

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 6  
DALLAS, TX

FILED  
2019 DEC -9 PM 2:15  
REC'D  
EPA REGION VI

IN THE MATTER OF:

Encore Medical LP

RESPONDENT

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Administrative Compliance Order on Consent  
USEPA Docket No. RCRA-06-2020-0919

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**ADMINISTRATIVE COMPLIANCE ORDER ON CONSENT**

**I. PRELIMINARY STATEMENT**

1. This Administrative Compliance Order on Consent (“ACOC”) is entered into by the United States Environmental Protection Agency, Region 6 (“EPA”) and Respondent, Encore Medical LP, (“Encore Medical LP” or “Respondent”), and concerns the facility located at 9800 Metric Boulevard Austin, TX 78758 (the “Facility”).
2. Notice of this action has been given to the state of Texas, under Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2)<sup>1</sup>.
3. For the purpose of these proceedings, Respondent admits the jurisdictional allegations herein; however, Respondent neither admits nor denies the specific factual allegations and

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<sup>1</sup> On December 26, 1984, the State of Texas received final authorization for its Base Hazardous Waste Management Program (49 FR 48300). Subsequent revisions have been made to the Texas Hazardous Waste Program and authorized by the EPA. Except as otherwise provided, all citations to the EPA Authorized Texas Hazardous Waste Program refer to Title 30 of the Texas Administrative Code (“TEX. ADMIN. CODE”), as amended, effective on February 26, 2016. 80 Fed. Reg. 80672 (December 28, 2015); 40 C.F.R. 272.2201: Texas State-Administered Program: Final Authorization. References found within this CAFO are to the EPA authorized version of the TEX. ADMIN. CODE and citations may vary slightly from the Texas published version of the TEX. ADMIN. CODE. The corresponding C.F.R. citations are also provided.

conclusions of law contained in this ACOC. This ACOC states a claim upon which relief may be granted.

4. Respondent explicitly waives any right to contest the allegations and its right to appeal the proposed final order contained in this ACOC and waives all defenses which have been raised or could have been raised to the claims set forth in the ACOC.
5. Respondent consents to the issuance of the ACOC hereinafter recited and consents to the specific stated Compliance Order, Section VI, of this ACOC.

## II. JURISDICTION

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

### III. STATEMENT OF PURPOSE

8. This ACOC provides for the resolution of EPA Region 6's investigation of Respondent's Facility.
9. In entering into this ACOC, the mutual objectives of EPA, Region 6 and Respondent are to remedy, and/or prevent the potential endangerment to human health and/or the environment from activities involving solid waste and hazardous waste, and to ensure that the injunctive relief that Respondent will complete as described in the Section VI, Compliance Order, is protective of human health and/or the environment.

### IV. STATUTORY AND REGULATORY BACKGROUND

10. Federal regulation of hazardous waste is primarily based on RCRA, enacted on October 21, 1976 to amend the Solid Waste Disposal Act, and the Hazardous and Solid Waste Amendments ("HSWA") enacted by Congress in 1984 to further amend the Solid Waste Disposal Act. RCRA establishes a "cradle-to-grave" program to be administered by the Administrator of EPA and authorized states for regulating the generation, transportation, treatment, storage, and disposal of hazardous waste. See 42 U.S.C. § 6901 et seq.
11. RCRA's Subchapter III (RCRA §§ 3001-3023, 42 U.S.C. §§ 6921-6940, known as "Subtitle C") required EPA to promulgate regulations establishing performance standards applicable to facilities that generate, transport, treat, store, or dispose of hazardous wastes. Together, RCRA Subtitle C and its implementing regulations, set forth at 40 C.F.R. Parts 260 – 279, comprise EPA's RCRA hazardous waste program.
12. Pursuant to its authority under RCRA, EPA has promulgated regulations at 40 C.F.R. Parts 260 through 272 applicable to generators, transporters, and treatment, storage, and disposal

facilities. These regulations generally prohibit treatment, storage, and disposal of hazardous waste without a permit or equivalent “interim status.” They prohibit land disposal of certain hazardous wastes, and provide detailed requirements governing the activities of those who generate hazardous waste and those who are lawfully permitted to store, treat, and dispose of hazardous waste.

13. Pursuant to 40 C.F.R. § 261.2, a “solid waste” is any discarded material that is not otherwise excluded under 40 C.F.R. § 261.4(a), or that is not excluded by variance. A discarded material is any material which is abandoned, recycled, inherently waste-like, or a military munition. Materials are solid waste, as defined in 40 C.F.R. § 261.2, if they are abandoned by being disposed of, burned or incinerated, or accumulated, stored, or treated (but not recycled) before, or in lieu of, being abandoned by being disposed of, burned, or incinerated.
14. A solid waste is a hazardous waste if it is not excluded from regulation as a hazardous waste under 40 C.F.R. § 261.4(b), and it exhibits any of the characteristics of hazardous waste identified in 40 C.F.R. Part 261, Subpart C, or it is listed in 40 C.F.R. Part 261, Subpart D.
15. Characteristic hazardous wastes are assigned “D” codes in 40 C.F.R. Part 261, Subpart C, depending on the specific hazardous characteristic that the waste exhibits.
16. An ignitable hazardous waste has a flash point of less than 60 degrees centigrade (140 degrees Fahrenheit) and is assigned the D001 hazardous waste code pursuant to 40 C.F.R. § 261.21.
17. A corrosive hazardous waste has a pH of less than or equal to 2.0 or greater than or equal to 12.5 and is assigned the D002 hazardous waste code pursuant to 40 C.F.R. § 261.22, and a

reactive hazardous waste is assigned the D003 hazardous waste code pursuant to 40 C.F.R. § 261.23.

18. Listed wastes are assigned with “F”, “K”, “P”, and “U” codes in 40 C.F.R. Part 261, Subpart D, depending on the specific waste generated from a non-specific source, a specific source, or discarded commercial chemical products, off-specification species, container residues and spill residues therefrom.
19. 40 C.F.R. Parts 264 and/or 265 applies to owners and operators of facilities that treat, store and/or dispose of hazardous waste.
20. The relevant RCRA statutory and regulatory requirements to this ACOC require that generators of solid waste and hazardous waste must, among other things:
  - A. Determine whether their generated solid wastes are hazardous, pursuant to 40 C.F.R. § 262.11;
  - B. Comply with the statutory notification requirements of Section 3010 of RCRA, 42 U.S.C. § 6930;
  - C. Comply with the manifest requirements, pursuant to 40 C.F.R. § 262.20; and
  - D. Determine its generator status by meeting the exemption conditions set forth at 40 C.F.R. § 262.34 or comply with the specific requirements set forth at 40 C.F.R. § 270.10.

#### **V. FINDINGS OF FACT AND CONCLUSIONS OF LAW**

21. Respondent is an authorized corporation in the state of Texas, authorized on January 11, 2007, and is located at 9800 Metric Boulevard Austin, TX 78758.



22. Respondent is a “person” within the meaning of Section 1004(15) of RCRA, 42 U.S.C. § 6903(15); and 30 Texas Administrative Code (“TEX.ADMIN.CODE”) § 3.2(25), [40 C.F.R. § 260.10].
23. The Facility identified in Paragraph 1 of this ACOC is a “facility” within the meaning of 30 TEX.ADMIN.CODE § 335.1(59), [40 C.F.R. § 260.10].
24. Respondent’s Registered Agent for Service in the state of Texas is C T Corporation System who is located at 155 Federal Street, Suite 700, Boston, MA 02110.
25. Encore Medical LP owns a facility that manufactures orthopedic surgery products.
26. During the period of August to October, 2019 EPA conducted a RCRA investigation and record review (“Investigation”) of Encore Medical LP’s performance as a generator of hazardous waste.
27. During the Investigation, EPA discovered that Encore Medical LP, at a minimum, generated the following waste:
  - A. Characteristic of Ignitability: D001 (Ignitability)
  - B. F003
28. The waste stream identified in Paragraph 27 is “solid waste” and “hazardous waste” as defined in 30 TEX.ADMIN.CODE §§ 335.1 (138) and (69), [40 C.F.R. §§ 261.2 and 261.24].
29. From the Investigation, EPA determined that during 2014 through 2019 Encore Medical LP generated at a minimum the hazardous waste streams identified in Paragraph 27 in quantities that exceeded the threshold amount of 100 kilograms of hazardous waste per month, which

qualified Encore Medical LP for the small quantity generator (“SQG”) status established under 30 TEX.ADMIN.CODE, Chapter 335, Subchapter C, [40 C.F.R. Part 262], for the periods that such wastes remained onsite.

30. Encore Medical LP is a “generator” of “hazardous wastes” at the Facility, as those terms are defined in Sections 1004(5) & (6) of RCRA, 42 U.S.C. §§ 6903(5) & (6), 30 TEX.ADMIN.CODE §§ 335.1(65) & (69), [40 C.F.R. Parts 260 and 261].
31. As a generator of hazardous waste, Encore Medical LP is subject to Sections 3002 and 3010 of RCRA, 42 U.S.C. §§ 6922 and 6930, and the regulations set forth at 30 TEX.ADMIN.CODE Chapter 335, Subchapter C, [40 C.F.R. Parts 262 and/or 270].

**Claims i. Notification Requirements**

32. The allegations in Paragraphs 1-31 are realleged and incorporated herein by reference.
33. 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 the Administrator or authorized State a notification stating the location and general description of such activity and the identified characteristic or listed hazardous wastes 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).
34. Encore Medical LP did not file with the Administrator an initial or subsequent notification to accurately state the general description of its hazardous waste activities and its generation and management of hazardous waste during 2014 through 2019, in violation of Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

35. At all times relevant to this ACOC, Respondent failed to comply with its notification requirements in violation of Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

**Claims ii. Failure to Operate within Its Stated Generator Status**

36. The allegations in Paragraphs 1-31 are realleged and incorporated herein by reference.
37. During the Investigation, EPA determined that Encore Medical LP either operated as a Conditionally Exempt Small Quantity Generator (“CESQG”) and/or considered itself to be a CESQG.
38. Pursuant to 30 TEX.ADMIN.CODE § 335.78(b), [40 C.F.R. § 261.5(b)], as long as a CESQG complies with the applicable requirement under 30 TEX.ADMIN.CODE §§ 335.78(e), (f), (g), and (j), [40 C.F.R. §§ 261.5 (e), (f), (g) and (j)] the generator’s hazardous waste is not subject to regulation under 30 TEX.ADMIN.CODE, Chapter 335, Subchapters C, [40 C.F.R. Parts 262 through 268 and 270].
39. On more than one occasion from 2014 through 2019, Encore Medical LP exceeded the CESQG status and, for the period such hazardous waste remained onsite, operated as a SQG in violation of one or more of the requirements for SQG under 30 TEX.ADMIN.CODE, Chapter 335, Subchapter C, [40 C.F.R. Part 262 through 268 and 270].
40. At all times relevant to this ACOC, Respondent failed to comply with the SQG requirements in violation of 30 TEX.ADMIN.CODE Chapter 335, Subchapters C, [40 C.F.R. Parts 262 through 268 and 270].





penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.”

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

U.S. EPA, Region 6  
1201 Elm Street, Suite 500  
Enforcement and Compliance Assurance Division (ECDSR)  
ATTN: Joyce Johnson  
Dallas, Texas 75270-2102

## **VII. TERMS OF SETTLEMENT**

### **i. Modification**

43. The terms, conditions, and compliance requirements of this ACOC may not be modified or amended except upon the written agreement of both parties, and approved by a Regional Judicial Officer, and such modification or amendment being filed with the Regional Hearing Clerk.

### **ii. Indemnification**

44. Neither EPA nor the United States Government shall be liable for any injuries or damages to person or property resulting from the acts or omissions of Respondent, their officers, directors, employees, agents, receivers, trustees, successors, assigns, or contractors in carrying out the activities required by this ACOC, nor shall EPA or the United States Government be held out as a party to any contract entered into by Respondent in carrying out the activities required by this ACOC.

### **iii. Record Preservation**

45. Respondent shall preserve, during the pendency of this ACOC, all records and documents in its possession or in the possession of its divisions, employees, agents, contractors, or

successors, which in any way relate to this ACOC regardless of any document retention policy to the contrary.

**iv. Cost**

46. 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. 04-121), and any regulations promulgated pursuant to those Acts.

**v. Reservation of Rights**

47. Notwithstanding any other provisions of this ACOC, EPA retains all of its authority to take, direct, or order any and all actions necessary to protect public health or the environment or to prevent, abate, or minimize an actual or threatened release of hazardous substances, pollutants, or contaminants, or hazardous or solid waste or constituents of such wastes, on, at, or from the Facility, including but not limited to the right to bring enforcement actions under RCRA, CERCLA, and any other applicable statutes or regulations.
48. EPA reserves all of its statutory and regulatory powers, authorities, rights, remedies, both legal and equitable, that may pertain to Respondent's failure to comply with any of the requirements of this ACOC.
49. This ACOC shall not be construed as a covenant not to sue, release, waiver, or limitation of any rights, remedies, powers, claims, and/or authorities, civil or criminal, which EPA has under RCRA, CERCLA, or any other statutory, regulatory, or common law authority of the United States. Further, this ACOC does not resolve Respondent's liability for Federal civil penalties for the violations and facts set forth herein.

**vi. Termination and Satisfaction**

50. When Respondent believes that it has complied with all the requirements of this ACOC, including compliance with the Compliance Order, Respondent shall so certify in writing and in accordance with the certification language set forth in Section VI (Compliance Order). Unless the EPA, Region 6 objects in writing within sixty (60) days of EPA's receipt of Respondent's certification, then this ACOC is terminated on the basis of Respondent's certification.

**vii. Effective Date of Settlement**

51. This ACOC shall become effective upon filing with the Regional Hearing Clerk.

RCRA-06-2020-0919  
Encore Medical LP

**THE UNDERSIGNED PARTIES CONSENT TO THE ENTRY OF THIS  
ADMINISTRATIVE COMPLIANCE ORDER ON CONSENT:**


**FOR THE RESPONDENT:**

Date: 11-27-19

  
\_\_\_\_\_  
Encore Medical LP

**FOR THE COMPLAINANT:**

Date: 12-2-19

  
\_\_\_\_\_  
Cheryl T. Seager, Director  
Enforcement and  
Compliance Assurance Division



**FINAL ORDER**

Pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, 40 C.F.R. Part 22, the foregoing ACOC is hereby ratified. This Final Order shall not in any case affect the right of the EPA or the United States to pursue appropriate civil penalties, injunctive or other equitable relief or criminal sanctions for any violations of law, including those violations alleged herein. 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 Compliance Order, Section VI, and the Terms of Settlement, Section VII, as set forth in this ACOC. Pursuant to 40 C.F.R. § 22.31(b) this Final Order shall become effective upon filing with the Regional Hearing Clerk.

Date: \_\_\_\_\_

12/9/19



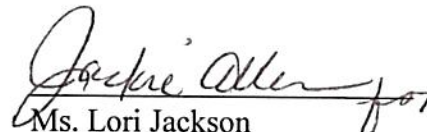
\_\_\_\_\_  
Thomas Rucki  
Regional Judicial Officer

**CERTIFICATE OF SERVICE**

I hereby certify that on the 9<sup>th</sup> day of December, 2019, the original of the foregoing Administrative Compliance Order on Consent hand delivered to the Regional Hearing Clerk, U.S. EPA - Region 6, 1201 Elm Street, Suite 500, Dallas, Texas 75270-2102, and that a true and correct copy of the ACOC was sent to the following by the method identified below:

**CERTIFIED MAIL - RETURN RECEIPT REQUESTED**

Registered Agent for Service  
C T Corporation System  
155 Federal Street, Suite 700  
Boston, MA 02110

  
Ms. Lori Jackson  
Paralegal

