

CIRCUIT COURT OF OREGON

MULTNOMAH COUNTY

IN THE MATTER OF:

OMNICARE INC.

Case No. **1012-17196**

ASSURANCE OF VOLUNTARY  
COMPLIANCE

1.

Omnicare does business in Oregon and is respondent herein. This agreement is between respondent and the Oregon Department of Justice (DOJ) acting pursuant to ORS 646.632.

**PROCEDURE**

2.

This Assurance of Voluntary Compliance (AVC) is a settlement of a disputed matter and entered for the purpose of avoiding delay, uncertainty, inconvenience, and expense of protracted litigation of potential claims. It shall not be considered an admission of a violation for any purpose. Omnicare expressly denies any allegations of wrongdoing and any liability.

3.

Respondent waives receipt of a notice from the State of Oregon pursuant to ORS 646.632(2) of the alleged unlawful trade practice and the relief to be sought.

4.

Respondent understands and agrees this AVC applies to respondent, respondent's principals, officers, directors, agents, employees, representatives, successors and assigns, jointly and severally, while acting personally, or through any corporation or other business entities, whose acts, practices or policies are directed, formulated or controlled by respondent for purposes of business conducted in the State of Oregon.

5.

Respondent and respondent's attorney agree and understand that following acceptance of the AVC by DOJ, DOJ may communicate directly with respondent for the purpose of executing and enforcing the terms of this agreement, resolving future complaints, and conducting undercover investigations of respondent to the extent permitted by law.

6.

Respondent understands and agrees that if this AVC is accepted by DOJ, it will be submitted to the Circuit Court of the State of Oregon for Multnomah County for approval, and, if approved, will be filed with the court pursuant to ORS 646.632(2).

7.

Respondent waives any further notice of submission to and filing with the court of this AVC. Respondent agrees to accept service of a conformed or court certified copy by prepaid first class mail sent to the address following respondent's signature or to respondent's attorney.

8.

If monies which are ordered to be paid in this AVC are not paid timely, DOJ may convert the AVC to a money judgment under ORS 646.632(2) without notice to respondent. Respondent agrees a copy of the money judgment may be sent to respondent, first class mail to the address following respondent's signature.

9.

Respondent understands that, in addition to any other sanctions which may be imposed under this AVC or under the law, violation of any of the terms of this AVC may result in contempt of court proceedings, civil penalties of up to \$25,000 for each violation, and such

further relief as the court may deem appropriate. ORS 646.632(4), ORS 646.642(1) and ORS 646.642(2).

10.

The parties acknowledge that no other promises, representations or agreements of any nature have been made or entered into by the parties. The parties further acknowledge that this AVC constitutes a single and entire agreement that is not severable or divisible, except that if any provision herein is found to be legally insufficient or unenforceable, the remaining provisions shall continue in full force and effect.

#### **DEFINITIONS**

11.

“Consultant Pharmacist” shall mean a licensed pharmacist who performs the Drug Regimen Review pursuant to 42 C.F.R. § 483.60(c).

“Promotional Activities” shall mean drug or drug therapy recommendations intended to increase revenue for respondent or a pharmaceutical company. “Promotional Activities” shall not include activities paid for by health insurance plans or third party payors whose purpose is to promote recognized medical best practices, recommendations consistent with the Oregon Medicaid Practitioner Managed Prescription Drug Plan, recommendations made in good faith, or activities consistent with 42 CFR 483.60(b) or (c) and the guidance relating thereto contained in the State Operations manual.

“Therapeutic Interchange” shall mean the substitution of a drug that has the same or similar therapeutic effects as the drug originally prescribed based on appropriate authorization of the prescriber. “Therapeutic Interchange” shall not mean to the substitution of a chemically

identical generic drug in the same dosage and form as the branded drug originally prescribed, which generally does not require authorization of the prescriber under state law.

“Therapeutic Interchange Program” shall mean a companywide effort to implement a particular therapeutic interchange. A therapeutic interchange program is separate and apart from and shall not mean the individualized drug reviews, recommendations, and monthly drug regimen reviews required to be made by consultant pharmacists under the Omnibus Budget Reconciliation Act of 1987 (OBRA ‘87), codified at 42 C.F.R. § 483.60(c).

### **REMEDIES**

12.

Respondent shall not represent or imply that DOJ acquiesces or approves of respondent’s past business practices, current efforts to reform its practices, or any future practices which respondent may adopt or consider adopting. DOJ’s decision to settle this matter or to otherwise unilaterally limit current or future enforcement action does not constitute approval or imply authorization for any past, present, or future business practice.

13.

Upon execution of this AVC respondent shall pay the sum of \$300,000 within ten (10) days of acceptance by the Court of the AVC, for deposit to the Department of Justice Account established pursuant to ORS 180.095 to be used by DOJ as provided by law.

14.

This AVC effects a full resolution, complete settlement and release by DOJ of Omnicare, together with its predecessors, successors, subsidiaries, affiliates, and its present and former directors, officers, shareholders, members, employees, administrators, partners, agents, attorneys

and accountants, both individually and in their official capacities from any administrative or monetary claim that could have been asserted pursuant to ORS 646.605 *et seq* against Omnicare, arising out of the sale of Risperdal and/or risperidone in the State of Oregon prior to the date of this AVC.

15.

Effective immediately upon execution by respondent of this AVC, respondent agrees to adhere to each of the following requirements:

A. *Promotional Activities by Consultant Pharmacists.* Respondent's Consultant Pharmacists shall not engage in Promotional Activities in the State of Oregon.

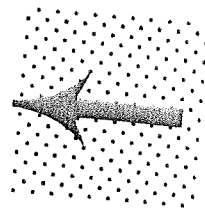
B. *Therapeutic Interchange Program Procedures.* To the extent not already implemented, Omnicare shall create procedures reasonably designed to ensure that all therapeutic interchange programs in the State of Oregon are developed and implemented by Omnicare consistent with Federal health care program requirements, and the requirements under applicable state and federal laws for obtaining prior authorization from the prescriber before making a therapeutic interchange of a drug. These procedures shall include the following: a. establishment of a centralized process for developing therapeutic interchange programs that will consider the relative therapeutic or pharmaceutical attributes of the drugs subject to the therapeutic interchange and, secondarily, the relative prices of the drugs subject to the therapeutic interchange; b. establishment of a centralized process for obtaining approval from senior management for therapeutic interchange programs before they are implemented; c. establishment of a centralized process for developing materials supporting therapeutic interchange programs which are accurate, not misleading, and include relevant information regarding the basis for the therapeutic interchange; d. procedures reasonably designed to ensure

that communications from Oregon Omnicare pharmacists, pharmacy technicians and other employees who are involved in the development or implementation of therapeutic interchange programs to prescribers related to therapeutic interchange programs are accurate, not misleading, and contain relevant information regarding the basis for the therapeutic interchange (e.g., a brief summary of the process by which Omnicare develops therapeutic interchange programs and a brief summary of the relative therapeutic or pharmaceutical attributes and relative prices to payors of the drugs subject to the therapeutic interchange program); and e. procedures to ensure that all prescriber authorizations required under applicable state and federal laws have been obtained before a therapeutic interchange of a drug is made.

**APPROVAL BY COURT**

APPROVED FOR FILING and SO ORDERED this 8<sup>th</sup> day of December, 2010.

  
\_\_\_\_\_  
Circuit Court Judge Kantor



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**APPROVAL BY COURT**

APPROVED FOR FILING and SO ORDERED this \_\_ day of December, 2010.

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Circuit Court Judge

**APPROVAL BY COURT**

APPROVED FOR FILING and SO ORDERED this \_\_\_\_ day of December, 2010.

\_\_\_\_\_  
Circuit Court Judge

**RESPONDENT'S SIGNATURE AND ACKNOWLEDGMENT**

**Corporate Respondent**

I, John L. Workman, being first duly sworn on oath depose and say that I am the Executive Vice President and Chief Financial Officer of Omnicare and am fully authorized and empowered to sign this Assurance of Voluntary Compliance on behalf of Omnicare and bind the same to the terms hereof.

John L. Workman  
Signature

John L. Workman  
Print Name

Executive Vice President & CFO  
Title

Address 100 E. RiverCenter Blvd, 16<sup>th</sup> Flr.  
Covington, KY 41011

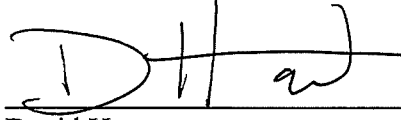
SUBSCRIBED AND SWORN to before me this 1<sup>st</sup> day of December, 2010.

Barbara J. Henderson  
Notary Public comm. exp. 7-14-12



ACCEPTANCE OF DOJ

Accepted this 9<sup>th</sup> day of December, 2010.

A handwritten signature in black ink, appearing to read "D Hart", written over a horizontal line.

David Hart  
Senior Assistant Attorney General