Statement of the
International Chiropractors Association
to the
State of Arizona Board of Chiropractic Examiners
July 10, 2007

The International Chiropractors Association (ICA) wishes to respond on behalf of its members in Arizona and the patients they serve to proposed rules first published via the Arizona Board's notice of April 27, 2007 and scheduled for consideration at the Board's meeting of July 12, 2007.

ICA is concerned that the language proposed in **R4-7-902-1,** *"Failing to disclose in writing to a patient or a third party payor that a licensee has a financial interest when referring a patient for a prescribed diagnostic test, treatment, good or service…"* is subject to significant misinterpretation by practitioners. This concern is based on the impression that is given by this language that such a referral is acceptable upon disclosure in writing, and without potential penalty when, in fact, a considerable body of federal regulations apply.

We refer to the federal anti-kickback statute known as the Stark law (after the bill's author, California Congressman Fortney Stark). This broadly worded statute makes it a crime to pay or receive remuneration of any kind for referrals or services "compensable" under any federal health care program. More specifically, the anti-kickback statute makes it a felony, punishable by up to five years in prison and a $25,000 fine, to "knowingly and willfully" solicit, receive, offer or pay any remuneration in return for (1) referring or arranging for services payable by any federal (or in many instances, state) health care program, or (2) purchasing, leasing, ordering or arranging for any goods, facilities or services which may be paid for in whole or in part by any federal or state health care program. Another sanction available under the statute is exclusion of any person or entity from participation in the Medicare program.

Additionally, the *Balanced Budget Act of 1997* added civil monetary penalties for violations of the anti-kickback statute in amounts up to $50,000 per violation and assessments equal to not more than three times the amount of remuneration paid under the arrangement. The details of this law are available online in the *United States Code*, under Section 42 U.S.C. 1320a-7a(7)) at the link below: **http://www.access.gpo.gov/uscode/uscmain.html** (Go to Title 42, Chapter 7, Sub-Chapter XI, Section A).

The Stark law was passed initially by Congress in 1989 to outlaw kickbacks from laboratories to doctors who referred business to them. That law was expanded in 1995 by what is commonly referred to as "Stark II" to include the following services:

radiology and other imaging services (including MRI, CT and ultrasound);
physical therapy;
occupational therapy;
radiation therapy;
durable medical equipment;
parenteral and enteral nutrients, equipment and supplies;
prosthetics, orthotics and prosthetic devices and supplies;
home health services;
outpatient prescription drugs; and
inpatient and outpatient hospital services.

The Stark law defines this list of services, together with clinical laboratory services as "Designated Health Services (DHS)."

ICA strongly recommends that the language proposed for **R4-7-902-1** be amended to provide greater clarity on the matter of referrals where economic interests exist, along with a reference to federal rules in this area.

ICA also wishes to express grave concerns over a number of aspects of the addition of “medically necessary” language (**12. R4-7-101**) on the basis proposed, to the code of regulations governing the practice of chiropractic in Arizona. ICA maintains an emphatic policy of zero-tolerance for fraudulent and deceptive practices. The Association has historically been very active in the education and regulatory processes, working to establish sound clinical practices that preserve the judgment of the attending doctor and their activities within the law, but also provide guideposts as to appropriate rationales for care. In this context, however, ICA considers the language being considered by the Board, with the intention of providing an additional bulwark against unnecessary, inappropriate or fraudulent behavior in the provision of care (**R4-7-902-12-e**), to be fraught with difficulties, inherently inappropriate, and likely to do far more harm than good to the public in consumers’ attempts to seek and obtain clinically indicated care.

Under “**R4-7-101.Definitions-12**” the language proposed for “medically necessary” is, from the perspective of the ICA, inappropriate. ICA feels an obligation to observe that the practice of chiropractic is not the practice of medicine and that the choice of the term “medically necessary” is in itself open to question, for a host of substantive reasons, in addition to the confusion it might create in the minds of the public. ICA would strongly urge the adoption of the term “clinical necessity” for discussion purposes, although such a language change would in no way ameliorate or negate the very legitimate concerns outlined herein with the greater, very serious issues related to the proposed regulation.

This proposed language is far too broad, too vague, and makes no provision for the judgment of the attending doctor. The unique nature of each chiropractic

patient requires both an analysis process and a clinical care decision on the part of the attending doctor that is based, indeed, on objective and subjective measures of patient status, but most important of all is based on the judgment of the attending doctor. In the absence of any agreed, proven and reliable standards by which clinical behavior might be measured, the application of any such new regulation inherently falls to the judgment of individuals. However well meaning the intentions of those individuals may be, enforcement of such a rule must fall into the realm of opinion. Opinions on what is and is not "consistent with the diagnosis, and with generally accepted clinical standards of care…" offers endless opportunity for diverse interpretations and potential abuse through arbitrary, prejudicial or mis-informed decisions. The limited research record can only offer general guideposts in this situation as it is impossible to extract any data immediately relevant to the needs and condition of a specific patient from aggregate data.

The language "medically necessary" has become an insurance term, not a quality of care term. This language has been cynically usurped by elements of the insurance industry and subverted and misused as a hammer and lever to limit the clinical range of the activities of doctors of chiropractic via extra-legislative means, with the objective of denying payment for care. Such economic motives have led many insurance companies, and those in their pay, to make demonstrably absurd claims, frequently before state regulatory boards, regarding the appropriateness of care with the sole objective of what can rightfully be considered cheating beneficiaries and providers alike, out of payment for legitimate services. Such claims have needlessly caused great disruption to the lives and practices of honorable practitioners acting within the law, eroded the credibility of the profession at large with policy makers and the public, and most importantly of all, denied consumers care they need and have paid for through insurance premiums.

The obvious third-party payment implications of this proposed addition to regulatory language becomes inherently problematic for the Board itself, given the shameful history of the abuse of such issues by the insurance industry, their contractors and paid chiropractic consultants. In recent years, the chiropractic profession has witnessed countless examples of paid chiropractic consultants attacking the care and decision making processes of honorable doctors of chiropractic acting within the law. Such consultants routinely resort to such tactics as perverting the research record, making absurd claims on what is and is not appropriate care, all based on the economic imperatives of those paying them, and reducing the regulatory process to a shameful farce. This willingness on the part of many paid chiropractic consultants to make any claim for monetary reasons, is one of the most disgraceful, shameful and destructive elements in the chiropractic profession today. The enactment of the "medically necessary" language as proposed would do nothing but further open the door to such a prospect, damaging both the profession and members of the public.

These observations are not some parade of imaginary horribles, but are anchored in the experience of the past several years.

Making medical necessity a condition of chiropractic service delivery and subject to Board interpretation as "unprofessional or dishonorable conduct" also raises profoundly serious questions about possible limitations on consumer freedoms to seek and obtain any legally authorized chiropractic service, including maintenance and preventive care, exceptionally frequent care, etc. Action by the Board to curb consumer rights via the imposition of "medically necessary" limitations on providers would very likely be found to be unacceptable and beyond the authority of the Board by state courts. ICA would strongly advise the Board to consider, perhaps on the advice of the Attorney General, how consumer rights to contract and act in the health care marketplace, according to their own determinations of need and appropriateness, might best be safeguarded in any potential regulations being considered by the Board.

ICA appreciates this opportunity to address what we consider to be serious, substantial concerns with proposed regulatory changes and would be happy to provide any additional information or answer any question the Board may have on ICA's comments herein presented.

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