CATLAB, LLC

Guy Sylvester, Owner/CEO
CATLAB, LLC
19 Levesque Dr.
Eliot Maine 03903

February 15, 2023

Lynne Caswell, Esq.
Legislative Analyst
Office of Policy and Legal Analysis
Maine Legislature
13 State House Station
Augusta Mine 04333

I. **Efficacy of the variance of testing:**

The industry has their opinion of each lab. What each lab does well, and why they use a particular lab, often based upon the results the (3) labs provide. I heard one of the speakers Monday, 02/13/2023 state that he heard an individual walking around a conference and speaking poorly about one of the labs. I hear the same thing over and over again about each lab's pro's and con's. However, what this speaker was referencing is the fact that if you talk to most individuals responsible for testing for their firm, they will tell you the following: *"Two of the labs in the Maine Cannabis Testing Program fail me for metals and mold all the time, the third lab passes me. Why would I send my samples to the two labs that fail me?"*

a. The two labs in the industry that fail most often, referenced are CATLAB and NOVA. The lab that consistently passes samples for metals and mold is Nelson. (By consistently I mean the belief in the industry is 1 out of 10 samples will fail with NOVA and CATLAB. The fail rate at Nelson is much lower). I do not have the actual numbers because the CDC and OCP will not release this data. (I have asked) However, NOVA has a major lawsuit against OCP to obtain this data. Not the names of the customers associated with the data. Just the data. I would urge the legislators to look at this data.
b. NOVA and CATLAB have state of the art equipment. Nelson's equipment and methods are antiquated.

METLAS:

i. NOVA and CATLAB digest metals by microwave digestion. This method allows for a very high efficiency rate, allowing for all the metals in the sample to be detected.

ii. Nelson uses a block digester. Block digesters have 50% of the efficiency that microwave digestion has. (Read up on it). CATLAB has also conducted in-house studies to compare the two methods and our findings were very similar. As a result, a customer that may receive results for Arsenic at 300ppm, would fail, as the state action level is 200ppm. However, 50% of that result would be 150ppm, and that result would be passing by the state action level.

c. Mold:

i. Nova and CATLAB use BioMerieux TEMPO and high-tech piece of equipment that count the colonies for mold. TEMPO® | Pioneering Diagnostics (biomerieux.com)

ii. Nelson makes their own agar, pour it into their own plates and incubates the mold using plate method.

iii. The TEMPO unit has manufacturers literature for incubating for 72 hours. However, the plating method, according to my own experience requires 7-10 days. Yet customers are stating they get data in 2-3 days from Nelson. Which means mold has not had an opportunity to grow. (I am a Board-Certified Microbial Consultant. Certified through www.ACAC.org)

iv. Again, resulting in Nelson yielding much higher pass rates than CATLAB and NOVA.

d. The larger concern with the aforementioned is that eventually the CDC will unify the methods and equipment leaving the majority of the growers in the state finding they will start to have a much higher failure rates due to the fact that all three labs will be required to use state of the art equipment. The other issue is that currently the consumer in the Adult Use industry is in fact purchasing products that should not be passing and has high levels of contamination.

e. I can also state that one of the owners of NOVA and myself/CATLAB pulled samples from an adult use dispensary, with the strains known to have failed at CATLAB or NOVA but passed at NELSON. The samples were purchased, mixed to yield a homogeneous sample. Both labs analyzed the samples and both labs failed for metals. These are samples that are being sold in AU dispensaries and stated to have passed the state standards for testing.

II. Efficacy of Audit Testing.

The EPA and FDA have required methods to follow. (EPA 600 series methods and SW0846). The Cannabis industry is Performance Based Method development. A lab develops a method then is

required to provide proof on accuracy, precision, and test results from a blind study. (A third party provides samples in which the results are unknown to the lab). The Blind results must meet a 100% accuracy requirement. All of these are part of the requirements for a method developed by a Cannabis Testing Facility. In Maine, there are no Auditors that have experience with Performance Based Methods. The lab methods are often compared to the EPA methods, which is the CDC Auditors background. *I would support Audit Testing of the labs so long as it was in addition to the annual audits associated with the current certification process.*

III. LD-48

The changes are slight, at first glance, from the current OCP testing requirements. Specifically: It appears to have changed the language and left out the "Measurement of Uncertainty." For Potency, this is 5% of the THC value a lab produces. Below is an email from the OCP on 09-22-2022 addressing the measurement of uncertainty. I believe this language should stay in LD-48. I just do not see it in the language, and I have not discussed with the OCP so I do not know why they removed it from the historical rules.

"I am writing because OCP has received a number of questions regarding our recently released guidance interpreting the implementation of PL 2021, ch. 558, An Act to Allow for a Variance in the Amount and Potency of Cannabinoids in Adult Use Edible Marijuana Products. Given these questions, we wanted to make sure all of our testing facility licensees are on the same page about pass/fail limits for potency testing of edible cannabis products.

Simply put, the law allows testing facilities, when determining whether a package of edible cannabis products passes or fails mandatory testing for potency, to account for the following: 1) up to 10% variance in excess of the 10 mg/serving potency limits (11 mg/serving); 2) up to 5 mg/package in excess of the 100 mg/package potency limits (105 mg/package); ***AND*** *3) the testing facility's own lab uncertainty for its potency testing, up to 5% (up to 0.5 mg/serving and 5 mg/package).*

If a testing facility is using the maximum allowable lab uncertainty for its potency analyses, then the maximum allowable passing potency value of a sample of edible cannabis products would be: ***11.5 mg/serving*** *and* ***110 mg/package****. We know that lab uncertainty is a dynamic value that can vary from analytic batch to analytic batch within and between testing facilities and over time, and therefore, it is inadvisable for your clients to depend on testing*

facility uncertainty when manufacturing edible cannabis products. For instance, one month your testing facility may have a +/- 5% uncertainty on your edibles potency method (thus the 11.5 mg/serving and 110 mg/package pass/fail limits would apply) and the next month you refine your process and get you get your uncertainty down to +/- 2% (bringing your internal pass/fail limits to 11.2 mg/serving and 107 mg/package) -- both months you're still trying to determine whether the samples you're analyzing are within the statutorily defined "ballpark" of 10 mg/serving and 100 mg/package, and your clients should be aiming for those serving and package potency sizes too.

The changes to the law last session were intended to give products manufacturing facility licensees greater flexibility when attempting to manufacture "maximum potency" edibles of 10 mg/serving and 100 mg/package. It was NOT intended to push manufacturers to make 11 mg/serving (and 105 mg/package) edibles, but instead, to not require remediation/destruction of a batch of edibles if the edibles were "slightly" over the statutory caps-- as was the case previously – anything above 10 mg/serving (after accounting for lab uncertainty) would fail mandatory testing.

I hope this e-mail answers your questions but as always, please do not hesitate to reach out if you have any questions.

Cheers!

-Gabi"

Lastly, I would add that after listening to Barry Chaffin at NOVA speak Monday, I support everything he wrote with respect to LD-48. He articulated the points very well. I would simply be repeating what he stated with respect to Water activity, Filth and Foreign Matter, etc. (They need to stay in the testing program.)

MEDICAL TESTING:

Picture a man walking his immune-compromised mother into a dispensary. She, now the patient, meets the Caregiver. The Caregiver prescribes a specific cannabis with specific Cannabinoids to help the ailments of the elderly woman. Does everyone realize that in 95% of these type of cases the cannabis prescribed has not been tested for contaminants: Pesticides, Heavy Metals, Solvents, Microbials, etc. Per

my own study, as well as looking at the data NOVA presented, there is a much higher level of contaminants in Medical Cannabis sold in dispensaries, simply due to the lack of testing. *I highly recommend that the Medical Cannabis in Maine get up to speed with the Adult Use when it comes to testing.*

Thank You

Guy Sylvester, CEO/Owner

CATLAB

Members of the Committee on Veterans and Legal Affairs:

Thank you for your invitation. My name is Barry Chaffin, I am one of the cofounders of Nova Analytic Labs. We are a cannabis testing facility located in Portland, ME. My partners, Greg Newland and Christopher Altomare, and I opened Nova in October of 2020, we were fully accredited by the Maine CDC and OCP by February of 2021 and shortly thereafter we received our ISO 17025 accreditation. My partners and I have a very extensive background in laboratory testing. We've worked as managers, consultants and even lab owners in a variety of analytical testing fields including environmental, pharmaceutical, food testing and clinical toxicology. We have experience in just about every single laboratory regulatory framework in this country.

We were asked to provide testimony regarding:

- The efficacy of the current mandatory testing requirements
- Variance in test results
- Efficacy in audit testing
- Comments on changes proposed in LD48

I hope to address all of the above with this testimony. I have attached documents and links to support the facts below.

First, I would like to address all the common complaints regarding the testing program and the AU Program in Maine.

<u>The claim that food and pharmaceuticals are not tested</u>

Foods and pharmaceuticals are absolutely tested, monitored, tracked and traced. There is an elaborate system of batch, audit, package and facility testing as well as other process monitoring mechanisms including strict facility rules and training all set up and coordinated by the FDA, EPA, USDA, Dept of AG and the CDC. Food and pharmaceuticals is a massive, global industry and dwarfs the scope of each state's cannabis programs. Accordingly, the scope of testing dwarfs the scope that OCP has put forth for cannabis. Food is subject to biologics testing like HIV and HEP A, testing for unlisted ingredients or allergens, harmful materials in the packaging, over 800 pesticides, a multitude of micro contaminants like listeria, botulinin and clostridium and many, many more. The cost to bring a drug or even a generic to market in the US can cost a pharmaceutical company hundreds of millions of dollars just in testing its safety. To say that this system is less regulated than the cannabis industry in Maine is just not correct. And, anyone that would prefer that system to what the OCP has put in place in Maine is the definition of "out of the frying pan and into the fire".

Even with the testing and monitoring system there are hundreds of recalls (thanks to track and trace) and thousands of cases of food bourne illness annually. So, even this program could be better.

To go a step further, cannabis is mostly not a food product in the fact that the majority of cannabis is not ingested, but rather inhaled. There are many studies establishing the safety limits of harmful contaminants, like pesticides, in ingested products. But there is very, very

little information on how these same contaminants affect the human body when inhaled and even less info for when they are combusted and inhaled. We just don't know. Eagle 20 is a perfect example. This was approved for use on certain crops and had acceptable limits for ingestion. There was no info on inhalation. Cannabis cultivators decided to use it on their crops thinking it was "safe". As it turns out, when Eagle 20 is burned it turns into cyanide gas. A lot of cannabis users were poisoned due to this misused product and untested cannabis.

The claim that labs are not standardized

Again, a misconception. Every lab in this state that is accredited to perform testing in the regulated market had to either use an already approved method from organizations like the FDA or AOAC or had to develop an in-house test that followed the guidelines, philosophy and good laboratory practices as set forth by the FDA. These methods had to be validated according to how the FDA requires in-house methods to be validated. On top of that the Maine AU Program outlines certain practices that each lab must follow. Then each lab must be inspected by the Maine CDC and after that must be inspected and accredited according to ISO 17025 guidelines, which is a national framework for testing labs. While there is not one single method that every lab must use for each test, there is a standardized protocol that each lab must follow when developing and proving the efficacy of each test. This is critical in order to not stifle innovation.

The claim that labs are inconsistent

To say that labs in this state are not consistent is based off purely anecdotal evidence. The OCP does not release or allow the release of any of the official testing data in the regulated market. I know this because we've tried to obtain it. This is the only real data that would exist to compare apples to apples. Anything outside this is subject to too many variables, especially related to representative sampling as none of these samples go through the official, regulated process of sampling, chain of custody, track and trace etc. We need transparency of test results in this state if we want to do a true comparison of lab data. And, we need more aggressive enforcement on labs for producing bad data. But, this does not mean that testing results are "useless". From most of the anecdotal evidence that I have seen presented at these hearings there has been, from what I can gather, a supposed 10% variance from lab to lab. While not ideal, this is actually scientifically acceptable. What the real concern should be is not variance, but bias. However, again, without the real data in the regulated market this conversation around variance is not productive.

The claim that testing costs are too high

I've included our fees for each full panel AU test per matrix. Also, going by the data released by OCP for cultivation, the current price for flower is averaging around $8 per gram. Using the different tiers that the AU program sets up for testing, 2.5kg to 10kg, testing would be anywhere from 3% of a cultivator's profit for a smaller batch to less than 0.7% of their profit

for larger batches. The smaller and larger batch sizes all require just one test, the cultivator is only required to provide more sample as they move up in batch size.

The claim that testing takes too long

Our current turnaround time average is 4 days. Most of 2022 we were at 3 days. Recent instrument downtime has increased that average, but that is temporary

The claim that no evidence exists that people have been harmed by Cannabis

This is the most harmful piece of misinformation that I hear. It reminds me of the propaganda around cigarettes or Teflon 30 years ago. We all know how that turned out. There are hundreds, if not thousands, of documented cases of contaminated cannabis causing illness and even death across the country. To list a few: at least 18 people were sickened due to moldy cannabis in Michigan last year that lead to a $200M recall of products; California has reported numerous instances of serious illness and death from Aspergillius, Penicillium and even cryptococcal meningitis from cannabis; CT and Mass both have had cases of overdoses from fentanyl laced illicit marijuana and VT just recently had a serious illness from pesticide contaminated products. These are only a few examples. I would encourage you all to search the web yourself. What you discover will enlighten.
The CDC performed a study in 2016, before the explosion of the regulated market as it is today, and discovered that cannabis users were 3.5x more likely to have a fungal infection than a non-cannabis user. This is due to the large amount of fungal species that thrive on the cannabis plant.

Why Testing is needed:

- As described above, there are contaminants found on cannabis that have been proven to cause harm to humans.
- Cannabis is a unique product in that there is very little information or studies regarding what is safe and what is not due to the federal illegality of the product. Also, due to the fact that cannabis is fused into many different products and consumed through many different routes such as ingestion, inhalation and even skin absorption it is very difficult to compare to other industries when setting "safe" levels of contaminants. The best method is to err on the side of caution.
- The failure rates from our lab for regulated versus unregulated product are staggering. As you can see from the table below, samples that are subject to the safety and tracking requirements under the AU Program rules have a much lower fail rate than those that do not.
- The concerning thing with this data is the failures in the regulated market will be destroyed (if they can't be remediated) but the products in the unregulated market have the potential to end up on the shelves for sale. Currently the Medical program is unregulated and does require mandatory testing or track and trace.

- It is very clear that the practices, most importantly testing and track and trace, under the Maine AU Program have significantly reduced the amount of potentially harmful product available to the public

Test	Failure Rate for Regulated Samples	Failure Rate for Unregulated Samples
Heavy Metals	**0.3%**	**5%**
Microbiological Contaminants (Bacteria and Yeast and Mold)	**9%**	**26%**
Moisture Content and Water Activity	**<1%**	**3%-5%**
Pesticides	**7.4%**	**19%**
Residual Solvents	**1.3%**	**4%**

LD48

Finally, onto our thoughts regarding LD48. We cannot support this bill as written. We feel there are several glaring flaws that will undermine the public health and safety:

- This bill removes the mandatory test of water activity. We do not support this. Water activity is an indication that the plant material has been adequately dried and cured. Higher levels of water activity mean there is more water available for harmful microbes to use and proliferate. A sample that may "pass" microbe testing may actually become contaminated just by sitting on the shelf if the water activity is too high, this is especially true if a product just barely passed minimum safe micro levels. This is true of plant and non-preserved edible products. Also, plant material that is not fully dried can be used to "trick" the contaminants test as higher levels of water will skew the weight of the sample thereby causing a false negative on some tests.
- This bill removes the filth and foreign material test. We do not support this. While some may see this as a superfluous test, it actually serves a very important purpose not only for testing the product in question, but also as an indicator of the quality of a licensee's facility in general. We've discovered rodent hairs or insect legs in some products which leads to their failure. And while some may say that they aren't concerned with "a few hairs or bugs in my weed" and the sample can easily be remediated, this can point to a larger cleanliness and safety issue of the facility or environment in which these products are created especially if a licensee exhibits continual failures in this test.
- Earlier in 2022 the OCP passed what they called "final form testing" and this was something that the industry in general wanted. However, LD 48 does just the opposite. It flips all of the mandated testing to strictly flower and allows concentrates and edibles to go mostly unchecked. Not only does this put the burden of testing solely onto the cultivators, it is a bad practice from a public health and safety standpoint. When the THC in flower is concentrated in oils, distillates, concentrates etc so are the heavy metals and pesticides. So, a flower that passed mandatory testing may produce a concentrate with

levels of contaminants far exceeding the acceptable limits. We have witnessed this first hand in our lab with some clients. Also, as described in the water activity section above, flower or trim with a high water content may "pass" some contaminant testing when it should not, and therefore any concentrate made with that product will be extremely contaminated at unsafe levels. We would recommend true full panel testing to the final form product before it is sold to consumers of ALL product types be it flower, concentrate, oil, edible etc. The only exception would be heavy metals and pesticides in edibles as long as the concentrate used to make the product has passed mandatory testing requirements.

- We do support the addition of audit testing as a SUPPLEMENTAL test to mandatory batch testing, but never as a replacement. Audit testing will give the state more power to monitor lab variances, lab shopping and bad actors in general. It should be viewed as a quality tool for the monitoring of the program while mandatory batch testing should be viewed as a tool for monitoring products for public safety. We do not support the rule that the licensee must pay for the audit test and we would recommend that the state or perhaps the lab or a combination of the two pay for this testing.

Seed2Health Testimony, VLA Education Session on Testing, February 13, 2023 with regard to LD 48 (An Act to Clarify Provisions of the Cannabis Legalization Act Regarding Labels, Packaging and Testing)

Following is the written testimony provided by the volunteer members of Seed2Health Learning Health Alliance on February 13, 2023. As per text of an email received on Friday, February 9 from the VLA legislative analyst, education about testing was sought by the Chairs of the Veteran and Legal Affairs/"VLA" Committee to assist in committee's review of LD 48, *An Act to Clarify Provisions of the Cannabis Legalization Act Regarding Labels, Packaging and Testing:*

*"The chairs are asking **each invited person/group** to speak for about 10 minutes and then be available for questions from the committee.*

*The committee is interested in the **efficacy of the current mandatory testing requirements, the variance in test results, the efficacy of audit testing, and any comments on the changes proposed by the Office of Cannabis Policy** in LD 48.*

The chairs ask that everyone attend in-person (except any out-of-state invitees)"

Statement of Arleigh Kraus

My name is Arleigh Kraus. I have a BS in biochemistry and 20 plus years of experience in laboratory sciences. I am a registered medical cannabis caregiver in the State of Maine and the Chair of the Adult Use and Medical Cannabis Committee for the Town of Warren, Maine, and serve as a founding member of the Maine Craft Cannabis Association, a founding member of Seed2Health Learning Health Alliance, and as a board member of Medical Marijuana Caregivers of Maine. I am the owner of a small organic vegetable and poultry farm and Windhill Organics, which is a medical cannabis company located in Mid-coast Maine.

I come before you today in my role as a member of Seed2Health Learning Health Alliance along with Andrew Thacher, Greg Newland and Kevin McAloon who are also members.

We are speaking about testing on behalf of all of our members. These people include registered "patients" in Maine's Medical Cannabis Program, academics and researchers, experts in learning health sciences, clinicians and pharmacists, therapeutic formulators, as well as licensed cannabis caregivers in the medical program.

These cannabis caregivers work closely as guides with people who find cannabis helpful in living more fully with chronic diseases, and others who use cannabis to recover from injury and sickness, or simply to live a more balanced life.

In many instances, these cannabis caregivers work in concert with treating clinicians, pharmacists, herbalists, other practitioners of complementary and alternative medicine many of whom consider themselves as healthcare caregivers - people whom we refer to within Seed2Health as "Member Guides".

To each of us as Members and Member Guides, testing is a critically important component of

Maine's medical cannabis program. Tests inform us not only about safety ***and*** efficacy associated member health. Tests also inform us about environmental health, plant health and worker health.

In addition to contributing perspectives from my experience in cannabis, testing, and growing many farm products and beneficial plants, a primary role for me within Seed2Health is to connect and make compliant the voluntary consensus guidances that we are creating with the rules, law and policies in Maine.

As an example, within Seed2Health guidances, we support and are working hard to advance one of the stated goals of LD 48 to eliminate redundant and/or unnecessary tests, while building in a smart, cost-effective approach that is value-based. If there is not true value to the end consumer in a given rule or law, we look for ways to find that value. When we can't find that value, we will inform regulators suggesting steps that could be changed or eliminated. Some of us refer to this as "intelligent testing."

Given the enormous complexities of testing within contexts of the cannabis plant, the varied ingredients in the many forms of end products, and ultimately the varied needs of different types of people - and animals - consuming the therapeutic, we hope that members of the VLA will concur that our cannabis programs in Maine must engage and rely on consensus building among those directly affected by testing and those who bring expertise and clarity - before legislative debate. This has not happened with LD 48.

As you will hear from my Seed2Health colleagues, the issues associated with testing cannabis are extremely complex - in many instances the market is, as some say, "ahead of the science."

Secondly, we should seek and build upon cross-market transparency in testing data to inform our consensus building so that we can learn together what is working and what is not - the tagline of Seed2Health.

We need to replace top down approaches to policy and rule setting by a single "expert" perspective with access to data - and engage together with that data in learning and shaping what's best. We need research and insights to do this that do not impose on our privacy or legitimate proprietary interests. This type of data and cross-market learning is missing and needed - especially as it comes to the best use and value of testing.

Andrew will tell you a bit more about Seed2Health and how it is seeking to advance an innovative type of immersive learning that we call learning health. This learning lies within our collective experiences and is informed significantly by lab testing. He will touch upon what we call consensus guidances, and various education and awareness initiatives that members of the Alliance have hosted, as well an event we are shaping for this summer where Testing will be a major topic.

Greg Newland, a co-founding principle of Nova Analytic Labs (which hosted an educational event last summer) will shed light on the various ways that we have been educating ourselves on Testing as well as developing consensus guidances to address issues regarding inter-lab testing

variability.

And then Kevin "Mac" McAloon will speak briefly to the critical role of testing in his work within Maine's Medical Cannabis Program with people and their treating clinicians who are seeking to restore health following disease and injury, or live with pain and other symptoms associated with cancer and other chronic diseases. In each case, Mac supports how the patient is leading the way and the roles that testing can and does play.

Andrew?

Statement of Andrew Thacher
Thank you Arleigh and good afternoon, members of the VLA Committee. My name is Andrew Thacher. I am a registered medical patient in Maine's Medical Cannabis Program and the co-founder of Seed2Health LLC, a self-funded research-stage firm that is supporting Seed2Health Learning Health Alliance and is headquartered in Brunswick at Tech Place.

I have been a grateful summer resident of North Haven Island for all but one of my 67 years. Of note, I am working with Melissa Parkerton, a registered medical cannabis caregiver on North Haven, where we are teaming with patients whom she serves on some very innovative developments. We are learning together what patients, their loved ones and their health providers are seeking from the medical program. Notably, the group recently explored with Greg Newland the use and value of a Certificate of Analysis from a certified testing laboratory -a topic that nobody knew much about.

You've asked us to shed light on the work we are doing with regard to Testing in collaboration with Greg Newland, Chris Hudalla and their labs here in Maine along with others both here in Maine and across the country.

For starters, if you have not seen it, I would urge you to watch an excellent one hour video on testing that we hosted in May, 2021 with Chris Hudalla of ProVerde Labs. The discussion explains many cannabis testing complexities and was found very helpful by our colleagues and members of the VLA. A link to the PDF summary of the discussion with a link to the video is provided below:

See - State of the State_Cannabis Testing in Maine and Beyond_050921_Discussion Panel with C Hudalla and Notes_with updated links.pdf - Guidances 1 - Plant/Cannabis as Catalyst or copy the the following URL if hyperlink is not enabled https://3.basecamp.com/4213185/buckets/24960819/uploads/5816245130

In collaboration with many Mainers as well as experts from across the country, we are developing what we call voluntary consensus guidances and other resources to support something we call *learning health*. The guidances we are creating together are open source and expected to continuously evolve as new understanding is introduced in conjunction with various services and innovations that we are developing.

Simply stated, learning health is a different way of understanding and advancing one's own health; and in so doing, creating the possibilities for understanding what we might learn collectively for the benefit of others. In short, learning health learns safely, usefully, and verifiably from our experiences. The tagline we use is: *Learning what works together...and what doesn't.*

We began synthesizing and harmonizing perspectives of members, member guides and experts in many fields nearly six years ago within the context of learning health using medicinal cannabis as the initial therapeutic catalyst. And there is a not a day that goes by that we do not encounter something else we ought to know about testing

Today, we are collaborating around 15 plus topics comprising Seed2Health Test Guidance for Cannabis. This is one of many classes of Consensus Guidance being developed.

We see these consensus guidances continuously evolving as they learn with deep expertise of Alliance members who are scientists, researchers and practitioners and the lived experiences of members who are seeking health and health restoration on their own or in collaboration with member guides.

Target objectives of the Testing guidances include:

- Implement aspects of the Seed2Health Label Guidance for Cannabis addressing both an untested product market (a market similar to the "cottage industry" standards for small, craft markets) and three classes of tested products which we currently group by business size and safety risk. The three tier sizes are intended to level the cost for testing which grows considerably on a per unit basis when not spread across large batches of tested product.
- Reduce test result variability across testing labs by working together to detect test result differences when they occur, mitigate adverse impacts and make corrections that reduce future variability;
- Eliminate redundant testing and test requirements that do not create value and determine new capabilities and innovative ways to enhance testing value where it is needed.
- Create as open source content reference points a knowledgebase for research use especially among federal, state and other rules and guidelines bodies to help them evolve and implement laws, rules and guidelines associated with testing.

When it is possible to connect a therapeutic profile to a member profile for purposes of safe and secure learning - the ultimate goal of "learning health" - we see testing becoming even more valuable. This is because the immune compromised individual or an individual taking potentially contra-indicated pharmaceuticals is different in terms of safety and efficacy related criteria. Accurate and cost-effective testing will add value to the health of both beneficial plants as well as those engaging with them.

Complicating testing are at least three big factors:

1. The route of administration by which an individual will use the therapeutic. Our digestive system and our skin protect us in ways that are different from when we

inhale cannabis. This affects what tests are beneficial as well as the correct detection limits to accept.

2. The variability among labs. Each lab employs their own equipment and there are no standardized methodologies as of yet. Inter-lab test result variability depends on cross-market adoption of well-considered processes for sampling and many other steps to minimize the consequences of not yet having standardized methodologies.
3. The complexity of cannabis as a plant and a final product, its myriad matrices or product types and the 600+ chemical "constituents" expressed by cannabis. These realities call for varied testing approaches that can affect cross-market consistency within acceptable standards of deviation - a problem that is not a significant issue when labs practice with integrity.

With an initial eye on reduction of inter-lab testing variability, our work developing testing guidances is focused on transparent, consensus-based understanding that is aligned with the goal of an informed member at the lowest possible cost and the highest possible value in terms of safety and efficacy.

Importantly here, we must balance all costs in order to support smaller market participants and a testing market that can thrive and successfully compete against untested and unregulated markets that support neither testing nor regulatory and reporting costs .

So as you can hear, in this very high-level fly over, testing is complex. Regulating testing without engaging the expertise within our labs and those who understand the science makes little sense. And perhaps most importantly, we must educate and support a future of engage with an increasingly informed consumer, patient, clinical and health practitioner base.

To this end, I will close letting everyone know that we will be hosting this summer a more comprehensive event for anyone interested in learning from experts about many topics including testing - explained in each case by experts from the vantage point of a registered patient (including Seed2Health Alliance Members), their loved ones, and physicians and health guides.

Statement of Greg Newland

Good afternoon. I am Greg Newland and the Co-founder and Chief Scientific Officer at Nova Analytic Labs. I have more than 25 years of experience working in, managing, owning and operating testing laboratories under the regulatory requirements of the FDA, CDC, CLIA, CAP, ISO, and GMP. I Co-Founded Nova Analytic Labs in Portland in 2019 and began operations in October of 2020.

I am also a founding member of Seed2Health Learning Health Alliance where I am working with other members to educate them and others on laboratory testing and create with them voluntary consensus guidances that meet the goals stated by Andrew.

Mandatory testing on products that serve the largest communities of patients as well as recreational users should not be debated. The manner testing is performed and the tests that are performed can surely be discussed by means of intelligent data gathering. The scientists and other participants in this alliance have worked tirelessly on a volunteer basis to provide as much information as possible and have met to discuss the most intelligent approach to testing that

serves not only the consumers and patients but the market as a whole. This group is focused on ensuring that the end user is well informed about the safety and efficacy of the product that they are using. The only way to ensure this is through a well thought out Intelligent Testing approach. The only way to have the information we need to make these decisions, is to have mandatory testing for all products. Data analytics can then be used to craft Intelligent guidelines that benefit all consumer and market participants.

We hosted an event last summer under a tent where we gathered individuals from multiple disciplines of the Cannabis business to share the work they were doing to help educate all of us on the value of this plant and its uses.

My role in Seed2Health is to bring laboratories from not only Maine but from any other state that is willing to share their knowledge and experiences to build this Intelligent testing approach.

We have done deep dives into all of the currently required tests from the AU market and determined their value to the consumer and to all other business participants. We bring panels of volunteers together to determine what tests are sufficient, which may be redundant, and what needs to change to ensure that the information that is shared with the consumer is reliable. All work done within this group is intentionally not self-serving and is consensus based.

Our goal is to be able to present a set of well thought out testing guidances that accommodate a diversity of products based on factual information and a multitude of experiences from across the country. Spanning edibles, concentrates, tinctures, lotions, flower and even suppositories, the list is virtually limitless. Some of this work has already been presented to the OCP. Later this Spring, we will be publishing our first set of over 15 open standard guidances that cover everything from field sampling to water activity.

Statement of Kevin "Mac" McAloon
Hello my name is Kevin McAloon. I am a registered caregiver with the OCP and I am a partner in Canneutics, LLC a manufacturer of whole plant cannabis oils used in low dose formulations. We serve many patients in Maine through our distribution network. Our goal is to make our fully tested and properly labeled formulations available to as many patients in Maine as possible.

Medical use of cannabis is a reality that ailing citizens rely upon. But to serve them well, we need a policy to inform patients through proper labeling and accurate, cost-effective testing.

The importance of a transparent label is tantamount to good public health policy. A policy promoting full transparency on lab testing is good for patients and it is critical to us at Canneutics where we strive to "help patients lead the way forward."

Quality control and testing is a methodology that informs good natural medicine. When we see the State collecting all the revenues from the cannabis market, it would make sense to have an testing/packaging/labeling audit capability sponsored by the State no to punish errors in any audits but to promote good medicine.

MAINE CANNABIS
INDUSTRY ASSOCIATION

February 13th, 2023

Good Afternoon, Senator Hickman, Representative Supica and honorable members of the Veteran and Legal Affairs Committee

My name is Joel Pepin and I am the President of the Maine Cannabis Industry Association. I am also the Co-Founder of JAR Cannabis Company, a vertically integrated operator in both the adult use and medical cannabis markets. Thank you for having me here today to speak about LD48, and specifically the testing portion of this bill relating to adult use cannabis products.

Last session, before this committee, MCIA successfully introduced LD1846, a bill to reform testing in the adult use marijuana program. LD18146 ultimately had the VLA Committee's support. LD1846 was signed into law by Gov. Mills on April 4th, 2022 and streamlined testing protocols for adult use operators in the following ways:

-Removed the requirement of multiple redundant tests during the life cycle of a cannabis product that previously existed
-lowered the testing costs per batch of cannabis
-revised statute to allow for variances levels in edibles are experienced regularly by all manufacturers batch to batch.
LD1846 did all of this without undermining the Public Health for the people of Maine.

I personally don't understand why OCP wants to roll back the progress of LD1846 with LD48. Specifically, LD48 strikes out the .6mg variance for low dose servings and the 5mg variance for multi serving edible packs. It also establishes what is referred to as "testing matrix's", which I have concerns about.

The added language is Section 1 Paragraph F roles back the final form testing we fought hard to establish last session. I am not comfortable with that language, and feel as though its completely counterproductive to implement further unnecessary testing

burden and cost on licensed operators to address issues that don't exist in our industry or marketplace.

In Spring of 2022, The Office of Cannabis Policy released a study produced by Advocates for Human Potential, who was hired by OCP to analyze the Cannabis markets in Maine of all types. This study provided comprehensive information on the adult use, medical and illicit markets in Maine. One of the strongest findings of the study was that licensed operators & the licensed marketplace were by far the most successful tool in Maine's history at reducing the size of the illegal market. The high costs of testing and excise tax are among the most expensive components of producing adult use cannabis. Lowering these costs will help us continue eroding the illicit cannabis market in Maine.

Any law change that increases the costs and burden to licensed operators that also doesn't solve or address public health issues with cannabis is a major step back and a win for Maine's illegal marijuana market.

Thank you,

Joel Pepin
President – Maine Cannabis Industry Association
Co-Founder – JAR Cannabis Co.

February 13, 2023

Maine State Legislature
Veterans and Legal Affairs Committee
19 Union Street
Augusta, ME 04330

Good Afternoon Senator Hickman, Representative Supica and honorable members of the Veterans and Legal Affairs committee:

My name is Matthew Bayliss, I am a resident of South Portland, I've been a registered caregiver for over a decade, and I am a licensed adult use cultivator since the program's inception.

The Office of Cannabis Policy's (OCP) regulatory framework is a house of cards, built on quicksand and held together by three faulty towers that were hastily constructed by the consulting firm Freedman and Koski, of whom the state contracted after legalization passed. Mr. Hudak, OCP's new director, is one of that firm's founding members. Mr. Freedman now heads a Washington DC-based cannabis lobbying firm that is funded by Atria. Mr. Hudak was also a member of this firm and less than two weeks ago, they published a paper that was co-authored by him. Mr. Koski joined Metrc in 2019 as the COO and is now the CSO.

The three faulty towers are the Metrc track and trace program. The taxing structure, which is crushing every operator in the state, and mandatory testing, which is the focus of today's panel. My focus today will center around the yeast and mold portion of our testing panels specifically. I was one of the original licensees and when I proudly brought my first samples to Nelson Analytical Lab and asked them what data backed up the 10,000-ppm threshold for yeast and mold. I was told matter-of-factly that OCP just pulled a number out of a hat, there's no data to back up that flower that tests in excess of 10,000 ppm is harmful to human beings. I was also told that day that most of the outdoor grown cannabis they were testing at that point was in excess of 250,000 ppm. I've been smoking outdoor grown cannabis for 30 years and I've never heard of anyone falling ill, including myself. We are surrounded by yeast and molds in the air; this is how Oxbow and Allagash make their open fermentation sour beers that are some of the best in the world. They bring the beer outside or open the windows and the brews are inoculated by the yeasts and molds in the air giving it a unique local flavor.

Now I'd like to bring your attention to OCPs sanctioned flower remediation via ozone generator. Because so many operators are frequently in excess of the 10,000 ppm threshold, OCP allows them to remediate that flower with an ozone generator. OCP consistently flaunts their commitment to public health and safety, but where is the data that backs up that ozone remediated flower is safe for human consumption? As far as I know, it doesn't exist, and I demand that OCP bring forth an answer. Right now, the adult

use market is oversaturated with ozone-remediated flower. The consumer is completely unaware of this, so at the very least, it should be labeled as such. As an operator that grows clean cannabis, that has passed every test we have ever run without ozone remediation, it's completely unfair for my business to compete with a saturated market and wholesale prices that are well below what my company needs to remain viable.

When OCP conducted stakeholder outreach in regard to LD48, they focused specifically on the testing portion. They did not talk to us about the cartoon portion, as an example. I confronted policy Director Gabi Pierce about the genesis of adding audit testing on top of mandatory testing. The reason for my query, was in the fall of last year, OCP conducted cultivation inspections on all adult use licensees. Part of those inspections required operators to call up security camera footage of sample collection, and they did this for every operator. At that time, I let Ms. Pierce know that I believed this bill and these inspections were inextricably linked and I asked her what OCP had found that would cause them such concern. The response I received was par for the course from Ms. Pierce, which was a smirk, a shoulder shrug, and an eye roll.

This is exactly what I think is going on: OCP is letting larger operators do whatever the heck they want without as much as a slap on the wrist. I would like to know if there are any occurrences of OCP fining cultivators or suspending or revoking AU licenses. I think it's time for FOIA requests for all communications pertaining to testing and remediation via ozone generator. Specifically, communications to and from Andrew Freedman, Lewis Koski, Eric Gunderson, Gabi Pierce, Anya Trundy, Vern Maloch, John Hudak and Hannah King.

I take no joy in leveling these accusations, I entered the market in good faith and spent hundreds of hours working with regulators and legislators openly and candidly. After four years of banging my head into the wall, I can say unequivocally that the level of ineptitude and arrogance at OCP is completely unacceptable. There is, however one exception, Vern Maloch is a good man with a good heart, he has shown me on multiple occasions that he genuinely cares about the success of all licensees. The rest of OCP leadership are political operatives that have no place in our industry.

I do not want to stray too far from the focus of todays panel, but if the committee so pleases, I'd be more than happy to relay troubling interactions I've had with Anya Trundy, Eric Gunderson, and John Hudak in addition to a troubling interaction with Andrew Freedman at my warehouse 2 years ago.

Sincerely,

Matthew K. Bayliss
Gele Business Owner / Operator
Gele, LLC
9 Industry Rd
South Portland, ME 04016
matt@gardenofgele.com

BRETT MESSER
BRIGID FARM
(207) 571-9433

REAL WORLD VARIATION

10%

CURRENT ACCEPTED VARIATION IN MAINE STATUTE

12% During the initial research, we sent three samples to three labs, and looking at the same sample results, we saw a 12% variation between laboratories.

32% After our initial theory of inconsistent results we further investigated by sending the same sample to multiple labs, multiple times. We observed a 32% variation at the same testing laboratory.

41% Using the same data from the previous experiment, we observed a 41% variation between laboratories.

17% Finally, we again conducted our original experiment by sending one sample to three labs, where we once again observed an outside of standard variation.

Cannabis Analysis

Composition

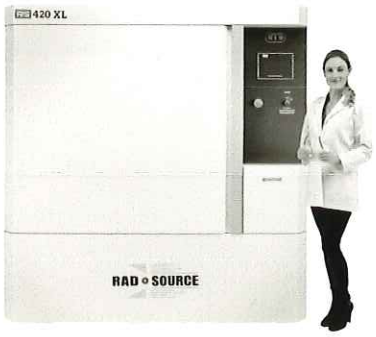
- Cannabinoid content for potency THC / CBD
- Other cannabinoids
- Terpenoids
- Water content / water activity

Contaminants

- Chemical contaminants
  - Pesticides
  - Residual solvents
  - Heavy metals
- Microbial contaminants
  - Yeasts and molds
  - Bacteria
  - Mycotoxins

REMEDIATION MACHINE

Cannabis sterilization machine that uses radiation to reduce the presence of microbial contamination.



The existing Adult Use Cannabis Program testing requirements versus the proposed requirements in LD 48 – *An Act to Clarify Provisions of the Cannabis Legalization Act Regarding Labels, Packaging and Testing*

✓ - required test
O - optional test
I - required if not tested for in a previous matrix

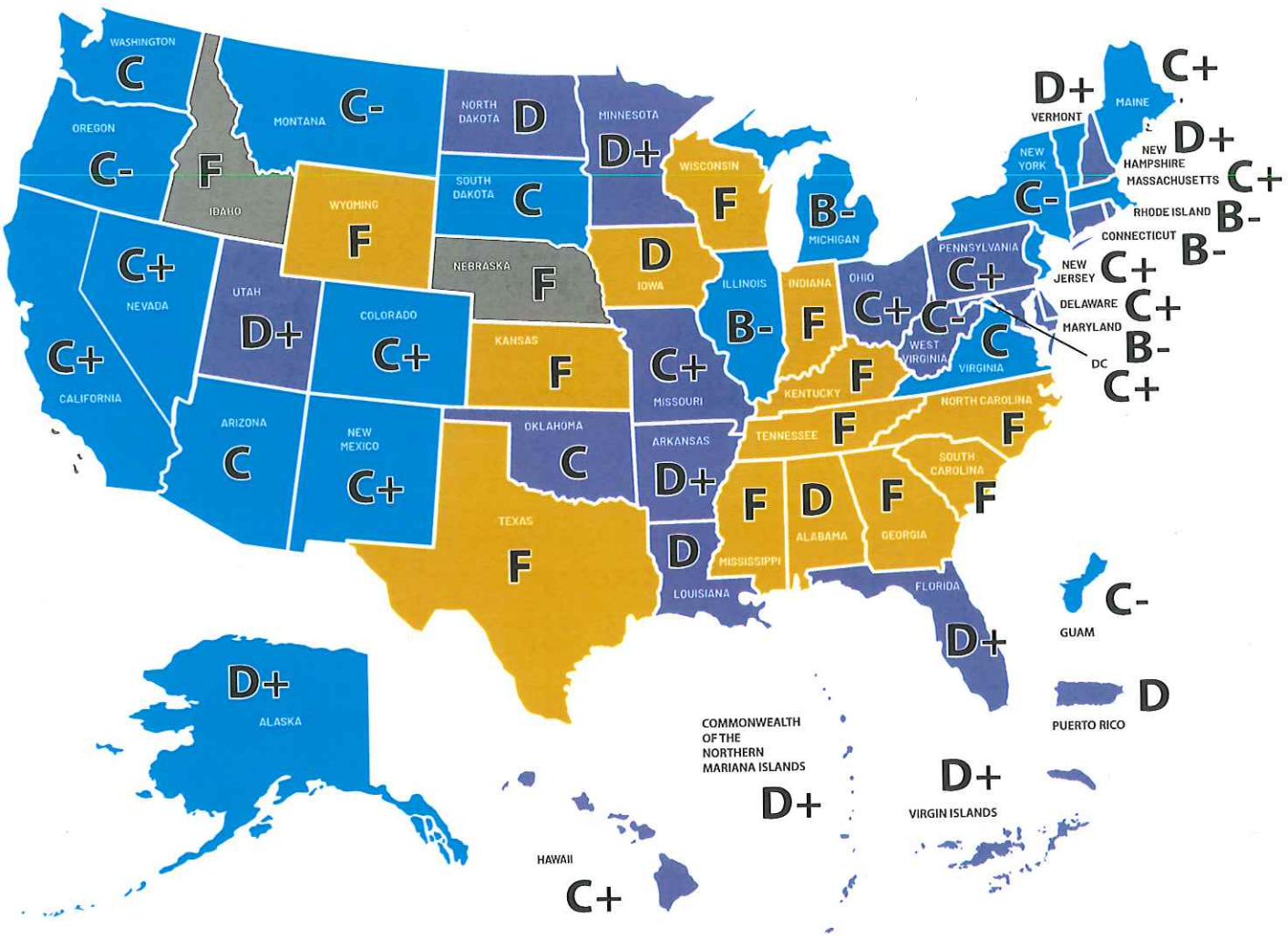
Matrix	Filth & foreign materials	Dangerous molds & mildews	Harmful microbes	THC potency, homogeneity, & cannabinoid profiles	Water activity	Other harmful chemicals	Residual solvents	Pesticides
Matrix	**Existing Requirements***							
Flower for Processing						O		O
Flower for Retail	✓	✓	✓	✓	✓	✓		✓
Concentrate for Processing						O	O	O
Concentrate for Retail	✓	✓	✓	✓		I	✓	I
Edible Products	✓	✓	✓	✓	✓	I	I	I
Matrix	**Proposed Requirements**							
Flower for Processing						✓		✓
Flower for Retail	✓	✓	✓	✓	✓	✓		✓
Concentrate for Processing							✓	
Concentrate for Retail				✓			✓	
Edible Products	✓	✓	✓	✓	✓			

**Please note that this is a simplified version of the existing testing requirements for the purposes of discussion.*

As outlined in the table above, LD 48 proposes the following changes to the mandatory testing of adult use cannabis and adult use cannabis products:

- Flower for Processing: Required testing in two analyte categories, replacing optional testing in those categories
- Concentrate for Processing: Required testing in one analyte category rather than optional testing; removal of optional testing in two other analyte categories as those would become required tests in the "Flower for Processing" matrix
- Concentrate for Retail: Simplified testing requirements
- Edible Products: Simplified testing requirements as three tests would become required in previous matrices

LD 48 also defines the word "matrix" for the purposes of cannabis testing.



MAP KEY

Blue	Medical and adult use program
Purple	Full medical cannabis program
Yellow	CBD-specific program [includes low-THC]
Gray	No medical or adult use program

KEY FOR STATE GRADES

A+	96-100
A	93-95
A-	90-92
B+	83-89
B	77-82
B-	70-76
C+	63-69
C	57-62
C-	50-56
D+	43-49
D	37-42
D-	30-36
F	Below 30%

Americans for Safe Access

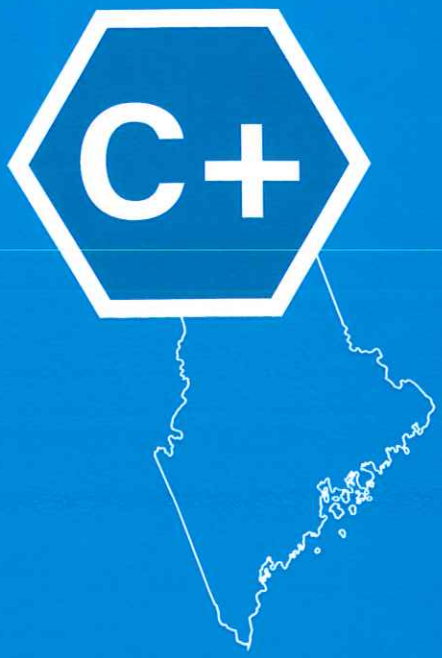
MAINE

Improvements and Recommendations

Maine continues to have a strong medical cannabis program, relative to the rest of the states across the country. In 2022, policymakers made permanent some policies improving accessibility, like curbside pickup and delivery. Physicians are also able to consult with patients via telehealth, which helps cut down on some of the administrative burdens patients face.

Even though Maine ranked well relative to other states around the country, there are still a number of things policymakers can do to improve the patient experience.

In 2023, ASA recommends that legislators extend the stricter adult use/recreational third-party testing standards to products intended for medical cannabis patients. Additionally, the state should consider allowing multiple years-long registrations at no cost to avoid burdening patients with unnecessary paperwork or administrative fees. In light of the adult use/recreational laws, Maine should also focus on passing provisions included in ASA's *Medical Cannabis Equity Checklist* found in this report.



BASE CATEGORIES POINTS: 480
PENALTIES: -10
POINT TOTAL: 470/700
SCORE PERCENTAGE: 67.14%

106,164	7.75%	35	3,033 : 1
Registered Patient Population	of Total Population Represented by Patients	Retail Locations Currently in Operation	Patients : Retail Locations

CATEGORY	POINTS
PATIENT RIGHTS AND CIVIL PROTECTIONS	**90/100**
Arrest Protection	25/25
Affirmative Defense	20/20
Parental Rights Protections	20/20
Employment Protections	20/20
DUI Protections	0/10
Explicit Privacy Standards	5/5
ACCESS TO MEDICINE	**95/100**
Authorizes Retail Access	10/10
Alternative Accessibility Methods	20/20
– Authorizes Delivery	10/10
– Authorizes Curbside Pickup	10/10
Personal Cultivation	15/15
Collective Gardening	5/5
Sufficient Number of Licensed Retailers	30/30
Reciprocity	15/20
AFFORDABILITY	**60/100**
Sales Tax Break for Patients and Caregivers	20/20
Covered by State Insurance or Health Aid	0/20
Reasonable Registration Fees	20/20
Financial Hardship Waivers or Discounts	20/20
Donation Program	0/10
Allows Multi-year Registrations	0/10

CATEGORY	POINTS
PROGRAM FUNCTIONALITY	**100/100**
Legal Protections Within Reasonable Time Frame	20/20
Reasonable Possession Limits	10/10
Reasonable Purchase Limits	10/10
Telemedicine for Physician Certification	15/15
Patient and Physician Representation in Program Decision Making	20/20
Reasonable Caregiver Standards	5/5
– Background Checks	2/2
– Number of Caregivers	3/3
Reasonable Physician Standards	5/5
Access to Administration Methods	10/10
– Allows Dried Flower	5/5
– Allows Edibles, Concentrates, and Other Forms	5/5
Provides Access to Minors on School Grounds	5/5
HEALTH AND SOCIAL EQUITY	**87/100**
State Program Protections	25/25
Housing Protections	20/25
Access for Minors	5/10
Access in Underserved Areas	10/10
List of Qualifying Conditions is Exhaustive or All Inclusive	10/10
Allows Patients to Medicate Where They Choose	7/10
Organ Transplants	5/5
Ownership or Employment Restrictions	5/5

CATEGORY	POINTS
CONSUMER PROTECTION AND PRODUCT SAFETY	**48/200**
Cultivation Operations	**7/50**
Quality Management Systems	0/10
Staff Training	0/10
Standard Operating Procedures	3/8
– Facility and Equipment Sanitation	0/1
– Workplace Safety	1/1
– Storage	0/1
– Batch and Lot Tracking	1/1
– Security	1/1
– Waste Disposal	0/1
– Water Management	0/1
– Records Management	0/1
Pesticide Usage Limitations	2/2
Environmental Impact Regulations	1/2
Required Testing	0/8
– Cannabinoids	0/1
– Terpenes	0/1
– Microbials	0/1
– Aflatoxins	0/1
– Pesticides	0/1
– Heavy Metals	0/1
– Foreign Matter	0/1
– Moisture Content	0/1
Packaging and Labeling	1/3
– Cannabinoids	1/1
– Terpenes	0/1
– Pesticides	0/1
Complaints, Adverse Event Reporting and Recall Protocol	0/7
Manufacturing Operations	**18/50**
Quality Management Systems	0/10
Staff Training	10/10
Standard Operating Procedures	3/7
– Facility and Equipment Sanitation	0/1
– Workplace Safety	1/1
– Storage	0/1
– Batch and Lot Tracking	1/1
– Security	1/1
– Waste Disposal	0/1
– Records Management	0/1
Environmental Impact Regulations	1/3
Required Testing	0/10
– Cannabinoids	0/1
– Terpenes	0/1
– Microbials	0/1
– Aflatoxins	0/1
– Pesticides	0/1
– Heavy Metals	0/1
– Residual Solvents	0/1
– Homogeneity	0/1
– Foreign Matter	0/1
– Water Activity	0/1
Packaging and Product Labeling	4/5
– Cannabinoids	1/1
– Terpenes	0/1
– Ingredients	1/1
– Allergens	1/1
– Nutritional Content	1/1
Complaints, Adverse Event Reporting and Recall Protocol	0/5
Dispensary Operations	**23/50**
Staff Training	20/20
Standard Operating Procedures	3/7
– Facility Sanitation	0/1
– Workplace Safety	1/1
– Storage	0/1
– Batch and Lot Tracking	1/1
– Security	1/1
– Waste Disposal	0/1
– Records Management	0/1
Product Testing	0/10
– Product Meets Requirements Before Sale	0/5
– COA Disclosure	0/5
Complaints, Adverse Event Reporting and Recall Protocol	0/13

CATEGORY	POINTS
Laboratory Operations	**0/50**
Independent or Third-Party	0/5
Laboratory Sampling	0/5
Method Validation	0/4
Quality Management Systems	0/5
Staff Training	0/20
Standard Operating Procedures	0/7
– Facility and Equipment Sanitation	0/1
– Equipment and Instrument Calibration	0/1
– Workplace Safety	0/1
– Sample Tracking	0/1
– Security	0/1
– Waste Disposal	0/1
– Records Management	0/1
Result Reporting	/4
SCORE PENALTIES	**10/100**
Gives Regulatory Preference to Adult Use	10/20
Classifies Cannabis as a Medicine of Last Resort	0/15
Administrative or Supply Problems	0/15
Requires Vertical Integration	0/10
Creates New Criminal Penalties for Patients	0/10
Limits Patients to a Single Retailer	0/10
No System for Adding Qualifying Conditions	0/10
Imposes Bans or Limits on THC	0/5
Imposes Bans or Limits on CBD	0/5

Patient Feedback

Even at prices substantially lower than most other states, patients surveyed in Maine's still reported overall prohibitive costs, highlighting the alarming cost to patients in other jurisdictions.

Background

For background information regarding this state, please visit www.safeaccessnow.org/states and click on the state.

Scoring Information

For information on how each section was scored, please check out the full scoring rubric at www.safeaccessnow.org/sos22rubric

Recommendations for Regulators

To aid government agencies in establishing sound rulemaking policies, ASA created the Patient Focused Certification (PFC) program. PFC is a third party certification and training program for the cannabis industry. PFC utilizes the American Herbal Products Association (AHPA) recommendations for botanical products, good agricultural (collection) practices (GAP), good manufacturing practices (GMP), and good laboratory practices (GLP) to thoroughly evaluate a business for compliance. PFC was the first and only first cannabis compliance organization to attain ISO/IEC 17065 accreditation in the U.S. cannabis market. PFC is available to companies cultivating, manufacturing, or distributing cannabis and hemp products, as well as to laboratories providing cannabis analytic services.

The PFC training program prepares individuals to understand state and local regulations and to learn required safety and operational protocols, while teaching them the basics of cannabis as medicine and common therapeutic uses of cannabis. PFC trainings are available online to anyone interested in learning more about medical cannabis. Trainings are available in Cultivation, Manufacturing, Distribution, and Laboratory. A full training course guide can be found at www.PatientFocusedCertification.org/training.

Learn more about PFC at www.PatientFocusedCertification.org.