Summary
The medicinal use of marijuana has been gaining traction. As several states have enacted laws authorizing the medical and recreational use of marijuana, the Department of Justice issued a new memorandum providing guidance regarding marijuana enforcement. The Department has prioritized enforcement efforts that are of particular importance to the federal government, targeting key areas of significant abuse and misuse. While the Department stopped far short of endorsing the “legalization” of marijuana, the agency will defer to state and local law enforcement agencies to address activity through enforcement of their own narcotic laws. This document is intended to summarize this topic.

Take-Away Points
- The Controlled Substance Act (CSA) lists marijuana as a dangerous drug and the illegal distribution and sale of the drug is a serious crime. Marijuana use and trafficking is illegal under federal law and states cannot authorize violations of federal law.
- Marijuana has been in Schedule I status since the Controlled Substances Act was passed by Congress in 1970, representing that the US government considered it to have "no accepted medical use in treatment in the United States."
- The Food and Drug Administration (FDA) is currently conducting an analysis at the Drug Enforcement Administration’s (DEA) request on whether marijuana’s classification should be changed from Schedule I status.
- The FDA previously reviewed marijuana’s Scheduling status in 2001 and 2006 and recommended it remain Schedule I.
- As of June 2014, 23 states and the District of Columbia have enacted laws authorizing some medical use of marijuana. Two of these states have also authorized legislation for recreational use.
- In the recent approved state legislation, many states only allow “low THC, high cannabidiol” products to be used medically in limited situations.
- In August 2013, the U.S. Department of Justice issued a new memorandum to these states outlining an updated enforcement policy. Marijuana remains an illegal drug under the CSA. The memorandum outlined eight enforcement areas that must be prioritized by federal prosecutors to address cases of abuse and misuse.
- DEA, federal government and the medical community do not accept smoked marijuana as a medicine.
- FDA has not approved the use of medical marijuana for any indications.
- The FDA has approved two medications containing cannabinoids, the active chemicals in marijuana.
- Clinical trials are currently in progress investigating other cannabinoid based medications.
- Similar to herbal products, each plant and batch could have varying amounts and types of cannabinoid-like substances. FDA would require standardization or some mechanism of quantifying the active ingredient to assure quality.
- NDC numbers are not available to allow adjudication of these products.
- The American Medical Association (AMA) called for additional clinical research in patients who have serious conditions for which preclinical, anecdotal or controlled evidence suggests possible efficacy.
- American Medical Association's policy making body voted November 2013, to reaffirm its opposition to marijuana legalization. The AMA rejected challenges to become “neutral” on legalization, supporting the American Psychiatric Association’s (APA) statement identifying public harms associated with marijuana use.
- According to the APA: “Current evidence supports, at minimum, a strong association of cannabis use with the onset of psychiatric disorders.” Cannabis can have an effect on neurological development, thus adolescents are most vulnerable.
Medical Marijuana: Botanical Versions
According to the January 2010 Medical Letter review, medical marijuana is both ingested and smoked to manage nausea and vomiting, anorexia, asthma, glaucoma and spasticity. “It appears to be modestly effective, depending on the dose, for some of these disorders, but well-controlled studies large enough to be convincing are lacking, and non-standardization of dosage makes the available data difficult to interpret.”

Marijuana contains approximately 480 substances and has not been formally reviewed or approved by the FDA for medical use. Medical marijuana is not standardized from batch to batch, and it does not possess an NDC or mechanism to formally process under the pharmacy benefit.

FDA-Approved Cannabinoid-Based Medications
While results from well-conducted, large-scaled clinical studies assessing the safety and effectiveness of medical marijuana are lacking, two cannabinoid-based drugs have been formally approved by the FDA – dronabinol (Marinol) and nabilone (Cesamet).

Dronabinol is a synthetic preparation of delta-9 tetrahydrocannabinol (THC), one of 66 active compounds, called cannabinoids, found in marijuana. It is a schedule III controlled substance, and is FDA approved for both nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments and treatment of anorexia associated with weight loss in patients with AIDS. It is available as a 2.5mg, 5mg and 10mg capsule.

Nabilone is similar to THC and is derived from cannabino. Nabilone is schedule II controlled substance and is also FDA approved for treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. It is available as a 1mg capsule. Express Scripts offers a quantity limit (Standard/Rx) to prevent stockpiling, misuse, or overuse of this product.

Express Scripts’ Position
Express Scripts does not recommend covering medical marijuana under the pharmacy benefit for the following reasons:

- Results from large, well done clinical studies validating safety and effectiveness are lacking
- Medical marijuana has not been formally reviewed and approved by FDA
- Botanical or crude versions of marijuana are not standardized
- Medical marijuana does not possess an NDC, which is required for claims adjudication
- To date, marijuana, whether it is used for medical or recreational purposes, remains a Schedule I controlled substance.

In contrast, Express Scripts recommends covering the two FDA-approved cannabinoid-based products (dronabinol and nabilone), which may prove helpful in select patient populations.

REFERENCES: