SUBJECT: INTERFERENCE – LAWFUL OFF-LABEL TREATMENT OF PATIENTS

SUBMITTED BY: Arizona Osteopathic Medical Association

REFERRED TO: <name of entity (please leave blank – staff will assign a reference committee)>

WHEREAS, patients and families must have confidence that their physician is able to educate them about all health care options and the risk and benefits of those options; and

WHEREAS, physicians may fear punishment and restriction of practice for making patients aware of or educating or advising patients about lawful, evidence-based health care options, including off-label approved treatments and health care-related research or data. Any restriction or sanction may limit options and access for patients to healthcare; and

WHEREAS, background drug labels of U.S. Food and Drug Administration (FDA)-approved drugs provide information about the drug, including the approved dosage, method of administration and patient population. Deviation from drug use as described on the label is termed off-label use and includes: 1) use for a different disease or medical condition; 2) administration in a different way; or 3) administration in a different dose; and

WHEREAS, off-label drug use is common and reported in up to 21% of prescriptions studied. It has become widely entrenched in clinical practice and continues to be predominant treatment options for many clinical conditions. Motivation for use may be stemmed by several factors including recommendations for use in patient populations that may not have been studied including pediatric, geriatric, or pregnant patients, use in terminally ill or patients with life threatening conditions, or use where the FDA approved drug's indications are applied to other drugs in its class for the same condition. Off-label use is common in psychiatric conditions, pediatric, oncology and neurology practices[1]; and

WHEREAS, federal law permits the use of marketed products in wider circumstances and physicians are permitted to prescribe drugs and devices in situations not covered by the approved label. The FDA is not authorized to regulate physicians' behavior, but the FDA is able to restrict manufacturers' ability to promote off-label use; and

WHEREAS, Medicare, Medicaid, and private insurers reimburse for off-label uses when there is evidence to support such uses. Responsible off-label prescribing requires physicians to: 1) evaluate whether there is sufficient evidence to justify off-label use; 2) press for additional information and research when evidence is lacking; and 3) inform patients about uncertainties and potential costs associated with off-label use; and

WHEREAS, not every patient responds to the "standard" or "one size fits all" treatment, and we must protect the rights of patients to seek out care options that are best for them. "Osteopathic physicians consider the impact that lifestyle and community have on the health of each individual, and they work to break down barriers to good health. Osteopathic physicians

are trained to look at the whole person, and osteopathic physicians integrate the patient into the health care process as a partner[2]"; and

WHEREAS, making a patient aware of or educating or advising a patient about health care options, including off-label treatments and health care-related research or data, does not require: a) the health care service be covered under the health care plan or the health care system through which the patient receives care; and b) a health professional, an entity that employs the health professional or a health care system to offer, provide or make the lawful health care service, including the off-label use of health care options, available to the patient; and

WHEREAS, this does not change the ethical responsibility of a physician, nor does it limit the ability of state licensing boards to sanction in cases of provider misconduct or unsafe practices; and

WHEREAS, the AOA H307- A/13 approved a policy paper and recommendations in 2013 on Interference state and federal laws. This policy discusses opposition to laws that 1) prevents physicians from asking their patients about risk factors that may affect their health or the health of their families; 2) requires physicians to discuss specific treatments that may not be medically necessary; 3) requires physicians to provide tests or treatments which are not supported by evidence; 4) places restrictions on the content of information that physicians can disclose to patients; and now, therefore, be it

RESOLVED, that the AOA proactively support the protection of a physician's ability to prescribe treatments and to speak freely about lawful, evidence-based, health care options, including off-label treatments or health care-related research, without fear of being sanctioned by regulatory boards, insurance companies or employers; and, be it further

RESOLVED, that the AOA support state efforts to protect patients and prevent sanctions for physicians, directly or indirectly through a subcontractor or otherwise, for making a patient aware of or educating a patient about lawful, evidence-based, health care options, including 1) off-label use of health care options; 2) health care-related research or data; and 3) for offering, providing or making available lawful, evidence-based health care options.

Explanatory Statement:

<insert text>

FISCAL IMPACT: $
N/A

ACTION TAKEN _____

DATE _____

[1] Wittich, CM, Burkle CM et al, Mayo Clin Proc, Ten Common Questions (and Their Answers) About Off-Label Drug Use. October 2012; 87 (10) 982-990 www.mayoclinicproceedings.org
[2] American Association of Colleges of Osteopathic Medicine Definition