# *CCNY Concerns with New York's Final Medical Marijuana Regulations*

On March 31, 2015, the New York State Department of Health (DOH) issued the final regulations for the state's medical marijuana program. The release of the final regulations followed a six week public comment period, during which DOH received more than a thousand comments suggesting ways that the program could be improved. Unfortunately, DOH choose to ignore nearly all of those comments and made no substantive changes to the regulations.

The result is a set of regulations that are likely to make New York's program one of the most restrictive programs in the country. Our over-riding concern is that the program will leave many suffering patients behind and could be completely unworkable. The regulations are more than a 120 pages and impossible to summarize here, but below are some of the key issues we have identified. You can read the full regulations here and DOH's response to the public comments here.

**No access for low-income patients:** The regulations do not create any incentive for producers and growers to provide a sliding fee scale or free medicine and equipment for low-income individuals nor will the state be using revenues from the program to off-set the costs of medicine, equipment, or travel for low-income patients. Medicine is restricted to more expensive extracts, and vaporization will only be allowed through expensive devices that use extracts (whole plant is prohibited). With only 20 dispensaries allowed for the entire state of New York, spanning more than 54,000 square miles, transportation costs will also be an issue for some patients. Since insurance will not cover these costs, New York runs the very real risk that low-income people will be shut out of the program entirely. Unfortunately, this will likely mean the exclusion of some of the most disabled and sickest New Yorkers, since we know that disability and catastrophic illness can be financially devastating. The regulations do include a provision for DOH to waive the $50 patient registration fee but gives no indication of how "financial hardship" will be determined. Moreover, a patient and his/her caregivers from a single family must **all** pay the fee, meaning that the cost to register could be $150 for a patient and his/her two caregivers. DOH says it *may* allow dispensaries to give away medicine to those in need, but this leaves the fate of low-income patients to depend entirely on the good will of industry.

**Access to dispensaries is limited:** The number of dispensaries statewide is limited to twenty. Given that NY has 19.7 million people and more than 54,000 square miles, it is hard to imagine how twenty dispensaries will meet the needs of patients across the entire state. This problem is exacerbated by the fact that regulations prohibit the use of delivery services without the prior written approval of the Health Commissioner. This limited access could create real problems for sick, disabled, or housebound patients. As noted above, delivery of medicine is prohibited unless registered organizations get prior written consent from DOH; this could make it difficult for

those patients who are sick and disabled and/or who live in rural areas to get the medicine they need.

**Too few patients covered and no clear rationale or process for including/excluding covered conditions:** Although the Commissioner of Health has the authority to add more conditions, the regulations only cover ten (cancer, HIV/AIDS, ALS, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication or intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, and Huntington's disease). Moreover, to qualify a patient must have: 1) one of the ten conditions; 2) one of the symptoms listed in the law (cachexia or wasting syndrome; severe or chronic pain; severe nausea; seizures; severe or persistent muscle spasms); AND 3) "a substantial limitation of function." Unfortunately, these requirements fail to acknowledge that medical cannabis may have a medical benefit absent any symptoms or functional limitations. For example, preliminary research suggests cannabis may help prevent tumor growth in some kinds of cancer – an effect having nothing to do with the symptoms listed in the regulations. The Commissioner retains the authority to add conditions in the future. Unfortunately, the response to public comments gives no indication of if or how these and other conditions are being considered. And while the response to the public comments notes that that the Commissioner will review the literature and current scientific evidence, the Commissioner has had since July 2014 to review the literature and current scientific evidence, and still has not made a decision on any conditions even though he is mandated by law to consider at least five before January 2016.

**No access to whole plant medicine and limits on forms of medical marijuana:** In a disappointing move, the Department chose to restrict access to the whole marijuana plant. The only forms of medical marijuana that will be allowed are "liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube, metered liquid or oil preparations for vaporization, and capsules for oral administration." This excludes edibles, lotions, creams, lozenges, massage oils, patches for transdermal administration, salves, suppositories, tinctures, and topicals. Smoking is prohibited by statute.

There is simply no good medical or scientific rationale for requiring patients to use processed oils and extracts or for excluding the many other forms of medical cannabis that are known to be beneficial. There are terpenoids and other therapeutic compounds that can be lost during extraction processes. This could interfere with the synergistic, entourage effect of cannabis known to be medically beneficial. Like with other botanicals and natural products, isolating specific compounds within cannabis may have unintended consequences and reduce the medical efficacy of the product. Other concerns include the health effects of the processing and patient and provider preferences for natural, unprocessed products. To date, of the 23 states with medical marijuana laws, but only one other has prohibited access to whole plant matter. Moreover, these concentrates can be expensive to produce and can drive up the cost of the medicine restricting access to low-income patients.

**Restrictive limits on the kinds of available medicine:** The draft regulations restricted the number of "brands" of medical marijuana to five initially. There are dozens of therapeutic strains, each having benefits for particular conditions. Had such a restriction been in place in a state like Colorado, it very well may have prevented the development of marijuana strains beneficial to some children with epilepsy. This limits the flexibility of patients and doctors to

find which medicine works best. Patients unable to find a strain that works for them may be forced to seek it on the illicit market. In addition to being bad for patients and doctors, the state's overly-restrictive program has likely deterred industry groups from entering the market.

**No mechanism for patient/expert input or evaluation:** The regulations make no provision for input by patients, providers, industry, or experts in the field, such as an advisory board. Nor are there any clear mechanisms for accountability and monitoring of the program. The program would benefit from an outside, independent evaluator to monitor and report on the program so that the public, as well as appointed and elected officials, could learn from the experience and refine the program going forward. However, DOH has made clear that they will not establish an advisory board or other formal mechanism for input and, thus far, have refused to specify how any such evaluation will take place.

**Restricted access for children and students:** The regulations prohibit the use of vaporized medical cannabis in any child care setting, including residential facilities, day cares, and foster care, group homes. This creates a real challenge for youth suffering from illnesses like cancer, MS, or HIV/AIDS, who may need to vaporize for immediate relief of their symptoms. Similarly, college students are not allowed to vaporize medicine on campus or in a dormitory or residence hall. Given the strict limits on the use of vaporization in public spaces, this provision leaves children and students with limited options for using their medicine.

**Only MDs can recommend medical marijuana:** The regulations restrict providers who can recommend medical marijuana to MDs only. This means that nurse practitioners cannot recommend medical marijuana to their patients even though this is permitted under the statute. This may create access problems, particularly in rural parts of the state where physicians are limited. The Commissioner retains the authority to add nurse practitioners to the list of practitioners who will recommend medical marijuana. DOH has said they will make this determination based on patient access once the program is up and running.

**Pharmacists are required to be on-site at dispensaries for them to be open:** The regulations require all dispensaries to hire a pharmacist(s), and a dispensary cannot be open for business unless the pharmacist is physically at the site. But with rare exception, pharmacists have not been trained in the endocannabinoid system or cannabis therapeutics and will not have any special knowledge about cannabis and potential medication interactions. DOH indicates that they will require pharmacists to take the same training that is required of doctors (a 4 hour online course). This creates an additional unnecessary burden and expense that will likely be passed on to patients.

**No provision for emergency or expedited access:** The program will not be operational until at least January 2016, but several patients, including children with severe epilepsy and cancer who might have benefited from medical marijuana, have already died since the bill was signed into law. During bill negotiations, Governor Cuomo removed a provision that would have allowed

such patients to have access to medical marijuana on a temporary, emergency basis. In July of 2014, he urged Health Commissioner Zucker to do everything in his power to expedite access to children with severe epilepsy. To date, however, there is no emergency access program, and patients continue to suffer needlessly and die. The regulations contain no provisions to provide emergency access to critically and terminal ill patients, and, in fact, in the response to public comments, the Administration makes clear that their only response to emergency access is a non-response -- wait until implementation of the full program by January 2016.

**No on-site consumption:** Unlike other states, New York has prohibited the consumption of marijuana products at dispensaries. Given that many patients will be using medical marijuana for the first time, dispensary staff should be allowed to educate patients and assist them in how to use the products. This is particularly important for vaporization. DOH has indicated that patient education can be conducted by the pharmacists using a placebo that has been pre-approved by DOH.

**No visitors at ROs:** The regulations prohibit any visitors – unless they are a registered patient or registered caregiver – from entering the dispensary without prior written approval from DOH. It is inconceivable that a family member would be precluded from entering a pharmacy with their loved one. This could create a hardship for the most severely disabled people who could very well need someone to accompany and assist them in making their purchase. We cannot reasonably expect that a caregiver will always be available to fill this role. DOH notes that, if due to unforeseen circumstances someone has to enter a dispensary without prior approval, a dispensary should record that information in a log and submit it to DOH.

**Too severely restricts access to who can enter the industry:** The financial and logistical requirements for applying for and being awarded a license and the limited number of licenses available unfairly bias the industry towards those with extraordinary financial resources. This will likely mean that local, New York-based groups will have a very difficult time qualifying, particularly entrepreneurs from low-income communities. In fact, the communities that have been most devastated by our current marijuana policies – low income communities of color – are the ones least likely to be able to benefit from this new industry. DOH says they favor a diverse industry and that they encourage applicants for licenses to consider how they "may include minority and women-owned businesses, small businesses, disabled veterans, and New York businesses in its operations." However, the regulations create no concrete incentives for applicants to do so.