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AMCNO Files Amicus Brief with the Ohio Supreme Court to Support Apology Statute

By Jennifer R. Becker, Esq. and Brian F. Lange, Esq., Attorneys With Bonezzi Switzer Murphy Polito & Hupp Co. L.P.A.

The AMCNO Medical Legal Liaison Committee tracks cases for the AMCNO Board of Directors that come before the Ohio Supreme Court and could impact or change the law in Ohio concerning our physician members. As a result, the AMCNO became aware of such a case and we have filed an Amicus Brief on behalf of our members in the case described below.

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The Ohio Supreme Court will soon consider whether evidence of a physician's acceptance of responsibility for his/her actions in conjunction with statements of apology can be excluded pursuant to R.C. 2317.43.

In the matter of *Johnson v. Randall Smith, Inc.,* 196 Ohio App.3d 722, 2011-Ohio-6000, the Eleventh District Court of Appeals reversed the jury's verdict in favor of the defendant-physician finding that the trial court erred in excluding the physician's statements of responsibility and apology. The Eleventh District concluded that because R.C. 2317.43, which bars these statements as evidence, did not become effective until September 13, 2004, and the statements at issue occurred prior to enactment, the trial court was prohibited from applying the statute retroactively. Therefore, the Eleventh District Court of Appeals concluded the physician's statements, including apologetic actions, were admissible at trial thereby warranting reversal of the jury's verdict.

The Ohio Supreme Court accepted jurisdiction and will now consider the decision of the Eleventh District Court of Appeals. The AMCNO filed an *Amicus* brief with the Ohio Supreme Court urging reversal of the Eleventh District Court of Appeals decision. An *Amicus* filing generally allows individuals and entities who are not parties to a case, but who have an interest in the outcome, to have an opportunity to be heard.

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Governor's Opiate Action Team Considering Prescribing Requirements

The Governor's Cabinet Opiate Action Team (GCOAT) was established in the fall of 2011 to address the continuing epidemic of abuse and overdose from prescription opioids. In addition, the State Medical Board of Ohio had established a committee to review the Medical Board Chronic Pain Rules, however, that committee has now been included as part of the GCOAT. The GCOAT is under the leadership of the Department of Health Director Dr. Ted Wymyslo and Department of Aging Director Bonnie Kantor-Burman. The group has already developed Opioids and other Controlled Substances guidelines for emergency departments and acute care facilities.

The GCOAT Reforming Prescribing Practices Committee is proposing a new rule for physicians when their patients reach a certain dosage threshold for controlled substances. The Committee is working "to develop recommendations regarding what triggers would cause actions by prescribers of opioids and other controlled substances, and what specific actions would be implemented." The proposed rule would establish mandated triggers and actions for patients that reach the threshold.

Most of the clinicians and organizations involved in this committee agree that establishing a standard for high dosage patients would be beneficial. However, a potential disagreement

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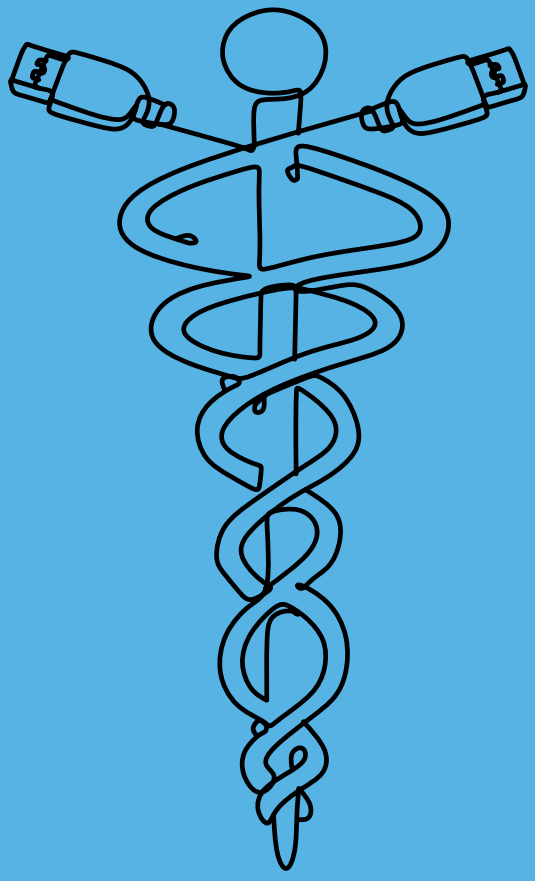

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AMCNO Files Amicus Brief with the Ohio Supreme Court to Support Apology Statute

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The *Amicus* brief filed on behalf of the AMCNO encourages the Ohio Supreme Court to find that R.C. 2317.43 applies to any civil actions or cases commenced after the effective date of September 13, 2004.

R.C. 2317.43(A) states:

> In any civil action brought by an alleged victim of an unanticipated outcome of medical care or in any arbitration proceeding related to such a civil action, *any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence* that are made by a health care provider or an employee of a health care provider to the alleged victim, a relative of the alleged victim, or a representative of the alleged victim, and that relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care are inadmissible as evidence of an admission of liability or as evidence of an admission against interest. (Emphasis added).

Since R.C. 2317.43 applies to civil actions brought after the effective date, the relevant question for the Court is not when the subject statements were made, but rather *when the civil action was filed.* In the subject case, the plaintiff did not commence the medical malpractice action until July 2007, which was well after the effective date of R.C. 2317.43. Therefore, the statute should apply and would serve to preclude the physician's statements of responsibility and apology.

The subject case also presented the question of whether R.C. 2317.43 is intended to be construed broadly in order to give proper effect and protection to a physician who apologizes to a patient, the patient's family or representative, for the discomfort, pain, suffering, injury or death resulting from the unanticipated outcome of medical care. Specifically, at issue was whether the statute was intended to include statements expressing acceptance of responsibility made in conjunction with the physician's expression of sympathy. The *Amicus* brief filed on behalf of the AMCNO encouraged the Ohio Supreme Court to find that it does include these statements and that these statements and accompanying conduct be excluded at trial.

R.C. 2317.43 was enacted to prevent these sincere statements of apology and sympathy from being introduced into evidence at trial because these are typical statements of a physician or medical provider after an unanticipated medical outcome. The decision of the Eleventh District, if left as is, limits the effectiveness of a physician's apology by requiring the medical care provider to remove any sense of accountability, admission or expression of responsibility from their statement to the patient or the patient's family. A physician would be limited to "I'm sorry." By precluding statements of responsibility from the physician's apology, the patient and/or their family are left without a direct explanation as to why the physician is offering a sympathetic statement or affirmation. Pursuant to the Eleventh District decision, an expression of sympathy is not admissible at trial, but anything beyond those words, including an explanation, would be admissible in future litigation and be taken wholly out of context.

"In construing a statute, the court's paramount concern is legislative intent. In determining legislative intent, the court first looks to the language in the statute and the purpose to be accomplished." *State ex rel. Savarese v. Buckeye Local School Dist. Bd. of Ed.,* 74 Ohio St. 3d 543, 545, 660 N.E.2d 463, 465 (1996). R.C. 2317.43 requires that "any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence" made to the "victim of an unanticipated outcome of medical care" as it relates to "the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care" be excluded from trial. Such expressions are inadmissible as evidence of an admission of liability or an admission against the medical provider's interest. *Id.*

It is indisputable that the goal sought to be attained in enacting R.C. 2317.43 was to prevent expressions of sympathy from being used against a physician or other medical provider at trial. What is in dispute, is the extent to which a physician or medical provider may express their apology, specifically whether they can accept responsibility for the discomfort, pain or even death the patient or their family are experiencing. Stated differently, the question is, "What did the General Assembly seek to prohibit from being introduced into evidence?" A broad interpretation of the words and actions included in R.C. 2317.43 permits this Court to give appropriate effect to the statute, and is consistent with the legislative intent and public policy. A broad interpretation also allows the statute to preclude from evidence the type of expressions R.C. 2317.43 was drafted to protect from later use against a physician or medical provider. *See* R.C. 1.49(A).

The AMCNO filed an *Amicus* brief in this case noting the potential negative impact on its members if left undisturbed. The decision of the Eleventh District, if not reversed, will have a negative impact on physicians throughout Ohio resulting in improper and prejudicial evidence being admitted at trial. ■

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Governor's Opiate Action Team Considering Prescribing Requirements

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exists over how the standards should be implemented — by rule or clinical guideline. Policymakers leading this discussion have made it clear that a guideline will not be sufficient and it has become necessary for the AMCNO and several statewide medical organizations represented on the GCOAT to send a letter on behalf of the Ohio House of Medicine in preference of adopting a clinical guideline.

The medical associations have encouraged the GCOAT Reforming Prescribing Practices Committee to continue to focus on consensus-driven solutions that do not negatively impact access to care for chronic pain patients. In regard to the "press pause/reassessment trigger threshold" being addressed, the associations do not believe there is sufficient published data and evidence-based research to support a mandatory rule at this time. Such a rule would establish a rigid mandate as to when and what must be performed when a patient reaches a certain dosage threshold. It could infringe upon the physician's ability to use sound clinical judgment in times when the required actions for high dose patients may or may not be necessary.

The associations stressed that adoption of a rule could result in an ineffective use of health care resources where clinicians are performing costly tests and providing services merely to comply with the rules. A rule would also shift focus from worst offenders to a scrutiny of all prescribers who do not have a pattern of practice below acceptable standards of care. The associations strongly encouraged the GCOAT to consider the adoption of clinical guidelines — like those in place for Emergency Departments and Urgent Care Facilities — and not promulgate general prescribing rules at this time. One option for strengthening the clinical guidelines is to have the Ohio State Medical Board adopt the proposed prescribing standards as a position statement. Establishing the proposed guidelines as a Medical Board position statement and practice guideline will inform the physician community that an appropriate standard of care has been established. In that way, the same standards can be established by the licensing boards of other prescribers through the same process.

The AMCNO will continue to provide updates to our members with regard to the GCOAT review process.

GCOAT Provides Background Data for the Emergency and Acute Care Facility Opioid Guidelines

The Governor's Cabinet Opiate Action Team (GCOAT) has developed guidelines to promote appropriate use of opioids/other controlled substances in the emergency and acute care setting. In addition to the ED Guidelines document, the GCOAT has also developed a detailed background document with supporting information as well as a corresponding patient handout. The patient handout is a key component to help educate and hopefully shift patient expectations about opioid prescribing in the ED/acute care setting. Detailed background information, including a list of frequently asked questions about the project and the development of the Guidelines is available at: http://www.healthyohioprogram.org/ed/guidelines.aspx

The ED Guidelines were developed to provide appropriate guidance for the prescribing of opioids and other controlled substances in the unique acute care environment where the treatment of pain is frequently indicated without the benefit of an established and ongoing physician-patient relationship. The GCOAT recognizes that guidelines cannot address every situation that may present within the challenging emergency/acute care environment. These ED Guidelines were created as recommendations, not protocols or standards of care. http://www.odh.ohio.gov/sitecore/content/HealthyOhio/default/vipp/data/rxdata.aspx

Ohio Department of Health (ODH) Announces Partnership with Medscape WebMD

The Ohio Department of Health (ODH) has announced that it has teamed with Medscape of WebMD, a leading online-source of information for healthcare professionals, to communicate urgent public health messages to its physicians, pharmacists and nurse members in Ohio. The Ohio Department of Health is part of the Centers for Disease Control and Prevention (CDC) national Health Alert Network (HAN) system. The infrastructure of the HAN system supports the immediate dissemination of vital health information at the state and local levels. The messaging system directly transmits health alerts, advisories, and updates to local health departments, hospitals and public health partners. Medscape will support these efforts by directly distributing health information including infectious disease outbreaks, environmental and product safety advisories, preparedness planning and response information, and public health developments among other alerts, to its network of registered clinical members throughout Ohio.

Upon receipt of medical alerts and updates, the Ohio Department of Health will supply information to Medscape for distribution to its local network of Ohio-based healthcare providers. Registered Medscape members will receive the latest information via email alert. *Note: According to data provided by Medscape, approximately 50 percent of physicians, 75 percent of physician assistants, 30 percent of pharmacists and 25 percent of nurses licensed to practice in Ohio are members of Medscape.* For additional information about the CDC national Health Alert Network visit www.bt.cdc.gov/han.

State Medical Board Continues Debate on MOL Pilot Program

In May 2012, the State Medical Board of Ohio (SMBO) officially voted to proceed with studying the components of Maintenance of Licensure (MOL), as one of several states participating in pilot studies with the Federation of State Medical Boards. After months of review and discussion by the AMCNO with regard to the MOL issue, the AMCNO board of directors voted to oppose the proposed State Medical Board of Ohio (SMBO) efforts to impose alternative Maintenance of Licensure requirements on physicians in Ohio and consider taking additional action if needed to assure that physicians in Northern Ohio are not adversely affected by the SMBO's participation in the MOL process.

Over the summer months, the AMCNO has attended the SMBO Maintenance of Licensure Ad Hoc Committee meetings. At the August board meeting, the SMBO did not reach agreement on the MOL issue and the SMBO staff was asked to provide a clear definition of how the SMBO would implement MOL in Ohio. The SMBO has given the Ad Hoc MOL Committee two more months to develop a plan for consideration by the SMBO at their October 2012 meeting.

Although the SMBO has yet to review an MOL plan, the board did approve the following position statement:

> "Maintenance of Licensure is a system of continuous professional development that requires all licensed physicians to demonstrate, as a condition for licensure renewal, involvement in lifelong learning that is objective, relevant to practice and improves care."

The SMBO is well aware of the AMCNO position on this issue and we will continue to monitor the SMBO discussion on MOL and report back to our membership. As noted in articles authored by the executive director of the SMBO and published in the *Northern Ohio Physician* — the state board welcomes comments/questions on this issue. If you have comments/questions about the SMBO MOL review process please email the SMBO staff at Benton.taylor@med.state.oh.us

Implementing ACA Could Impact State Finances

Over the summer months, Governor Kasich announced a fiscal year-end budget surplus; however, he also noted that implementing the Affordable Care Act (ACA) could impact the state's finances. Although Ohio's mandatory participation with expansion of Medicaid is now voluntary with the elimination of financial

penalties, the changes are projected to cost Ohio upwards of $1 billion through calendar years 2014-2015 as more citizens become eligible. According to the Ohio Department of Job and Family Services, Medicaid costs $19.8 billion a year in state and federal funds to administer in Ohio.

The costs associated with implementing the ACA may affect the state's ability to manage Medicaid and the issue has to be reviewed further before the state can determine whether to pursue the expansion of coverage to all citizens up to 135% of the federal poverty level, the costs of which will be borne entirely by the federal government over the first few years of its implementation. While the federal government promised to initially cover all of the costs related to newly eligible enrollees, states were projecting that Medicaid rolls would further swell as a result of more currently eligible citizens signing on because of increased awareness of the benefits and easier enrollment. The so-called "woodwork" or "welcome mat" effect, combined with increased rates for physician services, is projected to cost Ohio about $370 million in calendar year 2014 and $571 million in 2015, according to estimates developed by the Kasich administration. The state share of those additional costs is expected to reach $675 million by 2018 without the expansion, and $931 million if the additional coverage is enacted in Ohio according to the Ohio Office of Health Transformation (OHT).

Ohio anticipates 314,000 more people will enter the Medicaid enrollment even without the expansion. The total cost is about $1.3 billion, of which the state share is $369 million. By 2018, the woodwork effect is expected to increase Medicaid rolls by 440,000, according to OHT.

The state had planned to submit its Medicaid eligibility modernization waiver to the federal government but may postpone that request due to the ruling on the federal health care law that affects whether states will expand the poverty level under which individuals are eligible for Medicaid. Ohio Medicaid could either submit a different version of its eligibility modernization proposal or include it in their state budget request issued in 2013.

Ohio is also faced with the decision on whether or not the state will set up a health insurance exchange. Lt. Gov. Taylor, who also serves as director of the Ohio Department of Insurance (ODI), has not yet made a decision on whether or not Ohio will opt for a state-based exchange. The ODI estimates that an Ohio-based exchange would cost the state about $43 million a year to operate noting the law's Medicaid requirements are expected to add more than $360 million in state costs. A key part of the ACA, health insurance exchanges are intended to serve as a portal for consumers to determine whether they are eligible for Medicaid or federal premium subsidies to purchase private insurance, and shop for plans online. States that don't develop their own programs must join a version operated by the federal government. States can set up their own exchange or let the federal government set up an exchange. A third option is where states enter into a partnership with the federal government where the state retains certain functions of the exchange and the federal government administers the rest. The ODI director has stated that the administration was still awaiting guidance on the details before making that decision. States have until Nov. 16 to tell the U.S. Department of Health and Human Services how they intend to implement the exchange.

Plans Underway to Make Ohio Medicaid a Stand-Alone Cabinet Agency

The Governor's Office of Health Transformation (OHT) has decided to move forward with the creation of a stand-alone Medicaid agency. The OHT believes that this decision will allow both the Ohio Department of Job and Family Services (ODJFS) and the Office of Ohio Health Plans (OHP) to better serve individuals, health care providers, and our state and local partners. The recently passed Mid-Biennium Review gave the Medicaid Director cabinet-level operation authority. Creating a stand-alone agency will streamline administrative processes and reduce confusion among those we serve.

ODJFS and OHP will seek authority to create a stand-alone Medicaid agency in the SFY 2014-2015 operating budget, but they plan to begin work immediately in order to make the transition as smooth as possible. There will be no immediate changes to current operating procedures in the Office of Fiscal and Monitoring Services and the Office of Information Services. ODJFS legal staff who specialize in Medicaid already have been relocated and now report directly to Ohio Medicaid Director John McCarthy.

Greg Moody, director of the Governor's Office of Health Transformation, has plans to transform the Office of Ohio Health Plans (Ohio Medicaid) from a division of the Ohio Department of Job and Family Services (ODJFS) into a state agency effective July 1, 2014. The change of Medicaid to department status is the next step in a series of Kasich Administration reforms to improve the performance of Ohio's $18.8 billion Medicaid program.

Medicaid is the largest health payer in Ohio, serving 2.2 million Ohioans through a network of 75,000 health-care providers at a total cost of $18.8 billion in 2012. Ohio Medicaid/ODJFS is currently the single state agency responsible to the federal government for the administration of the state's Medicaid program, though five other state agencies-Ohio Departments of Developmental Disabilities, Mental Health, Aging, Health, and Alcohol and Drug Addiction Services-also administer Medicaid-funded programs, with cross-agency coordination provided by the Office of Health Transformation.

A multi-agency team will begin working immediately, and in collaboration with the legislature and affected stakeholders, to lay the groundwork for creating a stand-alone Medicaid department. Ohio's Medicaid program was established in 1968 as part of the Ohio Department of Public Welfare (now ODJFS). Ohio Medicaid has 388 employees. ODJFS has 3,280 non-Medicaid employees and a non-Medicaid budget of $3.6 billion. ODJFS will continue to oversee the state's public assistance, child protection, child support, workforce development and unemployment compensation programs. For additional information, see: www.healthtransformation.ohio.gov/OrganizeGovernmenttoBeMoreEfficient.aspx

Bureau of Workers' Compensation (BWC) Pharmacy Effort to Aid Injured Workers

A report completed by the Ohio Bureau of Workers' Compensation (BWC) outlined how the bureau's first ever formulary and a number of other pharmacy management initiatives are helping in efforts to increase positive outcomes for injured workers. This report includes early data showing a newly enacted formulary has driven down the number of narcotics prescribed to injured workers by 12 percent, or 1.1 million doses, supporting Governor John Kasich's efforts to address Ohio's opiate epidemic.

A review of prescriptions written from February to April 2012, compared to the same period in 2011 showed 1.1 million fewer prescribed doses of narcotics. This equals a 12-percent reduction in the number of doses and a 15-percent, or $2.1 million, reduction in costs. The same review showed the number of skeletal muscle relaxants (SMR) prescriptions dropped by 59 percent, resulting in a 58 percent, or $532,000, decrease in cost. SMRs are among the most commonly overused drug classes and are often prescribed in conjunction with narcotics. BWC began implementing its first ever formulary in September, however, BWC chose to start its study on Feb. 1, the first day that new restrictions on opiates were implemented. The formulary is helping improve the efficiency and effectiveness of treatment, limit the inappropriate use of medications and lower prescription costs. The formulary provides a concise list of medications that can be utilized for treatment of approved conditions related to an injured worker's claim and may include guidelines related to their use. For more information go to https://www.ohiobwc.com/home/current/releases/2012/072712.asp ■

NOMPAC Endorses Justices Cupp, O'Donnell and Judge Kennedy for the Ohio Supreme Court

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) PAC — the Northern Ohio Political Action Committee (NOMPAC) seeks to support judicial candidates that have a philosophy of judicial restraint, who interpret the law and not make the law — leaving public policy matters up to the legislative branch of government. The NOMPAC is pleased to endorse Justices Robert R. Cupp and Terrence O'Donnell in their bid for re-election to the Ohio Supreme Court as well as Judge Sharon Kennedy in her bid for election to the Ohio Supreme Court.

Prior to 2002, the Ohio Supreme Court was considered an "activist" court, one that "legislated from the bench." At that time, four of the seven justices consistently voted to overturn tort reform. In 2002, Ohio was declared a medical liability crisis state. Physicians were forced to leave Ohio or retire early because they couldn't find affordable medical liability insurance. **Beginning in 2003, when the make-up of the Court changed, the medical community successfully worked with legislators to pass more than 20 different tort reforms.**

The effects of medical liability reforms have been significant:

- Medical liability premiums have decreased an average of 22 percent in Ohio from 2006–2009;
- Medical liability closed claims are down 40 percent from 2005-2008;
- 8 years and 4 election cycles later, the majority of the Ohio Supreme Court is described as a court that believes in judicial restraint; and
- Due to this philosophical majority, this Court has upheld tort reform when challenged by the plaintiff's bar.

AMCNO physician leadership spends a moment with Justices Cupp and O'Donnell and Judge Kennedy. (l to r) Judge Sharon Kennedy, Dr. James Sechler, AMCNO president, Justice Terrence O'Donnell, Justice Robert Cupp, and AMCNO board member Dr. Robert Hobbs.

There are now 3 seats up for election this November. Justice O'Donnell and Justice Cupp seek re-election and Sharon Kennedy hopes to become Ohio's next Justice. Their values of judicial restraint and conservative judicial philosophies are needed to guide the Supreme Court in an uncertain time. For more information about the candidates, go to the AMCNO web site at www.amcno.org/nompac ■

Dr. John Bastulli, AMCNO VP of Legislative Affairs (second from right) poses with the candidates – Judge Kennedy, Justice O'Donnell and Justice Cupp

Over the summer months, the AMCNO through our political action committee — NOMPAC, participated in a fundraiser for at the home of AMCNO member Dr. John Bastulli where Justices Cupp and O'Donnell and Judge Kennedy presented their views on several topics. AMCNO members are encouraged to go to our website to learn more about the candidates. For more information about the candidates go to the AMCNO website at www.amcno.org/NOMPAC.

AMCNO Members – Consider a Contribution to NOMPAC

Election Day is right around the corner – and again physicians are faced with myriad issues. Physicians need to become engaged or it will be left up to the legislators and government to set the agenda. It is a fact that many health care issues and medical care options are decided by the legislature and government entities. Encourage your colleagues to join the AMCNO — the organization is geared to address legislative issues as well as provide avenues to share your viewpoints and perspectives along with your patients' concerns. The AMCNO needs your involvement. And please consider donating to the AMCNO PAC — NOMPAC, the Northern Ohio Medical Political Action Committee. NOMPAC was established to provide a mechanism for the AMCNO members to use the "PAC" model in support of legislators who support your perspectives during the election process.

Without NOMPAC's voice, our patients and physicians in Northeast Ohio would find themselves less represented at crucial times when decisions are made that significantly impact both. It is well understood that a strong NOMPAC requires significant revenues to have an impact during important election campaigns. We must support candidates who have been supportive of issues important to patients and physicians. A NOMPAC mailing will be arriving in your office soon — please take the time to read the information and consider a donation to NOMPAC or go online now to our website at www.amcno.org/nompac to donate online. Your support is greatly appreciated.

AMCNO To Provide Candidate Information to Members

The Academy of Medicine Cleveland & Northern Ohio Legislative Committee, in concert with our lobbyist and the Medical Legal Liaison Committee, will be providing AMCNO members with links via our website on where to obtain information on legislative and judicial candidates prior to the upcoming election on Tuesday, Nov. 6, 2012. In addition, over the summer months, the AMCNO executive committee was pleased to work with the Ohio State Medical Association (OSMA) in conducting several legislative candidate interviews. The AMCNO also plans to work with the OSMA to provide candidate information to members.

Patient Protection and Affordable Care Act ("ACA"): *An Analysis of the Anticipated Impact on Physicians*

David Valent, Esq. Reminger Co., LPA

On June 28, 2012, the U.S. Supreme Court upheld a significant portion of President Obama's backed health care law — The Patient Protection and Affordable Care Act ("ACA"). *National Federation Independent Business, et al. v. Sebelius, et al.* (June 28, 2012), No. 11-393. Since that time, there has been steady media speculation concerning this legislation's impact on patients. The less debated topic, however, is the impact this legislation will have on physicians. It is the goal of this article to anticipate how the law will affect physicians.

I. Introduction:

On March 19, 2010, President Obama signed the ACA into law. The ACA is intended to increase the number of Americans covered by health insurance, and decrease the cost of healthcare. The ACA, since the time of its contemplation, has inspired a great debate over the implications of the law, especially in the areas of coverage, affordability and quality of care. There has been a series of political and legal challenges concerning the law's application. In light of this, the Department of Health and Human Services ("HHS") has already issued over 12,000 pages of regulations elaborating on the original 2,700 page law. Moreover, the constitutionality of the law itself has recently been challenged, but was largely upheld.

One key and controversial provision of the law is the "individual mandate," which requires most Americans to maintain "minimum essential" health insurance coverage. 26 U.S.C. Section 5000A. This provision was a significant focus of the Supreme Court case decided this year, even though the provision is not slated to take full effect until 2014.

Chief Justice Roberts, who was appointed by President George W. Bush, provided a key vote to preserve the landmark health care law. Opponents of the health law had argued that it was unconstitutional, because it improperly interfered with Interstate Commerce and the relationship between citizens and the Federal Government. Arguing in support of the law, the Federal Government took the position that Congress had the authority to pass the individual mandate requiring health insurance, as part of its power to regulate Interstate Commerce. In the end, the Supreme Court disagreed with the Federal Government's argument, but nevertheless preserved the law. The Court found that the "fines" imposed against citizens who do not have health insurance amount to a tax, which is within Congress' constitutional taxing powers — and thus not an improper interference with Interstate Commerce.

It should also be noted that the Court did not find constitutionality in the entire ACA. To that end, another provision of the ACA at issue was the Medicaid Expansion Provision. The current Medicaid program offers federal funding to states to assist pregnant women, children, needy families, the blind, the elderly, and the disabled, in obtaining medical care. 42 U.S.C. Section 1396d(a). The ACA expands the scope of the Medicaid program and increases the number of individuals the states *must* cover. The Supreme Court, however, concluded that the Medicaid Expansion Provision violates the constitution by threatening the states with the loss of their existing Medicaid funding, if they decline to comply with the expansion. The Supreme Court held that this was an improper penalty and interference with the states. To that end, the Court held that Congress' extension of Medicaid remains available to the extent that states affirm their willingness to participate in the program, but did not find it proper to withhold funding and/or penalize those states who fail to comply with the expansion. Ohio has not yet officially determined whether it will choose to expand the Medicaid program, but it must decide by November 16, 2012. (For more information on this issue see the AMCNO legislative update on page 4).

Despite the recent Supreme Court decision, which largely affirms the constitutionality of the ACA, there is still a significant amount of uncertainty as to exactly how this law will impact physicians in the years to come, especially in light of the uncertainty as to whether states (particularly Ohio) will participate in the Medicaid expansion. That being said, we can nevertheless still anticipate and analyze some of the *potential* impact.

II. Key Provisions of the ACA to be Fully Implemented by 2014:

- Insurers are prohibited from denying coverage to children, and from discriminating against children based on pre-existing conditions.
- Insurers are prohibited from discriminating against adults due to pre-existing conditions.
- Insurers must offer coverage to everyone who applies.
- Insurers are prohibited from rescinding coverage, absent fraud by insured.
- Coverage for young adults is extended, so that young adults can stay on their parents' plans until they turn 26.
- Lifetime limits on insurance coverage are eliminated.
- Health insurance rate increases that exceed 10% annually are subject to heightened review to make sure they are justified.
- Medicare Part D prescription drug coverage gap is closed.
- Medicaid reimbursements will increase to match Medicare rates for primary care services.
- New insurance plans must cover certain preventative services such as mammograms and colonoscopies, without charging a deductible, co-pay or co-insurance.
- Provides new funding to state Medicaid programs that choose to cover preventative services for patients.
- Provides no cost preventative care for seniors on Medicare, such as annual wellness visits and personalized prevention plans.
- Requires all Americans who can afford health insurance to purchase it, and will help those who cannot with subsidies on a sliding scale.
- Creates incentives to expand the number of primary care doctors, nurses and physician assistants, including funding for scholarships, loan payments for primary care doctors and nurses working in underserved areas.
- Provides $50 million for 5 year demonstration grant to states to develop, implement, and evaluate alternatives to current tort litigation.
- Employers with 50 or more employees are required to provide health insurance coverage to workers, or face penalty/tax.
- Provides a 10% Medicare bonus for payment for physician care services, and a 10% Medicare bonus to general surgeons practicing in Health Professional Shortage Area ("HPSA"), such as rural communities.
- Physicians participating as Medicare providers will be penalized 1.5% of

Medicare payment, if they do not successfully participate in Medicare's Physician Quality Reporting Initiative. (Although other provisions of ACA will be implemented by 2014, this provision has already been pushed back to 2015).

III. ACA Impact on Physicians

In taking the pulse of physicians in our area, it is clear that the anticipated changes set forth in the ACA have created a substantial level of concern. Generally speaking, doctors question how the law will affect their incomes, their billing/business practices, their office management, and most importantly, their ability to make medical decisions that are in the best interest of their patients — without undue government interference. According to a survey by The Doctor's Company (a physician insurance provider), which was published in February 2012, 61% of physicians believe health care reform will have a negative impact on patient care.

One concern for physicians is that the new law will interfere with their practice of medicine by shifting decision making authority from doctors to government officials. Some physicians fear that a number of provisions in the new health law, particularly the provision known as "Independent Payment Advisory Board" ("IPAB"), may put government cost saving measures at odds with physician decisions that are in the best interest of the patient. The IPAB is a 15 person Board that will be charged with controlling/reducing Medicare spending. It is speculated that decisions by the IPAB may actually reduce the patient's access to needed health care in certain circumstances.

Another physician concern is that reimbursement for services will go down, while the total patient population will go up. To that end, a primary goal of the ACA is to increase the number of insured individuals nationwide and/or increase the population's access to health care. The "Individual Mandate" requires most Americans to have minimum coverage health care insurance, or face penalties by 2014. Also, if the Medicaid Expansion Provision is implemented in Ohio, according to Medicaid, an additional 916,500 Ohioans will be insured through the program by 2014. While the patient population is anticipated to increase, the payment for services to those patients will now more often be calculated based on government fee schedules – as opposed higher paying private insurance schedules. This change raises concern that some physician practices will not be able to remain profitable. Additionally, many physicians believe they are already working at full capacity to keep up with the demands of seeing the current patient population.

Further, physicians are cautious that with an increase in government funded care, there will be an increase in scrutiny over billing, coding and practice compliance issues. In the past several years, the government has initiated several measures to further detect alleged "overpayments" made to providers under the Medicare and Medicaid systems. These measures have resulted in more frequent compliance audits of providers. Moreover, the stakes/penalties for billing and/or coding errors are often higher, when government funded care is at issue, as compared to private. Now, under the ACA, physicians can expect more of their patients to be insured through government programs. Accordingly, physicians are concerned this change will bring further scrutiny and attention to billing, coding and practice compliance issues.

Supporters of the ACA highlight as a positive the benefit that under the law, an estimated 32 million more Americans will become insured. The goal of increasing the number of insureds with access to health care is in itself a positive step for improving the overall health of our nation's population.

Also, with an increased number of insured patients being anticipated, the demand for physicians may increase. An increase in employment opportunities should also follow. To address this issue, the ACA creates incentives to expand the number of primary care doctors, nurses and physician assistants. The law does this by including funding for scholarships and loan payments for primary care doctors and nurses working in underserved areas.

As a further positive for physicians, the number of uninsured patients seen by physicians should decrease. More patients will either be covered through government insurance programs, or will be forced to obtain private insurance, depending on their financial situation. Thus, the burden of providing care to patients who are unable to pay will be reduced.

The ACA is also appealing to some physicians, in that it is anticipated to encourage patients to seek more preventative care and/or routine care. One goal of the ACA is aimed at reducing the number preventable illnesses and/or conditions, through early intervention. This should in turn also reduce the number of medical emergencies.

VI. The Uncertainty: Status of Medicaid Expansion in Ohio:

In light of the fact that the Medicaid Expansion Provision was struck down by the U.S. Supreme Court, Ohio must now decide whether it will expand its Medicaid program. This decision does not have to be finally decided until November 16, 2012, after the election cycle.

If Ohio decides to expand its program, a Medicaid expansion would cover more Ohioans at the Federal Government's expense for the first three years. After the initial three years though, there would be additional expense to Ohio taxpayers. The most significant cost to the state, as a result of the plan, would be the number of currently eligible, but not yet enrolled, individuals who would become enrolled if the state chooses the expansion program.

If Ohio decides to opt out of the Medicaid Expansion, state costs for the program will be reduced, but some uninsured people with lower incomes will not necessarily have access to Medicaid. Instead, such individuals will have to participate in a health insurance exchange program, wherein the Federal Government would provide some subsidies to certain individuals. Thus, the number of insured individuals will still increase in Ohio, even if it opts out of the Medicaid expansion.

V. Conclusion:

In light of the above, change is inevitable, even though some of the specifics still remain uncertain. Some analysts suggest that when weighing the potential positives and negatives of the new law, the result will be that the make-up of many physician practices will change. One possibility is that we will see more boutique practices, wherein cash is demanded from patients, in an effort to avoid dealing with government provisions and insurance regulations. On the opposite end of the spectrum, some speculate we may see fewer individual/small physician groups. The thought here is that smaller groups will join with larger groups, particularly hospitals, since larger groups may have more resources to help navigate compliance issues and the ever changing health care laws and insurance regulations.

In the end, only time will tell exactly how the ACA reform measures will impact physicians and the practice of medicine.

(Continued on page 10)

Patient Protection and Affordable Care Act ("ACA"): *An Analysis of the Anticipated Impact on Physicians*

(Continued from page 9)

We can count on the fact that these changes will likely be seen gradually. As with other recent health law reform measures, there is a good chance that implementation of certain provisions of the ACA will be delayed and/or adjusted in the months and years to come.

For further information and/or questions please do not hesitate to contact David Valent, with Reminger's Health Care Law Group, at (216) 430-2196. ■

AMCNO Position Statement on Health Care Reform

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

The AMCNO is committed to working with Congressional leaders, state legislators and other stakeholders to implement health care reform. The AMCNO will continue to work toward health system reform initiatives that will:

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

As the health care debate continues in the future, the AMCNO will continue to strive for changes in the health care system that will address the AMCNO points noted above, and establish a more efficient and complete health care delivery system while preserving the physician-patient relationship.

Institute of Medicine (IOM) Concludes Review of Geographic Adjustments to Physician Payments

The AMCNO has been sending comments to the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for a number of years outlining our concerns with the geographic payment adjustment formula. Under the health care reform law, HHS was directed to evaluate the accuracy of the geographic adjustment factors used for Medicare physician payment and the Institute of Medicine (IOM) was chosen to study the issue.

The June 2011 IOM report validated the AMCNO concerns when the IOM noted that payment options should be based on geographic areas as defined by the Office of Management and Budget, and one which uses Metropolitan Statistical Areas (MSAs) and Metropolitan Divisions (MDs) to form localities in each state. The report called for breaking up the large Medicare geographic physician payment areas into smaller sections that would result in higher pay rates for physicians in urban areas including Northern Ohio. The AMCNO believes that this option is viable due to the fact that it is based upon the localities used to pay other Medicare providers, such as hospitals, skilled nursing facilities and ambulatory surgery centers, which allow for a more focused recognition of geographic cost differences. Currently, the state of Ohio is designated as a statewide locality.

The IOM Phase II report has now been released and it illustrates how the IOM recommendations would impact Medicare rates. The report indicates that changing the way that Medicare payments are adjusted to account for regional variations in the cost of providing care would result in payment increases for some hospitals and practitioners and decreases for others. Geographic adjustments should be used to ensure the accuracy of payments, said the committee that wrote the report, but they are not optimal tools to tackle larger national policy goals such as improving access to care in medically underserved areas. Adjustments to Medicare payments based on geography are intended to account for regional variations in wages, rents, and other costs incurred by hospitals and individual health care practitioners. In its previous report, the committee recommended changes to the data sources and methods used to calculate payment adjustments to achieve greater accuracy.

According to the report, changes in pay rates would shift between -5% and 5% for 96% of the counties across the country, with pay rates for Northern Ohio counties shifting about 3.5%. To date, CMS has stated that they will not expand the number of pay locales to 441 from 89, which at present includes 34 statewide jurisdictions (including Ohio), noting that increasing the number of payment areas could be an administrative challenge, although Medicare already uses MSAs to determine hospital payments.

Due to the timing of the release of IOM's report CMS was unable to address the full scope of the IOM recommendations in the proposed 2013 physician fee schedule rule, however, the AMCNO has asked CMS to carefully review and evaluate the IOM reports and make changes in the Medicare program to use more accurate data when adjusting pay rates based on where physicians and hospitals are located. CMS plans to address the IOM Phase I and Phase II recommendations more fully in future rulemaking. The AMCNO physician leadership will continue to monitor these issues and provide additional information to our membership as it becomes available. To view the latest IOM report go to http://www.nap.edu/catalog.php?record_id=13420 ■

AMCNO Workers' Compensation Group Rating Program 2013

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) is pleased to offer a Workers' Compensation group rating plan to our members that can help you save money on the premiums you pay to the Ohio Bureau of Workers' Compensation. This plan is made possible through our longstanding partnership with CompManagement, Inc., (CMI) a Sedgwick CMS Company. CMI has begun the review process for 2013 group participation, which means you can find out how much you can save! AMCNO practices already enrolled in the AMCNO Group Rating Program will receive a letter regarding review for renewal with the program as well as contact information for CompManagement.

CompManagement will review the application and determine your potential savings and contact you with a cost analysis. If you decide you want to participate, all you need to do is sign and send in the enrollment paperwork included in your cost analysis. This is a no-cost, no obligation review. If you are currently a member of another medical association in the state and participating in a group rating plan other than through the AMCNO you are probably paying higher member dues to remain in that plan. Upon review, you may find that the AMCNO dues are substantially less per member and we provide group discounts which cost effectively enables our physician members to take advantage of the worker's comp group rating program along with other AMCNO benefits and services at reduced cost. If you have questions regarding the program contact Ms. Linda Hale at the AMCNO offices at (216) 520-1000, ext. 101.

To receive a free, no obligation savings quote, contact CompManagement's Customer Support Unit at (800) 825-6755, option 3 or visit http://resources.compmgt.com/AC3/GroupRating.aspx?Organization=AMCNO to complete online. ■

AMCNO Joins AMA Alliance to Standardize Reports Used in Physician Profiling

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) has joined an American Medical Association (AMA) effort supported by more than 60 organizations designed to turn the data reports physicians receive from health insurers into more useful tools to enhance the quality and value of patient care.

The "Guidelines for Reporting Physician Data" aim to make physician data reports, which are complex and unique to each health plan, easy to understand and use. Created by the AMA with input from public and private health insurers, state and specialty medical societies, and employer and consumer coalitions, the guidelines provide a roadmap for improving the usefulness of physician data reports for data-driven decision making.

In particular, the guidelines call for greater standardization of the format of reports, increased transparency of the reporting process and a heightened level of detail. Among the organizations that support use of the new guidelines are the National Committee on Quality Assurance, Cigna, Midwest Business Group on Health and UnitedHealth Group. A guide from the AMA also helps physicians verify the accuracy of profiling reports and use the data for practice improvement.

The AMCNO has long advocated for legislation in the state of Ohio that would standardize physician profiling reports as well as increase transparency in the health insurers reporting processes. The AMCNO has introduced legislation at the state level as well to address physician profiling issues and we will continue to pursue passage of the legislation along with providing strong support for this important AMA initiative.

To view the guidelines go to: http://www.ama-assn.org/ama/pub/physician-resources/practice-management-center/health-insurer-payer-relations/physician-efficiency-quality-data/practice-data/take-charge-of-your-data/physician-reporting-guidelines.page ■

Ohio Law Preventing Medicaid Providers From Contributing To Campaigns Held Unconstitutional

By Maureen P. Tracey and Diane Citrino, Thacker Martinsek LPA

On August, 3, 2012, a three-judge panel for the United States Court of Appeals for the Sixth Circuit sided with a group of physicians from Northern Ohio, including several AMCNO members, and struck down as unconstitutional an Ohio statute making it a crime for candidates for Ohio Attorney General or county prosecutor to accept campaign contributions from Medicaid providers. The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), the Ohio Osteopathic Association and the Ohio State Medical Association had joined as amicus curiae in the case after a lower court upheld the Ohio statute, fearing that, if left to stand, the trial court's decision would have a chilling effect on physician speech — particularly at a time when candidates for office at all levels of state and local government are increasingly weighing in on issues related to health care reform and health care policy generally — and would stigmatize physicians that serve a Medicaid population.

Though Ohio's Secretary of State had defended the law, arguing that it was necessary to protect against the corruption — or appearance of corruption — that could result when a Medicaid provider donates money to the very public officials that are charged with enforcing laws related to Medicaid fraud, the Court of Appeals noted that the Secretary offered no evidence whatsoever that corruption or the appearance of corruption between Medicaid providers and county prosecutors or the Ohio Attorney General was a particular problem at any time before, during, or after passage of R.C. § 3599.45. Further, even if the Secretary's rationale could be accepted, the Court said, the law was "vastly more restrictive than necessary" to achieve the goal of protecting against corruption. According to the State's own statistics, in a one-year period only .003% of Ohio's 93,000 Medicaid providers were implicated in Medicaid fraud. Thus, the Court said, "the statute here restricts the First Amendment rights of nearly 100,000 Medicaid providers who do not commit fraud, based on an attenuated concern about a relative handful of providers who do."

Due to the law's overly-broad infringement of the First Amendment rights of Medicaid providers, the Court struck down the law as unconstitutional and ordered the lower court judge to enter judgment in favor of the plaintiffs. ■

What's Next for Health System Reform in Ohio?

With this summer's Supreme Court decision to uphold the Affordable Care Act (ACA) paired with the upcoming election, many Ohioans, especially physicians, are asking what is next for health system reform in Ohio.

To address this question, the Academy of Medicine of Cleveland & Northern Ohio (AMCNO) and the Ohio State Medical Association (OSMA) are hosting an event, **"From the ACA to ACOs and Beyond: What's Next for Health System Reform in Ohio?," to be held on Thursday, Sept. 27** from 6:00 – 8:00 p.m. at the Cleveland Clinic – Main Campus.

The event will feature a panel of public officials discussing the state of Ohio's next steps on ACA implementation as well as a roundtable of physician leaders addressing how health system reform will impact patient care. A cocktail and hors d'oeuvres reception will begin the evening's program.

For more information, contact the AMCNO offices at (216) 520-1000, ext. 100 or go online to our website at www.amcno.org and go to Education and Events to view the brochure.

AMCNO MEMBERSHIP ACTIVITIES

AMCNO Resident Recruitment a Success

The AMCNO staff was on hand at residency orientations around the region to welcome new residents and to discuss AMCNO membership opportunities. In all, more than 350 new physicians from the following institutions joined the AMCNO as resident members: Cleveland Clinic Foundation, Fairview Hospital, MetroHealth Medical Center, University Hospitals, St. John Hospital and St. Vincent Charity Medical Center. AMCNO membership entitles these new physicians to many benefits including receiving weekly updates on all manner of health care related news as well as legislative and regulatory updates under review by the Ohio General Assembly and the United States Congress, legislative representation at the Statehouse by the AMCNO lobbyist, seminars, publications and opportunities to serve on AMCNO committees and more. Welcome to all new resident members!

Do you know of a resident interested in free AMCNO membership? Direct them to apply online at www.amcno.org and click on BECOME A MEMBER. ■

Residents from the Cleveland Clinic fill out AMCNO membership applications

Residents from University Hospitals take a moment to review the AMCNO membership application

First-Year Medical Students Meet with AMCNO Physician Leadership

The AMCNO and AMEF were pleased to co-host the Case Western Reserve University Society Dean Mixer for first-year medical students. The event was held at the Cleveland Botanical Gardens where the AMCNO physician leadership mingled with the students and the society deans and provided information and answered questions about the activities of the AMCNO and AMEF. The AMCNO president, Dr. James Sechler, provided brief comments to the group and encouraged the first year medical students to become involved in the AMCNO. He explained that the AMCNO is a group of dedicated physicians who are working to improve quality of care, while providing education and community outreach in our region. He also mentioned the advocacy activities of the AMCNO and noted that the students should consider getting involved because the association and affiliation with doctors in practice can clearly help them to focus on what their career has to offer and how to move toward their goals.

During the event the students asked AMCNO physician representatives about the activities of the AMCNO and AMEF; and how they could participate as medical students. Many expressed interest in the Affordable Care Act (ACA) and the impact it will have on the region; several students had questions about their career and specialty choices, while others expressed an interest in volunteering and outreach activities.

AMCNO staff was on hand to provide membership information and we were pleased to welcome over 100 new medical student members. ■

Dr. William Seitz, Jr. (left), AMCNO past president greets a medical student at the CWRU event

Dr. James Sechler provided background and information about the AMCNO during the event

Drug Shortages: Seeking a Remedy to a Growing Problem

We have probably all witnessed the healing properties of an antibiotic that cures a pesky infection at some point in our lives. But what happens to a patient when the medicine that has been successfully holding their cancer at bay suddenly becomes unavailable? The frightening reality is that for many patients, and the providers who are treating them, drug shortages are increasingly too common.

How Big is the Problem?

While drug shortages are just recently gaining significant media attention, they have been a growing concern for the past six years. In 2011, demand exceeded the supply for over 200 drugs, including some of those used to treat childhood cancers (methotrexate) and adult cancers (Doxil). Approximately 80 percent of the shortage was for sterile injectable drugs. Drug shortages are not just affecting the availability of cancer drugs, but also antibiotics, electrolyte/nutrition drugs, anesthetics, vaccines and medicines used to treat attention deficit hyperactivity disorder (ADHD).[1]

According to the American Hospital Association, almost 100 percent of hospitals reported at least one drug shortage in the past six months. Furthermore, almost half of all surveyed hospitals reported experiencing a shortage of at least one drug every day last year. For hospitals experiencing drug shortages, 82 percent had to delay treatment and 35 percent reported patients suffered adverse outcomes because of the drug shortage.[2]

What is Causing the Problem?

The Food and Drug Administration (FDA) attributes over half (54%) of all drug shortages to quality issues that require plants to temporarily or permanently close.[3] Shortages have been most problematic for sterile injectable drugs, which are more complicated to produce and thus more likely to have manufacturing problems. Furthermore, most sterile injectable drugs have one manufacturer that produces at least 90 percent of the drug.[4]

Also contributing to the drug shortage problem is consolidation in the pharmaceutical industry, which has resulted in fewer suppliers. Of the drugs on the FDA's shortage list, over 50 percent have three or fewer manufacturers, meaning big consequences when production problems arise.[5] When one manufacturer has to shut down even temporarily, the remaining drug manufacturers often aren't able to quickly produce sufficient supplies to meet the demand.

For drugs that only have one supplier, production problems are an even greater cause for concern. This was the case for the drug Doxil, which is used to treat a range of cancers, including ovarian cancer, the HIV-related Kaposi's sarcoma and the bone cancer multiple myeloma. When the sole supplier, Ben Venue Laboratories, temporarily suspended manufacturing and distribution at its Bedford, Ohio plant in November 2011 due to serious quality control problems, pharmacists, doctors and patients were left scrambling to find sufficient supplies to meet the demand.

Quality problems alone do not fully explain the shortages. Sometimes a scarcity of the underlying raw materials slows down drug manufacturing. Halting production of lower-cost drugs when the patent runs out and focusing instead on the production of newer, higher-cost drugs is a manufacturing decision that further exacerbates the drug shortage problem. Delays in the FDA's approval of new manufacturing facilities, processes, and drugs are also a culprit. These problems stem partly from a lack of sufficient funding that would allow the FDA to hire enough inspectors and reviewers, but also from bureaucratic hurdles.[6]

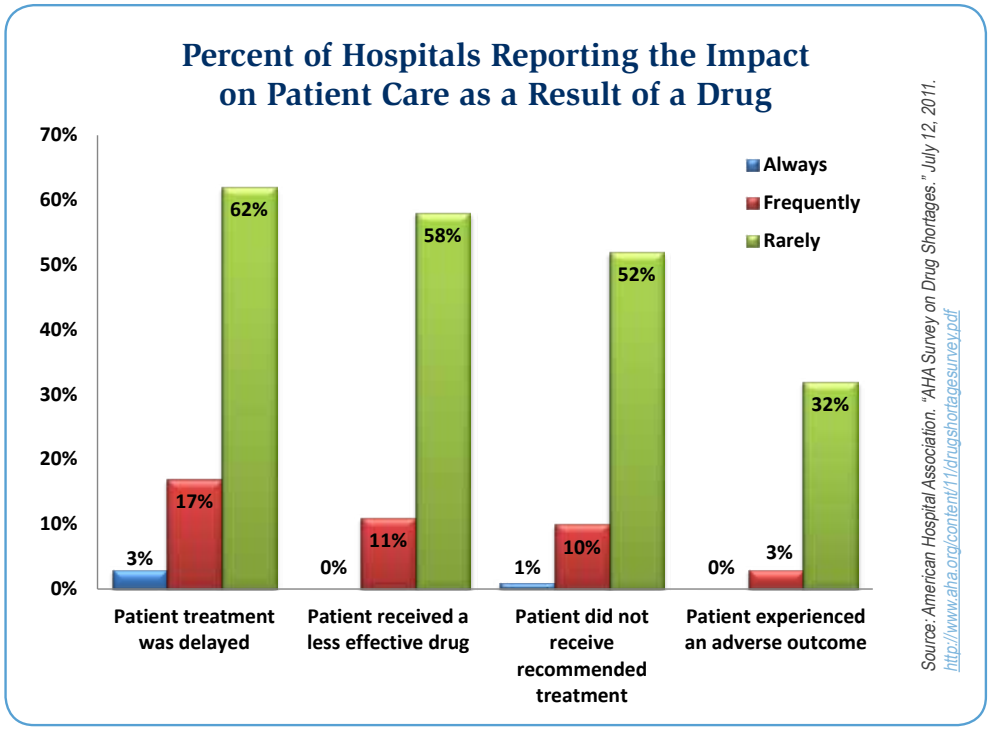
What are the Consequences?

While various groups might disagree about the primary source of the problem, what is indisputable is that real patients suffer when the medicines they need are unavailable. In some cases patients aren't able to finish full courses of treatment. Sometimes patients have to stop treatments that are very effective in treating their condition and switch to new drugs that aren't as effective as the initial drug, or that have worse side effects. In other cases, doctors aren't starting patients on treatments because they either don't have a sufficient supply of the drug or they are concerned there won't be enough available to finish a full course of treatment.

The most upsetting consequences stemming from the drug shortage are those faced by patients, yet a host of other consequences that can't be ignored also result from drug shortages. For example, most hospitals typically do not receive advance warning of an impending drug shortage, nor information about how long it might last. When faced with an acute drug shortage situation, hospital pharmacy staff are sometimes able to dilute higher doses of a medicine. In other cases they use substitutes, which can sometimes be significantly more expensive. In yet other cases they have no choice but to ration drugs.

There are disadvantages to all of these consequences. For one, the amount of time hospital pharmacy staff must spend diluting higher doses of medicines is significant.[7] Today, pharmacists spend eight to nine hours a week dealing with drug shortages, compared to three hours a week in 2004. Another disadvantage caused by the drug shortage is the risk for errors causes by confusion about dosing and appropriate substitutes.[8] All of these hurdles that hospital personnel face to provide patients with the highest level of care add up to big costs. A recent study found that drug shortages could cost hospitals across the nation at least $415 million per year.[9]

(Continued on page 16)



Drug Shortages: Seeking a Remedy to a Growing Problem

(Continued from page 15)

Who is Addressing the Problem?

Various entities have been working on solutions. To address the acute need for the cancer drugs Doxil and methotrexate, which had both been in short supply, the FDA allowed temporary drug shipments from India and Australia in February. While simply a stop-gap measure, these steps helped fill a critical need.

Long-term solutions are also being put in place to help avert drug shortages. In the past, FDA regulations only required companies of sole source, medically necessary drugs to provide the FDA with a six month advance notice of discontinuations. Last October, President Obama issued an Executive Order directing the FDA to broaden reporting of potential shortages of certain prescription drugs and expedite regulatory reviews of new manufacturing sites, drug suppliers and manufacturing changes.

Legislation to further increase the FDA's authority to avert shortages by requiring drug makers to report drug discontinuations and supply interruptions, improving coordination between federal agencies and speeding the approval of generic drugs was passed by Congress and sent to the president on June 26. A provision easing requirements for hospitals that repackage shortage drugs is also being considered. Under current law, if one hospital within a health system repackages a shortage drug, they are unable to provide that repackaged shortage medication to an affiliated hospital.

How is it Affecting Northeast Ohio Hospitals?

Despite national reports that there have been half as many shortages this year compared to the same time period last year, most local hospitals haven't seen any signs that the drug shortage problem is abating.[10] According to those on the front lines locally, there has been no predictable pattern to the drug shortage. It remains a significant problem, and it is affecting all types of drugs. Mirroring the national picture, the majority of the problem is with sterile injectable drugs, but it is not isolated to that group of drugs. Furthermore, area experts have noted that much of what has been done nationally to address the problem has yet to be effective in halting shortages.

In response, Northeast Ohio hospitals are adapting and being proactive in addressing drug shortages. Hospitals have put in place robust early warning systems. Hospital staff devote time to monitoring drug inventories on a daily basis while also examining what drugs patients coming in are expected to need. When an insufficient inventory exists, the need for alternative therapies is explored.

Sometimes hospitals purchase drugs from independent compounding pharmacies when there are drug shortages. Yet even this tactic is not without complications. Recently, when one area hospital called a compounding pharmacy to help address a shortage of the sterile injectable drug sodium bicarbonate, the hospital was quoted a 24-fold price increase over what is typically paid for the drug. Given the drastic price increase the hospital chose to rely on its own in-house compounding instead. Clearly, though they sometimes alleviate a shortage, relying on independent compounding pharmacies is creating other complexities that need to be mitigated.

To help the area's hospitals address the drug shortage, The Center for Health Affairs has begun having initial conversations with pharmacists and other key individuals at local hospitals to learn about the extent of the problem. In late June, a survey was sent to hospital staff pharmacists to gain an even deeper understanding of where the biggest problems lie. The survey findings, as well as potential steps to help hospitals with daily management and regulatory barriers, will be discussed during a face-to-face meeting in mid-July at The Center for Health Affairs. The Center is also forming a task force to work on regional solutions.

Conclusion

Patients — and the providers who treat them — must have access to the full arsenal of prescription drugs to treat their conditions. A shortage of a drug necessary to treat even one patient is one too many. Yet last year patients with a variety of ailments — including more than 550,000 cancer patients in the U.S. — were affected by drug shortages.[11] To be sure, the drug shortage problem is multi-faceted and unfortunately there is no single magical solution. Given the complex nature of the problem, hospitals and other stakeholders are working together to develop solutions to help prevent and alleviate drug shortages.

Editor's note: *This article was submitted to the AMCNO for publication by the Center for Health Affairs. The AMCNO is working with the CHA to raise awareness about the drug shortage impact among physicians and hospitals.* ■

In June The Center for Health Affairs conducted a survey of its member hospitals to assess how they have been impacted by the pharmaceutical shortage. There are many factors that play into the pharmaceutical shortage and there is little expectation that these will be resolved anytime soon. As a result, Northeast Ohio hospital pharmacists and other stakeholders, including the Academy of Medicine of Cleveland and Northern Ohio, are working to share best practices and determine next steps to address this growing problem. The group has identified several issues and next steps including the following:

1. Address restrictions on compounding in Ohio with the Board of Pharmacy, including advocacy to ease restrictions on compounding for non-specific patients (non-anticipatory compounding) and to allow compounded pharmaceuticals to be distributed across hospitals in a system.

2. Discuss ways to better communicate shortages and potential alternative medications. Evaluate whether developing an alert system, similar to those already in place at several of the region's larger hospitals, might be useful for smaller hospital members.

3. Share information about the pharmaceutical shortage and its impact on Northeast Ohio hospitals with the region's physicians.

4. Provide more effective communication regarding medication shortages with EMS personnel.

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Summary of Law on Health Information Exchanges

In the July/August issue of the *Northern Ohio Physician*, the AMCNO prepared a detailed summary of items included in the Mid-Bienniem Review (MBR) addressing the use and disclosure of protected health information (PHI) by covered entities. The AMCNO had asked CliniSync, Ohio's statewide health information exchange, to provide background information on the MBR and how it will impact physicians and hospitals. The following is an *interpretation* of the MBR law as it relates to CliniSync. The State of Ohio will write the final rules around the new law. As new information becomes available the AMCNO will provide background to our members.

The following summary of Ohio Revised Code Chapter 3798 reflects how the new law will affect CliniSync and its Participants. It does not constitute legal advice. Final rules will be developed by the State of Ohio.

Ohio Revised Code Chapter 3798 was recently adopted and becomes law on September 10, 2012. Chapter 3798 establishes new rules on providing information to and retrieving information from a health information exchange (HIE). The following is a brief summary of the new law.

Definition of "Health Information Exchange" (R.C. 3798.01): Under the new law, a "Health Information Exchange" is defined as "any person or governmental entity that provides in this state a technical infrastructure to connect computer systems or other electronic devices used by covered entities to facilitate the secure transmission of health information." However, "health information exchange" specifically excludes health care providers engaged in direct exchange, including direct exchange through the use of a health information service provider.

Comment: CliniSync falls under the definition of a "Health Information Exchange."

Definition of "Direct Exchange" (R.C. 3798.01): Under the new law, "Direct Exchange" is defined as "the activity of electronic transmission of health information through a direct connection between the electronic record systems of health care providers without the use of a health information exchange."

Comment: The CliniSync Direct Suite product enables the ability of providers to engage in a "Direct Exchange." However, providers using direct exchange are not themselves an HIE, as noted in the definition of HIE above.

Approved HIE (R.C. 3798.01): The new law also establishes the concept of an "approved health information exchange," which is defined to mean " a health information exchange that has been approved or reapproved by the Ohio Department of Jobs & Family Services [ODJFS] or that has been certified by the office of the national coordinator for health information technology {ONC} in the United States department of Health and Human Services." Thus, there are two separate ways for an HIE to be designated as an "approved health information exchange." While the new law does not expressly require every HIE to be approved, certain provisions of the new law apply only to approved HIEs (e.g., the immunity for HIEs (see below) applies only to approved HIEs).

Comment: While neither method of certification is currently available, CliniSync intends to pursue certification as an HIE by ONC when available. The law does not prohibit HIEs from operating prior to certification and CliniSync continues to function as an HIE.

Patient Authorization to Disclosure PHI to HIEs (R.C. 3798.04): The new law prohibits providers from using or disclosing protected health information (PHI) without patient authorization unless the use or disclosure is permitted without authorization by the HIPAA privacy rules and, if applicable, the federal drug and alcohol program rules at 45 CFR Part 2.

Comment: This provision essentially reiterates the federal HIPAA privacy rule requirements. Note that all uses and disclosures permitted by HIPAA without patient authorization (e.g., disclosures for treatment, payment, health care operations) are permitted. Generally, a disclosure of PHI to an HIE for exchange among providers would be a disclosure for treatment purposes permitted by HIPAA without authorization. Nevertheless, CliniSync has adopted "opt-in" policies that require providers to obtain a patient's authorization prior to disclosing the patient's PHI to ClinSync.

Disclosures to HIEs (R.C. 3798.06): In addition to permitting disclosures with patient authorization (see above), the new law also permits providers to disclose PHI to an HIE without patient authorization so long as all of the following are met: (1) the disclosure is to an approved HIE, (2) the covered entity is a party to a valid participation agreement with the approved HIE that meets the requirements of rules adopted by ODJFS, (3) the disclosure is consistent with all procedures established by the approved HIE, and (4) prior to the disclosure, the covered entity furnishes to the individual or individual's personal representative a written notice that complies with rules adopted by ODJFS.

Comment: CliniSync requires that providers obtain authorization from patients to disclose their records to CliniSync. Accordingly, in most cases a disclosure to CliniSync will not be a disclosure without authorization and, thus, will not need to comply with R.C. 3798.06.

Requirements of Covered Entities (R.C. 3798.07): The new law establishes requirements for providers applicable to all disclosures by providers to an HIE (both with or without patient authorization). When disclosing to an HIE, the provider must:

1. restrict disclosure consistent with federal laws,
2. if involving PHI of a minor, restrict disclosure to comply with state and federal laws on minor consent and control of information,
3. restrict disclosure in a manner consistent with written request from a patient to restrict disclosure of all of the individual's PHI, and
4. restrict disclosure in a manner consistent with written request from the patient concerning specific categories of PHI to the extent that rules adopted by ODJFS require the covered entity to comply with such a request (such rules have not yet been adopted).

Comment: CliniSync is working to develop policies and tools to assist providers in meeting these requirements. Such tools will include prompts asking if information is restricted by federal law (e.g., drug and alcohol information protected by 42 CFR Part 2) or is of a minor, to address these additional issues. Providers will also need to be mindful of requests by patients for restrictions on disclosure of PHI to HIEs and honor such requests.

Pre-Emption of Conflicting Laws (R.C. 3798.12): The new law provides that any disclosure to an HIE that complies with Chapter 3798 is not subject to other Ohio statutes, regulations, or guidance, that conflict with Chapter 3798. Thus, other Ohio laws that might otherwise impede disclosure of PHI to an HIE are superseded by the new law. However, the new law clarifies that the following are not superseded: (1) mandatory reporting requirements of PHI, (2) confidentiality of peer review records under R.C. 2305.252, (3) confidentiality of quality assurance records under R.C. 5122.32, (4) physician-patient privilege under R.C. 2317.02(B), and (5) rules regarding minor consents and minor receipt and control of such PHI.

Comment: This provision will allow providers to disclose PHI to CliniSync without running afoul of other Ohio laws (such as older laws requiring certain information disclosures to be in writing or be accompanied by specific language). Note that this law does not supersede federal law, so the federal restrictions established by 42 CFR Part 2 on disclosure of drug and alcohol program information continue to exist and

(Continued on page 18)

Summary of Law on Health Information Exchanges

(Continued from page 17)

must be followed by providers covered by 42 CFR Part 2.

Immunity (R.C. 3798.08): Under the new law, a provider is given immunity from civil and criminal penalties for accessing PHI from an approved HIE and for disclosing PHI to an approved HIE in a manner that complies with Chapter 3798.

Comment: The new law protects providers who disclose PHI to or get PHI from approved HIEs so long as the provider complies with the new law.

Other Requirements of Covered Entities (R.C. 3798.03): The new law provides that all covered entities in Ohio must:

1. provide the patient (or patient's representative) access to any designated record set maintained by the provider consistent with the HIPAA regulation at 45 CFR 164.524, and
2. implement and maintain appropriate administrative, technical, and physical safeguards to protect the privacy of PHI in a manner consistent with the HIPAA regulation at 45 CFR 164.530(c).

Comment: These requirements essentially duplicate federal HIPAA requirements already applicable to providers in Ohio.

Forthcoming Rules (R.C. 3798.13 – 3798.16): The new law requires ODJFS to promulgate rules regarding the following: (1) standards to be used to approve HIEs, (2) the process to be used to apply for status as an approved HIE, (3) the content required of HIE participation agreements, (4) the content required of written notice to patients that PHI will be disclosed to an HIE, (5) procedures for patients to request restrictions on the disclosure of PHI to HIEs, (6) a standard patient authorization form permitting disclosure of PHI to an HIE, and (7) criteria for classifying mentally or physically disabled persons as "minors" for purposes of Chapter 3798.

Comment: CliniSync will monitor the future rules adopted by ODJFS and provide additional communications on such rules as needed. ■

AMCNO Partners with Area Organizations on Inaugural Ohio Health Literacy Conference

In partnership with the Academy of Medicine of Cleveland and Northern Ohio, Better Health Greater Cleveland, Case Western Reserve University, City of Cleveland Department of Public Health, Cuyahoga County Board of Health, MetroHealth and Visiting Nurse Association of Ohio, St. Vincent Charity Medical Center and Project: LEARN are bringing together leaders in the field of health literacy to increase awareness; share resources; and build capacity for a statewide collaboration among health care providers for the inaugural Ohio Health Literacy Conference October 26, 2012, at the Renaissance Cleveland Hotel. Registration is $40 per person.

Health literacy is a patient's ability to understand and act on health information. It is also a provider's ability to communicate so patients can act on health information. It isn't about person's ability to read or write; it's about understanding and the action that results from that understanding. Dr. Cynthia Baur, Senior Advisor for Health Literacy, at the Centers for Disease Control (CDC) and author of the national action plan for health literacy, will present a keynote address and discussion.

All health care providers, physicians, nurses, administrative staff, social workers, dietitians, health plan administrators, adult literacy professionals, public health professionals and health literacy professionals from hospitals, universities and other organizations throughout Ohio are encouraged to attend this important conference. Complete conference and registration information is online at www.stvincentcharity.com/OHLC.

2012 AMEF GOLF OUTING

On a picture-perfect day in August, golfers enjoyed the Chagrin Valley Country Club at the Academy of Medicine Education Foundation's (AMEF) 9th Marissa Rose Biddlestone Memorial golf outing. Foursomes competed in a shotgun start tournament that raised more than $50,000 for AMEF. The funds will be utilized for medical student scholarships, annual CME seminars and the *Healthlines* radio program. The 2012 AMEF scholarship recipients were invited to join the group for dinner: Paul Adenuga CWRU, George Asaad OU, Nida Degesys NEOMED, Caitlin Hicks CCF Lerner, Arielle Kanters CWRU and Lina Ortega CWRU.

1st Place Team: Dr. Matt Levy, Wilson Beers, Brad Martin & Dr. Lawrence Kent

2nd Place Team: Dr. John Bastulli, Richard Garcia, Mark Janack & Marc Mingione

3rd Place Team: Jeff Leimgruber, Mike Mainwaring, John Meyerhofer & John Mills

Skill prizes were also awarded for the following:

Closest to the pin: John Bastulli, Jr., Jesmin Ehlers, Dr. Anthony Bastulli, and David Bastulli

Longest drive: Jim Brown on #5 and Jim Brown on #10

Longest putt holed: Doug Charnley

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Get your clubs ready for next year's event on August 5, 2013 at Canterbury Golf Club.

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