DEPARTMENT OF VETERANS AFFAIRS Veterans Health Administration

Washington DC 20420

April 1, 2005 In Reply Refer To: 124E

PROGRAM ANNOUNCEMENT

REQUEST FOR APPLICATIONS ON CHIROPRACTIC CARE RESEARCH

1. Purpose

Chiropractic care involves a variety of therapies for patients seeking care for musculoskeletal symptoms such as back pain, neck pain, and headache. The Department of Veterans Affairs (VA) Office of Research and Development (ORD) offers this program announcement to stimulate interest and solicit relevant research proposals on chiropractic care. Proposals may be submitted to VA's Biomedical Laboratory Research Service (BLR&D), Health Services Research and Development Service (HSR&D), Rehabilitation Research and Development Service (RR&D), or Clinical Science Research and Development Service (CSR&D).

2. Background

Chiropractors, the third largest health care profession from whom patients seek care, numbers more than 66,000 providers in the year 2001. The majority of chiropractic patients seek care for musculoskeletal symptoms. Chiropractic care involves a variety of therapies, but the use of spinal manipulative therapy (also called chiropractic adjustments) is the most common treatment and the one most specifically associated with chiropractic care. There is an increasing amount of research on the use of spinal manipulative therapy (SMT) and/or chiropractic care for a variety of musculoskeletal conditions. [1,2,3]

With PL 107-135, the Department of Veterans Affairs Health Care Programs Enhancement Act of 2001, VA was authorized to bring chiropractors into the VA system as VA providers of care. Prior to this, chiropractic services were available to veterans via the fee basis method of purchasing care in the community. By the end of 2005 each VISN should have one or more facilities where chiropractors are now directly hired by VA and work alongside other health care professionals in the delivery of care.

P.L. 107-135 also established the Department of Veterans Affairs Advisory Committee to "provide direct assistance and advice to the Secretary in the development and implementation of the chiropractic health program." The recommendations of the Chiropractic Advisory Committee, accepted by VA, are that chiropractors within VA should work within the context of multidisciplinary teams on referrals from the patient's primary care provider. Additional details of chiropractic care positions within VA are mostly left to the individual VA facilities, including such issues as privileging, incorporation into care lines, medical staff membership, etc. The Committee also recommended that "the Office of Research and Development develop an appropriate research agenda for chiropractic care." This Request for Applications (RFA) is in response to that recommendation.

3. Sample Research Issues

Research considered responsive to this announcement and of interest to the various components of VA's Office of R&D, is described below.

- a) <u>Efficacy</u>, <u>Effectiveness</u>, <u>and Cost</u>: Although there is a moderate amount of literature, including randomized clinical trials (RCTs) regarding the efficacy of spinal manipulative therapy for some musculoskeletal conditions, particularly low back pain, additional research is needed on many questions. Some of these questions include:
 - What is the efficacy and effectiveness (relative to other forms of care) of spinal manipulative therapy for low back pain, neck pain, headache, and other musculoskeletal conditions?
 - What are the patient clinical factors or techniques that produce better outcomes with SMT than with other forms of care [4]
 - What is the cost of care, cost effectiveness and cost utility of care, and is it possible to determinate the number of treatments needed for maximal therapeutic benefit?
- b) Patient Safety: Patient safety is of utmost importance to VA. Cervical spine manipulation in the older VA population may be a particular concern. While reports of serious adverse effects from spinal manipulative therapy are rare, systematic data are lacking. Important issues include a need to better understand the rate of serious adverse effects following spinal manipulation and whether there are patient, clinical, or provider technique factors that are associated with an increased risk. Incorporating measures of patient safety into RCTs, use of case-control studies, and the development of methods that could be used to implement a national VA database of spinal manipulative procedures (which could then be a resource for cohort analyses) are all encouraged.

- c) <u>Organizations and Health Systems</u>: Integrating a new clinical discipline into VA is always a challenge, and research regarding the organizational and health system factors that are associated with successful integrations is encouraged. Organizational and health systems factors for consideration include how chiropractors are hired (staff versus contract models), initial privileging, placement within care lines at VA, type of VA facility, organizational culture, local facility educational initiatives, use of care pathways, chiropractic personal characteristics, relationship with local chiropractic colleges, etc. For example, does utilization of services and satisfaction differ depending on the placement of the chiropractic provider within the VA (e.g., within primary care, within PMR, etc)? ORD's expectation is that research in this area will be primarily observational in nature, taking advantage of natural variations in the ways chiropractors are integrated into VAs around the country.
- d) <u>Measures</u>: The development of psychometrically sound and valid measures is a necessary requirement for high quality research. Areas for which such measures are needed include descriptions of chiropractic and other musculoskeletal interventions in terms that promote reproducibility across practitioners, assessments of the appropriate outcome measures for patients with musculoskeletal symptoms, biomarkers and biomechanical measures to assess the risk, prognosis, and response to different treatments of musculoskeletal symptoms. Researchers should consider whether veterans preferences and utilities for certain outcomes may differ from those reported in non-veteran populations.

4. Pilot Projects

Pilot projects that will approach existing problems from a new perspective and/or use new avenues of investigation will also be reviewed for funding. These pilot projects differ from traditional merit review proposals in that preliminary data, while useful, is not required. However, these pilot proposals should be based on a rational hypothesis derived from critical review and analysis of the literature and/or logical reasoning.

5. Eligibility

VA clinician and non-clinician scientists currently eligible to apply for research funding from any of the four ORD Services (Biomedical Laboratory Research and Development, Clinical Science Research and Development, Health Services Research and Development, Rehabilitation Research and Development) may submit an application under this RFA. Principal Investigators with other VA funding, including Merit Review funded by any of the ORD Services, are eligible to apply to this program; funding under this RFA

would be in addition to the "single Merit Review rule" in Biomedical and Clinical R&D Services. For further information about eligibility, please review VA Handbook 1200.15.

6. Application Preparation and Submission

Proposals can be sent to any of the four ORD Services. The same proposal cannot be sent to more than one ORD Service at the same time. Please follow the submission and funding guidelines of the ORD Service to which the proposal will be submitted. Visit the following website for the latest submission deadlines, forms, and Handbooks for each of the four ORD Services: http://www.research.va.gov/.

7. Due Date

This is an ongoing announcement with multiple receipt dates. Until further notice, research proposals may be submitted for any of the regular receipt dates established by the relevant Service.

8. Review

Established deadlines and review procedures for each service apply. Proposals will be evaluated on the basis of scientific quality, significance and innovation of the research question(s), rigor of the methodological approach, feasibility, and relevance to this announcement and VA.

9. Inquiries

For further information, please direct all questions regarding this RFA including questions about areas of research investigation, eligibility, application preparation funding, and review to: Andrew A. Guccione, PT, PhD, DPT, at 202-461-1517or andrew.guccione@va.gov.

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References

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- 2. Bronfort G, Haas M, Evans RL, Bouter LM: Efficacy of spinal manipulation and mobilization for low back pain and neck pain: a systematic review and best evidence synthesis. Spine J 4:335-56, 2004
- 3. Bove G, Nilsson N: Spinal manipulation in the treatment of episodic tension-type headache: a randomized controlled trial. JAMA 280:1576-9, 1998
- 4. Childs JD, Fritz JM, Flynn TW, Irrgang JJ, Johnson KK, Majkowski GR, Delitto A: A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. Ann Intern Med 2004 141:920-8, 2004