Standard of Care Considerations When Recommending Cannabis (Marijuana) as a Medicine

The International Academy on the Science
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Statutes that allow the recommendation of medical marijuana present a real malpractice risk to physicians and medical providers. Despite a rapidly growing medical and recreational marijuana industry, there has been no definition of a standard of care for the use and recommendation of marijuana for medicinal purposes. This issue has been essentially ignored Federal regulators and legislatures. Most of the medical opposition to medical marijuana is borne from concern over serious medical and social consequences in patients resulting from marijuana use.

When considering what constitutes the "standard of care," it is important to embrace practices that reduce the risk to patients as well as reducing the risk of potential malpractice litigation of providers. In legal terms, the "Standard of Care" is the level at which the average, prudent provider in a given community would practice. It is how **similarly qualified practitioners would have managed the patient's care under the same or similar circumstances.** (1).

Pure Cannabis-based medicines such as Marinol, Cesamet, Epidiolex, and Sativex are already FDA approved and on the market as medications that may be prescribed. Providers "recommending" state-approved cannabis are clearly recommending a non-FDA approved substance. The recommendation of marijuana as a medicine generally has malpractice risk because "recommendations" for the use of marijuana are lacking the standard safe practices required of modern-day medicine. Research demonstrates that the use of marijuana even for pain has fallen into question (2). Extensive literature review and several international organizations have concluded that the use of cannabinoids for chronic non-cancer pain is not yet supported nor proven by research and its use for pain is considered limited (3,4).

Questions must also be answered as to what form of the drug is to be provided (smoked, vaped, gummies, oils etc.), what doses are safe and effective, what side effects should be expected, and what long-term side effects might be experienced. Patients must also be notified and cautioned of these side effects and the problem that such delivery vehicles present unreliable doses to the patient.

Several of the elements necessary for the standard of care to be met are listed below.

Medical Evaluation- As with any medical disorder, a thorough and complete medical evaluation must be performed, documented, and updated regularly by a licensed medical provider. This is a

central and essential part of any medical evaluation. This process should also include specific documentation of other medical treatments and other successful or failed medications. The documentation of these elements must be entered into the patient's medical record which is appropriately retained, stored, and made readily available for other providers also treating the patient. The patient's mental health history must be explored as cannabis use can damage mental health. (5) The few Cannabinoid products that have been approved for use by the FDA, including Epidiolex (a CBD product) and Marinol and Cesamet (synthetic THC) have extensive warnings of the many risks of use. The FDA drug label for Marinol issues a warning that the drug "may cause psychiatric and cognitive effects and impair mental and/or physical abilities. Avoid use in patients with psychiatric history." (Table 1)

Concentration/Dose- Research is now suggesting that THC concentrations should not exceed 10% (4), and that higher concentrations have been associated with psychosis and other psychiatric disorders. It is worth also noting that state statutes allowing "medical" applications of marijuana include smoking, oils, vaping for example that can have 70-90% THC concentrations, and generally do not have specific dose restrictions.

Failure to warn – The question of side effects and whether a less problematic and less toxic medication might be available, must be made available to the patient, and there must also be a rationale provided if the practitioner proceeds in recommending marijuana over a less toxic medication. The patient must be warned on any drug interaction which may harm them or render a medically necessary drug for the patient (such as coumadin) dangerous or ineffective. This rationale and patient notification must be clearly documented in the medical record.

Failure to monitor- Ongoing monitoring of symptoms, toxicity, need for dosage change, need for additional medication are all elements of good medical care.

REMS- Risk Evaluation and Mitigation Strategies are widely used for high-risk therapies such as opiates. While REMS for marijuana administration are not widely used, as they become available it is strongly recommended to be a requirement for prescribing/recommending providers.
These elements are generally not required in existing statutes.

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