IN THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the matter of

Schedules of Controlled Substances:
Proposed Rescheduling of Marijuana **DEA Docket No. 1362**

Hearing Docket No. 24-44

Submitted by:

Jason K. Castro, Esq; Nicholas Garulay; and The Doc App, Inc., (d.b.a. My Florida Green)

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BRIEF IN SUPPORT OF A PATIENT-CENTERED, FEDERALLY-REGULATED MEDICAL MARIJUANA FRAMEWORK WITH INTEGRATED LICENSING, API ACCESS, AND PATIENT BENEFITS

COMES NOW, The Doc App, Inc. ("The Doc App"), joined by Nicholas Garulay, as President and CEO, by and through undersigned counsel, Jason K. Castro, Esq., submits this brief in support of a federally regulated framework for medical marijuana under a Schedule III classification. This framework prioritizes accessibility, transparency, and efficient data management by incorporating secure API access, clear licensing standards, and patient-centered solutions like digital benefits cards. Serving over 43,000 patients, The Doc App functions as an independent bridge between patients, dispensaries, physicians, and state regulatory bodies, ensuring high standards of care and compliance, particularly for veterans and low-income patients. In support thereof alleges as follows:

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1. Federal Medical Marijuana Benefits Card for Veterans and Qualifying Patients

A Federal Medical Marijuana Benefits Card would grant veterans and eligible patients consistent access to medical marijuana through federally recognized dispensaries. By reducing the need for state-by-state variances, this card would enable affordable, equitable access under uniform federal standards.

Key Components of the Benefits Card Program:

- **Eligibility and Verification**: Veterans and other federally covered patients could receive this benefits card upon verification, providing access to approved dispensaries.

- **Cost Assistance and Insurance Integration**: Recognizing the card under Medicare and VA healthcare could lower costs for low-income patients, enhancing affordability across diverse populations.
- **Fraud Prevention**: Integrated with platforms like The Doc App, the card system could securely track dosage, purchases, and doctor approvals, mitigating misuse risks.

This benefits card aligns with DEA's objectives by providing structured, controlled patient access that promotes safe usage and compliance.

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2. API Access for Seamless Stakeholder Communication

To facilitate data management and transparency, regulatory frameworks should support API access for licensed platforms, allowing secure, real-time data exchange among patients, dispensaries, and government entities.

API Integration Logistics:

- **Data Security and Privacy**: A standardized API protocol would ensure secure data sharing, reducing redundancy and enhancing oversight.
- **Efficient Allotment Tracking**: Platforms like The Doc App would offer real-time tracking of medical marijuana allotments, enabling patients to stay within recommended guidelines and engage in responsible self-treatment.
- **Coordination with State and Federal Regulators**: API access would enable platforms to provide secure, verifiable patient usage data to dispensaries and regulators, ensuring compliance with both state and federal standards.

API access promotes regulatory transparency, safer patient management, and a robust network connecting patients, dispensaries, and regulatory bodies.

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3. Digital Benefits Card with QR Code Access and Enhanced Monitoring for Product Recalls

To enhance patient accessibility and streamline dispensary verification, the Benefits Card program should include a digital option accessible on a secure app like The Doc App. This digital card would integrate a scannable QR code for quick verification, and incorporate real-time monitoring for product recalls, ensuring patient safety and regulatory compliance.

Digital Benefits Card Logistics:

- **Secure Digital Storage and QR Code Accessibility**: A secure, app-based card with a QR code would allow dispensaries to access prescription details quickly, protecting patient privacy and reducing delays.

- **Real-Time Dosage and Allotment Data**: Real-time integration with patient allotment data ensures dispensaries can verify dosage limits and authorized prescriptions accurately.
- **Automated Compliance and Security Protocols**: QR code access would allow only authorized dispensaries to retrieve patient prescriptions, with measures in place to ensure compliance and prevent misuse.

Enhanced Product Recall Monitoring:

- **Automatic Alerts for Patients and Physicians**: In the event of a recall, affected patients and physicians would receive immediate notifications, safeguarding patient health.
- **Integration with Dispensing Records**: Recall notifications linked to dispensing records would ensure only impacted patients receive alerts, promoting accuracy and trust.
- **Supporting Safe Treatment Outcomes**: This recall monitoring reinforces DEA safety standards, creating a feedback loop that benefits both patients and regulators.

This approach provides a digital benefits card with QR code-based access to prescriptions, alongside enhanced recall monitoring to support patient safety and compliance.

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4. Licensing Standards for Technology Platforms to Avoid Conflicts of Interest

Technology platforms like The Doc App play a pivotal role in linking patients, dispensaries, and regulators without compromising program integrity. Regulatory guidelines should require licensed technology providers to operate independently, with no financial ties to dispensaries or prescribers.

Licensing Standards to Protect Program Integrity:

- **Independence and Transparency**: Licensed platforms should act as unbiased intermediaries, sharing information securely without influencing patient care.
- **Federal and State Compliance**: Platforms must meet data privacy, security, and accuracy standards, ensuring secure management of patient allotments, dosage records, and transaction logs.
- **Certification and Oversight**: Certification should confirm adherence to federal standards for patient data protection and operational independence, supporting compliance and patient trust.

These standards ensure that platforms like The Doc App act as independent, compliant resources in the medical marijuana framework.

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5. Implementing a Self-Treatment Model with Real-Time Data and Analytics

A self-treatment model supports patients in managing their medical marijuana use based on their specific needs, guided by real-time analytics on strains, dosages, and efficacy. The Doc App provides data-driven insights, helping patients, particularly veterans, make informed decisions.

Self-Treatment Model Logistics:

- **Real-Time Strain and Dosage Data**: Patients can access data on effective strains and dosages, facilitating tailored, safe use.
- **Allotment Monitoring**: Platforms like The Doc App provide real-time tracking of allotments, empowering patients to stay within recommended limits and responsibly self-manage their treatment.
- **Education and Patient Autonomy**: Educational resources integrated within the platform foster patient autonomy, allowing self-management under physician guidance and real-time data support.

This self-treatment model promotes safer use, aligns with patient autonomy, and meets DEA's objective of structured, controlled access.

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6. Preventing Monopolistic Control and Ensuring Market Access

To protect patient access, regulatory standards should prohibit vertical integration within the medical marijuana industry. Consolidating medical and recreational markets, as proposed in Florida's Amendment 3, could monopolize access, putting profits over patient needs.

Federal Guidelines to Foster Market Competition:

- **Distinct Licensing for Medical Marijuana Dispensaries**: Federal regulations should restrict medical dispensaries to medical sales, ensuring patient-centered care.
- **Accessible Licensing Fees**: Affordable fees would allow smaller, patient-centered providers to compete, preventing monopolies.
- **Patient-Centric Licensing Standards**: Regulations should prioritize providers focused on quality and condition-specific care, safeguarding against profit-driven models.

Maintaining a competitive medical market ensures patients retain access to dedicated, compliant providers.

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7. Supporting Physician-Directed Exemptions for Dosage Caps

Federal dosage caps should include flexible exemption mechanisms to avoid undermining care for patients with unique needs. Guidelines should respect clinical judgment, allowing physicians to recommend higher doses where necessary.

Exemption Mechanism Details:

- **Physician Authorization**: Exemption requests would be submitted by physicians, with API-based accessibility to dispensaries for verification.
- **Benefits Card Integration**: Exemptions would appear on the digital benefits card, enabling patients to access prescribed dosages seamlessly while ensuring compliance.

This exemption protocol supports patient autonomy and aligns with DEA objectives, enabling safe and effective treatment without federal overreach.

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8. Federal Research Mandates to Establish Evidence-Based Standards

A Schedule III reclassification should mandate federal research into dosing, strain efficacy, and safe treatment practices. *Alliance for Cannabis Therapeutics v. DEA* highlighted the importance of scientific evidence in controlled substance regulation. Partnerships with platforms like The Doc App would allow the DEA to leverage real-world data to develop accurate, evidence-based guidelines.

Role of Patient Data in Research:

- **Anonymized Data Contributions**: Platforms like The Doc App could provide anonymized data on patient outcomes, aiding studies on strain effectiveness, dosage, and side effects.
- **Support for Research Partnerships**: Federal support for research partnerships would create an evidence-based framework, refining treatment guidelines over time.

Conclusion

The proposed rescheduling of marijuana to Schedule III presents an opportunity to establish a safe, accessible, and patient-centered regulatory framework. A federally backed Medical Marijuana Benefits Card, secure API access, and independent licensing standards will ensure compliance, prevent misuse, and enable self-treatment models. These recommendations align with DEA's goals, safeguard patient rights, and provide equitable access to treatment for

veterans and other vulnerable populations needing compassionate care. Proposed statutory language for consideration is attached hereto, titled, Proposed Federal Medical Marijuana Access and Protection Act (MMAPA)

Respectfully submitted,

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Enclosure:

Proposed statutory language for consideration is attached hereto, titled, *Proposed Federal Medical Marijuana Access and Protection Act (MMAPA)*

Certificate of Service

I hereby certify a copy of this document with attachments has been sent by email to the addresses listed below this 11th day of November, 2024:

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Proposed Federal Medical Marijuana Access and Protection Act (MMAPA)

Section 1: Short Title

This Act may be cited as the "Medical Marijuana Access and Protection Act" (MMAPA).

Section 2: Findings and Purpose

(a) **Findings**
Congress finds the following:

1. Veterans, patients with chronic conditions, and individuals with debilitating illnesses often benefit from medical marijuana.
2. Federal rescheduling of marijuana to Schedule III enables structured access under federal oversight, ensuring that medical marijuana is accessible for legitimate medical purposes while preventing misuse.
3. Vertical integration and monopolistic practices can restrict patient access, reducing market competition and prioritizing profit over quality patient care.
4. Independent technology platforms that manage patient information serve a critical role in providing unbiased, data-driven support to bridge patient, provider, and regulatory needs.
5. Technology solutions, such as digital benefits cards with QR codes and real-time data tracking, enhance patient access, safety, and regulatory compliance.

(b) **Purpose**
The purpose of this Act is to:

1. Create a federal medical marijuana benefits card program, including a digital benefits card with QR code functionality.
2. Implement a federal licensing structure for dispensaries, technology platforms, and testing facilities, ensuring compliance with federal standards.
3. Prevent conflicts of interest by mandating arm’s-length relationships between dispensaries, physicians, and technology platforms.
4. Support a self-treatment model with real-time data access to enhance patient autonomy and treatment efficacy.
5. Establish federal research mandates to promote evidence-based medical marijuana standards and support patient safety with proactive product recall monitoring.

Section 3: Federal Medical Marijuana Benefits Card Program

(a) **Establishment of Card Program**
The Department of Health and Human Services (HHS), in coordination with the Department of Veterans Affairs (VA) and Centers for Medicare & Medicaid Services (CMS), shall implement a Medical Marijuana Benefits Card Program (MMBCP) to ensure veterans and eligible patients have access to medical marijuana under federal programs.

(b) **Eligibility and Enrollment**

1. Veterans, Medicare recipients, and other individuals verified under federal healthcare programs may qualify for the benefits card if recommended by a licensed physician for conditions such as PTSD, chronic pain, and other qualifying diagnoses.
2. Verification and enrollment procedures shall ensure only eligible individuals access the program, with measures in place to prevent fraud and unauthorized use.

(c) **Benefits and Cost Assistance**

1. The benefits card shall cover approved dosages, strains, and forms of medical marijuana as prescribed, ensuring that patients have access to the treatment they need at an affordable rate.
2. Federal programs like VA and Medicare shall recognize the benefits card, providing cost assistance to reduce financial barriers for low-income and veteran patients.

(d) **Monitoring and Usage Tracking**

1. The benefits card system shall integrate with licensed patient management platforms (Section 4) to securely track dosages, purchases, and doctor recommendations.
2. Real-time tracking shall enable immediate alerts for product recalls, notifying affected patients and their physicians.
3. Any patient misuse or excess purchases shall trigger a review by the issuing agency, ensuring adherence to prescribed limits.

(e) **Digital Card and QR Code Accessibility**

1. The benefits card may be accessible digitally through a secure app platform, such as The Doc App, where a scannable QR code enables dispensaries to instantly access the patient’s approved doctor’s recommendation or prescription.
2. This digital implementation improves accessibility, enhances patient privacy, and ensures compliance with federal standards.

Section 4: API Access and Data Integration Standards

(a) **Standardized API Access Protocol**

1. HHS, in coordination with DEA and CMS, shall establish an API Access Protocol to enable secure, real-time data sharing between licensed patient management platforms, dispensaries, and regulatory bodies.
2. API access shall ensure up-to-date information on patient allotments, treatment history, and dosage, allowing for streamlined compliance and allotment tracking.

(b) **Data Security and Privacy Requirements**

1. Licensed platforms and dispensaries must comply with federal data privacy standards, ensuring that all API transmissions are secure and patient confidentiality is maintained.
2. Patients shall have access to real-time data on their medical marijuana usage, allotment, and remaining dosages through compliant platforms.

Section 5: Licensing Standards for Dispensaries, Technology Platforms, and Testing Facilities

(a) **Federal Licensing Requirements**

1. Dispensaries, technology platforms, and testing facilities that wish to participate in the federal medical marijuana program must obtain a federal license issued by HHS.
2. Licensing standards shall ensure compliance with federal privacy, security, and operational guidelines, including measures to prevent conflicts of interest.

(b) **Independence and Anti-Conflict Provisions**

1. Technology platforms, such as patient management systems, shall operate independently of dispensaries and medical practices, ensuring an arm's-length relationship between providers, patients, and platforms.
2. Licensed platforms must certify that they have no direct financial interests in dispensaries or physician practices, promoting unbiased, data-driven care.

(c) **Accessible Licensing Fees**

1. Licensing fees shall be tiered based on business size, ensuring that smaller, patient-centric providers have affordable entry into the market, promoting competitive access to care.
2. Fees collected from licensing shall fund federal research and compliance monitoring efforts under this Act.

(d) **Certification and Compliance**

1. Technology platforms must undergo certification verifying their compliance with federal standards for patient data protection, impartiality, and secure API integration.
2. Annual compliance audits shall ensure continued adherence to standards, with penalties for violations.

Section 6: Self-Treatment Model with Real-Time Data Access

(a) **Support for Patient Self-Treatment**

1. The medical marijuana framework shall support a self-treatment model, empowering patients to select appropriate strains, dosages, and delivery methods based on personal and medical preferences.
2. Licensed patient management platforms shall provide patients with real-time data on strain efficacy, condition-specific outcomes, and dosage guidance based on prior patient experiences and doctor recommendations.

(b) **Patient Education and Autonomy**

1. Federal regulations shall protect the right of dispensaries and licensed platforms to provide accurate educational materials on strains, dosage, and safe usage, ensuring that patients have access to the information necessary for informed self-treatment.
2. Educational resources should emphasize safety and responsible use, particularly for patients new to medical marijuana, to promote a patient-centered and safe treatment model.

Section 7: Distinct Licensing for Medical and Recreational Dispensaries

(a) **Separation of Medical and Recreational Markets**

1. To prevent monopolistic control, medical marijuana dispensaries shall operate independently of recreational marijuana businesses.
2. States shall issue separate licenses for medical and recreational dispensaries, ensuring that medical providers are dedicated to patient care rather than profit-driven recreational sales.

(b) **Preventing Vertical Integration**

1. Licensed medical dispensaries shall not engage in cultivation or processing unless explicitly licensed for those roles, ensuring arm’s-length operations and reducing conflicts of interest.

2. DEA shall monitor and enforce anti-vertical integration standards to foster market competition, protecting patient access and quality of care.

Section 8: Federal Research Mandates for Evidence-Based Standards

(a) **Establishment of Research Program**

1. HHS, in coordination with DEA, shall establish a research initiative to study dosing, strain efficacy, and treatment outcomes to develop evidence-based standards for medical marijuana.
2. Licensed patient management platforms and dispensaries may collaborate with federal research bodies to contribute anonymized data for research, enhancing the understanding of medical marijuana's effects and best practices.

(b) **Funding and Resource Allocation**

1. Licensing fees collected under this Act shall be allocated to fund ongoing research efforts, ensuring a continuous commitment to evidence-based treatment standards.
2. Results from federally funded studies shall inform future updates to dosage guidelines, strain recommendations, educational materials, and patient safety protocols.

Section 9: Exemption Mechanisms for Physician-Directed Dosage Caps

(a) **Exemption Protocol for Higher Dosages**

1. Patients who require dosages above federally imposed THC caps may apply for a physician-directed exemption, which must be supported by medical documentation and submitted through a licensed platform.
2. Approved exemptions shall be integrated with the patient’s benefits card and accessible to dispensaries via the API system for verification.

(b) **Automatic Integration and Oversight**

1. Exemptions shall automatically update patient allotment records, allowing access to recommended dosages without delay.
2. Oversight mechanisms shall monitor exemption usage to prevent misuse and ensure adherence to treatment plans.

Section 10: Implementation Timeline

(a) **Effective Date**

1. This Act shall take effect one year from the date of enactment to allow for the development of licensing frameworks, benefits card issuance, and API access protocols.

(b) **Regulatory Guidance**

1. HHS, DEA, and CMS shall issue regulatory guidance within six months of enactment, providing clear standards for licensing, patient management, and compliance monitoring under the MMAPA.

Drafted November 11, 2024
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