

Significant Legislative Rule Analysis
WAC 246-887-040 & 246-887-045

Rules Concerning Schedule II Nonnarcotic Stimulants and Adding Binge Eating Disorder in Adults to the List of Disease States or Conditions for which Schedule II Nonnarcotics can be Prescribed, Dispensed, or Administered
November 20, 2015

I. Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

In January 2015, the U.S. Food and Drug Administration (FDA) approved the use of Lisdexamfetamine (specifically the brand name Vyvanse) for the treatment of moderate to severe binge eating disorder (BED)¹ in adults. In approving Lisdexamfetamine to treat BED, the FDA reviewed two clinical studies.² The studies included 724 adults with moderate to severe BED. The studies found that Lisdexamfetamine decreased the number of binge eating episodes and decreased binge eating associated obsessive and compulsive features in patients with BED.

Washington State classifies Lisdexamfetamine as a Schedule II nonnarcotic stimulant. RCW 69.50.206. Practitioners may prescribe Schedule II nonnarcotic stimulants only for those disease states or conditions listed in RCW 69.50.402(1)(c)(ii). Additionally, the Pharmacy Quality Assurance Commission (Commission), in consultation with the Medical Quality Assurance Commission and the Board of Osteopathic Medicine and Surgery, may establish by rule, disease states or conditions in addition to those listed in RCW 69.50.402(1)(c)(ii) for the treatment of which Schedule II nonnarcotic stimulants may be prescribed, dispensed, or administered.

The Commission is proposing amendments to WAC 246-887-045 to add binge eating disorder (BED) in adults to the list of disease states or conditions for which Schedule II nonnarcotic stimulants can be prescribed, dispensed, or administered. The Commission is also proposing, pursuant to its authority under RCW 18.64.005, amendments to WAC 246-887-040 to add

¹ BED was added to the Diagnostic and Statistical Manual of Mental Disorder Fifth Edition (DSM-5) in 2013. The DSM-5 defines BED as recurrent episodes of binge eating, characterized by an individual eating, in a discrete period of time (e.g., within any two hour period), an amount of food larger than what most people would eat in a similar amount of time under similar circumstances, combined with a sense of lack of control over eating during the episode. To support a diagnosis of BED, a patient must experience binge eating episodes, on average, at least once a week for a period of at least three months, and during these episodes, feel a sense of loss of control over eating and marked psychological distress about their behavior.

² Shire U.S., Inc. SPD489 in Adults Aged 18-55 Years With Moderate to Severe Binge Eating Disorder. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2015 Sept. 15]. Available from: <https://clinicaltrials.gov/ct2/show/study/NCT01718483?term=NCT01718483&rank=1> NLM Identifier NCT01718483; Shire U.S., Inc. SPD489 in Adults Aged 18-55 Years With Moderate to Severe Binge Eating Disorder. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2015 Sept. 15]. Available from: <https://clinicaltrials.gov/ct2/show/NCT01718509?term=NCT01718509&rank=1> NLM Identifier NCT01718509.

Lisdexamfetamine to the list of Schedule II nonnarcotic stimulants for purposes of RCW 69.50.402(1)(c).

Under the current statutory and rule language, practitioners cannot prescribe Lisdexamfetamine to patients suffering from BED. By adding Lisdexamfetamine to the list of designated nonnarcotic stimulants and BED to the list of approved disease states or conditions, practitioners will be able to use Lisdexamfetamine to treat BED in adults. Because Lisdexamfetamine is the only FDA approved medication to treat BED in adults and studies have demonstrated its success in treating some patients suffering from BED, these amendments are necessary to allow practitioners to use their discretion to treat their patients suffering from BED with Lisdexamfetamine.

II. Is a Significant Analysis required for this rule?

A significant analysis is required for this rule.

III. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

RCW 69.50.402(1)(c) states the requirements for practitioners to prescribe, dispense, or administer Schedule II nonnarcotic stimulants. Schedule II nonnarcotic stimulants are highly controlled due to their high potential for abuse. In an effort to curb the abuse of these drugs, the legislature enacted RCW 69.50.402(1)(c) to restrict the prescribing, dispensing, and administering of Schedule II nonnarcotic stimulants to specific disease states and conditions.

IV. Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

Under RCW 69.50.402(1)(c), practitioners cannot currently use Lisdexamfetamine to treat adults with moderate to severe BED. The proposed rule would include possible improved quality of life for BED patients without putting them at risk. Lisdexamfetamine is the only FDA-approved medication to treat moderate to severe BED in adults. Adding Lisdexamfetamine and BED to rules provides an additional avenue to treat BED in adults. Thus, to allow practitioners to prescribe, dispense, or administer Lisdexamfetamine for BED in adults, the Commission must make a rule amendment.

V. Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

There are two rule sections in this analysis. The first rule is WAC 246-887-045 Prescribing, Dispensing, or Administering of Schedule II non-narcotic stimulants. It lists those disease states and conditions the Commission has approved for treatment with Schedule II nonnarcotic

stimulants in addition to those conditions already listed in RCW 69.50.402(1)(c)(ii). The proposed rule adds BED to the list of conditions already listed in the rule.

The second rule is WAC 246-887-040 Designation of nonnarcotic stimulant drugs for purposes of RCW 69.50.402(1)(c). It lists the Schedule II nonnarcotic stimulants that practitioners may prescribe, dispense, or administer to any person pursuant to RCW 69.50.402(1)(c)(ii). Washington State classifies Lisdexamfetamine as a Schedule II nonnarcotic stimulant in RCW 69.50.206. The proposed rule adds Lisdexamfetamine to the list of “approved” Schedule II nonnarcotic stimulants and will enable practitioners to prescribe, dispense, or administer the drug.

There are no costs imposed upon licensees as a result of these rule amendments. The amendment provides practitioners with an option for treating BED in adults. Currently practitioners use medications “off-label” to treat BED. Practitioners also use psychotherapy, cognitive behavioral therapy, nutrition counseling, and other supportive services either independently or in conjunction with medications. Practitioners are under no obligation to use Lisdexamfetamine to treat BED. If practitioners decide to prescribe or administer the drug, there are no additional burdens such as documentation or recordkeeping requirements.

The benefits of the proposed rule include possible improved quality of life for BED adult patients. Vyvanse is the only FDA-approved medication to treat moderate to severe BED in adults. As discussed above, two clinical studies have demonstrated that Vyvanse is successful in reducing episodes of binge eating and reducing binge eating associated obsessive and compulsive features. Therefore the total probable benefits of identifying BED as a condition that can be treated with Schedule II nonnarcotic stimulants and including Vyvanse to the list drugs that can be prescribed to treat BED in adults outweigh the total probable costs.

VI. Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

There were no viable alternatives to this rulemaking. The only potential alternative was to not add Lisdexamfetamine and BED to the rules. However, not adding Lisdexamfetamine as a treatment option for BED would be denying BED patients in Washington the only FDA-approved medication treatment option. As the clinical studies demonstrated, Lisdexamfetamine has been successful in treating moderate to severe BED in adults.

VII. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

VIII. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

IX. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any federal regulation or statute applicable to the same activity or subject matter.

X. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. It is consistent with the FDA and does not conflict with federal law.