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# PHARMACEUTICAL WHOLESALER REGULATORY CHANGES FACT SHEET

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## INTRODUCTION

On November 1, 2001, various changes to the Board's regulations regarding pharmaceutical wholesalers became effective. A copy of the wholesaler regulations as they are presently in effect is attached. This fact sheet is being provided to inform you of the most pertinent changes and how they might effect your wholesaler's operations.

## DESIGNATED REPRESENTATIVE

- Most wholesalers must appoint a person to serve as the designated representative of the wholesaler. The designated representative must fill out a form provided by the Board and must have the following qualifications:
  - Proof of at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs,
  - Passage with a score of at least 75% of an examination given by the board relating to federal and state laws regarding wholesaling of prescription drugs, and
  - Proof that he or she is at least 21 years old.<sup>i</sup>
- The designated representative must be actively involved in and aware of the actual daily operation of the wholesaler, must be employed full-time in a managerial level position, must be physically present at the facility of the wholesaler during regular business

hours, and may only serve as the designated representative for one wholesaler.<sup>ii</sup>

- A wholesaler may not operate without a designated representative.<sup>iii</sup>
- A wholesaler is exempt from the requirement to have a designated representative where:
  - It is owned by a publicly-owned corporation, or
  - A majority of the wholesaler is owned by a pharmacist who is licensed by the Board, is a resident of Nevada, and is not an owner of any pharmacy licensed by the Board.<sup>iv</sup>

## JULY 1, 2002 DEADLINE FOR APPOINTMENT OF DESIGNATED REPRESENTATIVE

Every wholesaler must appoint a designated representative by July 1, 2002. A wholesaler may obtain a designated representative application from Candy Nally at (775) 850-1440. A wholesaler that does not have a designated representative after July 1, 2002 will be summarily suspended until it does have a designated representative.<sup>v</sup>

## MAINTENANCE OF STOCK OF DRUGS

- A wholesaler must now maintain "a stock of prescription drugs on its shelves sufficient to serve the expected and ordinary needs of the practitioners and pharmacies with which it ordinarily transacts business."<sup>vi</sup>
- A wholesaler may not have any controlled substances unless it

ordinarily sells controlled substances to its regular customers.<sup>vii</sup> If the wholesaler ordinarily deals in controlled substances, it must maintain a stock of such drugs on its shelves to serve its customers.<sup>viii</sup>

## **RESTRICTIONS ON PURCHASES & SALES**

- A wholesaler may not purchase or otherwise receive prescription drugs from a pharmacy.<sup>ix</sup>
- A wholesaler may receive returns of drugs it sold, but it may not receive more drugs than it sold and may not credit or pay more than the purchaser originally paid for the drugs.<sup>x</sup>
- In any month, a wholesaler may not sell, distribute, transfer or otherwise provide more than 10% of its total amount of prescription drugs to another wholesaler, distributor, or manufacturer.<sup>xi</sup>

## **INTERCOMPANY TRANSFERS**

An intercompany transfer is now defined to mean “any sale, distribution or other transaction involving a prescription drug” in which:

- The sale is made to a wholesaler or pharmacy licensed by the Board,
- The seller and the purchaser are wholly owned by a common owner, and
- The common owner is a publicly traded corporation.<sup>xii</sup>

## **RECORD STORAGE**

A wholesaler’s records must be kept on the site at which the wholesaler is licensed.<sup>xiii</sup>

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i	NAC 639.5935(1) & (2).
ii	NAC 639.5935(4).
iii	NAC 639.5935(5) & (6).
iv	NAC 639.5935(1).
v	NAC 639.5935(7).
vi	NAC 639.596(1)(g).
vii	NAC 639.596(3).
viii	NAC 639.596(2).
ix	NAC 639.5975(2).
x	NAC 639.5975(3).
xi	NAC 639.5975(1).
xii	NAC 639.593(3).
xiii	NAC 639.602(3).