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MedChi Final Report

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The 435th Session of the Maryland General Assembly concluded at midnight on Monday, April the 13th when it adjourned "Sine Die" with the traditional confetti release in both the Senate and House chambers. In this Session, the General Assembly considered 2,248 legislative bills and resolutions and the MedChi Legislative Committee reviewed 250 bills, taking positions on many of these.

Wrangling over the State Budget continued on Sine Die with Republican Governor Larry Hogan facing off with the Democratically controlled General Assembly which cut Governor Hogan's Budget and wanted to have the deleted monies used for (1) increased education aid, (2) healthcare expenditures including an improvement to the Medicaid reimbursement rate for doctors and (3) State employee COLA increases. Governor Hogan was more interested in conserving budgetary monies and providing certain targeted tax relief. In the end, the General Assembly passed the Fiscal Year 2016 budget, but Governor Hogan has the right (or not) to fund the General Assembly's priorities. To the extent that these programs are not funded by the Governor, the monies will remain unspent.

At the beginning of this 90 day Session, MedChi prioritized four major issues in its Legislative Agenda: (1) a repeal of Maryland's 2013 "sterile compounding permit" legislation; (2) making permanent the 2010 enactment of the Assignment of Benefits (AOB) law which was due to expire this year; (3) a preservation of the reimbursement of physicians in the Medicaid program; and (4) to defeat any legislation to limit physicians from dispensing medicines from their offices. At the conclusion of the 90 day Session, MedChi was successful with respect to all four of these priority initiatives.

There are currently four physicians who are serving in the Legislature; Doctor Dan Morhaim is a veteran of 20 years, while Doctors Terri Hill, Clarence Lam and Jay Jalisi have just completed their first year as members of the House of Delegates. Dr. Morhaim was particularly helpful recently in having an onerous proposed regulation on Controlled Dangerous Substance (CDS) licenses withdrawn. Drs. Hill, Lam and Jalisi have served as valuable information sources for fellow Delegates on a variety of issues affecting physicians and Dr. Hill sponsored the bill to repeal the "sterile compounding" law discussed below.

MedChi Initiatives

Assignment of Benefits: Senate Bill 92/House Bill 230 (*Health Insurance – Assignment of Benefits and Reimbursement of Nonpreferred Providers – Repeal of Termination Date*) is MedChi initiated legislation which has now made permanent the AOB law first passed in 2010, over the strenuous objection of the insurance industry. By the terms of the 2010 law, there was a five year "sunset," which would cause the bill to terminate on September 30, 2015. Senate Bill 92/House Bill 230 removed the "sunset" and made the law permanent.

However, the insurance industry did not give up in its attempts to disrupt the AOB law. The League of Life and Health Insurers of Maryland (Cigna, Aetna and United) initiated Senate Bill 803/House Bill 1157 (*Health Insurance – Nonpreferred Providers – Assignment of Benefits, Reimbursement, and Fraudulent Insurance Acts*). This legislation would have changed the formula for payment originally agreed to in the 2010 AOB law. The original formula guaranteed that hospital-based and on-call doctors would receive no less than what they had been receiving as of 2010 but could receive more under the fee schedule specified in the AOB law. The bills also would have removed the "greater of" language and would have made it a matter of insurance fraud and a criminal offense for a doctor to forgive the co-pay or deductible amount owed by the patient. There was a hearing on this legislation in the Senate Finance Committee, where MedChi's adamant testimony was well received. The House bill remained in the House Rules Committee and did not even receive a hearing. In the end, there was never a vote on either bill and therefore neither advanced.

The net effect: Maryland's 2010 AOB law – a major initiative of MedChi – will now be made permanent.

Sterile Compounding: Senate Bill 69/House Bill 181 (*State Board of Pharmacy – Sterile Compounding – Compliance by Nonresident Pharmacies and Repeal of Permit Requirement*) was MedChi initiated legislation to repeal the 2013 Maryland law regulating "sterile compounding." From its initial enactment, the 2013 legislation became problematic for physicians due to the fact that the Maryland Board of Pharmacy determined that the definition of compounding included the routine mixing of medicines in a physician's office. After the enactment of the 2013 law, a federal law was enacted which, in fact, properly regulated sterile compounding facilities and included an exemption for the mixing of medicines in a physician's office. The passage of the federal law illustrated the problems with the Maryland law which was contradictory to the federal statute and harmful to real medical practices. In 2014, certain specialties were exempted from the Maryland Sterile Compounding law and, with the passage of Senate Bill 69/House Bill 181, all medical practices will now be relieved as soon as Governor Hogan signs the bill, which is expected. On a related note, the Maryland Board of Pharmacy has repeatedly delayed the enactment of regulations following the 2013 law, including the latest delay until July 1st. With the full repeal, it is anticipated that the Board will also repeal the regulations.

Medicaid Budget: In the last weeks of Governor O'Malley's administration, he reduced Medicaid reimbursement for evaluation and management (E&M) Codes from 100% of Medicare to 87% of Medicare in order to balance the 2015 Budget (July 1, 2014 to June 30, 2015). The reduction took effect on April 1st. At the start of this Session, MedChi hoped that the 87% figure would not be further reduced. Due to an aggressive advocacy effort, the final Budget raised the reimbursement for E&M codes to 92% of Medicare. A return to 100% of Medicare is the desired path going forward, but physicians should believe that the proverbial rabbit came out of the hat as an actual increase was secured. The Budget also restored funding back to 250% of FPL for pregnant women. However, whether the Governor decides to fund these priorities, and at what level, remains to be seen.

Physician Dispensing to Workers' Compensation Patients: Since the summer of 2011, MedChi has successfully defended the ability of doctors to dispense medications from their

offices to their workers' compensation patients. Attempts by the Workers' Compensation Commission (WCC) and Maryland's workers' compensation insurance carriers to impose a draconian fee schedule on the prices paid, or to outlaw dispensing, were defeated in the 2012, 2013 and 2014 Sessions of the General Assembly. All the while, the proponents have used data from the Workers Compensation Research Institute (WCRI) to inspire a narrative that doctor dispensing was out of control and a major cost driver in the system. MedChi has consistently and publicly challenged the WCRI data.

To the credit of the Maryland WCC, its Chair, R. Karl Aumann, recently reported that WCRI data is substantially inaccurate (*e.g.* contrary to WCRI data, 40% of the workers' compensation Rxs are not dispensed in doctor's offices, the true number is 15.7%). As a result of the Maryland data reported by Chairman Aumann, all parties agreed to a two year moratorium (2015-2016 General Assembly Sessions) on bills that would limit or otherwise impact physician dispensing of medicines. Maryland's decision to put these issues on hold is in marked contrast to the continuing efforts of workers' compensation insurers in all other states across the nation to impose controls on physician dispensing.

Additional Passed Legislation

Scope of Practice: There were a number of initiatives to alter the "scope of practice" permitted to various licensed health professionals including, proposals regarding nurse practitioners, pharmacists and lay midwives. In all cases, MedChi proposed rigorous amendments to these proposals and, once amended, the respective legislation was successful.

a. Nurse Practitioners: Senate Bill 723/House Bill 999 (*Certified Nurse Practitioners – Authority to Practice*) changes the present law which requires an "attestation" by the Nurse Practitioner (NP) to identify a doctor who is available to the NP. As a practical matter, the doctor's name is placed on paperwork, but there is no actual legal requirement that there be actual collaboration. Given the ineffectiveness of the current attestation requirement, there seemed little point to insisting on its provision and, hence, MedChi proposed additional amendments to the bill to wit: (1) that new NPs be required to have a mentoring relationship with a doctor or experienced NP for at least eighteen months, and, (2) that NPs who did not collaborate in the appropriate case would be subject to discipline for their failure to do so. Ultimately, these amendments were accepted and the legislation was enacted.

b. Lay Midwives: While MedChi, along with numerous other parties including the Department of Health and Mental Hygiene (DHMH), and the Maryland Hospital Association continued to voice its concern about the safety of home births, MedChi in conjunction with other opponents was able to amend House Bill 9 (*Maryland Licensure of Direct-Entry Midwives Act*) to dramatically limit the practice of direct-entry midwifery and the conditions under which they may attend a home birth. These amendments include any number of restrictions (indeed, in many respects, the most restrictive provisions of any such law in the nation) and include but are not limited to the following: a prohibition on an at home vaginal birth after cesarean (VBAC); mandatory transfer and consultation provisions; increased education and training requirements; transition of newborn care within 72 hours; and the development of uniform informed consent and transfer forms

with physician community input. In addition, the new law will require extensive data and outcome reporting to determine the efficacy of the new law.

c. Pharmacy Bills: Senate Bill 346/House Bill 657 (*Pharmacists – Scope of Practice – Administration of Drugs*) began as legislation that would have authorized pharmacists to prescribe drugs and to administer certain drugs. MedChi objected to the inclusion of pharmacists as prescribers and to the breadth of drugs that could be administered. Through amendments suggested by MedChi, and with the help of Delegate Dan Morhaim, the provision allowing pharmacists to prescribe was deleted, and the bill was further limited to allow pharmacists to only administer certain "self-administered drugs" which could already be administered directly by the patient.

Senate Bill 347/House Bill 716 (*Health Occupations – Prescriber-Pharmacist Agreements and Therapy Management Contracts*) permits nurse practitioners with prescribing authority and podiatrists to enter into agreements with pharmacists for ongoing care of patients with certain diseases. Current law limited these agreements to physicians and pharmacists. Such agreements must be submitted to the appropriate health occupations board, along with any modifications.

Misuse and Abuse of Prescription Drugs/Heroin: The growing incidence of drug abuse and overdose deaths have garnered significant public attention. In February, Governor Hogan created the *Heroin and Opioid Emergency Task Force* and a separate *Inter-Agency Coordinating Council*. Both groups will work and support efforts to address Maryland's growing heroin and opioid crisis. In addition, there were a number of legislative initiatives passed this Session to combat the misuse and abuse of prescription drugs, the increasing incidence of overdose deaths attributed to heroin, and other related issues associated with drug abuse.

Senate Bill 607/House Bill 896 (*Joint Committee on Behavioral Health and Opioid Use Disorders)* is the most important of these initiatives. It creates a standing joint legislative committee comprised of five senators and five delegates which has oversight over: the prescription drug monitoring program (PDMP); State and local programs to treat and reduce behavioral health disorders; and State and local programs to treat and reduce opioid use disorders. The Committee is also charged with reviewing the extent to which health insurance carriers in the State are complying with federal and State mental health and addiction parity laws. The Joint Committee has a six year sunset.

Other related initiatives include:

a. Senate Bill 606/House Bill 887 (*Health Insurance – Abuse-Deterrent Opioid Analgesic Drug Products – Coverage*) will require insurance companies to cover two brand abuse deterrent opioid drug products and two generic abuse deterrent opioid drug products at equivalent cost sharing levels as non-abuse deterrent opioids. Abuse deterrent opioids are new formulations whose physical characteristics deter manipulation of the product.

b. Senate Bill 516/House Bill 745 (*Public Health – Overdose Response Program*) expands the Overdose Response Program within DHMH by authorizing an advanced practice nurse with prescribing authority or a licensed physician to prescribe and dispense

Naloxone to a certificate holder either directly or, under specified circumstances, *under a standing order*, as well as authorizing any licensed health care provider with prescribing authority to prescribe Naloxone to a patient who is believed to be at risk of experiencing an opioid overdose or in a position to assist an individual at risk of experiencing an opioid overdose. This legislation includes critical liability protections for physicians who prescribe or dispense Naloxone under the program.

c. Senate Bill 757 (*Public Health – Prescription Drug Monitoring Program – Required Disclosures)* is a departmental bill that expands the entities to which the PDMP must disclose prescription drug monitoring data to include: the State Child Fatality Review Team or a Local Child Fatality Review Team; a Local Drug Overdose Fatality Review Team; the Maternal Mortality Review Program; or a medical review committee appointed by or established in DHMH or a local health department. The information is only provided on approval of the Secretary of Health and Mental Hygiene and for the purpose of furthering an existing bona fide individual case review and includes the protections on information disclosure which MedChi insured were included in the program when originally created. The bill also clarifies that the PDMP must disclose data to the State Board of Physicians, on issuance of an administrative subpoena voted on by a quorum of a disciplinary panel of the board, for the purposes of furthering an existing bona fide investigation of an individual.

d. House Bill 971 (*Public Health – Substance Abuse Treatment Outcomes Partnership Fund*) expands the scope of the Substance Abuse Treatment Outcomes Partnership (S.T.O.P.) Fund in DHMH to include "eligible functions" that may be funded under S.T.O.P., including transportation to and from treatment services; treatment, prevention, or coordination staff; data sharing services among counties and other appropriate treatment providers; education or outreach programs and materials; in-community emergency behavioral health services or crisis stabilization units; and behavioral health programs in schools.

Failed Legislation:

Medical Malpractice Bills: In betting parlance, it would be known as a "push." The Trial Lawyers initiated a number of bills including Senate Bill 479/House Bill 398 (*Civil Actions – Noneconomic Damages – Catastrophic Injury*) which sought to triple the current "cap" on noneconomic damages for any "catastrophic injury" in a medical malpractice case. After long hearings in both the Senate Judicial Proceedings and the House Judiciary Committee, the bill was not voted on. Another Trial Lawyer entry was House Bill 470 (*Healthcare Malpractice – Certificates and Reports of Qualified Experts*) which would terminate any attack on the adequacy of a medical malpractice certificate of merit unless the issue was raised in the first 30 days of the case, which would have changed current practice which allows a defendant to question the certificate at any stage of the proceeding. House Bill 470 did not receive a vote and therefore was unsuccessful. There was a similar bill filed in the Senate, Senate Bill 127 (*Healthcare Malpractice – Certificate and Report of Qualified Expert – Objection*), which was given an unfavorable report by the Senate Judicial Proceedings Committee.

While the Trial Lawyers were not successful in their initiatives, the same could be said about the various bills filed by the hospital industry. These include House Bill 547 (*Medical*

Liability Efficiency Act 2015), House Bill 817 (*Health Care Malpractice – Limitation on Noneconomic Damages*), Senate Bill 188/House Bill 402 (*Taskforce to Study Establishment of Health Courts*), and House Bill 553 (*Maryland No-Fault Injured Baby Fund*). House Bill 817, which would have reduced the cap on noneconomic damages from its present level of $755,000 to $500,000, was given an unfavorable report by the House Judiciary Committee while the other bills did not receive a vote by the House Committee. It should be noted that the *Maryland No-Fault Injured Baby Fund*, which was the subject of an extensive media campaign and the primary focus of the hospital industry will continue to be the focus of concerted effort over the interim. Access to obstetrical care remains a significant concern, particularly in urban areas and for women with other health care issues. To that end, Senate Bill 187 (*Workgroup to Study Access to Obstetric Services)* was enacted. It creates a workgroup of stakeholders, including MedChi, that will look at the issue of obstetrical care access. While tort reform, the birth injury fund particularly, is not the focus of the workgroup's charge, it will undoubtedly be a subject under consideration.

Statistical Sampling for Medicaid Overpayments: House Bill 1101 (*Department of Health and Mental Hygiene – Health Program Integrity and Recovery Activities*) was a late entry proposed by the Office of the Inspector General at DHMH. The legislation sought to: (1) give the Inspector General or his designee subpoena power; (2) allow the use of civil money penalties; (3) allow "overpayments" by the Medicaid program to be recouped from providers using extrapolation – statistical sampling; and (4) authorized DHMH to require providers/applicants to obtain a surety bond as a condition of participation in the Medicaid program. MedChi organized a coalition which included nineteen other health provider groups in the State, including the Maryland Hospital Association, Johns Hopkins Medicine, the University of Maryland Medical System, MedStar, Pharma, the Maryland State Dental Association and the long-term care industry. In the end, the Chair of the House Health and Government Operations Committee, who had been promoting the bill, "put it in the drawer" with an expectation that the parties will consider the issues raised over the interim and address the matter in 2016.

There were a number of other bills, while supported by MedChi, did not pass. These include the following:

a. Senate Bill 152/House Bill 56 (*Tanning Devices – Use by Minors – Prohibition*) would have restricted the use of commercial tanning salons by those under the age of 18. This bill has been consistently introduced over the last number of years and attempts to make the law in Howard County, Maryland applicable throughout the State. It was voted down once again this year.

b. Senate Bill 37/House Bill 108 (*Tobacco Taxes – Healthy Maryland Initiative*) was a proposal to raise Maryland's tax on tobacco. The legislation has always been supported by MedChi but, given the anti-tax message of the last election, it would appear that this proposal may have continued difficulties during Governor Hogan's administration.

c. Senate Bill 537/House Bill 733 (*Pharmacists – Substitution and Dispensing – Interchangeable Biological Products*) would have allowed a pharmacist to substitute an FDA interchangeable biologic product. While the legislation received a favorable vote in the Senate with the MedChi amendments, it was placed "in the drawer" by the Chairman of the Health and Government Operations Committee (HGO). This is the second time

that the legislation passed the Senate (Sponsor Senator Joan Carter Conway) but received no vote in HGO. The Chairman of HGO has indicated concerns with the bill, especially the lack of approved FDA biosimilars. It is important to note that on March 6, 2015, the FDA approved the first biosimilar product in the United States (Zarxio – biosimilar to Neupogen for cancer treatment).

d. Senate Bill 742/House Bill 1090 (*Public Health – Restaurants – Meals for Children*) would have required restaurants that market and serve "children meals" to only include bottled water, low-fat or non-fat milk or 100% fruit juice as part of the meal. Senate Bill 574/House Bill 261 (*Sales and Use Tax – Bottled Water – Exemption*) would have removed the Maryland sales and use tax on bottled water. These bills were initiatives introduced by Sugar Free Kids and sought to support parent's efforts to raise healthy kids by helping to combat childhood obesity and juvenile diabetes.

e. Senate Bill 834/House Bill 990 (*Maryland Health Benefit Exchange – Qualified Health Plans – Standards*) was a comprehensive bill to address issues related to network adequacy and prescription coverage under Qualified Health Plans under the Exchange. While the bill did not pass, the Exchange is in the process of convening a workgroup to study and make recommendations related to network adequacy, an issue that the Executive Director of the Exchange acknowledged in her testimony on the bill.

f. House Bill 952 (*Public Health – Hydraulic Fracturing Chemicals – Information and Fund)* would have required companies that were permitted to conduct hydraulic fracturing to disclose the chemicals used in the process. It would have authorized providers to have access to that information and to disclose it for purposes necessary to protect public health. While the legislation was not successful, the General Assembly enacted related legislation that instituted a two year moratorium on all hydraulic fracturing activity in the State. If and when hydraulic fracturing is allowed in the State, the issue of access to chemical information will be revisited.

g. House Bill 1042 (*Environment – Nitrogen Oxide Emissions – Pollution and Combustion Control Technologies*) would have required Maryland coal-fired power plants to comply with EPA requirements for pollution control technology. The bill was introduced following the withdrawal of regulations that achieved that end. The bill did not advance as the Administration will be reintroducing the regulations to accomplish the objective of the bill. In essence, a win without the need to pass legislation.

Regulatory Matters: While the MedChi legislative efforts are focused on the proposals filed in the General Assembly, there are equally important proposals which come in the form of "regulations" being proposed by State administrative agencies. The MedChi Legislative Committee reviews all such regulatory proposals which are published on a bi-weekly basis in the Maryland Register. Objections to regulations can be raised before the General Assembly's Administrative, Executive and Legislative Review Committee (AELR) which has the authority to place a "hold" on regulations until objections are discussed and potentially remediated. Recently, MedChi initiated AELR review of two regulations one of which has now been withdrawn by the Department.

Proposed Regulation 10.19.03 – Controlled Dangerous Substances would have required all doctors to (1) complete a Department approved education module on substance use disorders

and (2) register with the PDMP. This regulation was withdrawn last week by DHMH after MedChi wrote an extremely detailed objection to the regulation and was joined in its objection by Johns Hopkins Medicine. On a related note, in House Bill 72 (*The Budget Reconciliation and Financing Act of 2015*) language was added that extends the timeframe for renewing CDS licensure from two to three years, consistent with the timeframe for DEA licensure.

MedChi also objected to Proposed Regulation 10.47.07 – Prescription Drug Monitoring Program and that regulation is currently on "hold." There have been discussions with the PDMP but no resolution. MedChi remains concerned that the PDMP is attempting to avoid the requirements of using the Technical Advisory Committee which comments on all government reviews of any doctor's prescription habits prior to the initiation of actions which may be adverse to the doctor.