



UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of:)
)
Professional Contract Sterilization, Inc.,) Docket No. CAA-01-2022-0059
)
Respondent.)

PREHEARING ORDER

As the parties have previously been notified, I am designated to preside over this proceeding. This proceeding is governed by the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. §§ 22.1 to 22.45 (“Rules of Practice” or “Rules”). The parties are advised to familiarize themselves with the applicable statute(s) and the Rules of Practice. Orders and decisions issued by the Administrative Law Judges are accessible on the website for the Office of Administrative Law Judges (“OALJ”) at www.epa.gov/alj.

Settlement. U.S. Environmental Protection Agency (“Agency” or “EPA”) policy encourages settlement of a proceeding without the necessity of a formal hearing, and the procedures regarding settlements are set forth in Section 22.18 of the Rules of Practice, 40 C.F.R. § 22.18. The benefits of a negotiated settlement may far outweigh the uncertainty, time, and expense associated with a litigated proceeding. With these considerations in mind, the parties are directed to engage in a settlement conference on or before **August 26, 2022**, and attempt to reach an amicable resolution of this matter. Without mentioning any specific terms of settlement, Complainant shall file a Status Report regarding this conference and the status of settlement on or before **September 2, 2022**. If the case is settled, a fully-executed Consent Agreement and Final Order shall be filed with the Regional Hearing Clerk no later than **September 23, 2022**, and a courtesy copy shall be filed with the Headquarters Hearing Clerk.

In the event that a fully-executed Consent Agreement and Final Order is not filed on or before **September 23, 2022**, the parties must prepare for hearing and shall strictly comply with the following prehearing requirements of this Order. *The pendency of settlement negotiations or the existence of a settlement in principle does not constitute a basis for failing to strictly comply with those requirements. Only the filing with the Regional Hearing Clerk of a fully-executed Consent Agreement and Final Order, or an order of the undersigned, excuses noncompliance with filing deadlines.*

Preliminary Statement. No later than **September 2, 2022**, each party shall file with the Headquarters Hearing Clerk, serve on the opposing party, and serve on the undersigned a

Preliminary Statement that (1) identifies the party's preference for the location of the hearing¹; (2) indicates the party's consent to service of orders and decisions issued by this Tribunal, and to service of documents filed by other parties, *by email only* during this proceeding (service by email includes sending a link via email to an online file sharing service); and (3) provides a valid email address at which the party will accept such service.²

Prehearing Exchange. This Order is issued pursuant to Section 22.19(a) of the Rules of Practice. *See* 40 C.F.R. § 22.19(a). Accordingly, the parties are hereby directed to engage in the following prehearing exchange of information:

1. Each party shall file with the Headquarters Hearing Clerk, serve on the opposing party, and serve on the undersigned:

(A) a list of names of the witnesses intended to be called at the hearing, identifying each as a fact witness or an expert witness, a brief narrative summary of their expected testimony, and a curriculum vitae or resume for each identified expert witness; or a statement that no witnesses will be called;

(B) a list of all exhibits, numbered in sequential order, that the party intends to produce at the hearing, along with a copy of each exhibit marked for identification as follows:

- i. Complainant's exhibits shall be identified as "CX."
- ii. Respondent's exhibits shall be identified as "RX."
- iii. Each exhibit shall be labeled numerically with the corresponding exhibit number on each page of the exhibit. For example, the first exhibit provided by Complainant shall be labeled on each page of the exhibit as "CX 1." The label for each exhibit shall be located at the bottom (footer) of the document and aligned to the right margin.
- iv. Any exhibit consisting of more than one page shall include page numbers at the bottom (footer) of each page, aligned to the right margin. The pages shall be numbered consecutively as follows: "Page X of [total of] Y," with "Page X" representing the page number in sequence beginning from the number 1 and "[total of] Y" representing the total number of pages in the exhibit. For example, to identify the third page of Complainant's first exhibit, which has five pages total, the bottom of the page shall read "CX 1 Page 3 of 5."

¹ The Rules of Practice provide that the hearing shall be held in the county where the respondent resides or conducts the business that the hearing concerns, in the city in which the complainant is located, or in Washington, D.C., unless the presiding judge determines that there is good cause to hold it another location or by telephone. 40 C.F.R. §§ 22.21(d), 22.19(d). The parties are hereby advised that notwithstanding the direction in this Order for each party to identify its preference for the location of the hearing, the hearing may be conducted by video conference depending upon conditions related to the ongoing COVID-19 pandemic.

² The Rules of Practice allow for electronic service, and in the interest of judicial efficiency, it will be this Tribunal's practice to serve the parties by email only. *See* 40 C.F.R. §§ 22.5(b)(2), 22.6 (authorizing service of most documents by email). If a party is unable to receive service by email, the party shall affirmatively state that it is unable to accept service by email and provide a valid address at which it may be served by regular U.S. mail.

(C) a statement specifying the amount of time needed to present its direct case, *see* 40 C.F.R. §§ 22.21(d), 22.19(d), and indicating whether the services of an interpreter are necessary with regard to the testimony of any witness(es). If the services of an interpreter are necessary, the statement shall also indicate the language that is to be interpreted.

2. In addition, Complainant shall submit the following as part of its Initial Prehearing Exchange:

(A) documentation showing that service of the Complaint was completed in accordance with Section 22.5(b)(1) of the Rules of Practice, 40 C.F.R. § 22.5(b)(1);

(B) a brief narrative statement, and a copy of any documents in support, explaining in detail the factual and/or legal bases for the allegations denied or otherwise not admitted in Respondent's Answer;

(C) all factual information and supporting documentation relevant to the assessment of a penalty, and a copy, or a statement of the internet address (URL), of any policy or guidance intended to be relied on by Complainant in calculating a proposed penalty;

(D) a copy, or a statement of the internet address (URL), of any EPA guidance documents and/or policies, including any updates or revisions to such guidance and/or policies, and any preambles to regulations that Complainant has relied upon with regard to the allegations set forth in the Complaint; and

(E) a detailed explanation of the factors considered and methodology utilized in calculating the amount of the proposed penalty, in accordance with the penalty factors and policies referenced in the proposed civil penalty section of the Complaint.

3. In addition, Respondent shall submit the following as part of its Prehearing Exchange:

(A) a copy of any documents in support of the denials made in its Answer;

(B) a copy of any documents in support of any asserted affirmative defenses and an explanation of the arguments in support of any such affirmative defenses;

(C) all factual information that Respondent considers relevant to the assessment of a penalty and any supporting documentation; and

(D) if Respondent takes the position that the proposed penalty should be reduced or eliminated on any grounds, such as an inability to pay, then provide a detailed narrative statement explaining the precise factual and legal bases for its position and a copy of any and all documents upon which it intends to rely in support of such position.

4. Finally, Complainant shall submit as part of its Rebuttal Prehearing Exchange:

(A) a statement and/or any documents in response to Respondent's Prehearing Exchange

as to provisions 3(A) through 3(D) above.

The prehearing exchanges called for above shall be filed pursuant to the following schedule:

September 23, 2022	Complainant's Initial Prehearing Exchange
October 14, 2022	Respondent's Prehearing Exchange
October 28, 2022	Complainant's Rebuttal Prehearing Exchange

Section 22.19(a) of the Rules of Practice provides that, except in accordance with Section 22.22(a), any document not included in the prehearing exchange shall not be admitted into evidence, and any witness whose name and testimony summary are not included in the prehearing exchange shall not be allowed to testify. 40 C.F.R. § 22.19(a). Therefore, each party is advised to thoughtfully prepare its prehearing exchange.

In general, hearings are scheduled following the submission of the prehearing exchanges. The parties will be provided with adequate notice of the scheduled hearing to enable them to meet the remaining deadlines contained in this Order.

Supplement to Prehearing Exchange. Any addition of a proposed witness or exhibit to the prehearing exchange, submitted pursuant to Section 22.19(f) of the Rules of Practice, must be filed with an accompanying *motion to supplement the prehearing exchange* only when supplementation is sought within 60 days of the scheduled hearing.

Motions. Prior to filing any motion, the moving party must contact all other parties to determine whether the other parties have any objection to the granting of the relief sought in the motion, and the motion shall state the position of the other parties. The mere consent of the other parties to the relief sought does not assure that the motion will be granted. Furthermore, all motions must be submitted in sufficient time to permit the filing of a response and a reply, as well as the issuance of a ruling on the motion, before any relevant deadline set by this or any subsequent order. *See generally* 40 C.F.R. §§ 22.16(b), 22.7(c). *Motions not filed in a timely manner may not be considered.*

Joint motions for the appointment of a neutral, filed pursuant to Section 22.18(d)(3) of the Rules of Practice, will not be entertained prior to the deadline for Complainant's Rebuttal Prehearing Exchange and shall be filed no later than seven days after that deadline. *Dispositive motions* regarding liability, such as a motion for accelerated decision or motion to dismiss under Section 22.20(a) of the Rules of Practice, must be filed within 30 days after the due date for Complainant's Rebuttal Prehearing Exchange. *Non-dispositive motions*, such as motions for additional discovery, motions for subpoenas, and motions in limine, must be filed no later than 60 days prior to the scheduled hearing.

Pursuant to Section 22.16(d) of the Rules of Practice, a party may submit a written request for oral argument upon filing a motion, a response to a motion, or a reply. 40 C.F.R.

§ 22.16(d). The requesting party shall propose an appropriate location for the argument. The OALJ has access to videoconferencing technology that may be utilized for oral arguments on motions, which may minimize the expenditure of time and monetary resources in connection with such arguments. A request for oral argument may be granted, in the undersigned's discretion, where further clarification and elaboration of arguments would be of assistance in ruling on the motion.

Default and Opportunity for a Hearing. The Complaint in this matter gave Respondent notice and opportunity for a hearing, in accordance with Section 554 of the Administrative Procedure Act ("APA"), 5 U.S.C. § 554. Respondent's Answer to the Complaint contained a request for a hearing. In this regard, Section 554(c)(2) of the APA sets out that a hearing be conducted under Section 556 of the APA. 5 U.S.C. § 554(c)(2). Section 556(d) provides that a party is entitled to present its case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. 5 U.S.C. § 556(d). Thus, Respondent has the right to defend against Complainant's charges by way of direct evidence, rebuttal evidence, or through cross-examination of Complainant's witness(es). Respondent is entitled to elect any or all three means to pursue its defenses.

Respondent is hereby notified that its failure to comply with the prehearing exchange requirements set forth herein may result in the entry of a default judgment against it. Complainant is notified that its failure to file its prehearing exchange in a timely manner can result in a dismissal of the case with prejudice.

Filing and Service.³ Consistent with Section 22.5 of the Rules of Practice, the original and one copy of all documents intended to be part of the record in this proceeding (excluding a fully-executed Consent Agreement and Final Order, which must be filed with the Regional Hearing Clerk) shall be filed with the Headquarters Hearing Clerk.⁴ Electronic filing is strongly encouraged.⁵ To file a document electronically, a party shall use a web-based tool known as the OALJ E-Filing System by visiting the OALJ's website at www.epa.gov/alj. Documents filed electronically are deemed to constitute both the original and one copy of the document.

Any party choosing to file electronically must first register with the OALJ E-Filing System at https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf. There may be a delay of one to two business days between the time a party applies for registration and the time at which

³ The parties are advised to visit the OALJ's website at <https://www.epa.gov/alj/filing-and-service-during-covid-19> for the most current guidance on filing and service procedures in light of the ongoing COVID-19 pandemic.

⁴ Pursuant to the Headquarters Hearing Clerk Pilot Project, the OALJ and Headquarters Hearing Clerk shall keep the official record and be the proper filing location for all contested cases in which an answer was filed after May 1, 2012. For more information, see the OALJ's website at www.epa.gov/alj.

⁵ More information about electronic filing may be found in the Standing Order Authorizing Electronic Filing in Proceedings Before the Office of Administrative Law Judges available on the OALJ's website at <https://www.epa.gov/sites/production/files/2014-10/documents/alj-standing-order-efiling.pdf>.

the party is able to upload documents into the system.

A document submitted to the OALJ E-Filing System is considered “filed” at the time and date of electronic reception, as recorded by the OALJ E-Filing System immediately upon reception. To be considered timely, documents submitted through the OALJ E-Filing System must be received by 11:59 p.m. Eastern Time on the date the document is due, unless another time is specified by the Judge. Within an hour of a document being electronically filed, the OALJ E-Filing System will generate an electronic receipt of the submission that will be sent by email to both the party submitting the document and the Headquarters Hearing Clerk.⁶

The OALJ E-Filing System will accept any type of digital file, but the file size is limited to 70 megabytes.⁷ Electronically filed textual documents must be in Portable Document Format (“PDF”). A motion and any associated brief may be filed together through the OALJ E-Filing System. However, any documents filed in support of a brief, motion, or other filing, such as copies of proposed exhibits submitted as part of a party’s prehearing exchange, should be filed separately as an attachment. Where a party wishes to file multiple documents in support of a brief, motion, or other filing, rather than filing a separate attachment for each such document, the documents should be compiled into a single electronic file and filed as a single attachment, to the extent technically practicable. Attached to this Order is further guidance on the use of the OALJ E-Filing System for purposes of electronic filing.

Alternatively, if a party is unable to file a document utilizing the OALJ E-Filing System, e.g., the party lacks access to a computer, the party may file the document by U.S. mail or facsimile.⁸ U.S. mail is currently being delivered to this Tribunal at an offsite location on a weekly basis only, and documents sent by facsimile will also be received offsite. To file a document using U.S. mail, the document shall be sent to the following mailing address:

⁶ The emailed electronic receipt will be the filing party’s only proof that the OALJ received the submitted document. The absence or presence of a document on the OALJ’s E-Docket Database webpage, available at https://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf, or on the Agency’s Administrative Enforcement Dockets webpage, available at <https://yosemite.epa.gov/oa/rhc/epaadmin.nsf>, is not proof that the document was or was not received. If the filing party does not receive an electronic receipt within one hour after submitting the document through the OALJ E-Filing System, the Headquarters Hearing Clerk may be able to confirm receipt of the document but not earlier than one hour after the document was submitted.

⁷ If a party’s multimedia file exceeds 70 megabytes, the party may save the file on a compact disc and send it by U.S. mail to the mailing address identified in this Order, or the party may contact the Headquarters Hearing Clerk at (202) 564-6281 for instructions on alternative electronic filing methods.

⁸ Because of the ongoing COVID-19 pandemic, this Tribunal’s ability to receive filings and correspondence by U.S. mail and facsimile is limited. If a party is without access to a computer and must file documents by U.S. mail or facsimile, the party shall notify the Headquarters Hearing Clerk *every time* it files a document in such a manner by calling the Headquarters Hearing Clerk at (202) 564-6281.

At this time, the Tribunal is not able to accept filings or correspondence by courier or commercial delivery service, such as UPS, FedEx, and DHL. Likewise, the physical office of the OALJ is not currently accessible to the public, and the Tribunal is not able to receive documents by personal delivery. *See* Order Urging Electronic Service and Filing (April 10, 2020).

Mary Angeles, Headquarters Hearing Clerk
U.S. Environmental Protection Agency
Office of Administrative Law Judges
1200 Pennsylvania Ave., NW
Mail Code 1900R
Washington, DC 20460

Facsimile may be used to file a document if it is fewer than 20 pages in length. To file a document using facsimile, the document shall be sent to this Tribunal's offsite location at (916) 550-9639. A document submitted by U.S. mail or facsimile is considered "filed" when the Headquarters Hearing Clerk physically receives it, as reflected by the inked date stamp physically applied by the Headquarters Hearing Clerk to the paper copy of the document.

Regardless of the method of filing, all filed documents must be signed in accordance with 40 C.F.R. § 22.5(c) and must contain the contact name, telephone number, mailing address, and email address of the filing party or its authorized representative.

A copy of each document filed in this proceeding shall also be "served" by the filing party on the presiding judge and on all other parties. 40 C.F.R. § 22.5(b). While the Rules of Practice ordinarily allow documents to be served by U.S. mail, commercial delivery service, or personal delivery, as well as by facsimile or email if service by those electronic means is consented to in writing, 40 C.F.R. § 22.5(b)(2), this Tribunal strongly encourages parties to serve all documents on opposing parties by electronic means only, *see* Order Urging Electronic Service and Filing (April 10, 2020). Documents filed electronically through the OALJ E-Filing System are deemed to have also been served electronically on the presiding judge. To serve a document on the presiding judge by U.S. mail or facsimile, the mailing address or facsimile number listed above shall be used. Service will be considered complete upon mailing or upon electronic transmission. 40 C.F.R. § 22.7(c).

Every filed document must show how and when the document was filed with the Headquarters Hearing Clerk and how and when the document was served on the presiding judge and each other party. This showing may be made through a written statement or Certificate of Service, an example of which is attached to this Order. 40 C.F.R. § 22.5(a)(3).

The parties are advised NOT to include, attach, or refer to any terms of settlement offers or agreements in any document submitted to the undersigned, and no copies of Consent Agreements and Final Orders shall be submitted, or attached to any document submitted, to the undersigned except those that are fully executed and filed with the Regional Hearing Clerk.

Privacy Act Statement; Notice of Disclosure of Confidential and Personal Information; Waiver of Confidentiality and Consent to Public Disclosure. The parties are cautioned that, unless redacted, all information filed with the OALJ will be made publicly available. Thus, the parties are hereby advised not to file any Confidential Business Information ("CBI") or Personally Identifiable Information ("PII") pertaining to any person. This may include information that, if disclosed to the public, would constitute an unwarranted invasion of

personal privacy, such as Social Security numbers, medical records, and personal financial information.

Where filing of such information is necessary, the parties are hereby advised to redact (i.e., remove or obscure) the CBI or PII present in the materials filed. If the filing party wishes for the presiding judge to view and consider the CBI or PII in making a ruling a rendering a decision, the filing party *must* follow the procedures specified on the OALJ's website at www.epa.gov/alj and in 40 C.F.R. Part 2 to protect the given information against public disclosure. *To the extent that any person fails to adhere to those procedures and files any unredacted CBI or PII pertaining to themselves or their client, that person thereby waives any claims to confidentiality and consents to public disclosure by EPA, including posting on the Internet, of all such information.*

Contact Information. For any questions about this Order, the Rules, or any other procedural, scheduling, or logistical issues, you may contact Emilie Schwartz, Attorney-Advisor, at (202) 565-2239 or schwartz.emilie@epa.gov.

SO ORDERED.



Susan L. Biro
Chief Administrative Law Judge

Dated: August 8, 2022
Washington, D.C.

In the Matter of *Professional Contract Sterilization, Inc.*, Respondent.
Docket No. CAA-01-2022-0059

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Prehearing Order**, dated August 8, 2022, and issued by Chief Administrative Law Judge Susan L. Biro, was sent this day to the following parties in the manner indicated below.



Mary Angeles
Paralegal Specialist

Copy by OALJ E-Filing System to:
Mary Angeles, Headquarters Hearing Clerk
U.S. Environmental Protection Agency
Office of Administrative Law Judges
Ronald Reagan Building, Room M1200
1300 Pennsylvania Ave., NW
Washington, DC 20004

Copy by Electronic and Regular Mail to:
Michael Wagner, Senior Enforcement Counsel
U.S. Environmental Protection Agency, Region 1
5 Post Office Square, Suite 100 (Mail Code OES 04-3)
Boston, MA 02109-3912
Email: wagner.michael@epa.gov
Counsel for Complainant

Robert A. Fasanella, Esq.
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53 State Street, 15th Floor
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Email: rfasanella@rubinrudman.com
Counsel for Respondent

Dated: August 8, 2022
Washington, D.C.

**OFFICE OF ADMINISTRATIVE LAW JUDGES
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C.

GUIDANCE ON USE OF OALJ E-FILING SYSTEM

The Office of Administrative Law Judges (“OALJ”) utilizes a web-based tool known as the OALJ E-Filing System to allow registered users to file documents electronically. Sending a document to oaljfilings@epa.gov or an email address of a staff member within the OALJ is not a valid method of electronic filing, unless otherwise specified in writing by the presiding Administrative Law Judge. The OALJ E-Filing System is accessible at www.epa.gov/alj. Documents filed electronically are deemed to constitute both the original and one copy of the document, and are deemed to have been both filed with the Headquarters Hearing Clerk and served electronically on the presiding Administrative Law Judge.

Any party choosing to file electronically must first register with the OALJ E-Filing System at https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf. Registration is not automated. There may be a delay of one to two business days between the time a party applies for registration and the time at which the party is able to upload documents into the system. Parties are advised to plan accordingly.

To be considered timely, documents submitted through the OALJ E-Filing System must be received by 11:59 p.m. Eastern Time on the day the document is required to be filed, unless another time is specified by the presiding Administrative Law Judge. Immediately upon reception by the OALJ E-Filing System, the document will be marked with the official filing date and time. The OALJ E-Filing system will then generate an electronic receipt of the submission that will be sent by email to both the party submitting the document and the Headquarters Hearing Clerk. There may be a delay of approximately one hour between submission of the document and transmission of the electronic receipt.

The OALJ E-Filing System will accept any type of digital file, but the file size is limited to 70 megabytes. Electronically filed textual documents must be in Portable Document Format (“PDF”).

A motion and any associated brief may be filed together through the OALJ E-Filing System. However, any documents filed in support of a brief, motion, or other filing, such as copies of proposed exhibits submitted as part of a party’s prehearing exchange of information, should be submitted separately as an attachment. Where a party wishes to file multiple documents in support of a brief, motion, or other filing, rather than filing a separate attachment for each such document, the documents should be compiled into a single electronic file and filed as a single attachment, to the extent technically practicable. For example, where a party is filing copies of 12 proposed exhibits as part of its prehearing exchange, those 12 proposed exhibits should be submitted together as one attachment consisting of a single electronic file, to the extent technically practicable.

The OALJ E-Filing System is not equipped either to accommodate or to protect the privacy of confidential business information (“CBI”) or sensitive personally identifiable information (“PII”) that could be used to identify or trace an individual, such as Social Security numbers, medical records, or personal financial information. If a party wishes to electronically file a document containing such information, the party shall redact (i.e., remove or obscure) that information from the document before filing the redacted version of the document through the OALJ E-Filing System. If the party wishes for the presiding Administrative Law Judge to consider the CBI or PII contained in the document, the party shall also file a paper copy of the unredacted version of the document by means other than the OALJ E-Filing System, in accordance with the procedures specified on the OALJ’s website at www.epa.gov/alj. To the extent that any person files any un-redacted CBI or PII through the OALJ E-Filing System, that person thereby waives any claims to confidentiality and consents to public disclosure of all such information.