STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

December 23, 2010

All Pharmacies
All licensed Residential Treatment Facilities (RTFs)

Re: Interim Guidance for Medication Practices:

I am writing to update the May 13, 2010 letter sent to all pharmacies and all RTFs to address concerns regarding federal requirements for the management, use and control of controlled substances in residential treatment facilities.

Advice given on 5/13/10 was that by 12/31/10, RTFs had to pursue methods for providing patient specific medications through one of the following:

1. Use of a 24-hour retail or long-term care pharmacy;
2. Use of a 24-hour hospital pharmacy; and
3. For all other controlled substances, an automated drug distribution device approved by the board and DEA is the only method.

Since that time, the DEA has clarified the federal requirements.

1. Use of a 24-hour retail or long-term care pharmacy (by prescription).
2. Use of a 24-hour hospital (by prescription).
3. Obtain upgraded automated drug distribution device (profile) with staff credentialed to administer medication. This requires the pharmacist to review each prescription order and to release the dose from the device.
4. A DEA registered prescriber (ARNP, MD for example) obtains a separate DEA registration for a specific RTF and accepts responsibility for accountability, storage, inventory, monitoring and use of the drugs.

To consider **non**-patient specific emergency starter supplies for an RTF would require Board of Pharmacy rule change.

There have been two RTF rule workshops to update the RTF rule to clarify medication issues. On November 16, DOH Office of Health Professions and Facilities was notified to implement Executive order 10-06 suspending non critical rule development and adoption. DOH pursued an exception to this rule development suspension, which has been granted. Therefore, RTF rule making will go forward.

Because RTF rule making is not yet completed, we are extending the time frame that any of these options are chosen until the completion of the rule. The department will include in rule making specific requirements for how RTFs should meet DEA requirements for controlled substances and Washington State Board of Pharmacy requirements for residents requiring legend drugs, particularly for facilities without access to a 24-hour retail pharmacy. In the meantime, please contact Tim Fuller, Board pharmacist consultant, for the approval process for automated drug distribution devices and contact DEA, for DEA Registered prescriber's DEA registration for each specific facility. Tim can be reached at tim.fuller@doh.wa.gov. For clarification of DEA requirements, contact Ruth Carter, Group Supervisor, DEA at: Ruth.A.Carter@usdoj.gov

Sincerely,

Susan Teil Boyer, MS, RPh, FASHP
Executive Director, Washington State Board of Pharmacy and Clinical Facilities
Department of Health, Health Systems Quality Assurance
Office of Health Professions and Facilities

cc: Grant Chester, Chief Investigator
Ruth Carter, DEA Regional Supervisor
Barbara Runyon, Nurse Consultant Advisor
Tim Fuller, Pharmacist Consultant