UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 6 DALLAS, TX

2016 SEP 30 PH 12: 46 REGIONAL HEARING CLERK

FILED

| IN THE MATTER OF: | § | |
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| | § | Consent Agreement and Final Order |
| OMNICARE, INC. | § | USEPA Docket No. RCRA-06-2016-0930 |
| | § | |
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| | § | |
| RESPONDENT | § | |
| | § | |

CONSENT AGREEMENT AND FINAL ORDER I. <u>PRELIMINARY STATEMENT</u>

- This Consent Agreement and Final Order ("CAFO") is entered into by the United States Environmental Protection Agency, Region 6 ("EPA" or "Complainant") and Respondent, Omnicare, Inc., ("Respondent") and concerns eleven (11) facilities in Texas, each with different levels of alleged noncompliance and for different periods. The facilities that are covered by this CAFO are listed below and collectively referred to as (the "Facilities"):
 - A. The facility located at 2770 Duniven Circle, Amarillo, Texas 79109 (the "Amarillo Facility");
 - B. The facility located at 9210 Cameron Rd., Suite 800, Austin, Texas 78754 (the "Austin Facility");
 - C. The facility located at 5449 Bear Lane, Suite 420, Corpus Christi, Texas
 78405, (the "Corpus Christi Facility");

- D. The facility located at 14450 Trinity Blvd., Suite 200, Fort Worth, Texas
 76155 (the "Fort Worth Facility");
- E. The facility located at 10650 W. Airport Blvd., Suite 150, Stafford, Texas
 77477 (the "Houston Facility");
- F. The facility located at 6101 43rd Street, Suite E, Lubbock, Texas 79407 (the "Lubbock Facility");
- G. The facility located at 1716 South Street, Nacogdoches, Texas 75964, (the "Nacogdoches Facility");
- H. The facility located at 101 East Expressway 83, Suite D, Pharr, Texas 78577 (the "Pharr Facility");
- The facility located at 12460 Network, Blvd., Suite 101, San Antonio, Texas 78249 (the "San Antonio Facility");
- J. The facility located at 105 Jordon Plaza Blvd., Tyler, Texas 75704 (the
 "Tyler Facility"); and
- K. The facility located at 7524 Bosque Blvd., Suite N&O, Waco, Texas 76712 (the "Waco Facility").
- Notice of this action has been given to the state of Texas, under Section 3008(a)(2) of the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6928(a)(2).
- 3. For the purpose of this CAFO, Respondent admits the jurisdictional allegations herein; however, Respondent neither admits nor denies the specific factual allegations and conclusions of law contained in this CAFO. This CAFO states a claim upon which relief may be granted.

- 4. The Respondent waives any right to contest the allegations and its right to appeal the proposed final order contained in this CAFO, and waives all defenses which have been raised or could have been raised to the claims in the CAFO.
- 5. The CAFO resolves only those violations which are alleged herein.
- 6. Respondent consents to the issuance of this CAFO as the most appropriate means of settling EPA's allegations without any adjudication of issues of law or fact, consents to the assessment and payment of the civil penalty in the amount and by the method set out in this CAFO, and consents to the compliance order in this CAFO.

II. JURISDICTION

- 7. This CAFO is issued by EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928, as amended by the Hazardous and Solid Waste Amendments of 1984 and is simultaneously commenced and concluded through the issuance of this CAFO under 40 Code of Federal Regulations ("C.F.R.") §§ 22.13(b) and 22.18(b)(2) and (3).
- 8. Respondent agrees to undertake and complete all actions required by the terms and conditions of this CAFO. In any action by EPA or the United States to enforce the terms of this CAFO, Respondent agrees not to contest the authority or jurisdiction of EPA to issue or enforce this CAFO, and agrees not to contest the validity of this CAFO or its terms or conditions.

III. FINDINGS OF FACT AND CONCLUSIONS OF LAW

- 9. Respondent is a Delaware corporation, authorized to do business in the state of Texas.
- 10. Respondent is a "person" within the meaning of Section 1004(15) of RCRA, 42 U.S.C.
 § 6903(15), and 30 TEX.ADMIN.CODE § 3.2(25), [40 C.F.R. § 260.10].

- Respondent owns or operates the Facilities at the respective locations identified in Paragraph 1.
- 12. The Facilities are pharmacies that dispense prescription medications, including controlled medicines, to patients who reside in long-term care facilities.
- 13. During the period from November 2014 through August 2015, EPA conducted a RCRA investigation and record review of Respondent's activities as a generator of hazardous waste in Texas, including a review of information voluntarily provided to EPA by Respondent (the "Investigation").
- 14. In 2014, EPA conducted site visits at several Treatment, Storage, and Disposal Facilities and pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927 obtained additional information on the hazardous waste that Respondent offered for transport and treatment (the "Responses").
- 15. During the Investigation and review of the Responses, EPA discovered that Respondent generated and offered for transport and treatment, hazardous waste having the:
 - A. Characteristic of ignitability (D001) and corrosivity (D002);
 - B. Characteristic for multiple toxicity waste D004, D005, D007, D009, D010,
 D011, D013, D024, D026; and
 - C. Listing for several P and U listed hazardous waste.
- 16. The Facilities are each a "facility" within the meaning of 30 TEX.ADMIN.CODE§ 335.1(60), [40 C.F.R. § 260.10].
- EPA determined that the Facilities are similar, in that the Facilities generate hazardous waste.

- 18. The waste streams identified in Paragraph 15 are "hazardous waste" as defined in30 TEX.ADMIN.CODE § 335.1 (70), [40 C.F.R. §§ 261.21, 261.22, 261.24, and 261.33].
- 19. From the Investigation and review of the Responses, EPA determined that in some instances Respondent generated the hazardous waste streams identified in Paragraph 15 in quantities that exceeded the threshold amount of 100 kilograms ("kgs") or 1000 kgs of hazardous waste per month, and in some instances, exceeded the threshold amount of, at a minimum, 1 kg of acutely hazardous waste per month, which qualified one location for small quantity generator ("SQG") status and other locations for large quantity generator ("LQG") status under 30 TEX.ADMIN.CODE, Chapter 335, Subchapter C, [40 C.F.R. Part 262], for the periods that such wastes remained onsite.
- 20. During the Investigation and review of the Responses, EPA determined that Respondent operated from 2010 through 2014 as a SQG at the Waco Facility and as a LQG at the Austin, Corpus Christi, Fort Worth, Houston, Lubbock, and Tyler facilities.
- 21. Respondent is a "generator" of "hazardous waste" as those terms are defined in Sections30 TEX ADMIN.CODE §§ 335.1(66) & (70), [40 C.F.R. § 260.10].
- 22. As a generator of hazardous waste, Respondent is subject to Sections 3002 and 3010 of RCRA, 42 U.S.C. §§ 6922 and 6930, and the regulations set forth in 30 TEX.ADMIN.CODE, Chapter 335, Subchapter C, [40 C.F.R Part 262].

Austin, Fort Worth, and Tyler

Claim i. Notification Requirements

- 23. The allegations in Paragraphs 1-22 are realleged and incorporated by reference.
- 24. Pursuant to Section 3010(a) of RCRA, 42 U.S.C. § 6930(a), any person generating a characteristic or listed hazardous waste shall file with EPA or the authorized state a

notification stating the location and general description of such activity and the identified characteristic or listed hazardous waste handled by such person. No identified characteristic or listed hazardous waste subject to this subchapter may be transported, treated, stored, or disposed of unless notification has been given as required by Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

25. Respondent did not file with EPA or Texas an adequate and timely notification of its hazardous waste activities at the Austin, Fort Worth, and Tyler facilities during the period from 2010 through 2014 in violation of Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

Austin, Fort Worth, and Houston

Claim ii. Failure to File Biennial Reports

- 26. The allegations in Paragraphs 1-25 are realleged and incorporated by reference.
- 27. Pursuant to 30 TEX.ADMIN.CODE § 335.71, [40 C.F.R. § 262.41] a generator who ships any hazardous waste off-site for treatment, storage and/or disposal, must prepare and submit a Biennial Report to EPA and to the Texas Commission on Environmental Quality ("TCEQ"), by March 1 of each even-numbered year in addition to the annual reporting, which is required under 30 TEX.ADMIN.CODE § 335.9.
- 28. For the years 2012 and 2014, neither the EPA nor the TCEQ received Biennial Reports that Respondent was required to file for the Austin, Fort Worth, and Houston facilities in violation of 30 TEX.ADMIN.CODE §§ 335.9 and 335.71, [40 C.F.R. § 262.41].

Austin, Fort Worth, Houston, Lubbock, and Tyler

Claim iii. Failure to Comply with the Manifest Requirements

29. The allegations in Paragraphs 1-28 are realleged and incorporated by reference.

30. Pursuant to 30 TEX.ADMIN.CODE §§ 335.10(a)(1) and 335.10(c), [40 C.F.R.

§ 262.20(a)(1)] a generator shall not offer its hazardous waste for shipment unless it prepares a standard manifest form (EPA Form 8700-22) according to the instructions found in the Appendix to 40 C.F.R. Part 262 and includes a Texas waste code for each hazardous waste itemized on the manifest.

31. EPA reviewed several manifests prepared by Respondent from 2011 through 2014, and determined that 21 manifests (9 at Houston from 2013 through 2014, 6 at Fort Worth from 2012 through 2014, 4 at Tyler from 2013 through 2014, 1 at Lubbock in 2014, and 1 at Austin in 2013) were not prepared as required by the regulations. Therefore, Respondent violated 30 TEX.ADMIN.CODE §§ 335.10(a)(1) and 335.10(c), [40 C.F.R. § 262.20(a)(1)].

All Facilities

Claim iv. Failure to make Adequate Hazardous Waste Determinations

- 32. The allegations in Paragraphs 1-31 are realleged and incorporated by reference.
- 33. Pursuant to 30 TEX.ADMIN.CODE § 335.62, [40 C.F.R. § 262.11(c)], a person who generates a solid waste, as defined in 30 TEX.ADMIN.CODE § 335.1, [40 C.F.R. § 261.2] must determine if the solid waste is a hazardous waste either by applying the required test method or by applying its knowledge of the hazardous characteristic of the waste in light of the materials or the processes used.
- 34. EPA reviewed Respondent's records for the period from 2010 through 2015, and determined that Respondent failed to make adequate hazardous waste determinations on all of Respondent's solid waste streams at the Facilities.

35. Respondent violated the requirements of RCRA and the regulations promulgated at 30 TEX.ADMIN.CODE § 335.62, [40 C.F.R. § 262.11] by failing to make the requisite hazardous waste determination on all solid waste streams generated by Respondent at the Facilities during the period from 2011 through 2014.

IV. COMPLIANCE ORDER

- 36. Pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), Respondent is hereby ordered to take the following actions, and within one hundred and eighty (180) calendar days of the effective date of this Order, Respondent shall provide the following to EPA in writing:
 - A. Respondent shall certify that it has assessed its solid waste streams at the Facilities to determine the accurate waste codes and has developed and implemented standard operating procedures ("SOPs") to ensure that Respondent is operating at the Facilities in compliance with RCRA and the regulations promulgated thereunder, including, but not limited to, procedures for: (a) making hazardous waste determinations; (b) managing hazardous wastes; (c) reporting, transporting, and disposing of hazardous waste; (d) preparing its manifests; and (c) meeting the requirements of the land disposal requirements;
 - B. Respondent shall certify that it has accurately and adequately complied with its RCRA Section 3010 notification for the Facilities and within the prescribed time period; and
 - C. Respondent shall provide, with its certification, a copy of Respondent's SOPs as described in subparagraph A above.

37. In all instances in which this CAFO requires written submission to EPA, the submittal

made by Respondent shall be signed by an owner or officer of the Respondent and shall

include the following certification:

"I certify under the penalty of law that this document and all its attachments were prepared by me or under my direct supervision in accordance with a system designed to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

Copies of all documents required by this CAFO shall be sent to the following:

U.S. Environmental Protection Agency Compliance Assurance and Enforcement Division Waste Enforcement Branch Compliance Enforcement Section (6EN-H3) 1445 Ross Avenue Dallas, TX 75202-2733 Attn: Dale Thrush

Where required, notice shall be sent electronically by email or facsimile to Dale Thrush,

respectively at Thrush.Dale@epa.gov or at 214-665-7446.

V. TERMS OF SETTLEMENT

i. Penalty Provisions

38. Pursuant to the authority granted in Section 3008 of RCRA, 42 U.S.C. § 6928, and upon consideration of the entire record herein, including the above referenced Findings of Fact and Conclusions of Law, which are hereby adopted and made a part hereof, upon the seriousness of the alleged violations, and Respondent's good faith efforts to comply with the applicable regulations, it is ordered that Respondent be assessed a civil penalty of Forty-Five Thousand, Four Hundred and Seventy-Nine Dollars (\$45,479.00).

39. The penalty shall be paid within thirty (30) calendar days of the effective date of this

CAFO and made payable to the Treasurer United States.

40. The following are Respondent's options for transmitting the penalties:

Regular Mail, U.S. Postal Mail (including certified mail) or U.S. Postal Service Express

Mail, the check should be remitted to:

U.S. Environmental Protection Agency Fines and Penaltics Cincinnati Finance Center P.O. Box 979077 St. Louis, MO 63197-9000

Overnight Mail (non-U.S. Postal Service), the check should be remitted to:

U.S. Bank Government Lockbox 979077 US EPA Fines and Penalties 1005 Convention Plaza SL-MO-C2-GL St. Louis, MO 63101 314-418-1028

Wire Transfer:

Federal Reserve Bank of New York ABA: 021030004 Account No. 68010727 SWIFT address – FRNYUS33 33 Liberty Street New York, NY 10045

The case name and docket number (In the Matter of Omnicare, Inc., Docket No. RCRA-

06-2016-0930) shall be clearly documented on or within the chosen method of payment

to ensure proper credit.

- Re: OMNICARE, INC. RCRA-06-2016-0930
 - 41. The Respondent shall send a simultaneous notice of such payment to the following:

Lorena S. Vaughn Regional Hearing Clerk (6RC-D) U.S. EPA, Region 6 1445 Ross Avenue Dallas, Texas 75202-2733

Mark Potts, Chief Waste Enforcement Branch (6EN-11) Compliance Assurance and Enforcement Division U.S. EPA, Region 6 1445 Ross Avenue Dallas, Texas 75202-2733 Attention: Dale Thrush

Respondent's adherence to this request will ensure proper credit is given when penalties are received by EPA.

42. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 13.11, unless otherwise prohibited by law, EPA will assess interest and late payment penalties on outstanding debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Interest on the civil penalty assessed in this CAFO will begin to accrue on the effective date of the CAFO and will be recovered by EPA on any amount of the civil penalty that is not paid within thirty (30) calendar days of the civil penalty's due date and will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 40 C.F.R. § 13.11(a). Moreover, the costs of the Agency's administrative handling overdue debts will be charged and assessed monthly throughout the period the debt is overdue. 40 C.F.R. § 13.11(b). EPA will also assess a \$15.00 administrative handling charge for administrative costs on unpaid penaltics for the thirty (30) day period after the payment is due and an additional \$15.00 for each subsequent thirty (30) day period the penalty remains unpaid. In addition, a penalty charge of up to six percent per year will be assessed monthly on any portion of the debt which remains delinquent more than ninety (90) days. 40 C.F.R. § 13.11(b). Should a penalty charge on the debt be required, it shall accrue from the first day payment is delinquent. 31 C.F.R. § 901.9(d). Other penalties for failure to make a payment may also apply.

ii. Supplemental Environmental Project

- 43. Respondent shall complete the Supplemental Environmental Project ("SEP") described in Appendix I of this CAFO, which is incorporated by reference as the Unwanted Pharmaceutical Disposal ("UPD") SEP in accordance with all provisions of this Subsection V.ii., as described below.
 - A. Within sixty (60) days of the effective date of this CAFO, Respondent shall begin work to implement the UPD SEP.
 - B. Respondent certifies the truth and accuracy of each of the following:
 - a. that all cost information that is provided to EPA in connection with EPA's approval of the UPD SEP is complete and accurate and that Respondent in good faith estimates that the cost to implement the UPD SEP is \$200,000;
 - b. that, as of the date of executing this CAFO, Respondent is not required to perform or develop the UPD SEP by any federal, state, or local law or regulation and is not required to perform or develop the SEP by agreement, grant, or as injunctive relief awarded in any other forum;
 - c. that the UPD SEP is not a project that Respondent was planning or intending to construct, perform, or implement other than in settlement of the claims resolved in this CAFO;

- d. that Respondent has not received and will not receive credit for the UPD
 SEP in any other enforcement action;
- e. that Respondent will not receive reimbursement for any portion of the UPD SEP from another person or entity; and
- f. that for federal income tax purposes, Respondent agrees that it will neither capitalize into inventory or basis nor deduct any costs or expenditures incurred in performing the UPD SEP.
- C. Respondent certifies that:
 - a. it is not a party to any open federal financial assistance transaction that is
 funding or could fund the same activity as the SEP described in Appendix
 I and this CAFO; and
 - b. it has inquired of the UPD SEP implementers whether they are a party to an open federal financial assistance transaction that is funding or could fund the same activity as the UDP SEP and have been informed by the implementers that they are not a party to such a transaction.
- D. The Respondent will submit annual status reports pursuant to Paragraph 37. The status reports will include at a minimum: (i) description of the activities to date;
 (ii) a budget summary table listing funds expended to date by budget category;
 and (iii) a discussion of any anticipated changes to the project scope or timeline.
- E. Respondent has three (3) years from the effective date of this CAFO to complete the UPD SEP.
- F. Within sixty (60) days after the completion of the UPD SEP, Respondent shall submit a completion report to EPA certifying: (i) that the UDP SEP funds have

been applied to the project; (ii) how the funds were used; (iii) an evaluation of the SEP's success; and (iv) that the UPD SEP has been completed in accordance with this CAFO, and Appendix I.

- G. The total expenditure for the UPD SEP shall not be less than \$200,000.Respondent shall include documentation of the expenditures made in connection with the UPD SEP as part of the UPD SEP completion report.
- H. Respondent agrees that any oral or written public statement, in print, film, or other media, made by Respondent making reference to the UPD SEP under this CAFO from the date of its execution of this CAFO shall include the following language:
 "This project was undertaken in connection with the settlement of an enforcement action, *In the Matter of: Omnicare, Inc.; USEPA Docket No. RCRA-06-2016-0930* to enforce federal laws."
- I. Respondent shall complete the UPD SEP in a timely and satisfactory manner, to ensure that the EPA and the public receives the benefits expected by the UPD SEP. For purposes of this CAFO, the UPD SEP shall have been satisfactorily completed when: (i) the program has operated for three (3) years; (ii) Respondent has spent no less than \$200,000; and (iii) Respondent is able to confirm and document that it has installed at least ten (10) permanent collection receptacles and/or conducted a minimum of thirty-five (35) one-day drug take-back events for its completion of the UPD SEP under this CAFO.

iii. Stipulated Penalties

44. Respondent shall be liable for stipulated penalties to be paid to the Treasurer United States, in accordance with the payment instructions set forth in Section V.i. (Penalty

Provisions) of this CAFO, unless excused by force majcure, for its failure to: (i) begin work to implement the UPD SEP sixty (60) after the effective date of this CAFO; (ii) meet interim milestones to submit required progress reports or to provide the SEP completion report, beginning thirty (30) days after an annual report and sixty (60) days after the UPD SEP completion report at a rate of \$1000 per day and thereafter that each specific failure continues; or (iii) satisfactorily complete the UPD SEP, in which case a stipulated penalty will be calculated at a rate that is proportionately determined on the objective basis of the total UPD SEP expenditure of \$200,000 and the actual number of installed permanent collection receptacles and/or the actual number of take-back events that are included in the definition of satisfactorily completed, described in subparagraph 43.1 above. For example, if the total number of installations and/or events are 50% of 10 and/or 35 then the stipulated penalty in this instance would be (\$200,000 * 50%) =\$100,000. Additionally, if Respondent abandons work on the SEP, or notifies EPA within sixty (60) days of the effective date of this CAFO that it must terminate the UPD SEP for good cause, Respondent will pay a stipulated penalty of \$160,000 together with interest accruing from the date the CAFO became effective, said interest to be assessed in accordance with Paragraph 42 of this CAFO.

- 45. When appropriate, EPA may reduce or waive stipulated penalties to address certain situations such as:
 - A. where all elements of a SEP have been satisfactorily completed, but the Respondent has expended less than the agreed upon amount on the SEP, the EPA may, in its discretion, choose to reduce or waive stipulated penalties otherwise due under the settlement agreement;

- B. where a SEP has not been satisfactorily completed, but the Respondent can demonstrate that the partially completed SEP provides some of the expected environmental and/or public health benefits, the EPA may, in its discretion, choose to reduce or waive stipulated penalties otherwise due under the settlement agreement; or
- C. where a fully completed SEP does not produce the environmental or public health results required by the agreement, the enforcement case team may, in its discretion, deem the SEP satisfactorily completed and choose to reduce or waive the stipulated penalties otherwise due under the settlement agreement. This may occur when a SEP is being implemented to test a new technology or process, or where circumstances beyond Respondent's control have had an impact on the results.

iv. Force Majeure

46. Force majeure for purposes of Section V.ii. (Supplemental Environmental Project) of this CAFO, is defined as any event arising from causes beyond the control of Respondent, of any entity controlled by Respondent, or of Respondent's contractors that delays or prevents the performance of any SEP obligation despite Respondent's best efforts. The requirement that Respondent exercise best efforts to fulfill the obligation includes using best efforts to anticipate any potential force majeure and best efforts to address the effects of any potential force majeure: (i) as it is occurring; and (ii) following the potential force majeure such that the delay and any adverse effects of the delay are minimized to the greatest extent possible. Force majeure does not include Respondent's financial inability to perform its SEP obligation.

47. If any force majeure event occurs or has occurred that may delay the performance of the UDP SEP, Respondent shall provide notice by electronic or facsimile transmission as soon as possible, pursuant to Paragraph 37 of this CAFO, but not later than seventy-two (72) hours after the time when Respondent first confirmed that the event might cause a delay. Within ten (10) days thereafter, Respondent shall provide written notice to EPA with an explanation and description of the reasons for the delay; the anticipated duration of the delay; all actions taken or to be taken to prevent or minimize the delay; a schedule for implementation of any measures to be taken to prevent or mitigate the delay or the effect of the delay; Respondent's rationale for attributing such delay to a force majeure event if it intends to assert such a claim; and a statement as to whether, in the opinion of Respondent such event may cause or contribute to an endangerment to public health, welfare or the environment. Respondent shall include with any notice available documentation supporting a claim that the delay was attributable to a force majeure. Respondent shall be deemed to know of any circumstance of which Respondent, any entity controlled by Respondent, or Respondent's contractors knew or reasonably should have known. Failure to comply with the above requirements regarding an event shall preclude Respondent from asserting any claim of force majeure regarding that event; however, despite the late notice, if EPA is able to assess to its satisfaction whether the event is a force majeure under Paragraph 46 and whether Respondent has exercised its best efforts under Paragraph 46, EPA may, in its unreviewable discretion, excuse in writing Respondent's failure to submit timely notices under this Paragraph.

v. Cost

48. Each party shall bear its own costs and attorney's fees. Furthermore, Respondent specifically waives its right to seek reimbursement of its costs and attorney's fees under the Equal Access to Justice Act (5 U.S.C. § 504), as amended by the Small Business Regulatory Enforcement Fairness Act (P.L. 104-121), and any regulations promulgated pursuant to those Acts.

vi. Termination and Satisfaction

49. When Respondent believes that it has complied with all the requirements of this CAFO, including compliance with the Compliance Order, completion of the SEP, and payment of the civil penalty, Respondent shall so certify in writing and in accordance with the certification language set forth in Section IV (Compliance Order), Paragraph 37. Unless the EPA objects in writing within sixty (60) days of EPA's receipt of Respondent's certification, then this CAFO is terminated on the basis of Respondent's certification.

vii. Effective Date of Settlement

50. This CAFO shall become effective upon filing with the Regional Hearing Clerk.

viii. Appendix I

51. Appendix I represents the description of the SEP to be performed by Respondent, and is incorporated by reference into this CAFO as the UPD SEP.

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THE UNDERSIGNED PARTIES CONSENT TO THE ENTRY OF THIS CONSENT

AGREEMENT AND FINAL ORDER:

FOR THE RESPONDENT:

Date: 9/20/16

Omnicare, Inc.

FOR THE COMPLAINANT:

Date: 9.26.16

John Blevins Director Compliance Assurance and Enforcement Division

FINAL ORDER

Pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, 40 CFR Part 22, the foregoing CAFO is hereby ratified. This Final Order shall not in any case affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. This Final Order shall resolve only those causes of action alleged herein. Nothing in this Final Order shall be construed to waive, extinguish or otherwise affect Respondent's (or its officers, agents, servants, employees, successors, or assigns) obligation to comply with all applicable federal, state, and local statutes and regulations, including the regulations that were the subject of this action. The Respondent is ordered to comply with the terms of settlement and the civil penalty payment instructions as set forth in the CAFO. Pursuant to 40 CFR § 22.31(b) this Final Order shall become effective upon filing with the Regional Hearing Clerk.

Date: 09-30-2016

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Thomas Rucki Regional Judicial Officer

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CERTIFICATE OF SERVICE

I hereby certify that on the 30^{H} day of \underline{Sept} . 2016, the original of the foregoing Consent

Agreement and Final Order was hand delivered to the Regional Hearing Clerk, U.S. EPA -

Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, and that a true and correct copy of

the CAFO was sent to the following by the method identified below:

CERTIFIED MAIL - RETURN RECEIPT REQUESTED 70010360000366744317

Omnicare, Inc. c/o Frances E. Phillips Gardere Wynne Sewell LLP 1601 Elm Street, Suite 3000 Dallas, TX 75201-4761

(DON ori Jack

Paralegal

APPENDIX I

SUPPLEMENTAL ENVIRONMENTAL PROJECT ("SEP")

PROJECT TITLE

Pollution Reduction through Unwanted Pharmaceutical Collection and Destruction

GEOGRAPHICAL AREA

USEPA Region 6: Arkansas, Louisiana, New Mexico, Oklahoma, and Texas

SEP CATEGORY

Pollution Reduction

PROJECT SUMMARY

Individuals who take prescription medications often have unused, leftover, or unwanted medications that are frequently left in medicine cabinets for long periods of time or discarded by flushing the medications, mixing them with other unwanted materials (coffee grounds, kitty litter, etc.), and/or disposing in the regular trash. Through this project, Omnicare would work with local law enforcement agencies to increase the availability of pharmaceutical "take-back" options such as scheduled, one-day take-back events and/or sponsoring permanent collection receptacles available to household generators.

PROJECTION DESCRIPTION

Historically, law enforcement agencies have been among the only locations authorized to house permanent drug collection receptacles that can be used for controlled substances. In September 2014, the U.S. Drug Enforcement Agency ("DEA") issued a Final Rule that allows other DEA registrants to participate in and promote proper collection and disposal of unwanted medications, including controlled substances. Now, collection of unwanted medications is commonly affected through DEA-sponsored take-back days, which occur twice per year, and permanently-placed collection receptacles inside DEA registrants such as law enforcement agencies and community pharmacies.

Omnicare believes that law enforcement offices are uniquely qualified to house permanent collection receptacles. However, we understand that some local law enforcement agencies (particularly those in rural communities) are reluctant to house permanent drug collection receptacles due to the high cost of proper disposal via incineration. In addition, having only two drug take-back days per year sponsored by the DEA may not offer as much opportunity for individuals to properly and timely dispose of unwanted medications. As a provider of pharmacy services to residents of assisted living and independent living facilities, Omnicare is uniquely positioned to educate residents of these facilities and communities about the appropriate methods for proper disposal of unwanted medications. Omnicare proposes to expend \$200,000 over a period of three (3) years to enhance the availability of drug take-back options to household users in Arkansas, Louisiana, New Mexico, Oklahoma, and/or Texas by a combination of the following actions:

- Donating permanent drug collection receptacles to local law enforcement agencies and providing funds for those agencies to dispose of collected medications via incineration;
- Sponsoring one-day drug take-back events either at law enforcement agencies, community pharmacies, and/or other authorized locations; and
- Publicizing the unwanted pharmaceutical disposal events and/or receptacle locations through fliers, posters, newsletters, mailings, or other feasible means to residents at assisted living facilities and to the general public.

EXPECTED ENVIRONMENTAL AND/OR PUBLIC HEALTH BENEFIT

Collecting unused or unwanted medications from household users and sending them for disposal via incineration will prevent these wastes from entering the environment via sewer systems or unregulated trash. In addition, providing increased options for collection and disposal of unused or unwanted medications could prevent household users from leaving these items in medicine cabinets or other places in the home where they could be accessed by children or other unauthorized recipients.

REPORTING

Annual Status Reports

The Regulated Entity will submit an annual project status report to the EPA Contact. Status reports will include the following information:

- A description of activities completed to date;
- A budget summary table listing funds expended to date by budget category; and
- A discussion of any anticipated changes to the project scope or timeline.

Final SEP Completion Report

The SEP Completion report will be submitted at the end of the project period of three (3) years and contain at a minimum:

- A detailed description of the project as implemented;
- A summary table identifying project deliverables and tasks along with the associated completion date;
- A description of any operating problems encountered and the solutions thereto;
- A full expense accounting including itemized costs, documented by copies of purchase orders, contracts, receipts and/or canceled checks;
- Certification and demonstration that the SEP has been fully implemented pursuant to the provisions of the Consent Agreement and Final Order and this SEP Agreement;
- A description of the environmental and public health benefits resulting from

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implementation of the SEP along with quantification of the outcomes and benefits;

- Examples of brochures, educational or outreach materials developed or produced as part of the SEP; and
- Photographs documenting the SEP.