#### Law Offices SCHWARTZ, METZ & WISE, P.A. A PROFESSIONAL ASSOCIATION

10 WEST MADISON STREET BALTIMORE, MARYLAND 21201

www.schwartzmetz.com

BALTIMORE TELEPHONE: 410-244-7000

TELEPHONE: 410-269-1618 FACSIMILE: 410-332-4505 FACSIMILE: 410-269-5443

ANNAPOLIS

# **MedChi Final Report**

## **April 11, 2011**

## Introduction

The 428<sup>th</sup> Session of the Maryland General Assembly concluded at midnight on Monday, April 11<sup>th</sup>. In its 428<sup>th</sup> Session, the General Assembly considered 2,370 legislative bills and resolutions.

For its part, the MedChi Legislative Committee reviewed and commented on 205 of these proposals.

For the General Assembly, this was the first year of a four year term with approximately one-third of the elected officials being new to the General Assembly. The initial year of a term is typically non productive in the sense that significant proposals are usually enacted in the second and third year of the four year term. This was certainly true in 2011 when even several of the Governor's legislative proposals foundered (regulation of septic systems in rural areas, offshore electrical wind turbines).

Surprisingly, several big proposals were successful. The General Assembly enacted a new sales tax on alcohol which was considerably less than the "dime a drink" proposal (90 million a year as opposed to 210 million a year). Moreover, most of the new revenue was seized by the local counties for school construction with only \$15 million (15 million out of 90 million) being given to the disability community. Nevertheless, this tax increase was significant. Additionally, in state tuition for illegal immigrants was approved although another big issue – gay marriage – did not pass due to opposition in the House of Delegates. Hence, there was significant legislation passed in this first year and it is likely that bills that were unsuccessful this year will be reconsidered in 2012.

## MedChi Agenda

MedChi's Agenda, however, was remarkably successful. Three MedChi initiatives which were dictated by the MedChi House of Delegates were enacted into law. Two of the initiatives involved Electronic Health Records (EHR).

House Bill 736/Senate Bill 722 (Electronic Health Records – Incentives for Health Care Providers – Regulations) are on the Governor's desk. These bills provide that the incentive program for EHR must be paid in cash by insurance companies to a participating physician. This legislation is the completion of a MedChi initiative first begun in 2009. Maryland is the only state in the nation which requires health insurance companies to provide incentives for EHR adoption. As a result of the 2009 legislation, the Maryland Health Care Commission (MHCC) was detailed to establish a one-time payment to Maryland doctors for EHR adoption. The MHCC convened all stakeholders in this process in December 2010 to propose regulations which established a one-time payment to Maryland primary care doctors (broadly defined) of \$8.00 per patient (not to exceed \$15,000 per practice) from each insurance carrier. However, these regulations did not require "up front" cash unless both the doctor and the carrier agreed. However, many small primary care practices needed "up front" cash in order to afford EHR adoption. House Bill 736/Senate Bill 722 changed the regulation so as to allow the doctor to demand "up front" cash. In addition, the legislation directed MHCC to study the expansion of the incentive beyond primary care and to deliver a report to the General Assembly on this issue on or before January 1, 2013. Delegate Shawn Tarrant was the sponsor of House Bill 736 and Senator Jim Rosapepe the sponsor of Senate Bill 722. For MedChi, this bill was the "capstone" of a successful 2011 General Assembly Session.

Additionally, House Bill 784/Senate Bill 723 (*Medical Records – Health Information Exchange*) was another MedChi supported initiative which prohibited Maryland's Health Insurance Information Exchange (Exchange) from selling "de-identified" health insurance information prior to the issuance of regulations specifying privacy protections. The bill was amended to reflect a Resolution of the MedChi House of Delegates designed to control the sale of health information by insurance intermediaries such as Axolotl, a company which has a business relationship with the Exchange.

The Exchange is currently being developed to serve as the network over which EHR records will be transferred from one health provider to another. While the Exchange is under the supervision of MHCC, it has designated a group known as CRISP to actually operate the Exchange. While CRISP is dedicated to the privacy of health information, it has relationships with groups such as Axolotl which is a for profit company in the business of selling health insurance data. While CRISP had amended its contract with Axolotl to provide for increased confidentiality, the passage of House Bill 784/Senate Bill 723 insures that such information will be protected by Maryland law over and above any contractual undertaking. The details of House Bill 784/Senate Bill 723 respecting the sale of health information were negotiated by CRISP representatives and Gene Ransom, the Executive Director of MedChi.

A third MedChi initiative which is on the Governor's desk is Senate Bill 371/House Bill 306 (*Health Occupations Boards – Discipline of Health Care Practitioners – Failure to Comply with Governor's Order*). This bill came within seconds of passing in 2010 when it was next up for final vote when the witching hour of the General Assembly tolled and time ran out. This proposal removes the criminal penalty for a doctor who does not respond positively to a Governor's Emergency Order. MedChi President David Hexter had noted a number of years ago when the Governor's Emergency Order legislation passed and was advertised as a "model" state law that the Maryland version contained a criminal penalty for physician refusal whereas the true "model" only required disciplinary action against the physician. Dr. Hexter then proposed, and the MedChi House of Delegates agreed, that the Maryland law should be amended to be truly reflective of the model law. Senate Bill 371/House Bill 306 accomplish that objective.

## **Specialty Initiatives**

Various medical specialties had legislative initiatives. The Maryland Society of Eye Physicians and Surgeons (MSEPS) proposed, initiated and had enacted Senate Bill 701/House Bill 888 (*Health Insurance – Prescription Eye Drops – Refills*) which brings Maryland law into compliance with current Medicare guidelines. The new Maryland law will make the Medicare rule with respect to early refill of prescription eye drops applicable to non-Medicare patients insured by Maryland health insurance companies. The guidelines in question provide insurers must refill prescription eye drops if the patient runs out of eye drops by the 21<sup>st</sup> day or later of a 30 day prescription. In enacting Senate Bill 701/House Bill 888, MSEPS was able to achieve the same victory for Maryland patients that the American Academy of Ophthalmology had achieved not long ago with respect to Medicare patients.

Dermatology was not as successful with respect to Senate Bill 604/House Bill 1111 (*Tanning Devices – Use by Minors – Prohibition*). This proposal would change Maryland law by forbidding commercial tanning salons from offering ultraviolet tanning to minors. At the current time, Maryland allows minors to receive ultraviolet tanning with the written permission of their parents. The House Economic Matters Committee amended the bill to forbid children under 14 to tan but to continue parental consent from ages 14 to 18. The proponents of the bill which included the American Academy of Dermatology as well MedChi and the American Cancer Society asked the committee to vote down the bill as it would have been a prohibition not worth having. The good news: members of the House Economic Matters Committee were considerably more supportive of the ban this year than they had been in past years and it may well be that 2012 will be a year when success can be achieved.

Senate Bill 808/House Bill 782 (*Health Occupations – Imaging and Radiation Therapy Services – Accreditation*) was a initiative of several specialties (orthopedics, urology, cardiology, etc.) to change Maryland law to allow items such as MRIs, CAT scans and radiation therapy to be performed by doctors who were not radiologists. It was opposed by radiology.

Since 1993, Maryland law has confined certain activities to the exclusive province of radiology in the interest of preventing self-referral. Maryland has the strictest law in the nation - which does not seem to have reduced the percentage of imaging as it is reported that Maryland has the second highest use of imaging in the country.

This fight among specialties has been avoided by MedChi which has historically taken no position on such bills. The current flurry of activity was precipitated by a final decision of the Court of Appeals of Maryland in January 2011 which removed all doubts that certain imaging equipment could not be owned by orthopods, urologists and others. It would appear that the most responsible thing for MedChi to do – given the conclusion of the Court case – is to convene a Blue Ribbon Task Force to consider all issues in this dispute and hear all parties during the coming months with an eye toward seeking the passage of a Resolution in the fall meeting of the MedChi House of Delegates. It now seems clear that MedChi needs to be an "honest broker" between specialties rather than a non-participant and owes it both to its members and to the development of Maryland public policy to weigh in on this dispute.

## **Trial Lawyer Initiatives**

Senate Bill 887/House Bill 340 (*Health Care Malpractice – Certificate and Report of Qualified Expert – Objection*) was an initiative of the Trial Lawyers Association which has renamed itself as the Maryland Association for Justice. This legislation affected the filing of expert certificates and reports of medical malpractice cases. It addresses the situation where an expert report was dismissed by a judge. If enacted, Senate Bill 887/House Bill 340 would have allowed the refiling of an inadequate expert certificate and report at any time that another filing was deemed insufficient. Indeed, it would have allowed a 2<sup>nd</sup>, a 3<sup>rd</sup>, a 4<sup>th</sup> time, etc.

The plaintiff's lawyers were joined by Harry Chase who is the Director of the Health Care Arbitration Office in supporting the bill and had been filed by two veteran members of the House Judiciary Committee. Nevertheless, the House Judiciary Committee unanimously rejected the bill.

#### Federal Health Care Reform

The O'Malley Administration proposed two bills to bring Maryland law into compliance with the new federal health care law. Senate Bill 182/House Bill 166 (*Maryland Health Benefit Exchange Act of 2011*) created an Insurance Exchange where individuals could secure health insurance. The federal health care legislation required states to set up such Insurance Exchanges and Senate Bill 182/House Bill 166 was Maryland's attempt to do so.

Senate Bill 183/House Bill 170 (*Health Insurance – Conformity with Federal Law*) was the second initiative designed to replicate provisions of Federal Health Care Reform as they now stand with respect to new legal requirements on insurance companies relating to such things as pre-existing conditions and loss ratio.

Both initiatives were enacted although the Insurance Exchange bill was extensively amended to accommodate concerns of a wide variety of stakeholders including the health insurance agent and broker community. In addition, the final version required that the Insurance Exchange – once operational – had to return to the General Assembly for additional authority to operate.

## "Ethical" Regulation of Doctors

House Bill 818 (Manufacturers of Prescribed Products – Payments to Health Care Professionals – Prohibition) was an attempt to copy legislation in Vermont and Massachusetts which severely restricts pharmaceutical and medical device manufacturers from supporting doctors and various medical meetings. This legislation was generated in part with the controversy surrounding Dr. Mark Midei and the St. Joseph's Hospital heart program which is now being investigated by the federal government and the Maryland Board of Physicians. The bill, as drafted, would have effectively outlawed financial support of hundreds of medical conferences, health fairs and medical screenings which are presently performed.

When House Bill 818 was originally introduced, it appeared to have considerable political weight behind it. However, the flaws in the legislation became apparent during the hearing with the result that the sponsor of the bill "withdrew" it from consideration shortly after the hearing. This is an issue that is sure to be pursued in 2012 as the Health Secretary has indicated that he desires to study this issue over the interim.

## The One That Got Amended

Senate Bill 883/House Bill 1229 (*Prescription Drug Monitoring Program*) was enacted to establish a Prescription Drug Monitoring Program (PDMP) for the State of Maryland. The Program will be housed in the State Health Department and will be a central repository of information about schedules II, III, IV and V drugs. MedChi members Robert Lyles, Jr., M.D., Nicolette Martin, M.D. and Marcia Wolf, M.D. were actively involved in crafting and arguing for appropriate amendments for this bill to reduce the "chill" on physician prescribing practices.

The Governor became personally involved in passing this bill and a number of MedChi amendments were added to the final version. MedChi is appreciative of the work of the Senate Finance Committee and particularly Senator John Astle and Senator E.J. Pipkin for raising concerns about the bill. Unfortunately, the House HGO Committee denied all MedChi efforts to amend the bill. The Senate amendments, which were included in the final bill sent to the Governor, included the following changes proposed by MedChi:

- 1. Neither physicians nor dispensers of prescription drugs may be charged a fee to support this Program;
- 2. The Advisory Committee which had originally been weighted toward law enforcement individuals (federal and state drug enforcement, licensing boards and representatives of the State Health Department) is now weighted toward health professionals. (9 health professionals including 5 physicians, 1 nurse practitioner and 3 pharmacists, with 2 patient representatives and only 6 "law enforcement" representatives to include the Health Department, licensing boards and a local law enforcement official);
- 3. "Law enforcement" officials (to be understood as Health Department employees, licensing board representatives and federal, state and local law enforcement) are now restrained from accessing the PDMP unless it relates to a "...existing bona fide individual investigation";
- 4. Moreover, such requests from law enforcement will be reviewed by a Technical Advisory Committee (TAC) composed of 4 physicians and 1 pharmacist;
- 5. The TAC shall review all requests for information and provide clinical guidance and interpretation of the information to assist in how to respond to a judicial subpoena (federal, state and local law enforcement), or an administrative subpoena (licensing board). The TAC will provide clinical guidance and interpretation of the information requested to the party requesting a subpoena;

- 6. With respect to an administrative subpoena (a licensing board such as the Board of Physicians), an additional protection requires that such subpoena may not be issued by licensing board staff but must be "voted on by a quorum of the board of the licensing entity..."
- 7. On or before December 1, 2012, the Advisory Board shall report to the legislative committees on various issues including the status and funding of the Program and as to "whether a legislative safe harbor provision is recommended to address any access issues experienced by patients after implementation of the Program."
- 8. The PDMP will be required to supply the necessary software at no cost to dispensers of prescription drugs including physician dispensers. The technology of the program will be designed so that it is not subject to manipulation by a recipient of the data;
- 9. The initial provisions of the bill exempting Health Department employees from improper disclosure of the information has been stricken and it now provides any person who knowingly discloses the information in violation of the law shall be guilty of a criminal misdemeanor;
- 10. Moreover, the legislation contains a statutory admonition that the data may not be used "...as the basis for imposing clinical practice standards."
- 11. The Administration actually proposed an amendment (strongly objected to by MedChi) that the Program should consider "protocols ... to assist prescribers in patient care ..." MedChi lobbyist Jay Schwartz testified that it was "unthinkable" that a Health Department bureaucrat should be advising a doctor on patient care. The Senate Finance Subcommittee unanimously rejected that proposal.

Perhaps the most important MedChi amendment was the creation of the physician dominated TAC which consists of 5 health care professionals (4 doctors and 1 pharmacist). The TAC will review any requests for information from law enforcement (broadly understood) prior to the program being allowed to release the information in response to either a judicial subpoena, an administrative subpoena or any legal request. While MedChi supported the Program for its clinical value, it remains extremely skeptical of the law enforcement component. However, the amendments – with the restructuring of the Advisory Committee, the creation of a physician directed TAC and limitation of law enforcement access with recommendations from the TAC – make the legislation considerably more patient friendly than was the case at the beginning. Since the PDMP is not currently funded in the upcoming FY 2012 state budget and it may not rely on fees assessed to physicians and pharmacists, it will only become operational if it obtains adequate federal funds. Federal funding is not assured although the state has indicated that it will apply for various federal grants which are available.

This particular legislation was one "sleeper" in the 2011 Session but it united the physician community from pain management specialists to pediatricians to demand and effect the changes and amendments iterated above.

## Scope of Practice and Regulatory Issues

House Bill 100/Senate Bill 560 (Health Occupations—State Board of Naturopathic Medicine) would have licensed the practice of naturopathy in the State, making Maryland one of only 15 states that license this practice. MedChi opposed this legislation and it was defeated in both the House and Senate committees of jurisdiction. As proposed, the legislation adopted a scope of practice which was nearly identical to the practice of medicine as defined under the physician scope of practice. MedChi leadership met with representatives of the proponents in March, and while that dialogue may continue, significant changes in this legislation will have to be made before MedChi will change its position.

The pharmacists introduced a number of bills designed to limit physicians' ability to dispense pharmaceuticals and to expand pharmacists' ability to administer vaccines, particularly to children. (House Bill 986 – Pharmacist – Administration of Vaccines – Children; House Bill 1268/Senate Bill 884 – Prescription Drugs – Dispensing Permits; Senate Bill 713 – Pharmacists – Administration of Vaccines – Regulations; and Senate Bill 845 – Administration of Vaccines – Epinephrine and Diphenhydramine). The physician community was successful in defeating all of the proposals with the exception of change in the authority to administer the flu vaccine. DHMH Secretary Sharfstein was concerned about adequate access to the flu vaccine and advocated for a change to allow pharmacists to administer the flu vaccine to children 9 years of age and older. That change was enacted into law but the Department worked in concert with the physician community to defeat the balance of the legislative proposals. Undoubtedly, the pharmacists will return in next year's Session.

Senate Bill 5 (*Physicians—Medical Professional Liability Insurance Coverage—Notification and Posting Requirements*) would require physicians to provide notice to patients if they do not maintain malpractice insurance. No action is required by physicians who maintain insurance. MedChi supported this effort, as it has in the last several years. The bill passed the Senate but died in the House Health and Government Operations Committee.

House Bill 286 (Hospitals and Freestanding Ambulatory Care Facilities—Practitioner Performance Evaluation) requires that hospitals and freestanding ambulatory care facilities maintain a system to review practitioner performance as a condition of licensure. Much of what the bill requires is existing law in terms of peer review at hospitals. This legislation came about as a result of the St. Joseph Medical Center open heart controversy, and was intended to ensure that hospitals are properly reviewing utilization matters. Likewise, House Bill 600 (Health Care Providers—Investigations—Information Sharing Among State Agencies) allows the Health Services Cost Review Commission to disclose certain identifying physician information to the Office of Health Care Quality (OHCQ) and an investigatory body under the State or federal government. In addition, the bill requires the State Board of Physicians to disclose, for the purpose of investigating quality or utilization of care in an entity regulated by OHCQ or HSCRC, any information contained in a record to the Secretary of Health and Mental Hygiene, OHCQ, or HSCRC. The information continues to be protected from discovery in a legal proceeding. The Department of Health and Mental Hygiene will promulgate regulations to implement House Bill 600.

#### Public Health Issues

Senate Bill 771/House Bill 858 (*Education –Public Schools and Youth Sports Programs – Concussions*) passed on the final day of the Session. This initiative is the culmination of a two year intensive stakeholder deliberation. It requires the Maryland State Department of Education, in conjunction with a wide range of stakeholders, including licensed health professionals who treat concussions, to develop policies and implement a program to provide concession awareness to coaches, school personnel, students, and parents. Furthermore, the bill requires that a student or youth athlete who is suspected of sustaining a concussion or other head injury be removed from play. Once removed, a student or youth athlete may not return to play until he or she has obtained written clearance from a licensed health care professional trained in the evaluation and management of concussions.

Senate Bill 424/House Bill 196 (*Motor Vehicles –Use of Text Messaging Device While Driving – Prohibited Acts*) strengthens Maryland's ban on text messaging by including e-mail in the prohibition, clarifying that it applies to writing, sending and reading messages and further clarifies that the ban applies whenever one is in the travel portion of the roadway. These changes are in accordance with MedChi's House of Delegates Resolution calling for a ban on text messaging.

Senate Bill 743/House Bill 778 (Family Planning Works) was enacted. It extends benefits for family planning services to all women with family incomes at or below 200% of poverty regardless of whether they have had a child. Under current law, women with family income at or below 116% of poverty are eligible for family planning services. Women with family income at or below 200% of poverty are also eligible but only if they deliver a child under the Medicaid program. These women retain their family planning services but only for 5 years and must reaffirm their eligibility every year. The expansion enacted through this legislation will ensure that women at risk for unintended pregnancies, low-birth weight infants, poor pregnancy outcomes and other health complications will now have access to vital women's health and family planning services. It is estimated that more than 30,000 women will be newly eligible effective July 1, 2011. Funding for this expansion comes initially from federal grant dollars and is sustained through the significant projected cost savings associated with a decrease in the number of unintended pregnancies, poor birth outcomes, etc.

Senate Bill 786/House Bill 714 (Health Newborn Screening Program – Critical Congenital Heart Disease) requires the Department of Health and Mental Hygiene (DHMH) to adopt any federal recommendations that may be issued by the Secretary of Health and Human Services on the critical congenital heart disease screening of newborns. In addition, the bill requires the State Advisory Council on Hereditary and Congenital Disorders to develop recommendations on the implementation of critical congenital heart disease screening of newborns in the State. The Advisory Council must convene experts and affected stakeholders to examine the impact of implementing mandatory critical congenital heart disease screening. The Advisory Council must also review relevant studies and literature. The Advisory Council must submit its findings and recommendations by December 31, 2011.

The General Assembly did strengthen Maryland's ignition interlock program. There were a number of bills introduced, some mandatory and some permissive. The final legislation adopted (House Bill 1276/Senate Bill 803 – Drunk Driving Reduction Act) requires the MVA to establish an interlock program and mandates the participation of a driver as a condition of modification of a license suspension or revocation of a license or the issuance of a restrictive license if the driver is required to participate by a court order; is convicted of driving while under the influence of alcohol or under the influence of alcohol per se and had a blood alcohol concentration (BAC) at the time of testing of 0.15 or greater; is convicted of driving while under the influence of alcohol, under the influence of alcohol per se or while impaired by alcohol and within the preceding five years was convicted of any specified alcohol and/or drug-related driving offense; or was younger than age 21 and violated the alcohol restriction imposed on the driver's license or committed the specified alcohol-related driving offense.

A driver who is required to participate in the program under the bill must be in the program for six months the first time the requirement is imposed. For the second time, the driver must participate for one year. For the third or any subsequent time the requirement is imposed, the driver must participate for three years. A court and MVA may also impose a longer participation period in accordance with other Maryland Vehicle Law provisions.

The bill also expands the discretionary participation by authorizing MVA to include an individual who is currently prohibited from participation in the program under the "administrative *per se*" statute. This authority applies to a driver who takes a test of blood or breath with a BAC result of at least 0.08, but less than 0.15, and who is otherwise ineligible for modification of a license suspension or issuance of a restrictive license under existing provisions.

## Miscellaneous

Senate Bill 561/House Bill 1063 (*Health Insurance– Health Care Providers – Payment of Claims for Reimbursement by Carriers*) was a MedChi initiative directed at out-of-state insurance companies who did not abide by Maryland law respecting payment to physicians who treated insureds in Maryland. The bill was very controversial and raised animated opposition from most of the national insurance companies although, in fact, most of the abuses identified by MedChi were the result of the so called Blue Card Program operated in Maryland by CareFirst. The bills were unsuccessful but it appears that they may have been unnecessary. It may be that Maryland law already applies to the conduct which prompted the legislation.

"Medical" marijuana became "legal" marijuana as the bill to permit physician dispensing of marijuana was tabled and, instead, the General Assembly passed legislation allowing a patient to be acquitted of an illegal possession charge if the patient could prove a medical reason for its use.

House Bill 82 (*Health Care Decisions Act* – "*Medical Orders for Life-Sustaining Treatment*" *Form*) passed providing for the application of a standard life-sustaining treatment form to be developed for all patient care settings.