AGENCY: Board of Pharmacy

RULE CITATION: All Rules Submitted

DEADLINE FOR RECEIPT: Monday, July 6, 2020

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

Please confirm that these rules were adopted after the close of the public hearing on May 26, 2020.

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2001

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In the Submission for Permanent Rule form, Box 2, please insert the new name of the rule. Please note, you will not strike the old name, but simply replace it.

In (a), line 4, what do you mean by "before service"?

In (b)(2), lines 12-13, consider simplifying this language and stating "While investigating, preparing for, or during a contested case..."

On lines 12-13, what do you mean by "among others who are authorized to serve subpoenas"? Who are you referring to?

In (b)(3), consider removing the parenthesis and separating the clause with commas.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder Commission Counsel Date submitted to agency: June 22, 2020

1	21 NCAC 46 .2	001 is amended as published in 34:18 NCR 1723 as follows:
2		
3	21 NCAC 46 .2	001 <u>FILING AND SERVICE</u> RIGHT TO HEARING
4	(a) Parties shal	l file all papers provided for in this Section with the Board, either before service or within five days
5	after service. The	ne Board shall consider a paper to be filed when the Board actually receives it. Parties shall direct
6	filings to the Inv	vestigations and Inspections Coordinator, North Carolina Board of Pharmacy, 6105 Farrington Road,
7	Suite 201, Chap	el Hill, North Carolina 27517.
8	(b) In addition	to filing all papers with the Board, the Board and other parties shall serve all papers as follows:
9	<u>(1)</u>	The Board shall serve a notice of hearing under Rule .2006 of this Section on all parties by any
10		method for service of process permitted by G.S. 150B-38(c).
11	<u>(2)</u>	Parties shall serve subpoenas under Rule .2013 of this Section by any method for service permitted
12		by G.S. 150B-39(c). In investigation or preparation for, or in the conduct of, a contested case, among
13		others who are authorized to serve subpoenas, Board staff may serve subpoenas on behalf of the
14		Board, pursuant to G.S. 1A-1, Rule 45.
15	<u>(3)</u>	Parties shall serve all other papers in the contested case on all parties (including counsel to the
16		Board) by any method for service permitted by G.S. 1A-1, Rule 5.
17	<u>(4)</u>	The Board shall serve all its orders by any method for service permitted by G.S. 150B-42(a).
18	(a) When the B	oard acts or proposes to act, other than in rulemaking or declaratory ruling proceedings, in a manner
19	which will affe	et the rights, duties, or privileges of a specific, identifiable person, such person has the right to an
20	administrative h	earing. When the Board proposes to act in such a manner, it shall give such person notice of the right
21	to a hearing by r	nailing by certified mail to that person at the last known address of that person a notice of the proposed
22	action and a not	ice of a right to a hearing.
23	(b) Prior to issu	ing the notice called for in Paragraph (a) of this Rule, and with the consent of the party or parties, the
24	Board may atter	npt to settle disputes through the informal procedures set out in Rule .2008(a) of this Section.
25		
26	History Note:	Authority G.S. 90-85.6; <u>90-85.38;</u> 150B 11; 150B 22; 150B-38; <u>150B-39; 150B-40;</u> 150B-41;
27		<u>150B-42:</u>
28		Eff. April 1, 1983;
29		Amended Eff. October 1, 1990; May 1, 1989; July 1, 1988; March 1, 1987;
30		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
31		<u>2017:</u> 2017.
32		Amended Eff. August 1, 2020.

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2004

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 5, you refer to "substantially affected that person's rights, duties, or privileges." Is the idea to address the definitions "contested case" and "person aggrieved" in G.S. 150B-2? If not, what does that phrase mean?

In (b)(1), to be consistent with the rest of the Subparagraphs, consider beginning this with an article.

In (b)(2) and (3), lines 14 and 16, what do you mean by "concise"? Who determines it?

In (b)(4), by "explicit' I take it you mean that there must be a stated request for a hearing?

1	21 NCAC 46 .20	004 is amended as published in 34:18 NCR 1723 as follows:
2		
3	21 NCAC 46 .2	004 REQUEST FOR HEARING
4	(a) Any time a	n individual If a person believes that a Board administrative action has substantially affected that
5	individual's pers	on's rights, duties, or privileges have been affected substantially by the Board's administrative action,
6	but <u>that person</u>	has not received <u>a</u> notice of a right to an administrative hearing, that individual person may file a
7	formal request f	or a hearing.
8	(b) Before an in	ndividual may file a request, that individual is encouraged to exhaust all reasonable efforts to resolve
9	the issue inform	ally with the Board.
10	(c) Subsequent	to such informal action, if still dissatisfied, the individual may submit a request to the Board's office,
11	with the request	bearing the notation: REQUEST FOR ADMINISTRATIVE HEARING. The request for hearing shall
12	contain the follo	wing information:
13	(1)	petitioner's name and address; address of the petitioner;
14	(2)	a concise statement of the Board action that the petitioner challenges: taken by the Board which is
15		challenged;
16	(3)	a concise statement of the way in which the petitioner has been aggrieved; and
17	(4)	a clear and specific an explicit statement of request for a hearing.
18	(d) A <u>(c) In o</u>	rder to preserve a person's rights with respect to a Board action, the person shall file a request for
19	administrative h	earing must be submitted to with the Board Board's office within 60 days after the person receives of
20	receipt of notice	of the Board action taken by the Board that the person challenges. which is challenged. The request
21	will be acknowl	edged promptly and, if deemed appropriate by the Board in accordance with 21 NCAC 46 .2005, a
22	hearing shall be	scheduled.
23		
24	History Note:	Authority G.S. 90-85.6; 150B-38;
25		Eff. September 1, 1988;
26		Amended Eff. August 1, 2002;
27		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
28		<u>2017;</u> 2017.
29		<u>Amended Eff. August 1, 2020.</u>

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2005

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 4, to mirror the language in (b), I suggest replacing "will" with "shall"

I also recommend replacing "will" with "shall" on line 5.

I take it on line 6 that this notice will be pursuant to G.S. 150B-38(b)?

1	21 NCAC 46 .20	005 is amended as published in 34:18 NCR 1723 as follows:
2		
3	21 NCAC 46 .2	005 GRANTING OR DENYING HEARING REQUEST
4	(a) The Board v	will grant a request for a hearing if it determines that the party requesting the hearing petitioner is a
5	"person aggrieve	ed" within the meaning of G.S. 150B-2(6). The Board will provide notice of the time and place for the
6	<u>hearing. If the p</u>	arty fails to appear, the Board may deny the party's request for failure to prosecute it or may proceed
7	to hear the matte	er in the party's absence.
8	(b) If the Board	determines the petitioner is not a person aggrieved, the Board shall issue a denial that shall constitute
9	<u>a final agency d</u>	ecision. The denial of request for a hearing will be issued immediately upon decision, and in no case
10	later than 60 day	rs after the submission of the request. Such denial shall contain a statement of the reasons leading the
11	Board to deny th	le request.
12	(c) Approval of	a request for a hearing will be signified by the issuing of a notice as required by G.S. 150B-38(b) and
13	explained in Rul	e .2006 of this Section.
14		
15	History Note:	Authority G.S. 90-85.6; 150B-11; 150B-38; <u>150B-40; 150B-42;</u>
16		Eff. July 1, 1988;
17		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
18		<u>2017; 2017.</u>
19		<u>Amended Eff. August 1, 2020.</u>

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2006

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 5 and (d), line 21, what are these "other privileges"? Does your regulated public know?

In (b), line 12, since you defined "service" as receipt in Rule .2001(a), requiring service within 10 days of the hearing conflicts with G.S. 150B-38(d), which requires mailing within 10 days before the hearing. Please amend this Rule to comply with the statute.

On line 14, do not use "should" in a rule. Why note state "... the party shall state this in the written response..."

On line 14, consider replacing "will" with "shall"

In (c), this is one long sentence. Consider breaking it up by ending the sentence on line 18, stating "allegations of the notice admitted." Then state "The Board may..." (And yes, I am recommending deleting "to be" between "notice" and "admitted")

In (d), lines 20 and 28, I recommend inserting a comma after "safety"

On line 24, so that I'm clear – you are saying the order is valid, even though it won't be effective without service pursuant to G.S. 150B-3(c)?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder Commission Counsel Date submitted to agency: June 22, 2020

10

21 NCAC 46 .2006 is amended as published in 34:18 NCR 1723 as follows:

3 21 NCAC 46 .2006 NOTICE OF HEARING

4 (a) Before imposing final discipline under G.S. 90-85.38 on a person who holds a license, registration, permit, or

5 other privilege issued by the Board, the Board shall file and serve a notice of hearing pursuant to G.S. 150B-38(b).

6 The Board shall give the party or parties in a contested case a notice of hearing not less than 15 days before the hearing.

- 7 Said notice shall contain the following information, in addition to the items specified in G.S. 150B-38(b):
- 8 (1) the name, position, address and telephone number of a person at the offices of the Board to contact
 9 for further information or discussion;

(2) the date, time, and place for a pre hearing conference, if any; and

11 (3) any other information deemed relevant to informing the parties as to the procedure of the hearing.

12 (b) <u>A party who has been served with a notice of hearing may file and serve a written response not less than 10 days</u>

13 before the date set for the hearing. If the party wishes to submit this written response instead of personally appearing

14 at the hearing, the party should note that desire in the written response, and the Board will consider the written response

15 <u>in lieu of a personal appearance.</u>

16 (c) If a party who has been served with a notice of hearing neither appears pursuant to the notice nor files and serves

17 <u>a written response as set out in Paragraph (b) of this Rule, the Board shall rule the party to be in default and the</u>

- 18 allegations of the notice to be admitted, and the Board may enter a final agency decision by default granting any relief
- 19 available to the Board.

20 (d) If the Board determines that the public health, safety or welfare requires such action, it may issue an order 21 summarily suspend suspending a license, registration, permit, or other privilege granted by the Board. license or 22 permit. Upon service of the order, the licensee licensee, registrant, or permit holder to whom the order is directed shall 23 immediately eease the practice of stop practicing pharmacy or cease the dispensing of and stop dispensing devices 24 and medical equipment in North Carolina. Failure to receive the order shall not invalidate the order. The Board shall promptly give notice of hearing pursuant to G.S. 150B-38 following service of the order. The suspension shall remain 25 in effect pending issuance by the Board of a final agency decision pursuant to G.S. 150B-42. However, pursuant to 26 27 Rules .2004 and .2005 of this Section, a person subject to a summary suspension may request a hearing on whether 28 the public health, safety or welfare permits terminating or modifying the terms of the summary suspension pending a final agency decision. Neither an order of summary suspension nor a decision on whether the summary suspension 29

- 30 order shall be terminated or modified is a final agency decision.
- 31
- 32 History Note: Authority G.S. 90-85.6; <u>90-85.12</u>; <u>90-85.38</u>; <u>150B-3</u>; <u>150B-3</u>; <u>150B-11</u>; 150B-38; <u>150B-40</u>;
 33 <u>150B-42</u>;
- 34 *Eff. July 1, 1988;*
- 35 Amended Eff. September 1, 1995; May 1, 1989;
- Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
 2017; 2017.

Amended Eff. August 1, 2020.

1

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2007

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (b), lines 7 and 9, please consider inserting a comma after "absent"

21 NCAC 46 .2007 is amended as published in 34:18 NCR 1723 as follows:

- 3 21 NCAC 46 .2007 WHO SHALL HEAR CONTESTED CASES
 - 4 (a) All administrative hearings shall be conducted by the Board, a panel consisting of a <u>A</u> majority of the Board shall
 - 5 conduct all hearings, as set forth in G.S. 150B-40(b), except as provided in the members of the Board, or an
 - 6 administrative law judge designated to hear the case pursuant to G.S. 150B-40(e).
 - 7 (b) The Board President shall be the presiding officer at any hearing, unless the President is disqualified, absent or
 - 8 otherwise determines that he or she is unable to serve in that capacity. In the event that the President does not preside,
 - 9 the Board Vice President shall be the presiding officer at any hearing, unless the Vice President is disqualified, absent
- 10 or otherwise determines that he or she is unable to serve in that capacity. In the event that neither the President nor the
- 11 Vice President preside, the Board shall designate another presiding officer. The presiding officer shall have all duties
- 12 and powers set forth in G.S. 150B-40(c). Matters involving device and medical equipment permit holders shall be
- 13 initially heard by a device and medical equipment subcommittee. The subcommittee shall be elected pursuant to
- 14 Section .2100 of this Chapter. Prior to issuing a notice of hearing, the subcommittee and the party or parties may agree
- 15 to follow the informal procedures set out in Rule .2008 of this Section.
- 16 (c) After hearing the matter, the device and medical equipment subcommittee shall propose a recommended decision
- 17 to the Board. Sanctions shall be consistent with G.S. 90-85.38. If the Board accepts the recommended decision, it shall
- 18 constitute a final agency decision for the right to judicial review. If the Board rejects the recommended decision, the
- 19 Board may propose an alternative decision or schedule the matter for a formal hearing before the Board.
- 20 21

22

History Note: Authority G.S. 90-85.6; <u>90-85.12</u>; 150B-11; 150B-38; 150B-40;

- Eff. July 1, 1988;
- 23 Amended Eff. September 1, 1995;
- 24 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
- 25 <u>2017; 2017.</u>
- 26 <u>Amended Eff. August 1, 2020.</u>

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2008

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

So that I'm clear – this rule addresses settlement that is contemplated by G.S. 150B-22, right? If so, you may want to add that to your History Note.

In (a), line 5, do you mean "or" instead of "of"?

On line 7, what do you mean by "prompt"? Do you even need it here – wouldn't "aid in the disposition" suffice?

In (a)(4), I take it that "appropriate" notice will be the notice required by G.S. 150B-38?

In the History Note, line 31, please separate the citations to G.S. 150B-38 and 39 with a semicolon, not a comma.

21 NCAC 46 .2008 is amended as published in 34:18 NCR 1723 as follows:

3 21 NCAC 46 .2008 **INFORMAL PROCEDURES** 4 (a) Prior to Before issuing a notice of hearing, the Board or the device and medical equipment subcommittee and the 5 party or parties may agree to conduct one of more conferences a conference in which a member of the Board or the 6 device and medical equipment subcommittee and the party or parties meet to consider the possibility of disposing of 7 resolving the dispute without a hearing or any other matter as may aid in the prompt disposition of the dispute. If such 8 a conference is held, the Board, or the device and medical equipment subcommittee, The member of the Board may 9 direct one or more of the following dispositions: 10 Submission to the Board with a recommendation to dismiss with no action; (1)11 (2)Submission to the Board with a recommendation that Board staff provide informal guidance to 12 resolve the dispute; 13 Submission to the Board with a recommendation to resolve the dispute or to expedite the hearing (2)(3)14 by consent order; consent; or 15 Scheduling, with appropriate notice, for contested case hearing. (3)(4)16 The Board must approve all recommendations under Subparagraphs (1), (2) and (3) of this Paragraph. All recommendations of dismissal must be approved by the Board. Any consent order proposed may dispose of the dispute 17 18 or set forth such matters as were agreed to between the parties that may expedite the hearing. All matters contained in 19 the consent order must be agreed to by the party or parties and approved by the Board at its next regular meeting. The 20 Board member or member of the device and medical equipment subcommittee who participated in the conference may 21 participate in Board discussions concerning any recommendation made but may not vote upon the recommendation. 22 The Board member who participated in the conference shall disqualify himself or herself in accordance with 21 NCAC 23 46..2011 Rule .2011 of this Section from participation in any hearing or decision in the matter discussed in the 24 conference if the matter results in a contested case hearing before the Board. 25 (b) After issuance of a notice of hearing, the The Board or the device and medical equipment subcommittee and the 26 party or parties may agree in advance to simplify the hearing by stipulation or any other method provided by G.S. 150B-41(c). by: decreasing the number of issues to be contested at the hearing; accepting the validity of certain 27 28 proposed evidence; accepting the findings in some other case with relevance to the case at hand; or agreeing to such 29 other matters as may expedite the hearing. 30 31 History Note: Authority G.S. 90-85.6; 150B-38, 150B-39; 150B-40; 150B-41; 150B-42; 32 Eff. July 1, 1988; 33 Amended Eff. April 1, 2001; September 1, 1995; October 1, 1990; May 1, 1989; 34 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, <u>2017;</u> 2017. 35 36 Amended Eff. August 1, 2020.

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2009

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In the Submission for Permanent Rule form, Box 2, please insert the new name of the rule. Please note, you will not strike the old name, but simply replace it.

1	21 NCAC 46 .2	009 is amended as published in 34:18 NCR 1723 as follows:
2		
3	21 NCAC 46 .2	009 <u>MOTIONS</u> PETITION FOR INTERVENTION
4	Except as other	wise provided in this Section, parties must file and serve motions related to a contested case at least
5	<u>ten days before</u>	the hearing, except those made during the hearing. The presiding officer may decide to hear pre-
6	hearing motions	either before the hearing or at the hearing before witnesses testify.
7	(a) A person de	siring to intervene in a contested case must file a written petition with the Board's office. The request
8	should bear the	notation: PETITION TO INTERVENE IN THE CASE OF (Name of case).
9	(b) The petition	must include the following information:
10	(1)	the name and address of petitioner;
11	(2)	the business or occupation of petitioner, where relevant;
12	(3)	a full identification of the hearing in which petitioner is seeking to intervene;
13	(4)	the statutory or non-statutory grounds for intervention;
14	(5)	any claim or defense in respect of which intervention is sought; and
15	(6)	a summary of the arguments or evidence petitioner seeks to present.
16	(c) The moving	party must serve copies of the petition on all parties to the case.
17	(d) If the Board	determines to allow intervention, notice of that decision will be issued promptly to all parties, and to
18	the petitioner. In	n cases of discretionary intervention, such notification will include a statement of any limitations of
19	time, subject ma	tter, evidence or whatever else is deemed necessary which are imposed on the intervenor.
20	(e) If the Board	d's decision is to deny intervention, the petitioner will be notified promptly. Such notice will be in
21	writing, identify	ing the reasons for the denial, and will be issued to the petitioner and all parties.
22		
23	History Note:	Authority G.S. 90-85.6; 150B-11; 1 50B-38; <u>150B-39; 150B-40; 150B-41;</u>
24		Eff. July 1, 1988;
25		Amended Eff. May 1, 1989;
26		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
27		<u>2017; 2017.</u>

28 <u>Amended Eff. August 1, 2020.</u>

1	21 NCAC 46 .20	10 is repealed as published in 34:18 NCR 1723 as follows:
2		
3	21 NCAC 46 .20	10 TYPES OF INTERVENTION
4		
5	History Note:	Authority G.S. 90-85.6; 150B-11; 150B-38;
6		Eff. July 1, 1988;
7		Amended Eff. May 1, 1989;
8		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
9		<u>2017:</u> 2017.
10		<u>Repealed Eff. August 1, 2020.</u>

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2011

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

Consider making the language in (b), lines 13-19, into its own paragraph.

On line 17, please replace the parenthesis with commas

In (c), line 28, consider inserting a "when" between "only" and "based"

On line 29, I take it "newly discovered" will be by the party? And is "due diligence" known to your regulated public?

On line 30, what is a "timely" motion? Where are you setting a timeframe for filing these? Is it timely if it is filed 10 days or more before the hearing?

In (d), line 36, replace "will" with "shall"

What is the purpose of the sentence on lines 36-37? Will the Board decide to hold a new hearing sometimes when this happens?

In (f), line 4, replace "will" with "shall"

- 1 2
- 3 21 NCAC 46 .2011 **DISOUALIFICATION OF BOARD MEMBERS** (a) Self disqualification. If for any reason a Board member determines that personal bias or other reason for that 4 5 Board member's disqualification exists in factors renders that Board member unable to hear a contested case, case and 6 perform all duties in an impartial manner, that Board member shall voluntarily decline to participate in the hearing or 7 decision. 8 (b) Petition for disqualification. If for any reason any party in a contested case believes case, in good faith, has 9 evidence that a Board member is personally biased or another reason for disqualification exists, otherwise unable to 10 hear a contested case and perform all duties in an impartial manner, the party may file and serve a motion for 11 disqualification, which must be supported by a sworn, notarized affidavit testifying to the facts relevant to disqualification. with the Board. The title of such affidavit should bear the notation: AFFIDAVIT OF 12 13 DISQUALIFICATION OF BOARD MEMBER IN THE CASE OF (Name of case). Ex parte communication by or 14 on behalf of a party with a Board member about the facts of a case at any time during either the investigation or 15 prosecution of potential violations shall be grounds for disqualification of that Board member, other than communications by Board counsel and staff during the course of seeking a summary suspension or communications 16 17 during any other proceeding before the Board. Before a hearing begins (or during the hearing, if applicable), both the 18 Board member and the party must disclose the communications between the Board member and a party about the facts 19 of the case to the Board and to the parties. (c) Contents of affidavit. The affidavit must state all facts the party deems to be relevant to the disqualification of the 20 21 Board member. 22 (d) Timeliness of affidavit. 23 (1)An affidavit of disqualification will be considered timely if filed ten days before commencement of 24 the hearing. Any other affidavit will be considered timely provided it is filed at the first opportunity after the party becomes aware of facts which give rise to a reasonable belief that a Board member 25 26 may be disqualified under this Rule. 27 (2)Where an affidavit for disqualification is filed A party may file and serve a motion for 28 disqualification less than then ten days before or during the course of a hearing hearing, only based 29 on newly discovered evidence that by due diligence could not have been discovered in time to file 30 a timely motion. Under these circumstances, the hearing shall continue with the challenged Board 31 member sitting. Petitioner shall have the opportunity to present evidence supporting the petition, 32 and the petition and any evidence relative thereto presented at the hearing shall be made a part of 33 the record. 34 The Board Board, before rendering its decision, shall decide whether the evidence requires justifies (d) 35 disqualification. disqualification before it renders the final agency decision in the contested case. The decision about 36 the disqualification of a Board member will be made by the other Board members. The Board is not required to grant 37 a new hearing if a Board member is disqualified during the course of a hearing.

21 NCAC 46 .2011 is amended as published in 34:18 NCR 1723 as follows:

1	(e) The presiding officer may determine the method of resolving the motion for disqualification in the presiding			
2	officer's discretion under G.S. 150B-40. This may include the authority to direct that the Board's Executive Director			
3	oversee an inve	oversee an investigation of the allegations and report the findings to the Board.		
4	(f) In the event	(f) In the event of disqualification, the disqualified member will not participate in further deliberation or decision of		
5	the case.			
6	(e) Procedure for determining disqualification.			
7	(1)	The Board will appoint a Board member to investigate the allegations of the affidavit.		
8	(2)	The investigator will report findings to the Board and make recommendations.		
9	(3)	The Board shall decide whether to disqualify the challenged individual.		
10	(4)	The person whose disqualification is to be determined will not participate in the decision case but		
11		may be called on upon to furnish information to the other members of the Board.		
12	(5)	When a Board member is disqualified prior to the commencement of the hearing or after the hearing		
13		has begun, such hearing will continue with the remaining members sitting provided that the		
14		remaining members still constitute a majority of the Board.		
15	(<u>6)(g)</u> If three o	r more members of the Board are disqualified pursuant to this Rule, the Board shall petition the Office		
16	of Administrati	ve Hearings to appoint an administrative law judge to hear the contested case pursuant to G.S.		
17	150B-40(e).			
18				
19	History Note:	Authority G.S. 90-85.6; 150B-11; 150B-38; <u>150B-39;</u> 150B-40; <u>150B-41;</u>		
20		Eff. July 1, 1988;		
21		Amended Eff. May 1, 1989;		
22		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,		
23		<u>2017;</u> 2017.		
24		Amended Eff. August 1, 2020.		

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2013

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 6, please insert a comma after "counsel"

Also, can't the presiding officer issue or sign subpoenas pursuant to G.S. 150B-40(c)(2)? Or is this to address subpoenas issued before the Board has convened to hear the case?

In (b), line 8, consider replacing "along with" with "and pay" because right now, it reads that the fees will be served.

21 NCAC 46. 2013 is amended as published in 34:18 NCR 1723 as follows:

2 3

21 NCAC 46 .2013 SUBPOENAS

- 4 (a) A party shall file and serve a request for a subpoena, attaching a proposed subpoena. A form of subpoena is
- 5 available on the Board's website at ncbop.org/lawandrules.htm. The Board may issue the subpoena in accordance with
- 6 G.S. 150B-39(c). Subpoenas must be issued and signed by the Board's Executive Director, the Board's legal counsel
- 7 or a Board staff member designated by the Executive Director.
- 8 (b) The party shall serve the subpoena along with the fees and expenses required by G.S. 150B-39(c).
- 9 (c) After service of the subpoena, the party serving the subpoena shall file and serve sworn proof of the method of
- 10 service, demonstrating compliance with G.S. 150B-39(c).
- 11 (d) G.S. 150B-39(c) governs the recipients' duties in responding to subpoenas. A party to the case or person subject
- 12 to the subpoena may object to a subpoena by filing a motion to quash. The movant shall file and serve the motion to
- 13 quash within 10 days of service of the subpoena or seven days before the contested case hearing, whichever is sooner.
- 14 The Board shall hear and rule on objections as provided in G.S. 150B-39(c).
- 15 (a) Requests for subpoenas for the attendance and testimony of witnesses or for the production of documents, either
- 16 at a hearing or for the purposes of discovery, shall be made in writing to the Board and shall identify any document
- 17 sought with specificity, and shall include the full name and home or business address of all persons to be subpoenaed
- 18 and, if known, the date, time, and place for responding to the subpoena. The Board shall issue the requested subpoenas
- 19 within three days of receipt of the request.
- 20 (b) Subpoenas shall contain: the caption of the case; the name and address of the person subpoenaed; the date, hour
- 21 and location of the hearing in which the witness is commanded to appear; a particularized description of the books,
- 22 papers, records or objects the witness is directed to bring with him to the hearing, if any; the identity of the party on
- 23 whose application the subpoena was issued; the date of issue; the signature of one of the members of the Board or the
- 24 Board's executive director; and a "return of service." The "return of service" form as filled out, shows the name and
- 25 capacity of the person serving the subpoena, the date on which the subpoena was delivered to the person directed to
- 26 make service, the date on which service was made, the person on whom service was made, the manner in which service
- 27 was made, and the signature of the person making service.
- 28 (c) Subpoenas shall be served by the sheriff of the county in which the person subpoenaed resides, when the party
- 29 requesting such subpoena prepays the sheriff's service fee. The subpoena shall be issued in duplicate, with a "return
- 30 of service" form attached to each copy. A person serving the subpoena shall fill out the "return of service" form for
- 31 each copy and properly return one copy of the subpoena, with the attached "return of service" form completed, to the
- 32 Board.
- 33 (d) Except as otherwise stated in a particular subpoena, any person receiving a subpoena from the Board may object
- 34 thereto by filing a written objection to the subpoena with the Board's office.
- 35 (e) Such objection shall include a concise, but complete, statement of reasons why the subpoena should be revoked
- 36 or modified. These reasons may include lack of relevancy of the evidence sought, or any other reason sufficient in law

1	for holding the subpoena invalid, such as that the evidence is privileged, that appearance or production would be see		
2	disruptive as to be unreasonable in light of the significance of the evidence sought, or other undue hardship.		
3	(f) Any such objection to a subpoena must be served on the party who requested the subpoena simultaneously with		
4	the filing of the objection with the Board.		
5	(g) The party w	tho requested the subpoena, in such time as may be granted by the Board, may file a written response	
6	to the objection	The written response shall be served by the requesting party on the objecting witness simultaneously	
7	with filing the response with the Board.		
8	(h) After receipt of the objection and response thereto, if any, the Board shall issue a notice to the party who requested		
9	the subpoena and the party challenging the subpoena, and may notify any other party or parties of an open hearing, to		
10	be scheduled as	soon as practicable, at which time evidence and testimony may be presented, limited to the narrow	
11	questions raised by the objection and response.		
12	(i) Promptly after the close of such hearing, a majority of the Board members with voting authority, or an		
13	administrative law judge assigned to the case pursuant to G.S. 150B-40(e), will rule on the challenge and issue a		
14	written decision	. A copy of the decision will be issued to all parties and made a part of the record.	
15			
16	History Note:	Authority G.S. 90-85.6; 150B-11; 150B-38; 150B-39; <u>150B-40;</u>	
17		Eff. September 1, 1988;	
18		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,	
19		<u>2017; 2017.</u>	
20		<u>Amended Eff. August 1, 2020.</u>	

1 21 NCAC 46 .2014 is amended as published in 34:18 NCR 1723 as follows: 2 3 WITNESSES 21 NCAC 46 .2014 4 Any party may be a witness and may present witnesses on the party's behalf at the hearing. All oral testimony at the 5 hearing shall be under oath or affirmation and shall be recorded. At the request of a party or upon the Board's own 6 motion, the The presiding officer may exclude witnesses from the hearing room so that they cannot hear the testimony 7 of other witnesses. 8 9 History Note: Authority G.S. 90-85.6; 150B-11; 150B-38; 150B-39; 150B-40; 150B-41; 150B-42; 10 Eff. July 1, 1988; 11 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 12 <u>2017;</u> 2017.

13 <u>Amended Eff. August 1, 2020.</u>

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2015

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On line 6, please insert a comma after "law"

10

21 NCAC 46 .2015 is amended as published in 34:18 NCR 1723 as follows:

3 21 NCAC 46.2015 FINAL DECISION

4 In a contested case, the Board shall issue a final agency decision in compliance with G.S. 150B-42. All final agency

5 decisions shall be drafted by Board staff or Board counsel and presented to the presiding officer. In the event that the

6 presiding officer determines that the drafted order does not reflect the Board's findings of fact, conclusions of law or

7 ruling, the presiding officer shall revise the drafted order to reflect the Board's decision. In all cases heard by the

8 Board, the Board will issue its decision within 60 days after its next regularly scheduled meeting following the close

9 of the hearing. This decision will be the prerequisite "final agency decision" for the right to judicial review.

11 *History Note:* Authority G.S. 90-85.6; <u>90-85.38; 150B-3;</u> 150B-11; 150B-38; <u>150B-40; 150B-41;</u> 150B-42;

12 *Eff. July 1, 1988;*

- 13 Amended Eff. May 1, 1989;
- 14 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
- 15 <u>2017;</u> 2017.
- 16 <u>Amended Eff. August 1, 2020.</u>

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2016

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (b), lines 12, 16, and 17, I am only asking – do you need "specifically"? Will simply stating to refer to the pages not suffice?

On lines 13, 16, and 17, what do you mean by "precisely"?

On line 16, replace "should' with "shall"

In (c), line 24, do you mean "shall' rather than "may"? If not, then will the presiding officer not set these terms?

In (d), line 26, do you mean all of Section .2000, or the provisions of this Rule?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder Commission Counsel Date submitted to agency: June 22, 2020

21 NCAC 46 .2016 is amended as published in 34:18 NCR 1723 as follows:

2

3 21 NCAC 46 .2016 PROPOSALS FOR DECISIONS

4 (a) When an administrative law judge conducts a hearing pursuant to G.S. 150B-40(e), that statute governs the

- 5 procedures before the administrative law judge. a "proposal for decision" shall be rendered within 45 days of the
- 6 hearing pursuant to the rules of the Office of Administrative Hearings, 26 NCAC 3 .0026.
- 7 (b) Within 10 days after the proposal for decision is served on the parties under G.S. 150B-40(e), a Any party may
- 8 file and serve written exceptions to this "proposal proposal for decision decision" and submit their its own proposed
- 9 findings of fact and conclusions of law. The exceptions and alternative proposals must be filed within ten days after
- 10 the party has received the "proposal for decision" as drafted by the administrative law judge.
- 11 (b) Any exceptions to the procedure during the hearing, the handling of the hearing by the administrative law judge,
- 12 rulings on evidence, or any other matter Exceptions must be written and refer specifically to pages of the record or
- 13 otherwise precisely identify the occurrence to which exception is taken. The exceptions must be filed with the Board
- 14 within ten days of the receipt of the proposal for decision. The written exceptions should bear the notation:
- 15 EXCEPTIONS TO THE PROCEEDINGS IN THE CASE OF (Name of case). the party takes exception. Each
- 16 proposed finding of fact should refer specifically to pages of the record or otherwise precisely identify the evidence
- 17 supporting the proposed finding, and each proposed conclusion of law must refer specifically to or otherwise precisely
- 18 identify both the findings of fact and legal support for the proposed conclusion. A party may file and serve written
- 19 arguments along with the exceptions and proposed findings of fact and conclusions of law.
- 20 (c) Any A party may ask to present oral argument to the Board. Board upon request. The party must file and serve
- 21 the request with the written submissions under Paragraph (b) of this Rule. The request must be included with the
- 22 written exceptions.
- 23 (d) Upon receipt of request for further If a party requests oral argument, notice will be issued promptly to all parties
- 24 designating the Board will notice the time and place for such oral argument. The presiding officer may set the terms
- 25 of oral argument, including order of argument and time limitations.
- 26 (d) After the procedures set forth in this Section, the Board will issue a final agency decision in accordance with Rule
- 27 .2015 of this Section.
- 28 (e) Giving due consideration to the proposal for decision and the exceptions and arguments of the parties, the Board
- 29 may adopt the proposal for decision or may modify it as the Board deems necessary. The decision rendered will be a
- 30 part of the record and a copy thereof given to all parties. The decision as adopted or modified becomes the "final
- 31 agency decision" for the right to judicial review. Said decision will be rendered by the Board within 60 days of the
- 32 next regularly scheduled meeting following the oral arguments, if any. If there are no oral arguments presented, the
- 33 decision will be rendered within 60 days of the next regularly scheduled Board meeting following filing of the written
- 34 exceptions.
- 35

37

36 *History Note:*

Authority G.S. 90-85.6; 150B-11; 150B-38; 150B-40; <u>150B-41; 150B-42;</u> *Eff. July 1, 1988;*

1	Amended Eff. May 1, 1989;
2	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
3	<u>2017:</u> 2017.
4	Amended Eff. August 1, 2020.

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2017

DEADLINE FOR RECEIPT: Monday, July 6, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 5, please insert a comma after "rehearing"

On line 6, do you need "expressly provided"? Wouldn't "stated" suffice?

And I take it the order you are referring to is the specific order for the individual, made following the contested case as set forth in this Section?

In (a)(1), lines 7 and 8, please insert a comma after "registration"

On line 8, I don't think you need "(a)" and "(b)" Why not just state "... or other privilege either revoked or actively suspended..."

On line 10, please insert a comma after "rehearing"

In (a)(2), line 12, please insert a comma after "registration"

In (a)(3), line 17, please delete "(a)" and "(b)"

On line 19, please insert a comma after "rehearing"

In (a)(5), line 26, please insert a comma after "permit"

On line 28, insert an "or" before "petition"

On line 29, please insert a comma after "rehearing"

In (a)(6), consider indenting lines 33-36 thusly:

(6) For the purposes of Subparagraphs (3), (4) and (5) of this Paragraph, the Board shall treat a permit holder or proposed permit holder the same as a prior permit holder or proposed permit holder if either of the following two conditions is true:

Amanda J. Reeder Commission Counsel Date submitted to agency: June 22, 2020 (a) the permit holder or proposed permit holder has the same pharmacy manager and there is more than 10 percent common ownership as the prior permit holder or proposed permit holder; or

(b) the permit holder or proposed permit holder has 50 percent or more common ownership as the prior permit holder or proposed permit holder.

To determine common ownership under this Rule, the Board shall consider business entities to be identical to other business entities if there is more than a 50 percent common ownership. Furthermore, to determine common ownership under this Rule, the Board shall combine the interests of individuals with the interests of any business entities in which the individuals have more than a 10 percent interest, as well as with the interests of individuals in the same family.

And on line 31, please insert a comma after "(4)"

In (b), Page 2, line 5, I take it that the Board may alter the Rule in the specific order issued after a hearing?

In (c), line 7, I suggest replacing "satisfy the limits" with "meet the requirements" or "meet the time limits"

In (d), line 11, why do you need this sentence?

On line 13, please insert a comma after "permit"

On line 14, so that I'm clear – you are referring to State rules and federal regulations that govern the practice of pharmacy?

On line 14, I suggest you delete "among other things"

On line 15, please insert a comma after "suspension"

On line 16, please insert a comma after "competence"

On line 17, please insert a comma after "suspension"

3	21 NCAC 46 .201	17 REAPPLICATIONS, H	REINSTATEMENT,	REHEARING,	AND
4		RECONSIDERATION			
5	(a) The following	terms govern reapplication, reinstatemer	nt, rehearing and other recor	sideration requests from	<u>n a final</u>
6	agency decision, u	unless otherwise expressly provided in th	at order:		
7	<u>(1)</u>	No individual who holds a license, reg	gistration or other privilege	from the Board who I	has that
8		license, registration or other privilege eit	her (a) revoked or (b) active	ly suspended indefinite	<u>ly or for</u>
9		more than five years may petition for rei	instatement, to have the rev	ocation or suspended lit	fted, for
10		reconsideration or rehearing or otherwise	e for modification or rescine	ling the order, until at le	<u>east five</u>
11		years from the effective date of the revoe	cation or suspension.		
12	<u>(2)</u>	No individual who has had an application	n for a license, registration of	r other privilege from th	e Board
13		denied may submit another application of	or petition for reconsideration	on or rehearing or other	wise for
14		modification or rescinding the denial, u	until at least two years fro	m the date of the mos	t recent
15		application that the Board denied. At that	t time, the individual must s	ubmit a new applicatior	n for the
16		Board to consider.			
17	<u>(3)</u>	No permit holder who has had that perm	nit either (a) revoked or (b)	actively suspended inde	efinitely
18		or for more than five years may submit a	nother application or petitic	n for reinstatement, to h	nave the
19		revocation or suspended lifted, for reco	onsideration or rehearing or	otherwise for modification	ation or
20		rescinding the order, until at least five ye	ears from the effective date of	of the revocation or susp	pension.
21	<u>(4)</u>	No proposed permit holder who has ha	d an application for a perm	nit denied may submit	another
22		application for a permit or petition for re	consideration or rehearing of	or otherwise for modific	ation or
23		rescinding the denial, until at least two y	years from the date of the m	nost recent application t	<u>hat was</u>
24		denied. At that time, the proposed perm	nit holder must submit a ne	w application for the E	<u>Board to</u>
25		consider.			
26	<u>(5)</u>	If any license, registration, permit or an	ny other privilege is subjec	t to a stayed suspension	on or an
27		active suspension for a period of five y	ears or shorter, the person	holding that privilege r	<u>nay not</u>
28		submit another application, petition	for reinstatement, to have	e the suspension lift	ed, for
29		reconsideration or rehearing or otherw	vise for modification or re-	scinding the order, bef	fore the
30		conclusion of that suspension.			
31	<u>(6)</u>	For the purposes of Subparagraphs (3), ((4) and (5) of this Paragraph	n, the Board shall treat a	a permit
32		holder or proposed permit holder the sa	ame as a prior permit holde	er or proposed permit h	older if
33		either of the following two conditions is	s true: (a) the permit holder	or proposed permit hol	lder has
34		the same pharmacy manager and there	is more than 10 percent co	ommon ownership as tl	<u>he prior</u>
35		permit holder or proposed permit holder	; or (b) the permit holder or	proposed permit holder	<u>r has 50</u>
36		percent or more common ownership as	s the prior permit holder of	or proposed permit hol	der. To
37		determine common ownership under th	nis Rule, the Board shall c	onsider business entitie	<u>es to be</u>

1	identical to other business entities if there is more than a 50 percent common ownership.
2	Furthermore, to determine common ownership under this Rule, the Board shall combine the interests
3	of individuals with the interests of any business entities in which the individuals have more than a
4	10 percent interest, as well as with the interests of individuals in the same family.
5	(b) The Board may alter the terms provided in Paragraph (a) of this Rule, after applying the facts and circumstances
6	of the matter and its application of the disciplinary provision in G.S. 90-85.38. Unless the Board expressly modifies
7	these terms in the final agency decision, the terms of Paragraph (a) of this Rule apply to that decision.
8	(c) If a person submits a petition or application that does not satisfy the limits set forth in this Rule, the Executive
9	Director shall not schedule any hearing on the petition or application before the Board until the limits set forth in this
10	Rule are satisfied.
11	(d) A person's ability to petition for reinstatement or to submit a new application under this Rule does not indicate
12	that the Board will grant any such petition or application. The Board will grant or reinstate a license, registration,
13	permit or other privilege only after a finding that the grant or reinstatement is appropriate under the Pharmacy Practice
14	Act and its rules and regulations. In making that decision, the Board will consider, among other things, the gravity of
15	the misconduct that caused the denial, suspension or revocation; the applicant's history; the applicant's current ability
16	to practice pharmacy with reasonable skill, competence and safety to the public; and the applicant's conduct since the
17	order of denial, suspension or revocation.
18	
19	History Note: Authority G.S. 90-85.6; 90-85.38; 150B-38; 150B-40; 150B-42;
20	<u>Eff. August 1, 2020.</u>