CLEVELAND
PHYSICIAN
Academy of Medicine of Cleveland/Northern Ohio Medical Association • March/April 2006
Volume 91 www.amcnoma.org No. 2

INSIDE THIS ISSUE

Riding the Wave of Change IN THE PRACTICE OF MEDICINE

From e-prescribing to the best laid plans of pay-for-performance, the 2006 annual seminar of The Academy of Medicine Cleveland/Northern Ohio Medical Association was as topical in subject matter as it was engaging to the many health care professionals in attendance.

Physicians and residents, registered nurses and practice managers from all over Northeast Ohio were on hand Feb. 17 to garner the volumes of information made available to them during this year's event, aptly entitled "Riding the Wave of Change in the Practice of Medicine."

Each of the presenters, widely respected as experts in their respective positions, fielded a bevy of questions from the audience, making connections between their offered material and the real-world experience of physicians in active practice. Punctuated by comments from AMC/NOMA President **Dr. George Kikano** acting as program moderator, the day's schedule was likewise bolstered by a timely legislative update provided during the luncheon hour by AMC/NOMA lobbyist Michael Wise.

Jointly sponsored by the AMC/NOMA, the Academy of Medicine Education Foundation and St. Vincent Charity Hospital, the seminar in aggregate was intended to inform attendees not only on what policies and initiatives have already taken place with regard to EMRs and P4P, but also what technologies and payment systems to expect in the coming years. As promised, the conference addressed such issues as why practice-based electronic health records are essential to quality measurement, and related to programs such as pay-for-performance; why information technology is a key enabler of quality improvement; how such payment experiments will continue to expand as reimbursements and quality of care become more formally linked.

From physicians and residents to practice managers and registered nurses, this year's seminar drew a wide variety of NE Ohio health care professionals.

***Dr. Kikano** offers his welcoming remarks to attendees at the onset of the day-long "Riding the Wave of Change in the Practice of Medicine" seminar.*

In sum, the 2006 annual seminar of the AMC/NOMA proved a successful interim step toward a fuller understanding of the issues presented therein, as well as an opportunity for all manner of area health care practitioners to come together, share their ideas and concerns with colleagues from around Northeast Ohio, and come away with a more comprehensive grasp of the program's content. By all accounts, including exemplary summary evaluations by attendees, "Riding the Wave of Change in the Practice of Medicine" concluded as a most worthwhile and informative event for those gathered.

How Information Technology is Linked to Quality Improvement

C. Martin Harris, MD, Chief Information Officer and Chairman of the Information Technology Division of The Cleveland Clinic Foundation began the day's program with his presentation, in general terms, on the new face of consumerism in health care. He termed it a challenge, in light of the "sheer volume" of medical information available today both to the patient and the practitioner. He used the example of direct-to-consumer advertising in print and electronic media that does not always best serve the doctor-patient flow of communication. For instance, he demonstrated an Internet search of the term "diabetes" that elicited some 13 million articles. Oftentimes a patient will come into the examining room armed with information, yes, but

(Continued on page 3)

AMC/NOMA
6000 Rockside Woods Blvd.
Ste. 150
Cleveland, OH 44131-0999

ADDRESS SERVICE REQUESTED

not necessarily the most accurate or appropriate for their personal medical needs, he said, thus presenting an additional challenge to the physician who must then distill much of this voluminous information for his/her patients. Couple this with the exponentially increasing amount of scientific information made available to physicians, (from approximately 100 seminal published articles in 1970 to more than 10,000 per annum in these first years of the 21st century), Dr. Harris said a new set of tools was required, then, to manage this new knowledge and disseminate it properly and efficiently from doctor to patient and back again. He then "walked" the audience through a virtual tour of the *e-ClevelandClinic* Web site and its associated online applications and services. Included in this were demonstrations of the ease with which physicians are already electronically managing prescriptions and alterations in medication via direct links with the emails of patients and participating retail pharmacies. He cited statistics of a "typical practice" in which 30% of incoming patient calls relate to prescription renewals or medication adjustment. The EMR system virtually eliminates the need for such, as patients initiate the process, a message is sent to the doctor, and in seconds the renewal and a notice of it are emailed to both the pharmacy and the patient. He noted the ease of this process is catching on nationwide and that e-prescribing seems to be the first electronic transaction doctors will see the benefit of and utilize. Dr. Harris then described an interaction in the exam room in which the functionality of the EMR was not only a useful clinical tool, but also how the technology allows the physician to assess if the patient's insurance will cover a screening test, for example, that the doctor is about to order and can discuss with the patient right then if it were to be their responsibility to pay — thereby streamlining the administrative end of a medical practice. He went on to detail the MyConsult program, already in use for 100 life-altering diagnoses, which offers patients an online second opinion within 48 hours, typically by a team of physicians weighing in on the electronic records submitted. Dr. Harris also described the advent of intelligent medical devices, and how in just a few short years from now they will not only be reporting device status/condition, but with the patient within 10 meters of their computer, the device will transmit physiological state of the patient including blood pressure, heart chamber pressure and the like, instantaneously over the Internet directly to their care provider.

Seminar attendees were taken on a virtual tour of e-clevelandclinic *by* ***C. Martin Harris, MD,*** *where access made available to patients and physicians is streamlining the practice of medicine in many ways.*

Another level or example of these "value-added" services includes CCF's DRConnect program, which facilitates specialty referrals in a way traditional phone calls and results by mail could never accomplish so effectively. He went on to outline more benefits of this burgeoning technology, including the many benefits it will hold for chronic medical conditions, maintenance and controls managed on a macro level across a practice or institution. Dr. Harris concluded his presentation by touching on the subject and the challenges in light of these developments, of what is known as interoperability — the exchanging and sharing of these electronic medical records among practitioners — as well as the inherent security and privacy issues such sharing brings with it. He noted the "good news" that Northeast Ohio was granted one of only six awards across the country — money to begin building such an exchange infrastructure. The major healthcare institutions in this area will carve out a model for electronic health records' interchange and place our area into "the forefront of the information exchange highway as it's built." He then ended by offering a hopeful look into the future of the "consumer-driven model of healthcare," wherein the tools technology will offer must be harnessed to provide value-added services to the patient, where a fundamental shift in thinking about the delivery of services will need to occur, and where patients will receive the best in their personalized care "when they want it, anytime or anywhere."

How to Obtain Affordable Standards-Based Electronic Health Records for Your Practice

Steven Waldren, MD, assistant director of the Center for Health Information Technology (CHIT) of the American Association of Family Practitioners (AAFP), presented an array of information relative to the actual electronic health market today and the practical application of the varied new technologies for the practicing physician. From his experience and the results of the associations' pilot program of widespread implementation, Dr. Waldren was able to offer many suggestions and solutions to the sometimes overwhelming process of "going paperless" for the typical physician office. This experiment also identified through trial and error both the common pitfalls and measurable successes of those who have implemented a standards-based integrated system to their business. He began by deconstructing the harmonization of standards, the inherent obstacles to defining them and identified physicians, health plans and vendors as the three major stakeholders in their eventual development. Beyond that, he addressed how adoption of these new tools will "fit into a new model of care." That is, keeping the needs of your patient population met during and after such a major transition for yourself and your entire front

President ***George Kikano, MD,*** *moderates a lively question-and-answer session following the presentation by Dr. Steven Waldren, Asst. Director of CHIT for the American Academy of Family Physicians.*

and back office. Dr. Waldren stressed the critical importance of pre-planning, of getting staff on board with an upcoming implementation "as close to 100% as possible," and understanding that an incremental transition into new technology seemed to work best for offices of all sizes and scope. In light of this, an acceptance of the fact that productivity will decrease for months, on average, while technology is installed and upgraded, tested and modified in practice, but that most participants in the pilot program reported the return to normal productivity in short order, if not measurably increased than before implementation. Dr. Waldren acknowledged the concern of cost, considering the variables in the current marketplace and especially with respect to the independent practitioner versus a larger institution considering the same vendors, for exam-

(Continued on page 4)

ple. Several questions from the audience asked him to address this as well, in the short- and long-term, and to all he offered the hope of a leveling of the market in the years to come, of course, as more adoption takes place, forcing the cost of initial investment downward. He alerted those interested to the various listservs, online forums and Web sites devoted to discussion of these issues — doctors helping other doctors with troubleshooting new technologies in the practice setting. In fact, Dr. Waldren demonstrated this in real-time by accessing www.aafp.org showing that many of these online participants were Ohio-based physicians, and that it may be quite useful to garner from their experience what has and has not worked for them, what types of vendor programs have been chosen in the state, etc. He likewise directed those interested to visit www.EMRupdate.com, an independent resource comparing prices and value of systems currently on the market. Following a detailed summary of what specifically the AAFP is accomplishing on these fronts on behalf of their membership, Dr. Waldren concluded his presentation with a more thorough examination of standards and what he termed "a very complex issue" in the context of healthcare on the national stage. He said CHIT is currently working on distilling elements of the EHR that would be most vital for exchange among physicians and the idea of continuity of care, and could that be done in a standards environment? For instance, data extracting of say, problems, allergies and medications — period — which would save time and unnecessary chart reviews. All of this standardized electronically too, so that whether one user views it as a Word document, for example, any could do so as a Web page and so on. He noted that his organization would be wrapping up the pilot phase by the end of March and actually be testing products and expecting results on certification for vendors by the end of 2006. He encouraged a visit to www.cchit.org for a more thorough review of the progress that has been made to date and which they hope will continue in the years to come.

During the luncheon hour, AMC/NOMA lobbyist Mr. Mike Wise, Esq., provided a timely update on the status of SB88, as well as a more general overview of the political landscape in Ohio's primary and general elections later this year. (See Statehouse Report pp. 8 & 9).

Pay for Performance: Principles, Measurement Challenges and Future Directions

Dennis O'Leary, MD, president of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), delivered an address that synthesized the complex administration-level policies of payment-for-performance into simple, yet hard-hitting, language for the individual practitioner in attendance. He outlined systems and incentive programs, both proposed and already in place across the country, but with a critical gaze from his perspective as the long-time head of JCAHO — claiming most are lacking the crucial components of figuring in real patient safety and quality improvement. It may well be the "golden times" of medicine in terms of new drugs, technological advancements and 21st century life expectancies, but with 40 cents of every dollar going to waste in the current system, it's the patient, he said, who gets lost in this mix. Dr. O'Leary cited statistics relative to this, and indicated the lesson is *not* lost on those setting policy in Washington, D.C. American improvements to quality are far behind those of other nations, he said, though our spending far exceeds others. And he noted these issues must be aligned more evenly if physicians are ever to benefit from performance-based payment policies. As the title of his presentation underscored, the challenges of measurement are myriad, and yet the stakes are undeniably high. Dr. O'Leary termed measurement "the Achilles heel" of all proposed programs, citing example after example of where they have failed to date. According to Dr. O'Leary, the "purchasers" of health care, or Medicare and Medicaid, for example, are intent not only on implementing programs that insist on quality measures set forth, but in several parts of the country they are already withholding/denying payments for adverse or unfavorable outcomes. On this point he went through a list of proposed "Incentive System Design Options" including no pay for "bad" care, a zero-based option, hold backs, "new" money or rewards and bonuses and the idea of paying for improvement versus achievement. Dr. O'Leary was critical of many of these, as they would bear out for the practicing physician, in particular. He warned, however, that while "P4P is not the great panacea" some believe it to be, "it is too late to go back to where we were." Physician payment will be linked to quality, the question he said is who will measure it and how. O'Leary briefly touched on examples of poor patient quality as "voluntarily" reported to his organization over the last decade, as well as concerns over hospital-acquired infection rates and others, by which simple human behavioral changes could render them preventable. He offered suggestions on the points of existing disparities in health care and the problem of low health literacy among patients, often a result of too little time being spent one-on-one with their primary care giver. It illustrated the way public policy gets in the way of good patient care, he said. Dr. O'Leary differentiated between perform-

Dennis O'Leary, MD, JCAHO President, outlined the plans of proposed pay-for-performance initiatives as they will relate to patient safety and quality measurements in the future.

CLEVELAND PHYSICIAN

THE ACADEMY OF MEDICINE OF CLEVELAND/ NORTHERN OHIO MEDICAL ASSOCIATION
6000 Rockside Woods Blvd., Suite 150
Cleveland, Ohio 44131-2352
Phone: (216) 520-1000 • Fax: (216) 520-0999

STAFF
Executive Editor
Elayne R. Biddlestone
Administrative Assistant
Joanna Bonacci
Membership & Marketing Coordinator
Linda Hale
Communications Coordinator
Sara Lieberth

THE CLEVELAND PHYSICIAN (ISSN# 1084-0982) is published bi-monthly by the Academy of Medicine Cleveland/ Northern Ohio Medical Association (AMC/NOMA), 6000 Rockside Woods Blvd., Suite 150, Cleveland, Ohio 44131. Periodicals postage paid at Cleveland, Ohio. POSTMASTER: Send address changes to CLEVELAND PHYSICIAN, 6000 Rockside Woods Blvd., Suite 150, Cleveland, Ohio 44131. Editorial Offices: AMC/NOMA, 6000 Rockside Woods Blvd., Suite 150, Cleveland, Ohio 44131, phone (216) 520-1000. $36 per year. Circulation: 2200.

Opinions expressed by authors are their own, and not necessarily those of the *Cleveland Physician* or The Academy of Medicine of Cleveland/Northern Ohio Medical Association. *Cleveland Physician* reserves the right to edit all contributions for clarity and length, as well as to reject any material submitted.

ADVERTISING
George H. Allen, Jr., Commemorative Publishing Company
P.O. Box 450807, Westlake, Ohio 44145
P: (440) 808-0240 • F: (440) 808-0494

ance measures and standards, practice guidelines and the inherent pitfalls if all are not evidence-based. In very specific terms he went on about patient safety indicators, data quality and the problems in acquiring the intangible. How does one measure things that didn't happen? It is a daunting problem, he said, with no clear answer. A member of the board for the National Quality Forum, Dr. O'Leary detailed its history, implementation, and its work on overseeing measures introduced by purchasers, provider organizations and physicians, as well as offering to be a clearinghouse on a national scale. He commended this work, despite political obstacles, and countered the unfavorable feedback from a recent Institute of Medicine report on the NQF by stating that without it, "pure and total chaos" would result. He then summarized his presentation with the very specific problems of data gathering, reporting, data quality and lastly the issue of the need for regularly updating measures considering evidence and practice changes. And finally, suggesting that short of doctors being threatened with some form of universal healthcare system, he believed it was the position of the Secretary of Health and Human Services to take the lead on these issues in the hope of developing the measurements and quality/safety initiatives that will work best for all involved.

CMMS Payment for Quality: A Paradigm Shift

Susan M. Nezda, MD, as the Chief Medical Officer of the Centers for Medicare and Medicaid Services for Region V, which includes Ohio and five other Midwestern states, rounded out the day's program with her discussion of the payment programs linked to quality — those currently implemented by her agency and those that are on their way in the coming years. From her experience of 17 years as an emergency physician before joining CMS, Dr. Nezda effectively related how government policy translates, or trickles down, to the individual practitioner. Throughout her address, however, she continually encouraged those gathered to shift that paradigm, as her title suggests, challenging physicians to take a lead role in the development of the measures by which they will be held responsible. She commended The Academy of Medicine Cleveland/Northern Ohio Medical Association on this point, for bringing these issues to the fore in a proactive manner by hosting the event. "This organization has done a fabulous job of highlighting the kinds of things that we, as physicians, can do to affect this," she said. Having participated in all the previous sessions, Dr. Nezda brought many of the day's topics together in her presentation, including the inherent difficulties in measuring quality and the necessity of electronic health records for successful implementation of many performance-based payment initiatives. Citing statistics and results of several studies related to these issues, Dr. Nezda addressed the fact that the costs and associated inefficiencies in the healthcare delivery system are definitely driving the restructuring of reimbursements. She pinpointed the physician-patient interface as the cornerstone of this system, where most of "the decisions regarding healthcare expenditures are made."

Susan Nezda, MD, as the Region V Chief Medical Officer for CMS, offers insights to fellow physicians on navigating the reimbursement programs being implemented by the Medicare agency.

Dr. Nezda also referenced the Institute of Medicine report, "Crossing the Quality Chasm" which is fast becoming the definitive text in determining what she called "the right care for the right person every time," and by which all providers will be measured. She spent time addressing the obvious difficulties in applying these concepts to both individuals and larger hospitals and systems, while she acknowledged CMS' view that "quality is not location-based, it's patient-based." The agency, she said, is under pressure to streamline the burgeoning budgets of Medicare and especially Medicaid, and that the Part B component seems to grab the most political attention. Dr. Nezda went through a number of such programs being honed for implementation, including payment for infrastructure, pay for coordinating care, pay for prevention, a pay for participation model and the physician voluntary reporting program in place this year (see sidebar). For these and several completed and upcoming demonstration projects, she directed the audience to www.cms.hhs.gov/researchers/demos/mma646/default.asp where one can track progress and gain a better understanding of this shift to value-based physician reimbursement. Dr. Nezda again encouraged real participation from physicians to help define and determine these policies by actively communicating with her office, their own medical boards, societies, hospital committees, etc., so that a caring, patient-focused model of healthcare be successfully developed. "Anyone who thinks there are problems with the system — their challenge is to lead the change," she said. ■

CMS first announced PVRP in October 2005 as a precursor to restructuring physician payment-based on performance of various quality measures. Physicians participate in PVRP by adding additional codes, called G-codes, to their Medicare claims forms. CMS has indicated it intends for PVRP to be a temporary measure and that any permanent physician pay-for-performance program will be accomplished through health information technology, rather than G-codes.

The 16 measures in the PVRP core starter set are:

1. Aspirin at arrival for acute myocardial infarction
2. Beta-blocker at time of arrival for acute myocardial infarction
3. Hemoglobin A1c control in patients with Type I or Type II diabetes mellitus
4. Low-density lipoprotein control in patients with Type I or Type II diabetes mellitus
5. High blood pressure control in patients with Type I or Type II diabetes mellitus
6. Angiotensin-converting enzyme inhibitor or angiotensin-receptor blocker therapy for left ventricular systolic dysfunction.
7. Beta-blocker therapy for patients with prior myocardial infarction
8. Assessment of elderly patients for falls
9. Dialysis dose in end-stage renal disease patients
10. Hematocrit level in end-stage renal disease patients
11. Receipt of autogenous arteriovenous fistula in end-stage renal disease patients requiring hemodialysis
12. Antidepressant medication during acute phase for patients diagnosed with new episode of major depression
13. Antibiotic prophylaxis in surgical patients
14. Thromboembolism prophylaxis in surgical patients
15. Use of internal mammary artery in coronary artery bypass graft surgery
16. Pre-operative beta-blocker for patients with isolated coronary artery bypass graft

OSMB Director Addresses Board, Outlines Long Range Plans for Agency

Richard A. Whitehouse, Esq., Executive Director of the Ohio State Medical Board (OSMB), attended a recent AMC/NOMA Board of Directors meeting both to formally introduce himself to the association and to provide an overview of his agency's objectives in the coming years.

To this end, Mr. Whitehouse disseminated copies of the OSMB five-year strategic plan, which encompassed long-term goals as well as a three-pronged strategy to accomplish them. He indicated that soon after being named to the position of Executive Director (May 2005) he was asked to work on the development of said strategic plan. The planning, he said, offered an opportunity for the agency to take a look at its operations and make necessary changes.

OSMB Director Richard Whitehouse spends a moment with AMC/NOMA President-Elect ***Paul C. Janicki, MD.***

Mr. Whitehouse presents to the board of directors in January.

As stated in their mission, the charge of the OSMB is to protect and enhance the health and safety of the public through effective medical regulation. Goals include ensuring that persons practicing medicine meet sufficient standards of education, training, competence and ethics among others. Their strategic plan is focused on three specifics: creating an ethics-driven/high-performance workplace; developing a holistic approach to "effective" medical regulation that helps maintain the efficacy of licensees and prevents adverse outcomes; and engaging in partnerships with stakeholders and others in order to leverage available resources and improve healthcare in Ohio. It is important, he said, to understand that their mission is to protect the public, much more than just handing out licenses. He indicated the OSMB was going to re-examine what issues they are currently working on and take another hard look at the medical practices act.

The issue of having the SMB track the physician workforce throughout the state was initiated by an AMC/NOMA board member. The association continues to request the SMB acquire and disseminate such information — which would clearly be useful for our work in liability reform, specialty-specific data tracking and much more. When Mr. Whitehouse's predecessor Mr. Tom Dilling visited in 2005, this issue dominated much of the discussion and follow-up between the SMB and the AMC/NOMA. The association was asking both if anything had been accomplished on this front since their last meeting and what future plans, if any, have been undertaken for such tracking. Mr. Whitehouse responded that his agency would like to have the means to measure costs and availability of healthcare in the future, and that he would bring the matter to the licensure committee to obtain feedback. The AMC/NOMA asked to be kept informed and involved on these decisions.

Subsequently, a question was raised by the board regarding expert witnesses and how they function in the state of Ohio. It was noted that some national specialty societies censure bad behavior of expert witnesses, that is, should they provide testimony that proves to be harmful or inappropriate they can be sanctioned by the society. A mention was made that out-of-state experts come into Ohio, provide their testimony and then leave and there should be a mechanism to sanction them should they act unethically. Mr. Whitehouse responded that such a project would take an act of the legislature and a sign-off by the Governor. Censure is but a strong statement of dissatisfaction. The state board does cooperate a great deal with other medical boards in other states on issues. He did not believe, however, that they could do anything about censuring expert witnesses in a similar fashion to the specialty societies without a change in the law. It was noted that HB 215 contained a section specific to expert witnesses. The bill set forth that a physician from another state that testified as an expert witness in Ohio in any action against a physician for injury or death, whether in contract or tort, arising out of the provision of or failure to provide health care services, is to be deemed to have a temporary license to practice medicine in Ohio for the purpose of providing such testimony and is subject to the authority of the State Medical Board of Ohio. Mr. Whitehouse indicated the subject raised might well be suited for an article in the state board report and even consideration as an SMB position paper (a vehicle which would broadly provide ethical/behavioral guidelines but effectually offer no legal recourse).

Mr. Whitehouse reiterated that his agency wishes to work collaboratively with associations and that this issue is of importance. The AMC/NOMA board then thanked Mr. Whitehouse for attending their meeting and Mr. Whitehouse stated he would come back any time upon request.

In a follow-up letter to Mr. Whitehouse's visit, the AMC/NOMA offered further suggestions on the issue of expert testimony in medical liability cases, including the notion of a complaint process being formed through the state board because these testifying physicians, resident Ohioans or not, are subject to licensure through the OSMB. The AMC/NOMA believes that while a position paper set forth by the agency on the subject of expert medical testimony would be of benefit, some sort of sanctioning process might better address a situation in which such testimony were offered irresponsibly or unethically. The AMC/NOMA is of the opinion that the SMB would serve as the most appropriate entity to set up such a process. Members of the board proactively offered to assist in any way possible should further consideration of the matter be undertaken. ■

AMC/NOMA Addresses Communication Issues in Letter to FDA

In the final months of 2005, The Academy of Medicine Cleveland/ Northern Ohio Medical Association Board of Directors carefully reviewed and adopted as policy, recommendations regarding postmarketing drug safety issues as forwarded by the American Medical Association. Significant interest from the board and in particular members of the Green Road Group, then initiated an ad hoc committee to further the AMC/NOMA's stand by submitting a letter directly to the U.S. Food and Drug Administration (FDA) in January 2006. Addressed to the members of the FDA's Center for Drug Evaluation and Research, the AMC/NOMA missive was sent in response to a request from the agency for public comment, specifically on the subject of risk communications developed by the FDA and also available on their Web site. In his letter dated Jan. 4, 2006, President **George Kikano, MD,** on behalf of the AMC/NOMA Board of Directors and membership, outlined several key positions supported by the association relative to improving the safe use of prescription drugs. Most specifically, the dissemination of risk information directed from the agency to physicians was discussed. Suggestions for improvements to the FDA Web site for the purposes of data access were offered — both for health care providers and the public. Expansion of the information provided in "Dear Doctor" letters was suggested by using electronic means of communication made directly to physician's email, on medical society Web sites and even downloads to personal digital assistants. Other recommendations included pharmaceutical representatives be kept informed on drug risks in a timely manner and passing that information on to physicians as well as major announcements of drug and device side effects prior to release of such information to the public. The full text of the submitted comments is provided below for membership review:

THE ACADEMY OF MEDICINE CLEVELAND

Northern Ohio Medical Association

January 4, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lanes, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2005N-0394

Dear Members of the FDA Center for Drug Evaluation and Research (CDER):

The Academy of Medicine of Cleveland/Northern Ohio Medical Association (AMC/NOMA), a physician organization representing over 4,300 physicians in Northern Ohio, would like to respectfully submit our public comments regarding the FDA's Communication of Drug Safety Information.

Recently, our board of directors agreed to adopt as our policy the American Medical Association (AMA) recommendations regarding postmarketing drug safety issues. Our organization completely agrees with the AMA that the FDA should address these recommendations. Our board adopted the AMA policy with some slight changes to the language. These recommendations are as follows:

1. *Urge the Food and Drug Administration (FDA) to issue a final rule, as soon as possible, implementing modifications to the format and content of the prescription drug package insert with the goal of making the information more useful and user-friendly to physicians;*
2. *Urge the FDA to collaborate with physician organizations to develop better risk communication vehicles and approaches;*
3. *Urge the FDA to apply new tools to gather data after drugs are approved for marketing, including a broader use if targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases;*
4. *Monitor the design and implementation of any independent drug safety board that may be instituted within the FDA, or external to the agency, and respond as appropriate;*
5. *Support adequate funding to implement an improved FDA postmarketing prescription drug surveillance program.*

We agree with the AMA that there is a need to look at the benefits versus the risks involved in drug therapy and any way that we can improve the safe use of prescription drug products post marketing is a laudable goal and one that should be pursued by the FDA.

The FDA has requested comments on the risk communications items developed by the FDA and posted on the FDA web site. Several AMC/NOMA board members have reviewed the web site and are of the opinion that while the site does provide a plethora of information about risks of drug products, accessing that data from the FDA site is a time-consuming task. Our physician members would concur with the AMA that other relevant communication tools must be developed in order to keep physicians apprised of the rapid changes that can occur relative to drug safety issues.

FROM THE EXECUTIVE OFFICES

6000 ROCKSIDE WOODS BLVD., STE. 150
CLEVELAND, OHIO 44131-2352
www.amcnoma.org
216-520-1000 • FAX 216-520-0999

For example, as noted by the AMA, "Dear Doctor" letters are not always read in a timely manner. Therefore, in addition to hard-copy mail these letters should be disseminated through other formats – such as publication in medical journals, medical society web sites, as well as through communications to physicians via blast fax, blast email, and direct downloads to personal digital assistants. In this age of information technology, usage of electronic means of communication, inclusive of e-prescribing systems, would be the most efficient way to notify physicians of drug safety issues. If the hard-copy letters continue to be sent out to physicians, we would agree that the format of the "Dear Doctor" letters must be altered to alert the physician of the need for action. The first part of the letter should clearly outline the possible severe outcomes to patients that could occur from a new adverse event, that the adverse event could be preventable if the drug is used correctly, and what steps the physician should consider to prescribe the drug appropriately.

We also agree with the AMA that pharmaceutical representatives should be trained to educate physicians on risk information about their products. These representatives gain access to our offices everyday to promote the benefits of their companies' products and these same representatives should be able to provide information to physicians about safety problems.

The AMC/NOMA believes that in order to better address patient concerns physicians would strongly recommend that the FDA provide physicians and other healthcare providers with major announcements on drug or device side effects through the above referenced communication routes, prior to their release to the general public. We realize that the FDA is prohibited from providing this early release of information to physicians due to regulations, but we believe that it would be helpful if physicians and healthcare providers were provided with this information prior to public release so that we could be prepared to address these matters with our patients.

With regard to our patients, your consumers, the FDA has sought comments whether or not the FDA Internet-based sources of drug information are easily accessible and understandable. We are of the opinion that anyone trying to access information on the FDA site may experience problems in accessing the information. It is our opinion that the information is not presented in a concise manner and this warrants further evaluation by the FDA. The web site should be evaluated for ease of usage as well as whether or not elderly consumers would be able to access the information on the site (Internet access, understanding of the data presented, etc.) Elderly patients often take multiple medications and drug-drug interactions and over and under dosing related to confusion or sight impairment is a real concern. Personal medication records should be encouraged if at all possible.

The physician members of the AMC/NOMA would be pleased to provide additional input relative to this issue in the future. Physicians are on the front line everyday prescribing medications to our patients and we must have drug safety issues brought to our attention as soon as possible. We stand ready to assist the FDA and other physician organizations in the future on this important issue.

Sincerely,

G. Kikano

George E. Kikano, M.D.
President
The Academy of Medicine of Cleveland/Northern Ohio Medical Association (AMC/NOMA)

By Mr. Michael Wise, Esq., AMC/NOMA Lobbyist

Political Engagement Especially Important in Contested Election Year

AMC/NOMA continues to aggressively advocate for physicians in Columbus. You have heard elsewhere about SB 88 and the leadership the Academy is providing on that issue. Another goal of AMC/NOMA is to increase the political participation of the medical community. 2006 is truly a year where not only your November vote is important but your May vote as well. 2006 will be the most contentious primary election year in Ohio in over 50 years. The partisan battles will take place in the fall of 2006 and I will write about that in the next issue. The spring of 2006 will be the real historic battle as Ohio sees the most money spent in its history on Primary Election races. If you are not an informed and active voter, this will be the year to start. You still have plenty of time to both register to vote and to educate yourself on the issues and candidates.

Each election year, the partisan candidates for office must file their petitions for office 75 days before the election. In 2006, that filing deadline was on February 16. The Primary Election will be on May 2. In those 75 days in between, we will see Republicans attack Republicans and Democrats attack Democrats. These attacks have already begun and will continue in an unprecedented fashion using an unprecedented amount of financial resources. This is all the result of a "perfect political storm." We have a monopoly of power with the Republicans, a term limited Governor, a series of ethical missteps by incumbent office holders and some very prodigious fundraisers pursuing statewide office. These factors give us our 2006 "storm."

The readers of this will all have the opportunity to participate in this historic election season. First, by registering to vote by April 2, 2006. Then, most significantly, by choosing a partisan ballot on election day. Each voter in Ohio will choose on May 2, whether they want a Republican, Democrat or Independent ballot. This is how a voter "chooses" his or her political affiliation. Ohio is relatively unique in this regard. Political affiliation is chosen by the ballot a voter uses not by any separate declaration. If a Republican or Democrat ballot is chosen, a voter will have the opportunity to vote in those respective primary races.

On the Republican side, (with dollars on hand as of January 31), for Governor, Attorney General Jim Petro ($2,200,000.00) will face Secretary of State Ken Blackwell ($1,500,000.00). For Attorney General, State Auditor Betty Montgomery ($1,800.000.00) faces State Senator Tim Grendell ($250,000.00). For Treasurer, incumbent Jennette Bradley ($260,000.00) faces opposition from County Auditor Sandy O'Brien ($185,000.00). For Secretary of State, Representative Jim Trakas ($40,000.00) squares off against Hamilton County Clerk of Courts Greg Hartmann ($480,000.00) and for Auditor, State Representative Mary Taylor ($200,000.00) is unopposed. For the Supreme Court, Appellate Judge Bob Cupp (former State Senator) runs unopposed for the Resnick seat. (all races as of February 14, 2006)

On the Democrat side, (with dollars on hand as of January 31), for Governor, Congressman Ted Strickland ($2,100,000.00) will face former State Representative Bryan Flannery ($58,000.00). For Attorney General, former Cleveland Law Director Subodh Chandra ($175,000.00) will face State Senator Marc Dann ($275,000.00). For Treasurer, former State Representative Richard Cordray ($706,747.00) faces the Montgomery County Treasurer Hugh Quill ($190,000.00). In the Secretary of State race, Franklin County Judge Jennifer Brunner ($185,000.00) is unopposed. For Auditor Mahoning County Treasurer John Reardon ($90,000.00) runs against State Representative Barbara Sykes ($8,670.00). For Supreme Court, Cuyahoga Juvenile Judge Peter Sikora opposes State Appellate Judge Bill O'Neill and AJ Wagner.

So, with over three months left to raise dollars, the candidates with Primary opposition have almost 10 million dollars already on hand for their races. It is not hard to envision a situation where over 10 million dollars is spent sometime in April by Republicans against Republicans and Democrats against Democrats. By the May election, we may know more, at an earlier date, about the respective candidates than we ever have. This may not be good for the respective candidates or political parties, but it may be very good for the average voter and for the good government advocates. The "perfect storm" may in fact be fresh winds of reform and change that serve the citizens of Ohio.

It is certainly not the role of AMC/NOMA to advocate for one political party versus another. AMC/NOMA does want each of its members to engage in the election cycle and to educate themselves about the medical issues that are in the public square and the candidate's positions on those issues. The candidates and their phone numbers will be posted on the AMC/NOMA Web site as well as our Ohio legislative update. If you are undecided about a candidate, please take the time to contact a candidate and ask about one of our issues. We, and the candidates, will all be better off for your effort.

Update on SB 88

The Academy of Medicine Cleveland/Northern Ohio Medical Association (AMC/NOMA) continues to provide leadership on the most significant medical malpractice legislation of the 126th Ohio General Assembly. Senate Bill 88 would require that the Superintendent of Insurance establish a pilot program to determine the benefits of using arbitration in medical negligence disputes. The bill suspends the provisions in existing law concerning arbitration of medical claims and requires the parties to a medical negligence claim arbitrate the claim in accordance with the Bill's provisions **prior** to filing a complaint. The Mandatory Nonbinding Arbitration provisions in SB 88 were created by AMC/NOMA in collaboration with other Ohio interested parties.

SB 88 continues the requirement in existing Ohio law for plaintiffs to file both an Affidavit of Merit and a Notice of Intent to Sue. However, both of these filings are processed by an Arbitration Panel instead of the Court of Common Pleas. The Bill also contains a modified "Loser Pay" provision to provide a significant incentive for the parties of a medical negligence claim to accept the arbitration ruling and to not proceed to a civil trial. SB 88 was introduced on March 2, 2005 in the Senate by Sen. Kevin Coughlin of Cuyahoga Falls. It is co-sponsored by Sen. Goodman of Columbus.

SB 88 is an aggressive attempt to lower the overall cost of resolving a medical negligence claim in Ohio. These so-called "loss costs" are creating a situation in Ohio in general, and in particular counties in Northeast Ohio specifically, where physicians are leaving the practice because of escalating medical liability premiums. Alternative Dispute Resolution (ADR) is an accepted mechanism to

(Continued on page 9)

reduce loss costs. Arbitration is a form of ADR that is often used in disputes involving complicated facts and standards of care. The mandatory arbitration provisions of SB 88 offer an excellent vehicle to further reduce these loss costs.

On Jan. 10, **Dr. John Bastulli** traveled to Columbus to offer testimony in support of SB 88 to the Senate Insurance committee and its new Chairman, Sen. Stivers of Columbus. (See related story in Sidebar) Dr. Bastulli updated the committee on a number of proposed changes to the Bill. These changes are a result of positive dialogue with "Interested Parties" to SB 88. Those changes included clarification that new Civil Rule 10, and its Affidavit of Merit provisions will continue to apply to medical malpractice claims. Dr. Bastulli also recommended that at a minimum, the arbitration pilot include the counties of Cuyahoga, Geauga, Lake and Summit. He also advocated language to clarify that the arbitration panel does have the ability to rule on the validity of that Affidavit as proscribed in ORC 2339.04.

Dr. Bastulli also had the opportunity to meet privately with Sen. Stivers. Sen. Stivers has heard from physicians in his district and he is supportive of SB 88. This was excellent news and we certainly look forward to working closely with Sen. Stivers in the coming months. There is no question that AMC/NOMA is very fortunate to have Sen. Coughlin as sponsor of our legislation and Sen. Stivers as chairman of the assigned committee. Please do not hesitate to leave a message for Sen. Coughlin at (614) 466-4823 or for Sen. Stivers at (614) 466-5981 to thank them for their leadership and support.

Since Dr. Bastulli's testimony, we have begun to receive more very positive input on the bill. We anticipate more changes in the next few weeks. Sen. Coughlin has communicated to us that he is still hopeful that this legislation can move out of the Senate before the summer recess. We will certainly keep you informed of all new developments but to date, the news is very positive. ■

AMC/NOMA Testifies Before Committee, Recommends Changes to SB 88

On Tuesday, Jan. 10, **Dr. John Bastulli,** AMC/NOMA Vice President for Legislative Affairs, offered proponent testimony on legislation mandating arbitration for medical negligence claims during the fourth committee hearing on the matter. While SB 88 garners bipartisan support on the committee, including Chairman Sen. Stivers' comment that "I'm very sympathetic to the crisis you're in right now," bill sponsor Sen. Coughlin has indicated he is working on a substitute version of the proposal with input from interested parties. Central to the AMC/NOMA's testimony was the creation of a pilot program in Northeast Ohio, narrowing the scope of the initial statewide arbitration provision. "At a minimum, the AMC/NOMA is advocating that Cuyahoga, Summit and other Northeastern Ohio counties be included in this regional arbitration pilot Dr. Bastulli noted that doctors in Ohio pay higher liability premiums than in many other states, those in the Cleveland area suffer the highest premiums in the state. "The AMC/NOMA believes that the current system falls far short of its social goals of promoting patient safety and compensating wrongly injured patients. Individuals truly harmed through medical negligence should be compensated through a fair and timely process," Bastulli said. "However, this process should be one that is equitable to all parties involved — including society as a whole." Additional amendments offered during his testimony included requiring an affidavit of merit in the arbitration process, revisions to the panel selection process, adding an opt-out for parties to pursue mandatory mediation should both parties agree, and adding a provision to the Ohio Revised Code requiring the plaintiff's counsel to notify the chair of any subsequent lawsuits. To read the full text of Dr. Bastulli's testimony, or for more information and background on the evolution of this proposed legislation initiated by the AMC/NOMA, visit http://www.amcnoma.org/webpages/Arbitration/index.htm . ■

***Dr. John Bastulli,** VP of Legislative Affairs for the AMC/NOMA (far left) and **Dr. Jonathan Myles** (far right) visited recently with the Hon. William Batchelder, a contender for the District 69 seat in upcoming state elections and Sen. Ron Amstutz, regarding potential changes to the arbitration legislation supported by the AMC/NOMA.*

Legislative Advocacy: Another Member Benefit

The AMC/NOMA needs your continued involvement and support in 2006 — as we continue our efforts lobbying the Ohio legislature on your behalf.

The Academy of Medicine Cleveland/Northern Ohio Medical Association asks that you send in you membership renewal promptly to ensure there is no lapse in your benefits and services. As you may already know, unlike other professional associations, the AMC/NOMA has NOT raised dues for more than 8 years! Please remit yours today in support of YOUR regional advocate, supporting the physicians of Northeast Ohio and promoting the practice of the highest quality of medicine for the patients they serve. ■

Program Touts Efforts, Community Service of AMC/NOMA

Ronald Savrin, MD, outlined the many benefits and services of The Academy of Medicine Cleveland/ Northern Ohio Medical Association when he appeared as guest on the weekly *Cleveland Connection* radio show of 102.1 FM WDOK. The Jan. 22nd interview, airing concurrent with the run of our advertising campaign on the station, was intended to highlight the AMC/NOMA's outreach and advocacy as initiated by the strategic planning and its goal of increasing visibility and awareness of the organization.

Dr. Savrin provided a brief historical review of organized medicine in our area, followed by a litany of the public services the AMC/NOMA offers the community including physician referral, the Pollen Line, 400+ Tel-Med topics, *Healthlines* and more.

Program host Jim McIntyre lauded the association's Mini-Internship program, in which he participated in November 2005. "What impressed me most was not the surgical expertise and skill of the physicians, which was very high, but the compassion they showed their patients," he said.

"Well, that's what physicians do," Savrin replied. "It's why we get up in the morning, why we go to work each day. Being a physician is not so much a profession or job as it is a calling."

Talk ensued on the legislative advocacy the AMC/NOMA ardently performs in the state capital. On this point, Dr. Savrin stressed that these efforts have a broad effect.

"Lobbying the legislature and playing the role of political activist is very important for the Academy," he offered, "but it's just as important — if not more important — for the patients in Northeast Ohio."

After touching on medical liability, medical student retention and access to care issues, Dr. Savrin was asked if

***Dr. Ronald Savrin** and Mr. Jim McIntyre following the Cleveland Connection radio interview on the services and benefits the AMC/NOMA offers both its members and the community at large.*

Cleveland was a good place to practice. He concluded: "We're known nationally, but the thing to remember is that although we have outstanding medical organizations, it's ultimately the physicians in this area who provide that service, that make us the best in the world." ■

The Importance of Financial Planning and Working with a Qualified Financial Planner

By: Philip G. Moshier, CFP
In conjunction with Sagemark Consulting, a division of Lincoln Financial Advisors, a registered investment advisor

Would you trust your medical diagnosis to a casual acquaintance? Do you cut your own hair or dry clean your own clothes? For some services, it makes more sense to pay a professional who has the expertise to deliver the best results. A professional financial advisor can help you build a sound estate plan, designed to help you reach your long-term planning goals.

Financial Planning is a comprehensive service. It includes the components of Estate and Asset Protection Strategies, Investment Management, as well as Retirement Planning, just to name a few. It is important to ask yourself the following questions in order to assure that you have a comprehensive plan in place that fulfills your short term as well as long term financial goals.

ESTATE and ASSET PROTECTION STRATEGIES:

- ***Does your current planning take full advantage of the tax credits and deductions provided by the Internal Revenue Code?***
- ***What have you done to mitigate the impact of future estate growth on your estate settlement costs?***

We have developed proprietary software to create an individualized "financial condition model" that addresses these concerns. Your "financial condition model" becomes the foundation for your estate plan. It is the essential tool for helping us determine the long-term adequacy of your financial resources. We work with you to identify the impact of possible future changes that can occur within your estate, and design strategies that help minimize any adverse effects.

INVESTMENT MANAGEMENT

- ***Does your current investment plan address the risk characteristics of your portfolio? Is it consistent with your long-term goals and objectives?***
- ***To what extent have you considered after-tax returns, fees and reporting capabilities?***

We have combined these time-tested beliefs with cutting-edge technology to deliver an innovative approach to manage your wealth. We leverage the power of technology to drive our disciplined five-step process:

Step 1 – Advice, consulting and planning
Step 2 – Portfolio modeling analysis and design
Step 3 – Investment policy statement development
Step 4 – Implementation, manager search and selection
Step 5 – Ongoing monitoring, due diligence and reporting

RETIREMENT PLANNING

- ***Have you done any financial modeling that examines the impact of income and estate taxes on the distribution alternatives you have selected?***
- *How will education funding and other accumulation goals impact your retirement plan?*

A key component of our retirement planning services is providing you with a present value analysis of your current retirement position, then analyze your needs and objectives to determine how much money you expect to spend between now and retirement,. Finally we examine your resources, including current salary, expected payouts from Social Security, your qualified plan benefits and any savings or investments. Where investments are appropriate, we utilize our five-step investment planning process.

Sagemark Consulting's services are offered to members of the AMC/NOMA at a discounted rate. Please review the attached brochure on the firm for further contact information and to take advantage of the financial planning available. ■

SAVE THE DATES

2006 Annual Meeting

Friday, April 28, 2006

Ritz-Carlton Cleveland ✦ 1515 West Third Street

6 p.m. Reception ✦ 7 p.m. Dinner ✦ Black Tie Optional

Induction of the 106th President,
Paul C. Janicki MD

50 Year Awardees - Annual Meeting Honorees

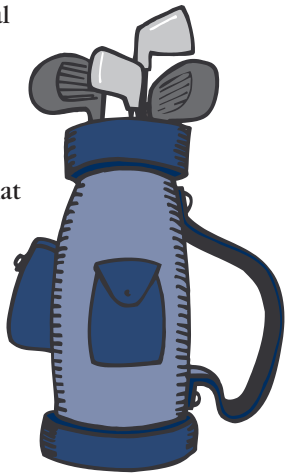
2006 Honorees

John D. Clough, MD
John H. Budd MD Distinguished Membership Award
John H. Sanders, MD
Charles L. Hudson MD Distinguished Service Award
Adrian M. Schnall, MD
Clinician of the Year Award
John F. Shelley, Esq.
Honorary Membership Award
Thomas L. Steinemann, MD
Outstanding Service Award
Michael A. Michael, MD
Special Honors Award

✦ Of special note this year, recipients of the 2006 Academy of Medicine Education Foundation scholarships will be in attendance and presented their awards during the meeting ✦

AMEF Memorial Golf Outing

The third annual **Marissa Rose Biddlestone Memorial Golf Outing** will be held Monday, August 28, 2006, at the Shaker Heights Country Club. Your participation in this charitable event will benefit the Academy of Medicine Education Foundation (AMEF) and its work in this community. Contributions assist in the expansion of educational programs for local medical schools, including the AMEF annual scholarship program as well as many new initiatives that support area physicians and the patients they serve.



For more information, or to register your foursome by phone, contact Linda Hale at (216) 520-1000 ext. 309.

Sharp Rise in *C. Difficile* Colitis

by K.V. Gopalakrishna, MD

Clostridium difficile (C. difficile) is an anaerobic spore forming bacillus, which causes pseudomembranous colitis. The disease associated with C. *difficile,* initially described in 1978, has now become the leading cause of nosocomial diarrhea in the United States and elsewhere.

TABLE 1. Clinical features of *Clostridium difficile*–associated disease (CDAD) in patients* with community and peripartum exposures, by case type and selected characteristics — New Hampshire, New Jersey, Ohio, and Pennsylvania, 2005

	Characteristic															
	Aged ≤18 yrs		Female sex		Previous antimicrobial use†		Contact with gastrointestinal illness§		Bloody diarrhea		Hospitalization necessary for CDAD treatment		Emergency department visit necessary		Relapse	
Type	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Community	11/23	(48)	15/23	(65)	15/23	(65)	7/23	(30)	6/23	(26)	6/23	(26)	3/23	(13)	8/23	(35)
Peripartum	0/10	(0)	10/10	(100)	9/10	(90)	0/10	(0)	2/10	(20)	4/10	(40)	2/10	(20)	5/10	(50)
Total	11/33	(33)	25/33	(76)	24/33	(73)	7/23	(30)	8/33	(24)	10/33	(30)	5/33	(15)	13/33	(39)

* N = 33.
† Defined as receipt of an antimicrobial within 3 months before diarrhea onset.
§ Defined as direct or household contact with another person with diarrheal illness.

Antimicrobial exposure, causing suppression of normal flora of the colon is considered the major risk factor for this disease. Nearly any antibiotic could cause this complication, however clindamycin in the 1970s and cephalosporins in the 1980s have played a prominent role. Metronidazole and oral vancomycin have become the choice of drugs in the therapy of C. *difficile* associated disease (CDAD). One to five percent of affected patients have severe diarrhea, leading to colectomy or death.

In recent years, there has been new information emerging from epidemiological and hospital surveys conducted here and in Canada.

1) Recent reports from CDC[1] indicate presence of severe CDAD in healthy persons living in the community and postpartum women, two populations previously thought to be at low risk.
2) CDC has reported recently[2] doubling of CDAD in U.S. hospitals from 1996 to 2003. The overall rate during this period was several fold higher in persons >65 years of age. They estimate CDAD to have cost >$600 million in excess healthcare costs and >600,000 excess hospital days in non federal facilities.
3) Several recent studies[3, 4] have documented emerging fluoroquinolone-resistant epidemic strain of C. *difficile* responsible for hospital outbreaks in at least 6 US states, Canada and Europe.
4) The C. *difficile* associated mortality per 100,000 discharges has risen from 20 to greater than 50 during the 11 year period between 1993-2003.

TABLE 2. Comparison of molecular characteristics of two *Clostridium difficile* isolates with historical standard-type strains and a recently recognized epidemic strain, by selected characteristics — Ohio and Pennsylvania, 2005

	Strain			
Characteristic	Standard	Epidemic	Ohio	Pennsylvania
Toxinotype	0	III	IX	XIV/XV
PFGE* pattern	<80% related to NAP1†	NAP1	85% related to NAP1	64% related to NAP1
Binary toxin	-	+	+	+
18-bp deletion in *tcdC*	-	+	-	+

* Pulsed-field gel electrophoresis.
† North American pulsed-field type 1.
SOURCE: McDonald LC, Killgore GE, Thompson A, et al. Emergence of an epidemic, toxin gene variant strain of *Clostridium difficile* responsible for outbreaks in the United States between 2000 and 2004. N Engl J Med 2005 (in press).

What can we do to control CDAD?

1) Educate ourselves and patients on the appropriate use of antimicrobials.
2) Better recognize and optimally manage CDAD.[5]
3) Use barrier precautions, isolate the patient, clean environmental surfaces with sporicidal agents and emphasize hand hygiene with soap and water over alcohol-based hand sanitizer as alcohol is not sporicidal.
4) Conduct carefully designed hospital surveillance.

Source: Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report

***Dr. K.V. Gopalakrishna** is a member of the board of directors for the AMC/NOMA, Chairman of Fairview Hospital's Dept. of Medicine as he maintains clinical professorships at both the Case School of Medicine and the Ohio State University Dept. of Medicine. He is board certified in Internal Medicine and Infectious Disease.*

Editor's Note: **The CDC provides an exhaustive list of informative links regarding this subject matter on its "Information for Providers" page at http://www.cdc.gov/ncidod/dhqp/id_CdiffFAQ_HCP.html**

REFERENCES:

1. Severe *Clostridium difficile*-Associated Disease in Populations Previously at Low Risk – Four States, 2005. *MMWR* 2005; 54:1201-1205.
2. McDonald LC, Owings M, Jernigan DB. Increasing rates of *Clostridium difficile* infection among patients discharged from U.S. short-stay hospitals, 1996-2003. *Emerg Infect Dis* [serial of the Internet]. 2006 Mar [cited 2006 Feb 07]. Available from http://www.cdc.gov/ncidod/EID/ vol12no03/05-1064.htm
3. McDonald LC, Kilgore GE, Thompson A, Owens RC et al. An epidemic, toxin gene-variant strain of *Clostridium difficile. N Engl J Med* 2005;353:2433-2441.
4. Loo VG, Poirier L, Miller MA, Oughton M et al. A predominantly clonal multi-institutional outbreak of *Clostridium difficile*-associated diarrhea with high morbidity and mortality. *N Engl J Med* 2005;353:2442-2449.
5. Bartlett JG, Perl TM. The new *Clostridium difficile*-What does it mean? *N Engl J Med* 2005; 353:2503-2505. ■

Legislation Represents Victory, Continued Advocacy Warranted

Dear Colleague:

As the President of The Academy of Medicine Cleveland/Northern Ohio Medical Association, I am pleased to report that the Deficit Reduction Act passed the Congress on Feb. 1, 2006, resulting in a halt to the 4.4 percent Medicare physician payment cut which took effect at the onset of the calendar year. The passage likewise included a one-year freeze on 2006 Medicare reimbursements to physicians at 2005 rates.

As you know, the AMC/NOMA doggedly pursued all available avenues toward this end. Throughout the summer and fall of 2005, we inundated our communications with news of the impending cuts, including several features in the *Cleveland Physician,* links to legislators' emails and sample letters on amcnoma.org as well as consistent coverage in our weekly news bulletins. From encouraging our membership to proactively contact their senators and congressmen and AMC/NOMA's direct communications to the Centers for Medicare and Medicaid Services (CMS), to bringing the message to the local community at large including a segment on the *Healthlines* radio program and a presentation at Tri-C's Encore Program (in which solid AMC/NOMA survey data underscored the access-to-care crisis), our advocacy efforts on your behalf certainly added to the grassroots endeavor.

It is important to note that while CMS has agreed to retroactively adjust claims after the Deficit Reduction Act was signed into law by President Bush, the claims adjustment process will not require that physicians resubmit — and in fact CMS will reopen the 45-day period in which one may change their 2006 participation status.

Although the passage of this legislation represents a victory to physicians across the country, there exists a continued need for advocacy and activism until the Sustainable Growth Rate formula used to configure reimbursements is permanently rectified. Medicare physician payments will continue to be threatened and at the least fail to adequately measure up considering practice cost inflation and other factors. And patients — all patients — will be affected as most private insurers and the Medicaid program use Medicare rates as a resource for their own reimbursements.

For the sake of our patients and our profession, we must not rest easy. Until the inherently flawed SGR formula no longer threatens the rights of our patients, you can be assured the AMC/NOMA will be at the forefront addressing these concerns in our region — on behalf of our membership, and the laudable goal of quality, affordable healthcare for its citizens. ■

George E. Kikano, MD

Be Clear, Consistent in Creating Employee Handbooks for the Medical Practice

by Chandra S. Bowling, Esq.

Creating a well-written employee handbook is an invaluable management tool for any medical practice. It can improve employee morale and loyalty, provide an overview of benefit options, prevent disagreement and confusion regarding company policies and avoid liability in employee lawsuits. In addition, a well-drafted employee handbook provides consistency that promotes a sense of fairness among employees. The handbook can also serve as a guide for managers and supervisors to ensure that they take appropriate action in a given situation, as opposed to being left to their own devices, which can lead to uninformed, inconsistent and possibly illegal decision-making.

When drafting an employee handbook, the tone should be friendly, positive and written in a style that is easy to understand by a diverse group of employees. Care should be taken to draft policies in a clear, careful manner so they will be interpreted the way intended. Avoid absolutes like "will," "must," and other words or phrases that commit an employer to act in a certain way in all instances. Instead, use words such as "may," "can" and "generally."

KEY COMPONENTS IN AN EMPLOYEE HANDBOOK

- **Equal opportunity statement.** Employers should indicate they are committed to equal employment opportunities. The policy should include a list of protected classes (e.g., race, sex, national origin, religion, disability, etc.) and a reporting procedure for alleged violations, including a no-retaliation provision. The policy should also provide procedures employees should follow to request an accommodation for a disability or religion.
- **Compensation and performance information.** Employers should provide the basics for compensation such as pay day, the number of vacation days employees receive and the schedule of paid holidays. Employers can also include general statements about how wage increases are handled, employee classification and policies on performance reviews so employees will know exactly how often they will be evaluated.
- **Work rules.** This section should include an employee code of conduct. This ensures that all employees are aware of the employer's expectations. This can include policies governing dress code, attendance, how employees should greet customers when they answer the telephone, alcohol use, drug and tobacco use in the workplace along with job responsibilities, use of computers and abuse. Employers should also set forth work hours, with expected start and dismissal times.
- **Leave of absence.** In this section, employers should indicate their policies regarding the amount of time employees can take off for medical reasons, including how long employees can remain on leave and still maintain group health benefits before being transferred to COBRA. In addition, if a medical practice has 50 or more employees (or is within 75 miles of another office which combined have at least 50 employees), then the practice falls under the federal Family and Medical Leave Act ("FMLA"). Under FMLA, employers are required by federal law to communicate FMLA rights in writing to its employees. These rights include that an employee can receive a total of 12 weeks of unpaid leave during a 12-month period for qualifying reasons — caring for a newborn or newly adopted child; caring for a spouse, parent or child with a serious medical condition; or the employee's own serious health condition. Employers can require employees to use available paid vacation, sick leave or personal leave to substitute for all of the 12-week FMLA leave. For purposes of FMLA, the 12-month period can be defined in several ways. Employers may use the calendar year, a fixed 12-month leave year, or a "rolling" period, which excludes the possibility of an employee taking 12 weeks of leave at the end of one fixed period only to take 12 more weeks at the beginning of the next fixed period. Employers must clearly designate their method for calculating the 12-month period, preferably in an employee handbook. In the absence of such a designation, employees are allowed to calculate leave under whatever method is most beneficial to them.
- **Overview of employer benefits.** Employers should provide a brief description of benefits available to employees. Typically, full detail regarding health and pension plans are set forth in plan descriptions contained in other documents; however, employee handbooks should provide a brief summary of benefit options and indicate where further information can be found.
- **Nonharassment policies.** It is critical that employers set forth a procedure for reporting sexual or other forms of harassment. Rather than focusing on violations of law, the policy should be clear that there is zero-tolerance for workplace harassment and provide guidance about the employer's expectations for appropriate workplace behavior. The policy should include a detailed reporting and investigating procedure as well as a no-retaliation provision. The reporting procedure should be consistent with the reporting procedures set forth in the employer's Equal Employment Opportunity policy.
- **At-will employment disclaimer.** This statement should provide that employees are "at-will" and the employment relationship may be terminated by the employer or the employee at any time, for any reason, with or without cause or notice. The disclaimer should appear prominently within the handbook and be in large and/or bold type print.
- **Acknowledgement.** All employees should be required to sign an acknowledgement statement that is placed in their employment files. The acknowledgement statement records the employee's receipt and understanding of the handbook and should reiterate the employee's at-will relationship with the employer.

Once you have created an employee handbook, it is a good idea to have your attorney review it prior to implementation. When introducing it to your

(Continued on page 18)

AMA Signs Agreement to Develop Physician Performance Measures

The AMA has signed a pact with Congress to develop more than 100 standard measures of performance, which doctors will report to the federal government. The performance measures are supposed to focus on diagnostic tests and treatments that are known to produce better outcomes for patients. In 2007, the agreement says, doctors will voluntarily report to the federal government "on at least 3 to 5 quality measures per physician." In addition, doctors "should receive" some additional payment to offset the costs of collecting and reporting the data. The pact states that by the end of 2077 physician groups will have developed performance measures to cover a majority of Medicare spending for physician services. Many medical specialty societies around the country were already developing performance measures and have objected to this confidential pact promulgated by the AMA and its timetable for assessing doctors' performance. Presidents of several specialty groups said they had not been consulted or informed and have written to the AMA stating that the AMA agreed to the imposition of P4P without getting an assurance that doctors would be adequately paid for treating Medicare patients. The Medicare payment system for each physician service was frozen this year. Under current law, doctors face cuts of more than 4.5 percent in each of the next eight years. Congress has often intervened to prevent or delay cuts. Congress could stipulate that doctors must report measures of clinical performance as a condition of getting a small increase in Medicare fees. Many specialty groups have written to Congress stating that the AMA cannot be the sole representative for the groups who are paramount to the development and implementation of quality measures. The AMC/NOMA will continue to monitor how this develops and provide additional information to our membership.

NPI Update

January marked the onset of claims filing with the use of the newly assigned National Provider Identifiers or NPI for Medicare claims, but remember — CMS says it must be listed in addition to your PIN or UPIN or one may expect their claim to be return unpaid. The use of the NPI on the claim is considered phase II of the transition to NPI from the current PIN/UPIN numbers. From now until Oct. 1, 2006, you are not required to use the NPI on a claim, however, the 10-digit NPI unique identifier set must be used on all health care claims, regardless of the payer, by May 23, 2007, or May 23, 2008 for small practices and health plans. Before you use the NPI on a Medicare claim, make sure your claims software or clearinghouse can handle the identifier. Have questions on the NPI? Go to http://www.cmsd.hhs.gov/NationalProvIdentStand/.

Physician Voluntary Reporting Program (PVRP)

The PVRP is changing — CMS has adopted a smaller core starter set of 16 measures (see pullout box on page 5). Physicians participate in PVRP by adding additional codes, called G-codes, to their Medicare claims forms. CMS has indicated it intends for PVRP to be a temporary measure and that any permanent physician pay-for-performance program will be accomplished through health information technology, rather than G-codes. For more information go to the Palmetto Web site at www.palmettogba.com

Elimination of Surrogate UPINs on Medicare Claims

CMS will not longer accept the Surrogate UPIN OTH000 to identify the ordering or referring physician claims effective for dates of service from 4/1/06 and later.

Responding to a HIPAA violation

Violations of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) can happen in your office or facility. The most likely scenario is the verbal disclosure of protected health information. If a provider takes proactive measures to prevent such violations and addresses HIPAA complaints appropriately, the liability associated with a HIPAA violation will be minimized.

Simple rules for avoiding verbal HIPAA violations

- Professionals should only share patient information if there is a legitimate professional reason to do so.
- Common area conversations should be avoided.
- Patient issues should not be discussed in a common area of the office unless the area is closed to third parties (i.e., drug representatives, patients, etc.) and the staff is aware that conversations in the area may be protected under HIPAA.
- Information should never be repeated outside of the office.

Responding to the allegation of a HIPAA violation

Upon receipt of a HIPAA complaint, a provider has an obligation to:

1. Document the complaint;
2. Determine if a violation occurred and how information was disclosed;
3. Mitigate damages and take steps to prevent further disclosure of information;
4. Provide the patient with an accounting of the disclosure upon request;
5. Apply sanctions against employees who fail to comply with HIPAA policies;
6. Keep a record of the sanctions that have been applied.

Imposition of employee sanctions

HIPAA requires that appropriate sanctions be imposed against employees who violate the Privacy Standards. These sanctions may take the form of a reprimand, requirement to attend additional training classes, suspension without pay, or even termination. It is important to understand that implementing sanctions against an employee may raise employment law issues and the HIPAA compliance officer should consult with a labor attorney prior to imposing sanctions in order to minimize liability.

HIPAA follow-up

The privacy officer must take appropriate steps to avoid future disclosures of confidential information. These steps may include additional HIPAA training, circulation of an interoffice memo or the revision of office policy. As a proactive measure, a provider should identify high-risk areas in the practice setting that pose a high probability of breach of confidentiality.

HIPAA enforcement

The DHHS Office of Civil Rights (OCR) is charged with enforcing the Privacy Rule. OCR's enforcement initiative is to promote voluntary compliance with the Privacy Rule. If you are contacted by OCR, you should immediately contact your legal counsel. Your legal counsel should be your contact person for the investigation. ■

Be Clear, Consistent in Creating Employee Handbooks for the Medical Practice

(Continued from page 16)

employees, you can help to alleviate any concerns by explaining that the handbook does not constitute a change in policies, but merely serves to put the policies, practices, and standards that the organization has always followed into writing. Once the handbook is in place, it is important that the policies be consistently and fairly applied to all employees. It is also important to update your handbook regularly and to change any policies, if needed, to conform to the actual practice of the employer or changes in the law.

Having a workforce which understands its expectations can then better focus on the needs of patients. A solid employee handbook will outline those expectations and can serve as an opportunity to establish strong relationships with your employees which in the end, will breed increased loyalty and productivity.

Editor's Note: Chandra S. Bowling is an associate with Squire, Sanders & Dempsey L.L.P. based in Cleveland. She focuses her practice in the areas of private and public sector labor and employment law. She can be reached at cbowling@ssd.com. ■

Welcome 2006-2007 AMC/NOMA Group Members

The Academy of Medicine Cleveland/Northern Ohio Medical Association gratefully acknowledges the following for their support of organized medicine in our region:

Marymount Hospital Group

University Hospitals Dept. of Obstetrics & Gynecology Group

Lutheran Hospital Group

University Hospitals Dept. of Anesthesia Group

UHHS Richmond Heights Hospital Group

The AMC/NOMA is pleased to have the support of these group members. The AMC/NOMA is more than 4,000 strong and we are proud to represent the physicians in Northern Ohio. Did you know that your hospital medical staff is eligible for group membership? For information on group dues or AMC/NOMA membership contact Linda Hale at (216) 520-1000 ext. 309. ■

CUYAHOGA COMMUNITY COLLEGE'S CENTER FOR HEALTH INDUSTRY SOLUTIONS

Discounted Class List for members of
The Academy of Medicine Cleveland/Northern Ohio Medical Association

- **CMC by PMI (35 CEU-AAPC, PMI)** March 1, 8, 15, 22, 29
- **CCS CERTIFICATION EXAM REVIEW for AHIMA Exam** Mar. 18
- **ADVANCED ICD-9-CM CODING CONCEPTS (4 CEU-AAPC, PMI)** Mar. 22
- **CPC CERTIFICATION EXAM REVIEW for AAPC Exam** April 8
- **CCS-P CERTIFICATION EXAM REVIEW for AHIMA Exam** April 22
- **CPC-H CERTIFICATION EXAM REVIEW for AAPC Exam** April 29
- **RADIOLOGY: HIGH TECH/DEMAND CODING (3 CEU-AAPC, PMI)** April 26
- **CMC by PMI (35 CEU-AAPC, PMI)** May 10, 17, 24, 31, June 7
- **CHART AUDITING by PMI (6 CEU-AAPC, PMI)** June 8
- **MEDICAL TERMINOLOGY/ANATOMY & PHYSIOLOGY (30 Hours)** May 1-June 7
- **MEDICAL CODING FUNDAMENTALS (48 Hours)** Mar. 6-April 26, Mar. 14-May 4
- **CUSTOMER SERVICE WORKSHOP FOR HEALTH CARE (3.5 Hours)** April 27

Members and/or their staff will need an exclusive AMC/NOMA course number to register and obtain their discount. For course numbers, call Linda Hale of AMC/NOMA at (216) 520-1000, ext. 309, or email lhale@amcnoma.org. For course information visit www.advancecareer.info, or contact Tri-C's Center for Health Industry Solutions at (216) 987-3071. ■

CLASSIFIEDS

The Academy of Medicine Cleveland/Northern Ohio Medical Association Medical Records Fact Sheet Update Effective January 2006

Retention of Medical Records

Medical considerations are the key basis for deciding how long to retain medical records. Rules relating to the maintenance of patient records are to be found in the American Medical Association, Council on Ethical and Judicial Affairs, Code of Medical Ethics. Current Opinion **7.05.** Under Ohio Law (R.C. §**4731.22 (B)(18)**), violations of the AMA ethical rules can result in disciplinary action by the Ohio State Medical Board. Most states, including Ohio, do not have a general state law that requires records be kept for a minimum length of time. Ohio Revised Code §**2913.40 (D)** mandates the retention of records associated with Medicaid for a period of at least six (6) years after reimbursement for the claim is received by the physician. It is recommended that records relating to a Medicare patient be kept for at least six (6) years after the physician received payment for the service. Medicare's Conditions of Participation requires five (5) year retention. Managed care contracts should be consulted to see if they provide any specified period of retention of medical records. In all cases, medical records should be kept for the length of tine of the statute of limitations for medical malpractice claims. Under Ohio Law an action for medical malpractice must be brought within one year after the cause of action "accrues" (R.C. §**2305.113**). However, there are various exceptions or special rules. For example, the statute of limitations in wrongful death cases is two years after the date of death. In the case of a minor, the statute of limitations does not begin to run until the minor has reached his or her 18th birthday. The statute can be "tolled" or otherwise extended in other situations, and the date on which a cause of action "accrues" can vary. As a practical matter, all of this makes it difficult to define the Ohio statute of limitations with absolute certainty. If you are discarding or destroying old records, patients should be given the opportunity to claim the records or have them sent to another physician. The AMC/NOMA recommends that physicians keep medical records indefinitely, if feasible.

Update on Charging for Copies of Medical Records

A physician who treated a patient should not refuse for any reason to make records of that patient promptly available on request to another physician presently treating the patient, or, except in limited circumstances, refuse to make them available to the patient or a patient's representative (not an insurer). A written request signed by the patient or by what the law refers to, as a "personal representative or authorized person" is required. Ohio Revised Code §**3701.74** obligates a physician to permit a patient or a patient's representative to examine a copy of all of the medical record. An exception arises when a physician who has treated the patient determines for clearly stated treatment reasons that disclosure of the requested record is likely to have an adverse effect on the patient, in which case the physician is to provide the record to a physician chosen by the patient. Medical records should not be withheld because of an unpaid bill for medical services. Ohio law establishes the maximum fees that may be charged by health care provider or medical records company that receives a request for a copy of a patient's medical record. Ohio law provides for certain limited situations in which copies of records must be provided without charge, for example, where the records are necessary to support a claim by the patient for Social Security disability benefits. **EFFECTIVE JANUARY 2006**, the maximum fees that may be charged, are as set forth below.

(1) The following maximum fee applies when the request comes from a patient or the patient's representative.

a) No records search fee is allowed;
b) For data recorded on paper: $2.59 per page for the first ten pages; $0.53 per page for pages 11 through 50; $0.21 per page for pages 51 and higher
For data recorded other than on paper: $1.76 per page
c) Actual cost of postage may also be charged

(2) The following maximum applies when the request comes from a person or entity other than a patient or patient's representative.

a) A $15.87 records search fee is allowed;
b) ***For data recorded on paper***: $1.05 per page for the first ten pages; $0.53 per page for pages 11 through 50: $0.21 per page for pages 51 and higher
For data recorded other than on paper: $1.76 per page
c) The actual cost of postage may also be charged

Ohio Law requires the Director of Health to adjust the fee schedule annually, (January of each calendar year) to reflect an increase or decrease in the Consumer Price Index over the previous 12-month period. If you have any questions regarding this fact sheet or other practice management issues, please contact the AMC/NOMA at (216) 520-1000.