



2017-2018 PUBLIC AFFAIRS COMMITTEE REPORT May 31, 2018

Submitted by: Jeff Lindoo and Julie Freeman

Board Liaisons: Amanda Brummel and Sarah Westberg

SECTION I: 2017-2018 CHARGES:

- Monitor regulatory activities to identify issues likely to come before the Legislature including but not limited to
 - Revision of Medicaid reimbursement structure as mandated by CMS Outpatient Covered Drug Rule
 - Opioid Risk Mitigation
- Review bills introduced and provide guidance to staff consistent with MPhA policies
- Make recommendations to the Board of Directors on issues for which policy positions have not yet been developed, or for modifications to existing policy positions
- Provide input into the development of strategies and grassroots initiatives to advance legislative and regulatory initiatives identified as association priorities.
- Participate in the coordination of efforts to modernize the Minnesota Pharmacy Practice Act to ensure pharmacists are able to practice to the top of their license and participate fully in new total cost of care models, advanced payment models, including accountable care organizations.
- Continue active involvement in Pharmacy Advocacy Taskforce initiatives.
- Revisit Medical Cannabis, Online Pharmacy and Telehealth Pharmacy policies assigned from House of Delegates
- Review of proposed Board Policies pertaining to Public Affairs
- Provide guidance to the Educational and Events Advisory Committee on topics to be included in MPhA educational conferences.
- Review recommendations from the Policy Manual Review Committee for updating and proposing new MPhA policies.
- Provide recommendation on creation of candidate endorsement policy.

SECTION II: DELIVERABLES/TIMELINE:

- Reports to MPhA Board – Monthly during session
- Reports to Membership – Weekly briefings during session
- Final Report to House of Delegates - May 4, 2018
- Committee co-chairs, please report to the incoming President in May as to whether you are willing to continue serving as co-chair and/or suggestions for co-chairs from your committee for the following year.

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SECTION III: REPORT OF COMMITTEE ACTION AND PROGRESS ON DELIVERABLES

The Public Affairs Committee accomplished the following on deliverables for the 2016-2017 reporting period:

- Reports were provided to the MPhA Board of Directors during the legislative session through our committee liaisons and in conversations with the Interim Executive Director and Board members active with the PATF.
- Reports were provided to the MPhA membership during the legislative session in Small Doses and other Action Alerts.
- This is the committee's Final Report to House of Delegates.

SECTION IV: ISSUES ADDRESSED BY THE COMMITTEE OUTSIDE OF STATED CHARGES

In addition to the stated charges, the Public Affairs Committee addressed the following issues/topics raised during the 2017-2018 reporting period:

MAIN LEGISLATIVE INITIATIVES

At the time this report is being written, virtually no MPhA legislative issue has been resolved. A current detailed legislative report is available on the MPhA website (www.mpha.org and click on "Legislative Alerts in the lower left corner) and in most issues of Small Doses.

The committee worked collaboratively throughout the year with the Pharmacy Advocacy Task Force (PATF). The main priority of the task force this session was working on bills which would allow patients access to pharmacist provided services.

Pharmacist Authority to Prescribe

This legislation was among the primary legislative initiatives for the PATF and for MPhA. Last year, language was introduced that would allow pharmacists to prescribe naloxone, hormonal contraceptives, travel medications and tobacco cessation medications. For reasons far more political than because of opposition to the idea, hormonal contraception was dropped and the language was scaled back this year to naloxone, travel medications, and tobacco cessation products. Throughout the legislative session, MPhA worked with the following stakeholders on the legislation to garner support and to work through modifications to the language that would make it more likely to pass:

- Minnesota Medical Association
- Minnesota Nurses Association
- Minnesota Nurse Practitioners
- Minnesota Chapter of American College of Obstetrics and Gynecology
- ClearWay Minnesota
- MN Department of Human Services
- Minnesota Retailers Association

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Minnesota Grocers Association
Minnesota Board of Pharmacy
Generic manufacturers
Brand manufacturers
Minnesota Health Action Group
MN Psychiatric Association
The Steve Rummmler Hope Network
Fairview Health Services
Health Partners

At this time, we have assurances from House and Senate HHS Chairs that they intend to include our legislation in their final omnibus bill in conference committee. We are hopeful, but not completely confident that will occur and continue to work daily for a positive outcome.

Pharmacist Authority to Administer Medications

In 2017, MPhA was approached by pharmacists in several practice settings about patients having difficulty accessing administration service for their injectable medications. As evidence for the need of administration services grew, legislation became a priority for the PATF and for MPhA and language that would allow pharmacists to administer medication by all routes was introduced. We were unable to get a committee hearing in either the House or Senate, but our administration language was amended onto legislation providing subsidies for pharmacies that provide deactivation or mail-back pouches for drug disposal.

Unfortunately, the disposal subsidy language was included in the HHS omnibus bill, but our administration language was not. In conversation with committee leadership and staff, we were advised to trim our language down to allowing only administration of IM and sub-cutaneous injections and patches to improve our chances of final inclusion in the House bill. At this time, our Senate author has agreed to accept our language as an amendment to a major piece of her legislation. But again, we are not completely confident that will occur.

Medicaid Drug Reimbursement

In visiting with DHS prior to session, MPhA was informed that the position of DHS is that Minnesota is not out of compliance with the CMS Covered Outpatient Drug Rule and is not obligated to conform to the rule until such time that the department chooses to make a change to pharmacy reimbursement. There is opposition in the department to push the legislature for a change. House & Senate leadership indicated no appetite for any increased spending in DHS and feedback from our national partner associations and direct conversations indicate that CMS shows no signs of acting against states that have not met the guidelines of the rule. Therefore, MPhA did not expend any further resources on this issue.

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Other non-priority legislation that MPhA monitored and/or became engaged on include:

Board of Pharmacy Agency Legislation

Board of Pharmacy legislation was not introduced in time to receive any action this year, but some segments of their proposed legislation is moving and will be covered below.

Opioid Related Legislation

Opioid Stewardship Legislation

This topic was very active throughout the session, with several proposals emerging to create an Opiate Stewardship Advisory Council, which would oversee various programs to deal with opiate abuse and rehabilitation in Minnesota. At the time of this writing, the House proposal would draw funds from the projected budget surplus and the Senate proposal would create funding from a tax or licensing fee on opiate manufacturers. MPhA has largely stayed out of this issue, except to help some legislature better understand the current marketplace, which is 90+% generics and to understand that the economics of the generic marketplace are vastly different from the brand marketplace.

Time Limitation on Filling of Opiate Prescriptions

It is likely that this language will pass in some form this year. At this time, House language limits the time between when an opiate prescription in any schedule is written and it is first filled to 30 days. Refillable opiates may not go more than 45 days between fills or the prescription becomes void. Senate language limits the time between when an opiate prescription in any schedule is written and when it is filled to 30 days, meaning that a refillable opiate could not be filled or refilled past 30 days from the date the prescription is written. MPhA is actively working to adopt the House language.

Drug Disposal

This bill would set aside \$1,000,000 to provide subsidies to Minnesota pharmacies to provide medication deactivation or mail-back pouches to patients with opiate prescriptions. Our medication administration language was amended onto this bill in committee, but was then left off when the disposal language was included in the House omnibus bill.

Electronic Prescribing

This legislation was a priority for the pharmacy members of the Minnesota Retailers Association. Since virtually all pharmacies are certified to receive electronic prescribing of controlled substances (EPCS) but physicians' practices are lagging in adoption, a few versions of the bill seek to find ways to incentivize physicians' offices to move to EPCS. That transmission will improve efficiency for pharmacies and help reduce the incidence of fraudulent controlled substance prescriptions. We do not know the final outcome of this legislation.



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PBM-Related Legislation

A group of interested members and organizations formed a coalition this year to raise money to add work on PBM issues to MPhA's lobbying contract with Buck Humphrey. Below are the key issues worked on by that coalition.

Gag Clause and Clawbacks

Numerous bills in the House and Senate were introduced by a number of legislators on the issues of "gag clauses" and "clawbacks". Gag clause refers to terms in a PBM contract that prevent the pharmacist from telling a patient when the usual cash price for a prescription is less than the copay that is being charged by their PBM. Clawback refers to a situation where the pharmacist is directed by a claim to collect an amount from the patient (copay) that is greater than the amount the pharmacy is to be paid for the claim. The PBM then "claws back" from the pharmacy the difference between the two.

At this time, language that looks to be advancing in the House would prohibit gag clauses and require a PBM to charge a copay that is no greater than the pharmacy's usual cash price. Language in the Senate only prohibits gag clauses, but also includes language that requires PBMs to allow claim overrides for early refill for the purpose of synchronizing a patient's medication refills, to charge a pro-rated copay for partial-month fills for the purpose of synchronization and to pay a full dispensing fee to the pharmacy for those partial-month fills. We are hopeful that a combination of the House and Senate language will be passed, since negotiations with the PBM industry have resulted in removing their opposition to the House and Senate language.

PBM Ownership Interest in Pharmacies

Another bill introduced by MPhA which would prohibit a health plan or PBM from requiring or providing financial incentives for a patient to use a pharmacy that is owned by the PBM has not advanced.

Licensure of PBMs

A bill introduced jointly by MMA and MPhA which would require licensure of PBMs has not advanced.

Peritoneal Dialysis Solution Dispensing/After Hours Medication Orders

A bill was introduced by Baxter Labs that would allow them to distribute peritoneal dialysis solutions to patients in Minnesota without a pharmacist present at the site was worked out in consultation with and not opposed by the Board of Pharmacy. It was also not opposed by MPhA. Language from the Board of Pharmacy was amended onto this bill that allows a pharmacist to accept medication orders from a prescriber after pharmacy hours when the pharmacist is not present in a licensed pharmacy. It also allows the pharmacist to use a secure electronic connection to access the pharmacy system from outside the pharmacy to review appropriateness, process the order and release it to a long-term care facility. This language was developed by the Board of Pharmacy at the request of MPhA. We are hopeful for final passage of this language.

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Medication Repository

A bill was introduced and shepherded through the legislature by a group of pharmacy, nursing and public health students that would expand Minnesota's cancer drug repository to include all types of medications. Appropriately packaged unused medications would be received from long term care facilities and then re-packaged and dispensed to patients who are low income and uninsured or underinsured. This legislation appears to be headed for final passage and the students are very confident there are non-profit organizations willing to step into this space and administer the program.

Veterinary Compounding

The Board of Pharmacy worked with the Veterinary Board to develop language that allows a veterinary compounding pharmacy to provide emergency-need medications to a veterinarian without an animal or herd-specific order from the veterinarian. The legislation is supported by the Board and all other stakeholders. MPhA had no position. It appears headed for passage.

RECOGNITION OF LEGISLATIVE PHARMACY CHAMPIONS

The Public Affairs Committee has forwarded a recommendation to the MPhA Board to grant honorary membership to several legislators who have been pharmacy champions. The award would be bestowed at our House of Delegates meeting on May 31. The Board will consider what is appropriate recognition if it is determined there is "value" to honorary membership.

SECTION V: JOINT POLICY COMMITTEE POLICY RECOMMENDATIONS TO THE HOUSE OF DELEGATES

The Public Affairs Committee respectfully submits the following proposal for consideration by the MPhA House of Delegates at the May 31, 2018 session of the House of Delegates:

During the 2016 process of MPhA policy review, certain policies were referred to the Public Affairs committee with recommendations to review. The MPhA Public Affairs Committee recommends the following policy revisions to the 2017 MPhA House of Delegates. ~~Strikethrough~~ language is existing language to be deleted. Underlined language is proposed new language. All other language is existing MPhA policy language.

Resolution 2018-002:

Category: PUBLIC HEALTH

Policy Manual Line Item: 80

Policy Manual Subcommittee 2016 Item 91

Year: 2004

Subheading: Online Pharmacies

Title: Online Pharmacies

Policy: 1. MPhA opposes the sale of prescription drugs without in-person evaluation of the patient by a licensed practitioner prescriber. ~~and presentation of a valid prescription to a licensed pharmacist.~~

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The requirement for an in person evaluation or examination shall be met if the examination has been completed in any of the following circumstances:

- (1) The prescriber examines the patient at the time the prescription or drug order is issued;
- (2) The prescriber has performed a prior examination of the patient;
- (3) Another prescriber practicing within the health care organization as the prescriber has examined the patient;
- (4) A consulting prescriber to whom the prescriber has referred the patient has examined the patient; or
- (5) The referring prescriber has performed an examination in the case of a consultant prescriber issuing a prescription or drug order when providing services by means of telemedicine.
- (6) The evaluation method is authorized by the Centers for Medicare and Medicaid Services.

2. MPhA supports all means or measures that limit online prescription drug sources to licensed pharmacies only. 3. MPhA encourages regulation or other means that require the disclosure of at least the identity, geographic address, pharmacist-in-charge, and current licensure of an online pharmacy. 4. MPhA encourages online search engines and all other solicitors of online advertisements to adopt policies that limit acceptance of advertisements from online prescription drug sources to licensed pharmacies only. 5. MPhA emphasizes that use of online pharmacies does not replace the need for effective patient counseling, education, and medication therapy management.

Resolution 18-003

Category: PHARMACY PRACTICE

Policy: MPhA Position Statement on Medical Cannabis

1. MPhA advocates for resolution of the federal and state conflicts surrounding the legal and regulatory status of cannabis and its various components.
2. MPhA supports legal and regulatory changes to facilitate clinical research related to the clinical efficacy and safety associated with the use of cannabis and its various components.
3. MPhA encourages health care provider education related to the efficacy and safety of cannabis, and comprehensive clinical management of patients using cannabis and its various components.
4. MPhA supports the engagement of a pharmacist's expertise in patient use of cannabis and its various components when federal, state, or territory laws establish a program of distribution.
5. MPhA supports the establishment of a USP monograph for the standardization of cannabis and its various components.

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Resolution 15-002 – MPhA Position Statement on Medical Cannabis

Submitted by: Referral from the House of Delegates to the Public Affairs Committee

1. MPhA advocates for resolution of the federal and state conflicts surrounding the legal and regulatory status of cannabis and its various components.
2. MPhA supports legal and regulatory changes to facilitate clinical research related to the clinical efficacy and safety associated with the use of cannabis and its various components.
3. MPhA encourages health care provider education related to the efficacy and safety of cannabis, and comprehensive clinical management of patients using cannabis and its various components.
4. MPhA supports the engagement of a pharmacist's expertise in patient use of cannabis and its various components when federal, state, or territory laws establish a program of distribution.

Language from 2015 That Was Re-Referred to Public Affairs Committee

5. MPhA supports the establishment of a USP monograph for the standardization of cannabis and its various components.

The Public Affairs Committee recommends the House of Delegates adopt the above statement as part of our policy on Medical Cannabis.

6. MPhA opposes the furnishing of cannabis and its various components for medical purposes unless performed by licensed health care professionals whose scope of practice includes the dispensing of prescription medications and who comply with state and federal regulations.

The Public Affairs Committee recommends the House of Delegates NOT adopt the above statement.

BACKGROUND: Former Dean Marilyn Speedie is a member of the USP Monograph Committee. The decision not to adopt statement #5 in 2015 was based largely on her statement that USP was opposed to the development of a monograph for cannabis at the time. The recommendation to adopt that same statement today is based on her comments that USP was currently debating the adoption of a monograph for cannabis and she felt that a statement from Minnesota would be helpful in that deliberation. At the same time the Public Affairs Committee voted to recommend the statement to the House of Delegates, they also voted to forward a letter to the USP stating that the Public Affairs Committee was recommending the MPhA Board and House of Delegates adopt the recommendation. That letter was forwarded in January 2018.