GEORGIA BOARD OF PHARMACY

Emergency Conference Call 2 Peachtree St., NW, 6th Floor Atlanta, GA 30303 March 23, 2020 11:00 a.m.

The following Board members were present:

Lisa Harris, President Mike Faulk, Vice-President Carrie Ashbee Michael Azzolin Michael Brinson Hal Henderson Bill Prather

Dean Stone

Staff present:

Tanja Battle, Executive Director Dennis Troughton, Director, GDNA Michael Karnbach, Deputy Director, GDNA Max Changus, Assistant Attorney General Kimberly Emm, Attorney Brandi Howell, Business Support Analyst I

Open Session

President Harris established that a quorum was present and called the meeting to order at 11:01 a.m.

Emergency Rule Regarding Medication Limitations: President Harris discussed the draft sent out by Ms. Emm regarding medication limitations. She asked if azithromycin should be included. Mr. Brinson commented that prescribers are just writing an increased number of prescriptions for this medication. President Harris responded that she understands that azithromycin does not do any good for COVID-19 unless it is taken with hydroxychloroquine. Mr. Brinson agreed that the Board needs to take action, and asked what happens if the pharmacist receives a prescription for hydroxychloroquine to be taken six times a day for 30 days and there is not a diagnosis on it. He added that if the diagnosis is not included, should the pharmacist still fill the prescription? Or should he/she just fill for 14 days like this rule says? Mr. Brinson stated that the pharmacist would have to call and try to explain to the nurse about what is going on, unless they note it is for malaria. Ms. Emm commented that if they note malaria, when that is not the case, they are creating a fraudulent prescription. President Harris stated that if the Board adopts this rule, it needs to make sure the Georgia Composite Medical Board is aware. Mr. Brinson agreed. Ms. Battle commented that the Medical Board has already been in discussions about this issue, but she is unsure what that board's intentions are regarding this matter. Mr. Prather suggested doing a press release regarding the matter.

President Harris asked for comments about azithromycin. She stated that she has not seen an uptick in overprescribing in her area, and there are COVID-19 cases there, but if a patient goes to urgent care they will give him/her a z-pack. Mr. Prather stated that he believes azithromycin should be included in the proposed draft. Mr. Azzolin asked, given the Board is going to require a diagnosis on the prescription, if it will be okay to take the diagnosis over the phone. President Harris asked if the pharmacist would be required to send the patient back to get a new prescription with a diagnosis code on it? Mr. Stone commented that we are trying to promote social distancing. Ms. Ashbee stated that she agrees with Mr. Prather's point about issuing a press release and stated to just point to these other examples where the Board is seeing this issue across the country.

The Board discussed suggested changes to the rule. Mr. Brinson made a motion to remove the word "azithromycin" from the proposed rule and adopt. Mr. Stone seconded. Discussion was held by

Mr. Azzolin circled back to the issue of whether the prescription should come with the diagnosis, or if the pharmacist should call the physician. President Harris responded that the diagnosis should be on the prescription, but if the pharmacist has to call for it, that would be permissible. Mr. Changus asked Director Troughton if the Board has ever done anything like this before such as imposing this sort of restriction for a particular drug? Director Troughton responded that he was not aware of such a time. Mr. Azzolin commented that in a hospital setting, all medications require a diagnosis. He stated that it is not always followed as it is a Joint Commission and CMS requirement, not Georgia law or rule. President Harris stated they require a diagnosis code and thinks that the Board can get the word out to urgent care and emergency rooms. Mr. Azzolin commented that there is a Georgia Emergency Medicine Association too. Mr. Prather agreed and stated the Board should issue a press release as well. Mr. Brinson commented that he does not think retail pharmacies would be affected that much, but hospitals are in dire straits trying to find these medications. President Harris stated that it would affect retail pharmacies as well as the patients will be coming to the local drug store to get this. With no further discussion, the Board voted unanimously in favor of the motion.

Ms. Emm stated that the Board will need to re-vote to include the changes made to section (a). Mr. Brinson made a motion to adopt Rule 480-10-0.38-.22 Medications Limitations. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Rule 480-10-0.38-.22 Medications Limitations.

No prescription or practitioner drug order for chloroquine, hydroxychloroquine, or mefloquine may be dispensed or distributed unless all of the following apply:

- (a) The prescription or practitioner drug order must include a diagnosis, whether written or verbal, from the prescriber consistent with the evidence for its use;
- (b) The prescription or practitioner drug order is limited to no more than a fourteen (14) day supply; and
- (c) No refills may be permitted unless a new prescription or practitioner drug order is furnished.
 (d) This emergency rule will not apply to patients previously established on any of the above listed drugs prior to the effective date of this rule.

Signature Discussion: Director Troughton stated that the question GDNA is receiving on this matter is concerning required signatures for prescriptions as the patient picks them up. He stated that it is not required by Georgia law or rule. He stated that any signature required is done so by delivery by mail or pharmacy. Director Troughton stated that the signature given at a pharmacy is based on insurance contracts/Medicaid contracts with the pharmacy. He stated that he is unsure as to whether or not this is a board matter. President Harris stated that for PBMs, the pharmacist can write "COVID-19" on the signature in case the pharmacy is audited showing the patient did not sign it. Mr. Stone stated that is what he is having to do. He added that sometimes he wonders if the Board should put something on its website reflecting this. Director Troughton commented that when he is asked questions about the signature, he can only respond by stating it is not required by Georgia law or rule. Mr. Faulk agreed that this was not a board issue.

Governor's Executive Order: Director Troughton provided the members with a copy of the Governor's Executive Order signed on March 20th related to pharmacists being permitted to dispense a 90-day supply of a prescription drug in the event that the patient has no remaining refills and the pharmacist is unable to contact the issuing practitioner to obtain refill authorization. He stated that members may start receiving calls regarding schedule IIIs, IVs and Vs being refilled without following this order. Director Troughton stated that Deputy Director Karnbach checked with DEA's office in Atlanta and there is no such federal waiver for schedule IIIs, IVs and Vs to be filled without authorization or reaching the physician if there are no refills. He stated that this will be a dilemma that needs to be cleared up. President Harris asked how this needs to be corrected.

Mr. Changus commented that, in reading the order, it is narrowly constructed to only address specific issues. Mr. Changus stated that if a board member is asked about it, he/she can tell the person what the order says and respond that the DEA has not changed its position on the matter. Mr. Changus continued by stating that he feels like the Board needs to be forward thinking in terms of how the practice of pharmacy operates under this new normal. He stated that if anyone has any thoughts on this matter to feel free to email him regarding such. He stated that he does not know if any action will be taken if people are following the best guidance in good faith. President Harris asked if someone could communicate to the Governor saying the Board would like to amend it? Mr. Changus agreed that would be sufficient. Mr. Azzolin commented by stating that most pharmacists will use logical judgement. Mr. Faulk stated that a pharmacist is not required to fill a prescription if he/she does not feel comfortable about it. Mr. Stone agreed. Director Troughton stated that his main purpose of discussing this with the Board is that they will likely get more questions about this if this crisis stretches out. He emphasized that the DEA has not made any changes regarding this matter. Director Troughton stated that the GDNA agents will be instructed to suggest individuals check with DEA for further clarification if needed.

GDNA Inspections: Director Troughton stated that GDNA will be cutting back its routine inspections, but they are responding to reports of impairment and/or diversion. He stated that Critical Point and USP say the engineering items for sterile compounding are in place. He stated that agents may walk in a facility at some point where they do not have masks or gloves, and in that situation the agent will just note observations and educate on the latest Board/Governor notices. Mr. Stone stated that they are all trying to limit contact and asked if agents were still out doing inspections. Director Troughton responded that hospital inspections, other than emergency situations, have ceased unless it was something where there was a public safety issue. He added that there are no routine retail inspections going on at this time. He stated that GDNA can be very useful to educate and calm pharmacies and one of the things GDNA will do, while being mindful of social distancing, is use this time to train and fulfill continuing education requirements.

Technician Remote Order Entry: President Harris stated that she and Mr. Stone were talking and each thinks the Board will have to address technicians doing remote order entry. Mr. Stone stated that he knows everyone is trying to take safety measures. He added that a lot of places are breaking their teams down. He stated that in terms of long-term care facilities, the technician does the data entry, it then goes to the pharmacist who verifies and checks. It is then sent to packing/assembly. He stated that the technician puts it together, the pharmacist checks after packing and then it is sent out to the home. Mr. Stone stated that they are trying to limit contact and having technicians enter prescriptions remotely with the pharmacist checking. He stated that he thought that it does not sound like a bad process and wanted to discuss it with the Board. Mr. Henderson stated in his area of practice they have to have the pharmacist in the pharmacy to maintain ratio. He stated that if the pharmacist and technician are working remotely, then that would achieve what we are trying to accomplish. He added that neither has to be in pharmacy and they are doing exactly what they would do if they were in the pharmacy. Mr. Azzolin commented that the technician would be only be a data entry person and not under the direct supervision of pharmacist. He stated that it seems they would not have to be licensed as a technician. Mr. Azzolin stated that he would argue in this case technicians would need to do that work in this type of environment. Mr. Stone stated that in this instance, the Board needs to do something to help these places because they are trying to protect the public. Mr. Faulk commented that this would be a conversation for another meeting. Mr. Stone responded by stating that this is a real issue and there is a pandemic going on now. Mr. Azzolin asked if there was a way to imply that a person is doing data entry. In this instance, the pharmacist would be the one ultimately reviewing the prescription and that pharmacist is still the secondary as it always has been, as long as that data person is not doing any clinical work. That offsite individual can do data entry and insurance adjudication? He added that the individual would be considered a technician, but would not be subject to being under the direct supervision of a

pharmacist. Ms. Emm commented that O.C.G.A. § 26-4-82(c)(3) states in part, "When electronic systems are employed within the pharmacy, pharmacy technicians may enter information into the system and prepare labels; provided, however, that it shall be the responsibility of the pharmacist to verify the accuracy of the information entered and the label produced in conjunction with the prescription drug order;" She continued by stating that this does require whomever is doing the data entry to be registered. Mr. Changus commented that when this law passed, it was meant to be very restrictive.

Hour of Operation: Ms. Battle commented that the board office has changed its operations due to the pandemic. She stated that operations will continue from 8 am to 5 pm through telework options that have been implemented for staff. She added that individuals may drop off documents between the hours of 1:00 p.m. and 3:00 p.m. Ms. Battle stated that calls are being returned and emails responded to in a timely manner.

Pursuant to O.C.G.A. § 50-14-1(3), the Board declares that special circumstances exist warranting the holding of this meeting on less than 24 hours' notice, those circumstances being the COVID-19 pandemic.

There being no further business to discuss, the meeting was adjourned at 12:15 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, April 15, 2020 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I Minutes edited by Tanja D. Battle, Executive Director