The Future of Cannabis Manufacturing in Georgia

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THE FUTURE OF CANNABIS MANUFACTURING IN GEORGIA

Ever since Georgia legalized non-smokable forms of medical cannabis in 2015, the question of how to provide qualified patients with safe access to legally permitted products has vexed the legislature. This quandary led to the formation of not one but two legislative commissions to investigate the dilemma and provide recommendations. The first of these was the Georgia Commission on Medical Marijuana. Although its efforts at legislation were ultimately unsuccessful, its validation of the problem precipitated creation of a second, more-focused commission, the Joint Study Commission on Low-THC Medical Oil Access. After eight months of hearings and comparative state law analysis, that commission released its final report in December of 2018.

The report’s two-page “Findings and Recommendations” first urges the federal government to reschedule cannabis from a Schedule I drug to a Schedule II drug. Rescheduling cannabis as a less restricted drug would open up new options for publically-funded research and distribution, options not currently being considered because of federal funding implications. The Commission goes on to state, however, “in the event the federal government fails to reschedule cannabis,” the Commission recommends that the General Assembly pass legislation during the 2019 Legislative Session pertaining to “the security and control of all aspects of the [cannabis cultivation] process” and “quality

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6 Id. pg 5
control.” Although the short report provides little guidance in terms of creating an effective regulatory framework, it clearly calls for the creation of a comprehensive regime to regulate the domestic cultivation and distribution of cannabis in Georgia.9

Detailed regulations backed by severe penalties for manufacturers’ noncompliance will be necessary to secure passage of any proposal though.10 To better protect their clients, attorneys interested in advising applicants will need to anticipate the regulatory framework likely to become law. Those looking to predict the shape of that framework must consider the commission’s brief report in the context of prior legislative history, which provides some guidance on how the legislature might handle key challenges not adequately addressed by the report. By examining the Commission’s report alongside previous proposals, we can gain a better idea of the considerations likely to guide future regulations, particularly those pertaining to the local cultivation and distribution of cannabis, and can make more accurate predictions about the future of cannabis manufacturing in Georgia.

Georgia’s first steps on the journey to the in-state production of cannabis began with the enactment of House Bill 1 in 2015.11 Indicative of its compassionate intent, the bill was coined “Haleigh’s Hope Act” in honor of Haleigh Cox, a child who suffers from epilepsy but is able to manage her debilitating disease through the use of medical cannabis oil.12 Although the law allows compassionate use, it does not provide any means for qualified citizens to access their physician prescribed medication without traveling outside the state.13 As a consequence, patients like Haleigh have been forced to cross state lines with their medicine, breaking both state and federal drug trafficking laws in the process.14 Since that original legislation, the list of covered diseases has been expanded from eight to sixteen ailments,15 but there has been little progress towards resolving the in-state access dilemma. In fact, Georgia’s House of Representatives rejected the only proposal submitted for a vote to date, House

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8 See Final Report of the Joint Commission on Low THC Medical Oil Access supra at 5-6.
9 See generally Id.
10 Torres, supra note 4.
11 Bluestein, supra note 1.
13 See Bluestein, supra note 1.
15 See H.B. 65.
Bill 722 (“H.B. 722”). Although this bill did not ultimately pass, much can be learned about the considerations likely to guide future legislation relevant to the manufacture and distribution of cannabis in Georgia by examining that proposal. The following list of measures relate to supply chain concerns associated with in-state manufacturing and are most likely to steer the legislative debate.

First, despite a disjunctive definition of “manufacturer,” H.B. 722 would have obliged each license holder to house all “cultivation, harvesting, manufacturing, packaging, and processing” at a single facility from which products would be shipped to their dispensary locations. Such a requirement forces manufacturers to be vertically integrated, and thus able to bring products to market single-handedly, increasing product control and the risks associated with transfer and mishandling. This vision of vertical integration was supported by the commission in the lead up to its report. If the legislature agrees with their assessment, it will likely require potential manufacturers demonstrate this structural capability before obtaining a license.

Second, as part of the licensing process, H.B. 722 would have required manufacturers of cannabis to demonstrate the ability to meet strict due dates for commencement of operations and pay a non-refundable fee of $20,000.00. These requirements work to front-load much of the expense of starting a manufacturing operation. Front-loading acts as a safeguard, relying on banking and zoning laws to ensure only legitimate business interests with strong community ties are able to secure the significant upfront investment and local support needed to obtain a license. The Commission similarly recommended a “one-year deadline for commencement of operations” and “[user] application and licensing fees.” Although the commencement timeframe and fee amount is subject to adjustment, the legislature is likely to employ similar requirements in keeping with this front-loading theory.

Third, H.B. 722 would have obliged the state to “register a minimum of two and a maximum of six in-state manufacturers” with each registered

16 See H.B. 722, 153rd Gen. Assemb., Reg. Sess. (Ga. 2016) at 31-2B-1(6); “Manufacturer,” is defined as any registered entity allowed to “cultivate, acquire, manufacture, possess, prepare, transfer, transport, supply or dispense medical cannabis, delivery devices or related supplies and educational materials.”
17 Id. at 31-2B-12(A).
19 Id. at 31-2B-4(B)(1).
20 See H.B. 722 at 31-2B-20(B).
21 See Final Report of the Joint Commission on Low THC Medical Oil Access at 5-6.
22 See H.B. 722 at 31-2B-4(C)(1-6).
manufacturer limited to the operation of four “distribution facilities, . . . based on geographical need throughout the state.” Such limitations on available licenses and consumer-facing dispensaries corral what would otherwise likely be a proliferation in cannabis dispensaries across the state. The Commission’s report was notably different, however, suggesting the state offer “ten grow licenses, ten manufacturing licenses, and an adequate number of dispensing licenses.” Considering its previous endorsement of a vertically integrated business model, it is curious that the commission did not explicitly dictate licensed manufacturers also be licensed growers and dispensers; however, the more interesting takeaways are the opinions of the commission that more licenses are needed than previously suggested and the number of dispensaries should be left to some discretion based on evolving needs. While compromise is sure to play a role in this determination, the legislature will undoubtedly include similar limits as a means of lessening opportunities for errant cannabis to become available outside the regulated market.

While limitations on the number of facilities reduces the risk of unaccounted for cannabis on a macro level, facility security measures and integrated tracking systems perform a similar function at the micro level. Under H.B. 722, not only would manufacturers have had to implement certain basic facility security measures, but they would have also had to track all processed products and submit monthly reports to the Commissioner with detailed distribution data. Although the Commission’s report does not mention security or tracking systems, future participants can be sure the legislature will require manufacturers take reasonable security precautions and maintain detailed records for state inspection along every stage of the manufacture and distribution process.

Fourth, in addition to these product control measures, H.B. 722 included provisions aimed at ensuring product safety, potency, and legitimacy. Manufacturers would have been subject to “reasonable [State] inspection,” at the behest of the Commissioner, including “independent laboratory testing” of product “content, contamination, and consistency,” and “examinations of

23 Id. at 31-2B-12(A).
24 See Final Report of the Joint Commission on Low THC Medical Oil Access at 5-6.
26 Id. at 31-2B-5.1(D)(17)(E).
27 Id. at 31-2B-13(H)(1-3).
28 Id. at 31-2B-12(G).
29 Id. at 31-2B-6(D).
30 Id. at 31-2B-12(B).
the business’s affairs and conditions.”31 These extensive inspection powers with no notice requirement may have in and of themselves been sufficient to assure regulatory compliance, but for good measure, H.B. 722 would have also assessed an annual user fee “equal to the cost of regulating and inspecting” a manufacturer’s operations.32 Assigning these costs to manufacturers would have created an even stronger incentive to comply as a means of reducing associated fees. Similarly, the Commission suggests “independent lab testing procedures with minimum standards for product purity and safety.”33 While it provides no further detail regarding actual testing procedures, the Commission previously floated the idea of utilizing those used by the state’s Board of Pharmacy.34 Whether the legislature chooses to utilize the inspection and product testing procedures set forth in H.B. 722, those of the Board of Pharmacy as opined by the Commission or its own newly created set, there will almost certainly be some prescription for inspection and testing to ensure quality control.

Fifth, in addition to the prior operational requirements, H.B. 722 dictated the manner in which manufacturers would have advertised and sold their products. For instance, “signage, marketing, display and advertising,”35 as well as “patient fees,”36 would have been subject to reasonable restriction. Manufacturers would also have been prevented from employing anyone under the age of twenty-one or with a criminal background.37 Perhaps most importantly though, manufacturers would only have been able to sell their products to patients registered with the state.38 Punishment for violations of these restrictions would have included up to two years imprisonment,39 up to $3,000.00 in fines,40 permanent debarment,41 and “any other applicable penalties in law.”42 By holding manufacturers liable for violations of these point-of-sale restrictions, such policies encourage manufacturers to make prudent decisions regarding how they sell products with the ultimate goal of limiting cannabis use to medicinal, rather than recreational, purposes. The commission’s report does not specify similar restrictions or penalties, although it does allude to heavy state oversight

31 Id. at 31-2B-5(D-G).
32 Id. at 31-2B-20(C).
33 See Final Report of the Joint Commission on Low THC Medical Oil Access at 5-6.
34 See Driscoll, supra note 18.
36 Id. at 31-2B-20(D).
37 Id. at 31-2B-12(I).
38 Id. at 31-2B-13(F) (1-6).
39 Id. at 31-2B-18(A).
40 Id. at 31-2B-18(A).
41 Id. at 31-2B-18(A).
42 Id. at 31-2B-18(F).
by both the Georgia Department of Public Health and the Georgia Bureau of Investigations.43 Considering the state’s aversion to facilitating the recreational use of cannabis, it is likely the legislature will create similar restrictions, although with perhaps more detailed parameters, and enhanced penalties so as to further deter violations.

Lastly, H.B. 722 would have charged the Georgia Commission on Medical Marijuana with several regulatory tasks.44 This state agency would have been entrusted with licensing authority, based on the evaluation of six prescribed criteria including technical expertise, employee qualifications, financial stability, security, capability and projected patient-fee assessment.45 The agency would have had to create and maintain a “patient registry program”46 to limit access to only those citizens with “qualifying medical conditions.”47 It would also be charged with oversight, inspection and enforcement duties to ensure manufacturer compliance. Additionally, H.B. 722 called for creation of a “task force” consisting of twenty specifically designated members to conduct “an impact assessment on the use of medical cannabis” and suggest appropriate modifications if necessary.48 Taken as whole, these safeguards would have given the State an unfettered ability to exert regulatory authority at each stage of the distribution process, from cultivation to consumption. Similarly, the Commission’s report suggests the duty of licensing be a state function, however, the only parameter it provides is that “half of the licenses [be] granted to large capital investment entities, and half to smaller capital investment entities.”49 It also mentions a state-run patient registry like H.B. 722 but it did not go so far as to suggest any post-implementation assessments.50 Depending on the extent to which the legislature allows for discretionary determinations, the responsibilities placed on the state’s regulatory body may be expanded or even narrowed from that proposed in H.B. 722, but regardless, the state will undoubtedly retain the exclusive ability to grant licenses and control the registration of qualified patients.

Despite H.B. 722’s inability to garner the requisite support to become law, it certainly presents a starting point for anticipating the framework likely to

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41 See Final Report of the Joint Commission on Low THC Medical Oil Access at 5-6.
42 See generally H.B. 722.
43 Id. at 31-2B-4(C)(1-6).
44 Id. at 31-2B-8(A).
45 Id. at 31-2B-1(11).
46 Id. at 31-2B-21; 31-2B-22.
47 See Final Report of the Joint Commission on Low THC Medical Oil Access at 5-6.
48 Id. at 5-6.
regulate the manufacturing of cannabis in the state. Because of its apparent inadequacy though, it would be prudent to consider the criticisms leveled against it. For instance, Senate Health and Human Services Chairwoman Renee Unterman was reported as generally feeling it “needed more work and discussion.” More pointedly, the Executive Director of the Prosecuting Attorneys’ Council of Georgia, Chuck Spanos, criticized it for assigning product tracking duties to manufacturers with purely profit-driven objectives. Considering the end result will have to include some means for qualified patients to access cannabis without leaving the state, the legislature may find it difficult to strike the right balance for a historically conservative state whose leadership has openly expressed a strong aversion to any law expanding access. It will likely need to propose a more tightly regulated program than that of H.B. 722 in order to become law, but thankfully, there are ways to achieve this goal without completely discarding the foundation laid in H.B. 722.

In response to general concerns, the legislature may decide to strengthen the State’s enforcement capabilities. It could provide the State with additional enforcement tools such as injunction, seizure and condemnation provisions, and concomitantly increase H.B. 722’s modest provisions for criminal prosecution and civil money penalties to enhance their deterrence factor. The legislature could also require outside compliance consultants to be on-site and independently liable for code violations, presumably at a premium cost to manufacturers akin to insurance. By augmenting the state’s ability to constrain and penalize manufacturers, general concerns regarding the law’s efficacy should be sufficiently assuaged.

Further, regarding Mr. Spanos’ concern that “the fox is guarding the henhouse,” perhaps the legislature could further explore limiting licenses to non-profit organizations. This essentially cosmetic fix may entail state-funded subsidies for start-up costs and reasonable allowances to cover operational expenses, but this trade-off could remove the pale of improper influence and set a decidedly more altruistic tone. Alternatively, the legislature could subject manufacturers to the Board of Pharmacy Licensure and its related disciplinary consequences under Chapter 4 of Title 26 of the Georgia Code, thereby holding cannabis manufacturers to the same standards held to be sufficient for regulation

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51 See Torres, supra note 4.
54 See Lee, supra note 52.
of other privately-owned, commercial prescription-drug dispensaries around the state. The legislature could also work more closely with prescribing physicians to determine definitively the amount of cannabis needed for Georgia’s relatively small patient population. If this effort could more accurately match supply to demand, it might reduce the amount of cannabis available for unauthorized end-users.

No matter the extent to which the legislature utilizes H.B. 722 or the commission’s recent recommendations, prospective manufacturers and their legal counsel can be assured that all of the aforementioned considerations will be taken into account and addressed, as they are crucial to building a consensus proposal able to become law. The more that attorneys practicing in this emerging area of law know regarding the development of these considerations, the more likely they will be able to forecast for their clients the future landscape of medical cannabis distribution in Georgia.

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