July 22, 2024

Hon. Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: Proposed Rule, Drug Enforcement Administration; Schedules of Controlled Substances: Rescheduling of Marijuana; Docket No. DEA-1362 (May 21, 2024)

Dear Administrator Milgram:

The Commonwealth Project presents these comments to the Drug Enforcement Administration ("DEA") in response to its Notice of Proposed Rulemaking and Request for Comments regarding the reclassification of marijuana from Schedule I to Schedule III of the Controlled Substances Act. First and foremost, The Commonwealth Project applauds the historic action taken by the Department of Justice ("DOJ") and the DEA to initiate rescheduling of marijuana from Schedule I to Schedule III under the Controlled Substances Act ("CSA").

The Commonwealth Project is a humanitarian effort working to legitimize and integrate medical cannabis within the existing US health care system. In particular, the Commonwealth Project prioritizes the health needs of individuals 65 and over. Our efforts are driven by a compassionate desire to assist millions of seniors facing increasingly complex health issues as they age by offering medical cannabis as part of their overall health care.

Current Challenges

There are roughly 56 million adults ages 65 and older in the United States today, or 17 percent of the population — an unprecedented number driven by aging Baby Boomers.[1] By the end of this decade, the U.S. Census Bureau projects the total to grow by another 17 million older adults. Individuals 65 and older are the fastest growing segment of the population using or interested in using medical cannabis as a component of their health care regimen.

[1] https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1144.pdf

With this explosive growth in older adults will come significant Medicare spending, testing an already deeply stressed system. One big driver: powerful prescription drugs, including opioids, which sometimes do not work as intended, can have unwanted side effects, and can be expensive and highly addictive.

Today, thirty-eight states, the District of Columbia, and four territories have state-level laws that allow the use of medical marijuana. The Commonwealth Project is seeking to speed the availability of medically administered Cannabis Based Therapies (CBT) to a range of demographics, most notably seniors over the age of 65. Scientific research has demonstrated that CBD therapies are particularly helpful and impactful for seniors struggling with pain management, insomnia, and psychiatric conditions such as anxiety and depression.

Doctors in states where medical cannabis has been authorized are currently prevented from "prescribing" a specific dosage of medical cannabis for their patients because of its status as a Schedule I drug, despite numerous studies showing that many U.S. physicians believe it can be therapeutic. Moreover, seniors currently don't have access to either a medically based cannabis healthcare experience or reimbursement through Medicare. Accordingly, the current status quo restricts seniors from having a comprehensive health experience that directly involves ongoing medical supervision with their physicians, guarantees access to new and safe products, monitors dosage and effectiveness, improves data collection, and promotes health equity, all of which limits uptake of CBT by seniors and its attendant benefits. The current situation creates an equity challenge; forcing seniors to pay out of pocket for medical marijuana restricts access and disproportionately affects historically underserved seniors.

In the meantime, cannabis companies in states that have legalized marijuana sales and use are filling that void — offering tips to seniors about formulations and doses, as well as creating and marketing products with no meaningful research into the effects on older consumers and without any clinical guidance. This and the proliferation of dubious online information means seniors have no trusted place to turn for credible clinical guidance — leaving them to the advice of friends, neighbors or an untrained salesperson working at a local dispensary.

Comments

Considering the challenges that all Americans, and particularly seniors face in accessing medical cannabis within their health care system, the Commonwealth Project urges the DOJ and the DEA to act swiftly and publish a Final Rule cementing this historic reform. A delay in promulgating rules would only serve to further perpetuate a status quo that is detrimental to the needs of today's seniors, who do not have the luxury of time.

At this time, researchers and suppliers of cannabis for medical research, as well as physicians, are offered certain protections under the Marijuana and Cannabidiol Research Expansion Act

(MMCREA) that allow them to legally distribute or discuss the harms and benefits of medical cannabis, respectively. However, federal lawmakers and stakeholders continue to voice concerns that MMCREA has not been implemented in line with Congressional intent and that researchers continue to face barriers from both the FDA and DEA.[2]

By rescheduling cannabis from Schedule I to Schedule III, there will be greater, but not complete, certainty for seniors, researchers, and physicians to engage in research or pilot health care projects that examine the benefits and distribution of medical cannabis. The final rule mandating rescheduling should include, at a minimum, an explicit assurance that participants, researchers, and individuals and/or organizations that engage or participate in health care projects will suffer no adverse consequences from any Federal agency.

Specifically, the Commonwealth Project also recommends that the DOJ issue a public memorandum that not only establishes greater assurance to these stakeholders, but that allows payer-providers to engage in research activities and pilot projects without facing any negative consequences or penalties from the Federal government. There is precedent by the DOJ to issue such a 'non-enforcement' memorandum. On August 29, 2013, former U.S. Deputy Attorney General published a memorandum, "Guidance Regarding Marijuana Enforcement," stating that the DOJ would not enforce federal marijuana prohibition in states that had, at the time, enacted laws legalizing marijuana in some form.

If the DOJ promulgates a final rule that reschedules marijuana from Schedule I to Schedule III under the CSA, physicians would be significantly less restricted in prescribing medical cannabis. As such, insurance plans would ultimately have to determine whether they will cover medical marijuana. It would also be up to the Centers for Medicare Services ("CMS") to determine whether Medicare Part D would cover medical marijuana for seniors. Currently, several prescription opioid pain medications – which are categorized as Schedule II substances – are covered under Part D, including hydrocodone (Vicodin®), oxycodone (OxyContin®), morphine, codeine, and fentanyl. However, a drug plan could decide that a patients' use of prescription opioids may not be safe and limit a patients' coverage of such drugs under its drug management program.

Under Medicare Part D, Medicare makes partially capitated payments to Part D sponsors for delivering prescription drug benefits to Medicare beneficiaries. If cannabis is rescheduled, medical marijuana manufacturers would have to negotiate with Part D sponsors on payment arrangements for the delivery of cannabis. These payment adjustments are then reported to CMS as Direct or Indirect Remuneration (DIR), which are reflected in drug rebates.

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[2] https://blumenauer.house.gov/sites/evo-subsites/blumenauer.house.gov/files/evo-media-document/2024-03-12%20Letter%20on%20MMCREA%20Implementation%20(3).pdf

If the DEA accepts HHS's recommendation to reschedule cannabis from Schedule I to Schedule III of the controlled substances act, cannabis will fall under an existing set of prescription requirements before use in a medical setting.

It is the goal of the Commonwealth Project to improve the health experience of individuals 65+ by allowing medical cannabis to be part of their overall health care. The Commonwealth Project is laying the groundwork for a robust and patient-centric research and care demonstration model for medicinal cannabis that takes into consideration the unique healthcare delivery challenges faced by America's seniors.

Specifically, the Commonwealth Project has been working with a range of partners (from payer-providers, research universities, retirement organizations and other stakeholders) to conduct a value-based medical cannabis demonstration model in a regulated state that breaks out the over 65 demographic. The pilot project would provide research needed to inform healthcare guidance for seniors' health care practitioners and safely shape the medical marijuana marketplace (i.e. safe, consistently-doses, accurately labeled products). Working directly with payer providers enables this project to gather real world data, validate the health outcomes, and calculate savings that an improved medicinal distribution model. The Commonwealth Project would share the findings of this project with the US government, toward the goal of establishing a more efficient, effective, and equitable distribution and oversight model for cannabis based therapies.

In states where marijuana is legal, doctors prescribed an average of 1,826 fewer daily doses of painkillers per year to patients enrolled in Medicare Part D — which would result in a cost savings of up to $500 million per year if medical marijuana access was legal nationwide.[3] Incorporating medical cannabis within health care will not only improve the health experience of individuals 65 and older but yield significant savings for the American taxpayer.

For these reasons, the Commonwealth Project encourages the DEA and the White House to move as expeditiously as possible on rescheduling, so that we can utilize rescheduling as a pivot point to move forward with research and demonstration trials that will bring the much needed and undisputed benefits of these therapies to as many seniors as possible.

The Commonwealth Project thanks the DOJ and the DEA for this important and historic rulemaking proposal and for the opportunity to comment.

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[3] Ashley Bradford, et al., "Medical Marijuana Laws Reduce Prescription Medication Use In Medicare Part D," *Health Affairs*, July 2016.

Sincerely,

Howard Kessler
Founder
The Commonwealth Project