

§ 17.21 Prehearing conferences.

(a) The presiding officer may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the presiding officer shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The presiding officer may use a prehearing conference to discuss the following:

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery and scheduling dates for completion of discovery;

(9) The date, time, and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The presiding officer shall issue an order containing all matters agreed upon by the parties or ordered by the presiding officer at a prehearing conference.

§ 17.23 Discovery.

(a) No later than 60 days prior to the hearing, unless otherwise ordered by the presiding officer, a party may make a request to another party for production, inspection, and copying of documents that are relevant to the issues before the presiding officer. Documents must be provided no later than 30 days after the request has been made.

(b) For the purpose of this part, the term *documents* includes information, reports, answers, records, accounts, pa-

pers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form readily accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions, and any forms of discovery, other than those permitted under paragraphs (a) and (e) of this section, are not authorized.

(d)(1) Within 10 days of service of a request for production of documents, a party may file a motion for a protective order.

(2) The presiding officer may grant a motion for a protective order, in whole or in part, if he or she finds that the discovery sought:

(i) Is unduly costly or burdensome,

(ii) Will unduly delay the proceeding, or

(iii) Seeks privileged information.

(3) The burden of showing that a protective order is necessary shall be on the party seeking the order.

(4) The burden of showing that documents should be produced is on the party seeking their production.

(e) The presiding officer shall order depositions upon oral questions only upon a showing that:

(1) The information sought cannot be obtained by alternative methods, and

(2) There is a substantial reason to believe that relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing.

§ 17.25 Exchange of witness lists, witness statements, and exhibits.

(a) At least 30 days before the hearing, or by such other time as is specified by the presiding officer, the parties shall exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including written testimony.

(b)(1) If a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the presiding officer will exclude such evidence if he or she determines that the failure to comply

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with paragraph (a) of this section should result in its exclusion.

(2) Unless the presiding officer finds that extraordinary circumstances justified the failure to make a timely exchange of witness lists under paragraph (a) of this section, he or she must exclude from the party's hearing evidence the testimony of any witness whose name does not appear on the witness list.

(3) If the presiding officer finds that extraordinary circumstances existed, the presiding officer must then determine whether the admission of the testimony of any witness whose name does not appear on the witness lists exchanged under paragraph (a) of this section would cause substantial prejudice to the objecting party. If the presiding officer finds that there is not substantial prejudice, the evidence may be admitted. If the presiding officer finds that there is substantial prejudice, the presiding officer may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless a party objects within 5 days prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 17.27 Hearing subpoenas.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may, when authorized by law, request that the presiding officer issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 20 days before the date fixed for the hearing unless otherwise allowed by the presiding officer, upon a showing by the party of good cause. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

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(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed for service of a complaint in § 17.7.

(f) If a party or the individual to whom the subpoena is directed believes a subpoena to be unreasonable, oppressive, excessive in scope, or unduly burdensome, or if it wishes to raise any other objection or privilege recognized by law, the party or individual may file a motion to quash the subpoena within 10 days after service or on or before the time specified in the subpoena for compliance if it is less than 10 days after service. Such a filing will state the basis for the motion to quash. The presiding officer may quash or modify the subpoena or order it implemented, as justice may require.

§ 17.28 Protective order.

(a) A party or a prospective witness may file a motion for a protective order with respect to discovery sought by a party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) When issuing a protective order, the presiding officer may make any order which justice requires to protect a party or person from oppression or undue burden or expense, or to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under 21 CFR part 20. Such orders may include, but are not limited to, one or more of the following:

- (1) That the discovery not be had;
- (2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;
- (3) That the discovery may be had only through a method of discovery provided for by this part other than that requested;
- (4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;