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**INDEPENDENT REGULATORY REVIEW COMMISSION**  
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

November 29, 2006

Jonathan W. McCullough, D.C., Chairman  
State Board of Chiropractic  
2601 North 3rd Street  
Harrisburg, PA 17110

Re: Regulation #16A-4313 (IRRC #2568)  
State Board of Chiropractic  
Patient Records

Dear Chairman McCullough:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at [www.irrc.state.pa.us](http://www.irrc.state.pa.us). If you would like to discuss them, please contact me.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kim Kaufman".

Kim Kaufman  
Executive Director  
wbg  
Enclosure

cc: Honorable Pedro A. Cortes, Secretary, Department of State

# **Comments of the Independent Regulatory Review Commission**

**on**

## **State Board of Chiropractic Regulation #16A-4313 (IRRC #2568)**

### **Patient Records**

**November 29, 2006**

We submit for your consideration the following comments on the proposed rulemaking published in the September 30, 2006 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Chiropractic (Board) to respond to all comments received from us or any other source.

#### **1. Need, Reasonableness and Economic impact of the regulation.**

##### *Standards for medical records*

In response to question #16 of the Regulatory Analysis Form, the Board states the following:

On December 6, 2001, the Board received a petition under 1 Pa. Code § 35.18 to promulgate a regulation that would establish medical necessity definitional parameters in order to assist licensees to discharge their regulatory documentation obligation and establish guidelines for peer review and utilization review concerning chiropractic care. The Board held a work session on March 7, 2002. After extensive discussion at public meetings over the ensuing months, the Board concluded that its rulemaking should be directed toward setting forth standards for medical records, not attempting to define what is medically necessary.

The House Professional Licensure Committee (House Committee) asked the Board to further explain the rationale for this regulation. We agree that the Board has not explained the basis for its apparent disagreement with portions of the December 6, 2001 petition. The Board also needs to explain its conclusion that the rulemaking should only be directed toward standards for medical records rather than attempt to define what is medically necessary. It is not clear how this conclusion is consistent with this rulemaking that requires documentation of "diagnosis and clinical necessity," defines separate levels of care and specifies how that care must be documented. The Board should respond to these concerns, provide support for the need for this rulemaking and explain its objectives.

##### *Purposes of patient records*

The House Committee also questioned whether the Board is taking a unique approach regarding the content of patient records. In its extensive comments on this regulation, Practice Masters,

Incorporated (PM) believes its suggestions will make the regulation consistent with documentation standards in the industry.

The Board should explain what factors it considered in developing this regulation. Specifically, the Board should explain how the regulation is consistent with documentation standards of other health care licensing boards and how it supports processes such as peer review, documentation for compensation and utilization review.

## **2. Section 5.1. Definitions – Clarity.**

### *Distinction between levels of care*

While the regulation defines four levels of care (elective, maintenance, palliative and supportive) along with preventive service, the distinction between them is not sufficiently clear. The House Committee expressed concern with the lack of distinction between maintenance care and palliative care and asked for examples of each type of care. The House Committee asks the Board to carefully review the comments submitted by PM regarding the definitions. We agree. The Board should review all of the definitions and provide a clear delineation between all of the levels of care and service specified in the regulation.

### *Clarity affected by use of the negative*

Several definitions include a description of what the term does not mean, rather than what the term does mean. This affects the clarity of the definitions. The Board should consider revising the following definitions for clarity: elective care, maintenance care, palliative care and preventive service.

## **3. Section 5.51. Patient records. – Clarity.**

### *Human performance and sense of well-being*

Subparagraph (c)(4)(i) requires the patient record to demonstrate “how human performance and the sense of well-being was enhanced.” These requirements are vague. What criteria must the licensee use in the documentation of these findings?

**Facsimile Cover Sheet**

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**To:** Tom Blackburn  
Cynthia Montgomery  
**Agency:** Department of State  
Licensing Boards and Commissions  
**Phone:** 7-2628  
**Fax:** 7-0251  
**Date:** November 29, 2006  
**Pages:** 4

**Comments:** We are submitting the Independent Regulatory Review Commission's comments the State Board of Chiropractic's regulation #16A-4313 (IRRC #2568). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by:

Date:

11/29/06