MEDICAL ASSISTANCE HANDBOOK PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Compounded Prescriptions

A. Prescriptions That Require Prior Authorization

All compounded prescriptions must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a compounded prescription, determination of whether the requested prescription is medically necessary will take into account:

1. The clinical rationale for using a compounded product in place of an FDA approved product

AND

2. Peer reviewed medical literature supporting use of the compounded product for the recipient's indication

OR

3. Whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF COUMPOUNDED PRESCRIPTIONS: The determination of medical necessity of a request for prior authorization of a renewal of a compounded prescription that was previously approved will take into account whether:

1. The recipient has a documented clinical improvement associated with use of the compounded product

OR

2. The recipient does not meet the clinical review guideline listed above, but in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the recipient.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request. If the guidelines in Section B. are met,

the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and duration of therapy

The Department will limit authorization of compounded prescriptions as follows:

1. Up to six (6) months of therapy for an initial request

2. Up to 12 months for a renewal of a previously approved request

E. References

1. Ensuring Safety of Compounded Preparations. The Pharmacists Letter, December 2012.
2. Miller, DG. (October 2013). *Pharmacy Compounding Law and Regulations*. Presentation at the Eastern Medicaid Pharmacy Administrators Association Annual Meeting, Ellicott City, MD.
3. Gudeman J., Jozwiakowski M., Chollet J., Randell M.; *Potential Risks of Pharmacy Compounding*. Drugs R D (2013) 13:1-8
4. Rood JM, Engels MJ, Ciarkowski SL, Wagenknecht LD, Dickinson CJ, Stevenson JG. *Variability in Compounding of Oral Liquids for Pediatric Patients: A Patient Safety Concern.* Am Pharm Assoc. 2014;54(4):383-389.
5. United States Food and Drug Administration. Compounding and the FDA: Questions and Answers. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#approved
6. Walls AP, Johnson S, Nguyen M. O'Lenic K, Pokorney T, Randolph s. *Compounding is Confounding Workers' Compensation*. 2014 CompPharma