



COVID-19 Town Hall #3 Q&A

Kim Gaedeke has been with LARA for nearly eight years where she serves as the Chief Deputy Director. She is also the Chair of the Economy and Workforce COVID-19 Task Force, Commissioner on the Interstate Medical Compact, and Member of NABP PMP InterConnect Steering Committee. Kim is responsible for overseeing a number of bureaus, including Professional Licensing; Community and Health Systems; Corporations, Securities and Commercial Licensing; Construction Codes; and Fire Services.

Andrew Hudson currently serves as manager of the Pharmacy and Drug Monitoring Section within the Bureau of Professional Licensing. This section conducts inspections for pharmacy licensure, renewal, and for cause and investigates allegations of drug diversion, overprescribing, and over-dispensing by licensed health professionals. Prior to joining LARA, Andrew served as an assistant attorney general for over four years, representing various licensing bureaus in administrative hearings and appeals, and he served as board counsel for the Boards of Veterinary Medicine, Physical Therapy, and Cosmetology.

Charlie Mollien, a pharmacist-attorney, earned his Doctor of Pharmacy degree from Ferris State University, Master of Science in Pharmacy Regulation and Policy from the University of Florida, and Juris Doctor from Western Michigan University. He is the director of pharmacy compliance, accreditation and patient safety and also HIPAA privacy officer for Meijer Pharmacy and Meijer Specialty Pharmacy. He's currently serving as MPA president and the chair of the Michigan Board of Pharmacy.

Brian Sapita is the Government Affairs Manager for the Michigan Pharmacists Association. He holds a degree in political science from Grand Valley State University. Upon graduation, Brian worked as a certified pharmacy technician for a little more than a year before starting his career in the Michigan Legislature where he worked for nine years. While there, he worked on health policy initiatives, such as the regulation of biosimilars, the expansion of practice for Advance Practice Registered Nurses and the regulation of pharmacy benefit managers.

Additional Panelists

Farah Jalloul, MPA Director of Professional Development
Larry Wagenknecht, MPA Chief Executive Officer

Moderator

Dianne Malburg, MPA Chief Operations Officer

Q&A

1. How should I record my hours worked during COVID so that they can count towards my CE for licensure? Is there a form for this?



- a. *For every hour worked during COVID-19 state emergency, licensees will receive a live hour of CE. There is no maximum on how many hours you may obtain. MPA created a form for licensees to record and track hours. The form was shared with LARA and was adopted. Licensees are encouraged to utilize it.*
 - b. *Form can be found [here](#)*
2. Do hours spent working outside of MI count for CE credits?
 - a. *Only the hours worked in the state of Michigan will be accounted for as CE credits. Hours obtained through this effort will only count for a licensee's Michigan CE credits.*
3. The Board of Pharmacy requires pharmacists and pharmacy technicians to complete specific CE hours. Is that still required?
 - a. *The Department is looking at this in a very reasonable manner, with some flexibility. For specific requirements, such as pain CE or other required CEs, licensees renewing during the COVID-19 emergency are not required to complete. These requirements are waived during this time for anyone that renews during the COVID-19 emergency. However, when the emergency ends, this will not be valid thus licensees will be required to comply with the CE rules.*
4. If I'm supposed to renew my license at the end of June, do I still need 10 hours of live CE or can it all be home study since COVID has made it difficult to get live CE?
Executive Order 2020-49 allows for hours worked during the COVID crisis to be counted towards live CE.
5. I'm a technician with a temporary license which expires this month, do I have to stop working when my license expires if I can't get into a testing facility in time, or is LARA extending the deadline?
 - a. *LARA is extending the deadline for temporary licenses. A notice went out to licensees affected this month. Another will go out to those affected next month.*
6. Can we deny someone entrance to our store if they are not wearing a face covering? Are there any legal ramifications of doing this?
 - a. *Each individual pharmacy can make their own policy decisions in terms of how they want to apply the Executive Order (EO).*
 - b. *The EO states that if you can medically tolerate a facemask, then you should wear one. The challenge is that how are you going to enforce that if you have a policy that says everyone has to have a mask. Disability laws protect those individuals. And if pharmacies are also subject to Section 1557 of the Affordable Care Act that provides additional discrimination rights for patients who are using healthcare services as well.*
 - c. *LARA encourages each pharmacy to consult with their legal counsel to avoid legal ramifications.*
 - d. *If the pharmacy required masks, they can offer other services, such as delivery/curbside pickup or encourage the utilization of a drive through.*
7. Is the facemask provision for anybody that enters the pharmacy, or does it include pharmacy staff as well?



- a. *Any employee who interacts with the public must wear a face covering.*
 - b. *EO 2020-71 is pretty specific, LARA encourages licensees to read it. The EO can be read [here](#).*
 - c. *Kim added that there might have been some confusion with MiOSHA standards/guidelines. OSHA is under the labor and economic opportunity department. They put out guidance for employers to maintain occupational health and safety of the employees in particular. They are just guidelines and will not be mandated.*
8. When do the pharmacy specific executive orders expire? What happens after they expire? Do you think the Executive Orders will be extended?
There are four pharmacy specific executive orders – it is not known if the EO's will be extended:
 - a. *2020-49 allows LARA to authorize CE credits for hours worked. It expires May 12 at Midnight. The Governor could be renewing but we are unsure at this time. LARA has reached out to the Governor's office for guidance on the expiration date of this EO.*
 - b. *2020-56 allowed for emergency refills, substitution of emergency refills, and remote supervision. This EO expires on May 19 at midnight.*
 - c. *2020-61 allowed licensees licensed under Article 15 working in health system facilities to operate outside of the scope of practice. This is in effect until the emergency has been ended.*
 - d. *2020-60 requires members of the public and employees who interact with the public to wear face coverings. Additionally, two hours per week need to be reserved for members of the high risk population to shop and pick up prescriptions.*
9. Is LARA currently conducting pharmacy inspections? What is the processing time and turnaround?
 - a. *Out of state licensees are generally completed within 30 days. For licensees in the state of Michigan, an onsite inspection must be conducted. However, with the current public health emergency, LARA has had to adapt virtual inspections via FaceTime, Zoom or Skype. For instance, to maintain social distancing standards, if the inspector needs to confirm that a pharmacy has hot and cold running water, a thermometer is placed beneath the running water to display an appropriate temperature.*
 - b. *Turnaround time is dependent upon the applicant. The applicant is contacted within 48 hours of the application being assigned to an investigator. Delays can occur if the contact person designated on the application is not the individual who then inquires about the status of the application. Logistical delays can also occur, including a pharmacy not having all of the requirements under the code or there is a change in the pharmacist in charge, which in return cause a delay in the inspection.*
 - c. *LARA encouraged licensees to email BPLHealth@michigan.gov for questions. The licensing staff can then connect applicant with their assigned investigator to address any issues.*
10. I applied for a pharmacy license before COVID happened, but haven't heard anything—is LARA still processing licenses? How long is the expected turn around for new licenses?
 - a. *LARA encouraged licensees to email BPLHealth@michigan.gov for questions. The licensing staff can then connect applicant with their assigned investigator/individual to address any issues.*
11. Will LARA take action against prescribers who continue to prescribe hydroxychloroquine even though the FDA has provided guidance that it should only be used in the hospital setting?



- a. *LARA thoroughly vets all allegations taken against a licensee. An allegation that involves misconduct of a prescriber or any other licensee is reviewed by a panel of board members from the appropriate licensing board. For the Board of Pharmacy, three pharmacists review the allegation and two of the three need to agree. If the members agree, then an investigation is opened to look into the facts. Then a subpoena for the appropriate records is issued. The case is then assigned to the Department's investigators. For pharmacy related allegations, the Department has a staff of six pharmacy specialists and four regulatory agents. The case is assigned to one of the individuals to interview all of the appropriate witnesses. In the case of a prescribing allegation, the Department generally has the case reviewed by an expert in the field, who has similar credentials to the licensee at issue.*
 - b. *Action is taken if needed.*
 - c. *All cases are evaluated on a case to case basis.*
 - d. *LARA's communication that was issued in regard to hydroxychloroquine was a clarification that enforced current practice. When you issue a prescription there needs to be a legitimate medical purpose for that prescription and hoarding a drug and supply is not acceptable.*
 - e. *The total dispensing data for the state of Michigan for hydroxychloroquine spiked an increase in new prescriptions since COVID-19. The notice was issued because LARA was concerned about the initial shortage of the drug. The objective of that communication was simply to remind licensees that hoarding, as well as self-prescribing without a legitimate medical reason is not appropriate.*
 - f. *Practitioners should not feel discouraged to issue a prescription for hydroxychloroquine, if they are working within judgement. The pharmacist must then utilize their clinical judgment as to whether the prescription presented is legitimate and to determine whether that drug should be dispensed or not dispensed. That decision lies with the pharmacist at the end of the day and that is what pharmacists have been trained to do. LARA relies on the pharmacist's expertise to make those clinical judgements in those decisions at the end of the day.*
12. How many remote pharmacy license applications has LARA received? Have you seen an increase since COVID-19 began?
 - a. *LARA has not seen a huge increase since COVID-19 began. Setting up a remote pharmacy during the middle of a pandemic might have its own challenges. LARA received three applications - two were denied because they did not meet the requirement. The other is pending.*
 - b. *LARA believes that there might be an uptake in the near future.*
13. Are any pharmacies licensed as a telepharmacy under the EO?
 - a. *No.*
14. Is LARA aware of any medication shortages in the community pharmacy setting?
 - a. *LARA is not aware of shortages within the community pharmacy setting. There has been some shortages here and there.*
 - b. *Shortages in the community setting were mostly in the area of respiratory care medication, such as albuterol inhalers. But that has been resolved.*
 - c. *Most of the concern lies a few months down the road. Since the distribution channel for most of our drugs come from China and India. In response to COVID-19, India has shut down outbound shipments for three or four weeks. That said, most wholesalers have a supply of inventory on*



hand that may last longer than that but it is unclear of what the exact impact might be this fall.

15. Does LARA have a stance/guidance on remdesivir?

a. *LARA does not have a stance on drugs in general. LARA forwards guidance from the FDA, similar to MPA. LARA encourages licensees to READ all FDA guidance in detail. There was a lot of misunderstanding about some of the FDA's initial emergency use authorizations around hydroxychloroquine, because people were not reading it, that it was approved for hospitalized patients and specific circumstances.*

16. Does my employer have to pay for my COVID-19 test if I think I was exposed while working at the pharmacy?

a. *LARA indicated that this is a workplace issue (MIOSHA) not a licensing/regulatory issue.*

17. Last week Brian mentioned a bill that would give pharmacists a tax break is there any update on that bill?

a. *The HEROES Act introduced by Congressman Huizenga and MiHEROES act introduced by Senator Victory bills mirror each other, one at a federal and one at a state level. The bills give tax breaks, up to \$12,500 a month up to four months to healthcare professionals. MPA is working on including pharmacy technicians in both bills. Stay tuned, MPA will share information as it develops.*