

BEFORE THE DIRECTOR OF THE
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
OF THE STATE OF OREGON

In the Matter of the Amendment of)
436-015, Managed Care Organizations) SUMMARY OF
) TESTIMONY AND
) AGENCY RESPONSES
)

This document summarizes the significant data, views, and arguments contained in the hearing record. The purpose of this summary is to provide the Director with a record of the agency conclusions about the major issues raised.

The proposed amendment to the rules was announced in the Secretary of State's *Oregon Bulletin* dated September 1, 2006. On September 21, 2006, a public rulemaking hearing was held as announced at 10:00 a.m. in Room F of the Labor and Industries Building, 350 Winter Street NE, Salem, Oregon 97301-3879. Fred Bruyns, from the Workers' Compensation Division, acted as hearing officer. Business Support Services audio-recorded the hearing and created a written transcript. The record was held open for written comment through September 27, 2006.

One person testified at the public rulemaking hearing. The transcript of the hearing is marked as Exhibit 4. In addition, three written documents were submitted as testimony.

Testimony list:

Exhibit	Testifying
1	William Fehrenbach, Medtronic Neurological
2	Kaiser Foundation Health Plan of the Northwest; Oregon Health Systems; and Providence MCO
3	Peggy Ayles, Oregon Self-Insured Association
4	Arden J. Olson, Harrang Long Gary Rudnick P.C., on behalf of: Kaiser Foundation Health Plan of the Northwest; Oregon Health Systems; and Providence MCO

Testimony: OAR 436-015

Exhibit 1

We are concerned about the misapplication by carriers of ACOEM (the American College of Occupational and Environment Medicine) guidelines in California and elsewhere to deny coverage for treatments that ACOEM does not even address. Specifically, ACOEM guidelines are focused on treatments mostly in the acute and subacute timeframes (often referred to as 90-120 days after injury). There are significant gaps related to the treatment of chronic conditions (those well beyond the initial 120 day timeframe), such as the treatment of chronic, intractable pain and the use of our intrathecal drug delivery system (which is not even mentioned) and spinal

Oregon Administrative Rules, Chapter 436, Division 015
Public Testimony & Agency Responses
Page 2

cord stimulation (which is mentioned in one sentence for one indication, is not evidence-based and otherwise is simply not addressed). These treatments are widely accepted throughout the country by payers when more conservative treatments have failed. Further, these treatments are supported by evidence-based, nationally-recognized guidelines such as the *Official Disability Guidelines* as promulgated by the Work Loss Data Institute, as well as those society-based guidelines as promulgated by the American Society of Interventional Pain Physicians (ASIPP).

We believe that inclusion of the following language is probably the best, most reasonable approach to prevent these problems from spreading:

“When issuing a denial of coverage based on use of any treatment guideline, an insurance carrier or network may only deny treatment for a compensable injury based on a respective treatment guideline if the treatment guideline specifically addresses the condition, injury and specific treatment for the indication being requested and the guideline concludes that treatment should not proceed. In no event shall an insurance carrier or network justify a denial of coverage by invoking any treatment guideline that does not specifically address the condition, injury and specific treatment for the indication in question and the guideline subsequently concludes that the treatment should not proceed.”

Response: ORS 656.260(1) and OAR 436-015-0009 prohibit insurers from forming, owning or operating a certified MCO, from directing or interfering with the MCO’s delivery of medical services, and from participating in the MCO’s service utilization review and dispute resolution process. MCOs are required to send written notice of their decisions to all parties who can appeal the decision. Disputes must first be processed through the MCO’s dispute resolution process prior to requesting director review. OAR 436-015-0030(5)(c) specifies that MCO standards, protocols, and guidelines may not necessarily apply to an individual medical services dispute submitted to the director. OAR 436-015-0030(9)(f) requires sufficient flexibility to allow treatment outside MCO standards, protocols, and guidelines. No additional rule is required in Division 015.

Testimony: OAR 436-015-0040 *Exhibits 2 & 3*

As an initial matter, SB 670 only related to MCOs seeking certification in Oregon, the "Applicant MCOs," because it amended ORS 656.260(4)(a), governing the process by which MCOs are certified. It has no necessary application to those entities already certified. The temporary rules, and the proposed permanent rules, both cite solely to SB 670 as the legislative authority for these rules. Therefore, to the extent OAR 436-015-0040 is applied to existing MCOs, it goes beyond the statutory authority cited in the "Statement of Need." That rule is therefore subject to challenge as written, and should be withdrawn.

Response: SB 670 did not amend ORS 656.260(5)(a), which requires the director to refuse to certify or revoke or suspend the certification of an MCO that fails to meet the requirements of ORS 656.260. SB 670 contained no language exempting current certified MCOs from meeting the requirements of the amendment to ORS 656.260(4). To do so would result in the delivery of unequal benefits to subject injured workers depending on the MCO’s certification date. For

Oregon Administrative Rules, Chapter 436, Division 015
Public Testimony & Agency Responses
Page 3

example, an injured worker's (who is subject to an MCO certified prior to January 2006) attending physician would not be able to advocate for temporary disability benefits for the injured worker. Therefore, the SB 670 amendments to ORS 656.260(4) are applicable to MCOs certified prior to January 2006, and this requirement will remain in the proposed rules.

Testimony: OAR 436-015-0005, 0030, 0040 *Exhibits 2 & 3*

The Division has stated that SB 670 amended ORS 656.260(4)(a) in such a way as to require that DCBS "review and approve" each and every Applicant MCO and existing MCO treatment guideline and protocol. In essence, DCBS's position appears to be that it has no discretion or choice on this issue under SB 670. SB 670 (ORS 656.260(4)(a)) provides the director with broad discretion on the extent to which it reviews the specifics of any Applicant MCO's plan to provide services. The suggestion that the director does not have discretion is, therefore, without merit.

Response: While the director agrees she has some discretion regarding interpretation of this issue, the terms "standards, protocols and guidelines" are terms used interchangeably throughout the workers' compensation industry, in particular the medical community. Since these terms are not defined in chapter 656, the director defined them in the proposed permanent rules. SB 670 requires the director to review and approve MCO treatment standards, which include MCO treatment protocols and guidelines. The director, in her discretion, believes reviewing and approving MCO treatment protocols and guidelines is the correct interpretation. This will provide the required level of oversight. Therefore, this requirement will remain in the proposed permanent rules.

Testimony: OAR 436-015-0005, 0030, 0040 *Exhibits 2, 3, & 4*

It was the methods used by DCBS to review MCO contracts' processes for ensuring "quality, continuity and other treatment standards" - not of each individual medical or treatment protocol - that was the target of SB 670. The legislative history clearly indicates that the legislative intent of SB 670 was essentially to conform the statute to the practices and procedures that the Department was using at that time as related to subsection (4) of ORS 656.260. In other words, everyone agreed that WCD was assessing Applicant MCO plans to determine if the services proposed "met," or were consistent with, standards that WCD had in place. The goal of SB 670 was only to allow stakeholders to obtain a better understanding of what WCD's review standards were, how they were identified, and how they were put in place.

Response: SB 670 amended the language in ORS 656.260(4)(a), thereby statutorily requiring the director to "review and approve" MCO treatment standards. See other responses.

Testimony: OAR 436-015-0005, 0030, 0040 *Exhibits 2, 3, & 4*

The result of this proposed rule will be one of two things. Either an MCO will provide WCD with a great deal of paper, or it will provide access to electronic protocol databases, either of which is incapable of furthering any real regulatory purpose absent staff at WCD being hired who are medically qualified to evaluate the appropriateness of the protocols or guidelines. The Department has said they do not have medical personnel equipped to review every medical protocol and decide whether an MCO is providing good or bad care for a particular condition. During consideration of Senate Bill 670, fiscal experts projected no financial impact on the Department of Consumer and Business Services. We do not believe that it is an appropriate use

Oregon Administrative Rules, Chapter 436, Division 015
Public Testimony & Agency Responses
Page 4

of the limited resources of either WCD or the MCOs to engage in an exercise that serves no real function in improving or protecting the care being offered to injured workers. We therefore respectfully request that WCD reconsider engaging in this exercise at all, and withdraw OAR 436-015-0040(5)(d).

Response: See other responses. As of this date, the director has already reviewed and approved all treatment protocols and guidelines submitted by current certified MCOs. To ensure MCOs deliver quality and continuity of care to injured workers in a timely, effective and convenient manner, the director promulgated rules requiring MCOs to describe the process they use to develop and review treatment standards, protocols, and guidelines. This includes, but is not limited to, a description of how the MCO will ensure the worker continues to receive appropriate care throughout the dispute resolution process, as well as requiring sufficient flexibility to allow treatment outside the MCO's standards, protocols, and guidelines. The director also promulgated rules defining treatment guidelines, treatment protocols, and treatment standards. Other regulatory safeguards that ensure MCOs provide medically necessary and appropriate treatment, and prevent inappropriate or excessive treatment, remain in effect (utilization review, peer review, dispute resolution, quality assurance, panel composition, and other reporting requirements, etc.). The rule also requires annual submission of any new and any changed standards, protocols, and guidelines for department review to help ensure MCOs are complying with the statute and providing appropriate care to workers. Therefore, this rule will not be withdrawn.

Testimony: OAR 436-015-0005, 0030, 0040 *Exhibit 3*

Medical treatment and surgical protocols have been developed by these organizations that provide treatment to all of their subscribers, not just to injured workers. WCD does not have the authority or expertise to judge the effectiveness of these protocols that apply to thousands of Oregonians.

Response: SB 670 amended the language in ORS 656.260(4)(a), thereby statutorily requiring the director to "review and approve" MCO treatment standards. See other responses.

Testimony: OAR 436-015-0005, 0030, 0040 *Exhibit 3*

If an injured worker feels he has been denied treatment because of the established protocols, he has access to a three-step process for appeal: first through the MCO, then through the Workers Compensation Division, and on up to the Workers Compensation Board. Based upon this process we feel that there does not need to be a change in WCD rules to require agency review of the protocols.

Response: SB 670 amended the language in ORS 656.260(4)(a), thereby statutorily requiring the director to "review and approve" MCO treatment standards. See other responses.

Testimony: OAR 436-015-0005, 0030, 0040 *Exhibits 2 & 3*

An issue in discussion around these rules has been the notion that some injured worker may challenge an MCO's treatment protocol and that such a challenge would prevail if the Department has not previously approved each and every protocol or treatment regimen. We submit that there is no such threat, and none has arisen in the sixteen years under the prior statute

that spoke of the Department "prescribing" standards for MCOs.

Response: Because no challenge has occurred in the past does not guarantee one would not occur in the future. SB 670 amended the language in ORS 656.260(4)(a), thereby statutorily requiring the director to "review and approve" MCO treatment standards. See other responses.

Testimony: OAR 436-015-0040 *Exhibits 2, 3, & 4*

The cost of the proposed rules is not insubstantial, and increases the regulatory burden to MCOs in an environment where most of the certified MCOs have ceased operating in this marketplace. That cost varies, however, from plan to plan, and falls generally into three categories:

- The cost of providing the WCD with treatment protocols and guidelines.
- The cost of reviewing "new or revised treatment protocols and guidelines developed or used by the managed care organization during the previous calendar year."
- The cost of corresponding with the WCD about the process.

Response: See below for additional specific testimony regarding these fiscal impacts and the agency's responses.

Testimony: OAR 436-015-0040 *Exhibits 2 & 3*

Fiscal impact: Providing WCD annually with treatment protocols and guidelines. DCBS's "low cost" solution appears to be the option to a plan to meet the requirements of the proposed rule by making the protocols and guidelines available to DCBS online. One of the MCOs has such a system, and there is a way without expense to provide remote access to the system, including access to the MCO protocols. There are two problems, however, with that solution. First, the materials in the system are written for physicians, and may well be misunderstood by non-physician reviewers. More importantly, there is no practical or low-cost way to limit access to the system simply to the MCO protocols, so making this election would in effect make a public record of all the MCO organization's other proprietary information. The MCO's only viable option, therefore, is to duplicate this material every year and provide it to DCBS. That process imposes tangible but varying costs in terms of staff time and other resources. Even MCOs that are part of larger organizations are required to conduct business in a fiscally prudent manner, and any increase in operational demands automatically affects client fees.

Response: In response to MCO testimony, the director adopted temporary rules allowing MCOs the choice of providing the director online access to the MCO's treatment protocols and guidelines, or submitting copies of the MCO's treatment protocols and guidelines. This option remains in the proposed permanent rules. The director recognizes complying with the SB 670 amendment to ORS 656.260(4)(a) fiscally impacts MCOs and other stakeholders. However, SB 670 amended the language in ORS 656.260(4), thereby statutorily requiring the director to "review and approve" MCO treatment standards. See other responses. Therefore, this requirement remains in the proposed permanent rules.

Testimony: OAR 436-015-0040 *Exhibits 2, 3, & 4*

Fiscal impact: Reviewing "new or revised treatment protocols and guidelines developed or used by the managed care organization during the previous calendar year." There are two

distinct costs involved in this requirement:

1. The cost to report new or revised protocols and guidelines developed by the MCO during the previous calendar year, and
2. The cost to report new or revised protocols and guidelines used by the MCO during the previous calendar year.

1. Costs associated with the former depend on whether the WCD requires MCOs to provide protocols and guidelines developed by the authors. One of the MCOs obtains treatment protocols and guidelines in part from the Official Disability Guidelines. The Work Loss Data Institute web page does not spell out the nature of the changes that were made to the guidelines, and if the MCO is required to review and report the changes, it would need to hire up to one full-time employee ("FTE") to accomplish the task, at a cost of \$40,560 to \$54,080. If the MCO is not required to review and report the changes, the incremental cost would be nominal.

2. Costs associated with the latter are driven by the volume of an MCO's business. At any point in time, each MCO is managing thousands of open claims, and in order to comply with the proposed rules on which protocols were used, each MCO would need to hire at least one FTE to review all claims for new or revised treatment protocols or guidelines used by the MCO. For one MCO, each required FTE represents an increase of 2.6% to 3.5% in its staff budget, a significant increase for a small business.

The proposed addition to OAR 436-015-0040(5)(d) provides that each MCO must provide WCD with copies of new or revised protocols and guidelines developed "or used" by the MCO during the previous year. Those two words are the most significant drivers of the burden of the proposed rules. As noted above, they would require MCOs to track which of a multitude of available protocols were actually applied to individual files, as opposed to which protocols and guidelines are in that MCOs universe available to physicians as guides when they might be applicable. We therefore most urgently request that those words be stricken from the proposed rule before it is made permanent. It is a very different thing to say "give us a copy of all of your protocols" - we have ways to ascertain what those protocols are because we have them.

Response: The director will amend the rules to reflect those treatment protocols and guidelines "adopted" (instead of developed or used) by the MCO. The director will amend the rules to allow MCOs the option to submit copies of either all treatment protocols and guidelines, or any new and any revised treatment protocols and guidelines adopted by the MCO during the previous calendar year. The option of MCOs being able to provide the director with online access, in lieu of copies, will remain in the proposed permanent rules.

Testimony: OAR 436-015-0040

Exhibits 2 & 3

Fiscal impact: Corresponding with the WCD. The WCD has not developed criteria for reviewing the treatment protocols and guidelines, nor do they have staff medically qualified to perform this review. Consequently, MCOs must plan for additional time and expense associated with correspondence to bring WCD staff "up to speed." Based on experience to date with certified plan amendments, the MCOs expect to incur between 20 and 40 hours of correspondence each year as a result of the proposed rules. A reasonable estimate of the impact

Oregon Administrative Rules, Chapter 436, Division 015
Public Testimony & Agency Responses
Page 7

of that additional administrative burden is an additional \$4,000 to \$8,000 per year.

Response: As of this date, the director has already reviewed and approved all treatment protocols and guidelines submitted by current certified MCOs. This has placed nominal additional administrative burden on the MCOs due to the WCD staff review. OAR 436-015-0030(9) contains some review criteria. WCD provided other review criteria to all current certified MCOs when WCD requested the process summary used by the MCO to develop and review treatment standards, protocols, or guidelines under OAR 436-015-0030(9).

Having reviewed and considered all data, views and arguments presented, I hereby submit this report as a summary of statements given and exhibits received. The agency will adopt amendments to the rules consistent with the above responses.

Dated this 19th day of October, 2006.

WORKERS' COMPENSATION DIVISION

Fred Bruyns

Fred Bruyns, Hearings Officer

Sandra Savage

Sandra Savage, MCO Coordinator