

Colorado State Board of Pharmacy

POLICY NUMBER: 30-13

Title: Out-of-State Prescription Drug Wholesaler Designated Representative Changes

Date Issued: October 21, 2010

Date Revised: April 21, 2011

PURPOSE: To delegate to board staff structured settlement authority to administratively handle complaints in cases where out-of-state prescription drug wholesalers fail to submit the proper application and fee to change a designated representative within fourteen days of the previous designated representative leaving that position as required by Board rule. This policy delegates to Board staff the disposition of such complaints (cases) by settling them as detailed below, potentially eliminating the need for direct involvement of the Board.

POLICY:

For the first instance of an out-of-state prescription drug wholesaler failing to make application and pay the required fee within 14-days of the previous designated representative leaving the position, the matter will be handled as follows:

- a) Board staff will initiate a complaint (case) against the registration of the out-of-state prescription drug wholesaler.
- b) If the out-of-state prescription drug wholesaler provides credible evidence in its response to the complaint that it submitted a timely application and fee to the Board to change the designated representative, or contests the alleged failure to make the application and pay the fee, the complaint and response shall be referred to the Board for disposition in the regular course of business.
- c) If the out-of-state prescription drug wholesaler does not provide credible evidence in its response to the complaint that it submitted a timely application and fee to the Board to change the designated representative, or does not contest the alleged failure to make the application and fee, disposition of the case will occur as follows:
 - i) If the application and fee are received by the Board by the 45th day following the previous designated representative leaving, the complaint will be dismissed with a confidential letter of concern.
 - ii) If the application and fee are received by the Board from the 46th through the 59th day following the previous designated representative leaving, the case will be referred to the Office of Expedited Settlement (“ESP”) with guidance for a non-negotiable fine of \$1000 and an agreement for future compliance with all designated representative changes. Should ESP fail to obtain a settlement in the matter, the matter shall be referred to the Office of the Attorney General (“OAG”) with the same settlement guidance.
 - iii) If the application and fee are received by the Board on or after the 60th day following the previous designated representative leaving, the case will be referred to the Office of Expedited Settlement (“ESP”) with guidance for a non-negotiable fine of \$5000 and agreement for future compliance with all designated representative changes. Should ESP fail to obtain a settlement in the matter, the matter shall be referred to the Office of the Attorney General (“OAG”) with the same settlement guidance.

For the second instance of an out-of-state prescription drug wholesaler failing to make application and pay the required fee within 14-days of the previous designated representative leaving the position, the matter will be handled as follows:

d) Board staff will initiate a complaint (case) against the registration of the out-of-state prescription drug wholesaler.

e) If the out-of-state prescription drug wholesaler provides credible evidence in its response to the complaint that it submitted a timely application and fee to the Board to change the designated representative, or contests the alleged failure to make the application and pay the fee, the complaint and response shall be referred to the Board for disposition in the regular course of business.

f) If the out-of-state prescription drug wholesaler does not provide credible evidence in its response to the complaint that it submitted a timely application and fee to the Board to change the designated representative, or does not contest the alleged failure to make the application and pay the fee, disposition of the case will occur as follows:

i) If the application and fee are received by the Board by the 45th day following the previous designated representative leaving, the case will be referred to the Office of Expedited Settlement (“ESP”) with guidance for a non-negotiable fine of \$1000 and agreement for future compliance with all designated representative changes. Should ESP fail to obtain a settlement in the matter, the matter shall be referred to the Office of the Attorney General (“OAG”) with the same settlement guidance.

ii) If the application and fee are received by the Board from the 46th through the 59th day following the previous designated representative leaving, the case will be referred to the Office of Expedited Settlement (“ESP”) with guidance for a non-negotiable fine of \$5000 and agreement for future compliance with all designated representative changes. Should ESP fail to obtain a settlement in the matter, the matter shall be referred to the Office of the Attorney General (“OAG”) with the same settlement guidance.

iii) If the application and fee are received by the Board on or after the 60th day following the previous designated representative leaving, the case will be referred to the Office of Expedited Settlement (“ESP”) with guidance for a non-negotiable fine of \$6000 and agreement for future compliance with all designated representative changes. Should ESP fail to obtain a settlement in the matter, the matter shall be referred to the Office of the Attorney General (“OAG”) with the same settlement guidance.

g) This policy is intended as settlement guidance only and is not intended to deprive the Board of its authority to exercise discretion in seeking a penalty within the range of reasonable alternatives in the event a case does not settle under the above terms and proceeds to a hearing.