and the patients we serve, and setting policy for the AMCNO. If you are interested in running for the board of directors please return this form with your name and contact information to the AMCNO, 6100 Oak Tree Blvd., Suite 440, Cleveland, Ohio, 44131. You may also FAX your information to Elayne Biddlestone at (216) 520-0999 OR call her at (216) 520-1000, ext. 100. Deadline: 12/31/07

Yes, I am interested in running as a candidate for the AMCNO board of directors _____

Name and Contact information:

_____

Ohio Medical Reserve Corps – Frequently Asked Questions

By: Paul Bender

LIABILITY COVERAGE FOR MEDICAL RESERVE CORPS MEMBERS
The Ohio Medical Reserve Corps (OMRC) was created to quickly mobilize healthcare professionals volunteers for an organized response. OMRC operates in most of the state's counties including all major metropolitan areas.

Ohio Revised Code 121.404 provides liability protection to registered OMRC volunteers during local, state or federally declared emergencies, disasters, drills and trainings. The statute also protects a registered volunteer's personal information on the Ohio Medical Reserve Corps database from public disclosure.

In short, a registered volunteer is not liable for the injury, death, or loss to person or property if: 1) the volunteer is officially registered on the state's volunteer database; 2) the registered volunteer was providing services within the scope of the volunteer's responsibilities during an officially declared emergency or disaster-related exercises, testing, or other training activities; and 3) the volunteer's act or omission is not willful or wanton misconduct.

Many questions have been raised concerning the statute, hence the OMRC legal team has provided responses to some of these questions in this article. This document only represents the legal team's opinion, and a court of law may rule differently.

Is Ohio Medical Reserve Corps data made available to the public?
No. Ohio Revised Code Sections 121.404 and 149.33 work together to protect volunteer registration information that is contained on the Ohio Medical Reserve Corps database. Personal information would not be released to the public in response to requests for information.

Who has access to this information?
State employees of the Ohio Community Service Council, the Ohio Department of Health, and the Ohio Emergency Management Agency (and perhaps other Divisions of the Ohio Department of Public Safety or the Governor's Office) and other staff at Ohio Community Service Council will be able to access the OMRC database when volunteers are needed for disaster response.

What does "personal information" include?
Personal information includes name, address, contact information, specific skills, responsibilities, assignments, and deployment plans, including training, preparedness and readiness. Note: information regarding the volunteers through summary statistical or aggregate form that doesn't identify an individual is a public record and would be released upon receipt of a proper request.

How long am I registered and do I need to renew to remain eligible for the limited liability protections afforded me by ORC 121.404?
Yes. Registration currently lasts between 3 and 4 years, with the requirement that a volunteer complete an updated or refresher training course during the third year in order to maintain a registered volunteer status. OMRC will maintain a list of current and refresher courses. Training will be tracked by the OMRC Database.

Who does this limited liability protection protect?
Ohio Revised Code Section 121.404 provides that registered volunteers are not liable to any person or government entity for injury, death or loss to persons or property arising from their acts or omissions while providing services within the scope of the volunteer's responsibilities during emergencies declared by the state or political subdivision. This limited liability protection also applies during disaster-related exercises, testing, or other training activities. The limited liability protection does not apply if the volunteer's act or omission is malicious, reckless or intentional. The protection is not like insurance. It simply provides registered volunteers with a defense to be raised in the event of a lawsuit.

Can I be sued under this protection?
Yes. Any volunteer can be sued. However, Ohio Revised Code Section 121.404 provides that no volunteer will ultimately be responsible for payment of any costs associated with damages for injury, death, or loss to persons or property, so long as the volunteer's acts or omissions were not malicious, reckless or intentional.

When does the limited liability protection begin and end? During drive time; on-scene; off-scene; or immediately upon activation?
The protection will extend to any activities reasonably related to your official volunteer status, once called upon to assist in disaster response. It will not apply to volunteers who self-deploy, whether registered or not. Keep in mind that if registered volunteers violate the law in any manner, they no longer receive limited liability protection because such conduct would be considered reckless.

Am I protected if I self-deploy?
No. The premise behind creation of the Citizen Corps database and the advance registration of volunteers was to assure the availability of a pre-identified, trained pool of volunteers for disaster response. The limited liability protections of Ohio Revised Code Section 121.404 and other related sections apply only to volunteers who are properly registered. OCSC may establish volunteer reception centers at the time of a disaster so that volunteers not already registered can do so and then be available to assist in disaster response.

Am I covered as a "Good Samaritan" in a medical emergency in which I take action on my own initiative or at the request of medical personnel?
It depends on the actions taken. However, Ohio Revised Code Section 121.404 would not apply to such situations. Ohio's "Good Samaritan" statutes would apply instead.

Who can declare a disaster?
The Governor and chief elected officials of political subdivisions in the state.

- For more information about Ohio Revised Code 121.404, or to learn how to register and what type of training is needed to become a volunteer go to http://www.serveohio.org, or contact the author at paul.bender@ocsc.state.oh.us ■

Medical Reserve Corps Training Update

On August 27, 2007, the Cuyahoga County Board of Health sponsored the first "Introduction to Medical Reserve Corps (MRC)" training session at Hillcrest Hospital. Approximately 30 people attended the training. The 4-hour session provided an in-depth look at the purpose and function of the MRC and volunteer core competencies, the Cuyahoga County's Emergency Operations Plan and the MRC volunteer role, local hazards/risks and the systems in place to respond to those risks, the role of public health in response to a man-made or natural disaster, and the issues, processes, and procedures related to recovery. Representatives from Cleveland Fire, Cuyahoga County Emergency Management, American Red Cross-Greater Cleveland Chapter and the Cuyahoga County Board of Health provided the training. It is anticipated that additional sessions will be offered on an ongoing basis. Notification of trainings will be made available on the Cuyahoga County Board of Health Web site at www.ccbh.net.

Current efforts are being made to establish an MRC leadership committee to develop policies and procedures, recruit additional volunteers, check credentials/perform background checks, and seek fiscal support.

If you are interested in volunteering for the Cuyahoga County Medical Reserve Corps, go to: www.serveohio.org/CitizenCorps/mrc/mrc.html and register. Ohio law (ORC 121.404) indemnifies MRC volunteers who have registered on the statewide database and who have completed an approved training once every 3 years. Approved trainings include: Introduction to Medical Reserve Corps (MRC), Basic Disaster Life Support (BDLS), Advanced Disaster Life Support (ADLS), Behavioral Health All-Hazards Training or the Ohio Veterinary Emergency Response Training. Volunteers are provided liability protection during local, state or federally declared emergencies, as well as disasters, drills and training sessions. Personal information is not subject to public disclosure.

For further information contact Rebecca Hysing at mrc@ccbh.net or (216) 201-2001 ext. 1602. ■

CORE COMPETENCIES FOR MRC VOLUNTEERS

We encourage all active members of a Medical Reserve Corps unit, at a minimum, be able to:

1. Describe the procedure and steps necessary for the MRC member to protect health, safety, and overall well-being of themselves, their families, the team, and the community.
2. Document that the MRC member has a personal and family preparedness plan in place.
3. Describe the chain of command (e.g., Emergency Management Systems, ICS, NIMS), the integration of the MRC, and its application to a given incident.
4. Describe the role of the local MRC unit in public health and/or emergency response and its application to a given incident.
5. Describe the MRC member's communication role(s) and processes with response partners, media, general public, and others.
6. Describe the impact of an event on the mental health of the MRC member, responders, and others.
7. Demonstrate the MRC member's ability to follow procedures for assignment, activation, reporting, and deactivation.
8. Identify limits to own skills, knowledge, and abilities as they pertain to MRC role(s).

Medical Student Picnic

More than 100 students, faculty, friends and family attended this year's medical school picnic of Case and the Lerner College of Medicine held August 19th on the Veale Gym lawn at Case. The event offered students a late summer retreat of food and outdoor fun. The AMCNO hosted a raffle for those in attendance, awarding prizes of gift certificates to popular local eateries. During the festivities, AMCNO staff enrolled 31 new members. Medical students enjoy the benefits of AMCNO membership at no cost throughout their training. In part, these include weekly medical news updates via email, legislative representation at the state house, and the advantage of AMCNO advocacy for the issues specific to Northeast Ohio physicians as well as seminars and social events allowing medical students the opportunity to network with physician members of the AMCNO. Welcome new members! ■

Medical students take a moment to sign up for AMCNO membership.

Medical students query AMCNO staff about the benefits of membership.

The winners of the AMCNO raffle line up for a photo op.

Academy of Medicine Education Foundation 2007 Scholarships

Scholarship applications can be obtained from the registrar or financial aid offices of eligible schools. The filing deadline is January 31, 2007 for medical students meeting AMEF scholarship eligibility criteria:

1. AMEF awards scholarships each year to third- and fourth-year medical students (MD/DO) who are or were residents of Cuyahoga, Summit, Lake, Geauga, Ashtabula, Lorain or Portage counties, and who demonstrate an interest in organized medicine, leadership skills, community involvement and academic achievement.
2. AMEF scholarships will be awarded to third- and fourth-year medical students attending the following institutions: Case Western Reserve University School of Medicine, Cleveland Clinic Lerner College of Medicine, Northeastern Ohio Universities College of Medicine and Ohio University College of Medicine. ■

Include AMEF in Your Charitable Giving Plans

AMEF uses funds to provide medical scholarships to assure that our medical schools continue training physicians to meet the need of patients in the future. In addition, your donation may assist with other worthwhile foundation activities that support public health and education initiatives. Look for AMEF's annual newsletter, *Foundation Facts,* in your mail soon and remember your profession in your giving plans!

Additional information on how to donate to AMEF can be found on the AMCNO Web site at www.amcnoma.org under the AMEF link.

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