

## RRC STAFF OPINION

*PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.*

AGENCY: Department of Health and Human Services

RULE CITATION: All temporary rules filed

RECOMMENDED ACTION:

- Approve, but note staff's comment
- X Object, based on:
  - X Lack of statutory authority
  - Unclear or ambiguous
  - Unnecessary
  - Failure to comply with the APA
- Extend the period of review

COMMENT:

It is staff's recommendation that the Commission object to the temporary rules filed by the Department of Health and Human Services, as the Board failed to comply with Session Law 2014-53, Section 4.

### **Failure to comply with Session Law 2014-53, Section 4:**

The statute requires the following:

**SECTION 4** No later than October 1, 2014, the Department of Health and Human Services shall establish and adopt temporary rules to implement the provisions of this act.

The legislation is very specific in stating that the Department of Health and Human Services "shall establish and adopt temporary rules" and that such rules should be "[n]o later than October 1, 2014." The Findings of Need for this Rule indicates that the rules were adopted on November 24, 2014. This is outside of the statutory deadline of October 1, 2014.

Abigail M. Hammond  
Commission Counsel

**Summary:**

Staff is concerned that should the Commission review and approve these temporary rules, the Commission would be violating the plain language of Session Law 2014-53, Section 4. It is staff's opinion that the temporary rules filed by the Department of Health and Human Services for 10A NCAC 26E .0701, .0702, .0703 should be objected to by the Commission for lack of statutory authority.

Abigail M. Hammond  
Commission Counsel

**GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2013**

**SESSION LAW 2014-53  
HOUSE BILL 1220**

AN ACT TO CREATE AN INTRACTABLE EPILEPSY ALTERNATIVE TREATMENT  
PILOT STUDY PROGRAM AND REGISTRY FOR THE SCIENTIFIC  
INVESTIGATION OF THE SAFETY AND EFFICACY OF HEMP EXTRACT  
TREATMENT FOR INTRACTABLE EPILEPSY.

The General Assembly of North Carolina enacts:

**SECTION 1.** The University of North Carolina at Chapel Hill and East Carolina University may, and Duke University and Wake Forest University are encouraged to, conduct research on hemp extract development, production, and use for the treatment of seizure disorders and to participate in any ongoing or future clinical studies or trials.

**SECTION 2.** Chapter 90 of the General Statutes is amended by adding a new Article to read:

"Article 5G.

"Epilepsy Alternative Treatment Act.

**"§ 90-113.100. Short title.**

- (a) This act may be cited as the "North Carolina Epilepsy Alternative Treatment Act."
- (b) The purpose of this act is to permit medical professionals to conduct limited-scope, evidence-based studies exploring the safety and efficacy of treating intractable epilepsy using hemp extract.
- (c) The General Assembly finds the following:
  - (1) There are children in this State suffering from intractable epilepsy for which currently available treatment options have been ineffective. Hemp extract shows promise in treating children with intractable epilepsy.
  - (2) Additional study of the use of hemp extract for the treatment of intractable epilepsy should be undertaken, and the medical research universities of the State of North Carolina are well-suited for this type of clinical exploration.

**"§ 90-113.101. Definitions.**

- (a) Caregiver. – An individual who is a parent, legal guardian, or custodian of a person diagnosed with intractable epilepsy.
- (b) Caregiver Registration Card. – A registration card issued by the Department of Health and Human Services under this Article to a caregiver.
- (c) Database. – The Intractable Epilepsy Alternative Treatment Pilot Study database, established by the Department of Health and Human Services pursuant to this Article, to register caregivers, patients, and recommending neurologists.
- (d) Department. – The Department of Health and Human Services.
- (e) Hemp Extract. – An extract from a cannabis plant, as defined in G.S. 90-94.1(a).
- (f) Intractable Epilepsy. – A seizure disorder that, as determined by a neurologist, does not respond to three or more treatment options overseen by the neurologist.
- (g) Neurologist. – An individual who is licensed under Article 1 of Chapter 90 of the General Statutes, who is board certified in neurology, and is affiliated with the neurology department at one or more of the following universities:
  - (1) The University of North Carolina at Chapel Hill.
  - (2) East Carolina University.
  - (3) Duke University.
  - (4) Wake Forest University.
- (h) Patient. – A person who has been diagnosed by a neurologist with intractable epilepsy.



(i) Pilot Study. – An evidence-based investigation of the safety and efficacy of treating intractable epilepsy using hemp extract conducted by one or more neurologists registered pursuant to this Article.

**"§ 90-113.102. Intractable Epilepsy Alternative Treatment Pilot Study database; departmental duties.**

(a) The Department shall create a secure, electronic, and online Intractable Epilepsy Alternative Treatment Pilot Study database registry for the registration of pilot studies, neurologists, caregivers, and patients as provided by this Article. The registry must be accessible to law enforcement agencies in order to verify registration of caregivers. The registry must prevent an active registration of a patient by multiple neurologists. At a minimum, the database shall consist of the following:

- (1) The name and address of each registered caregiver and the name of the pilot study the caregiver is associated with.
- (2) The name and address of each registered patient and the name of the pilot study the patient is associated with.
- (3) The name, address, and qualifying institutional affiliation of neurologists conducting pilot studies pursuant to this Article.
- (4) The name, institutional affiliation, affiliated registered neurologists, and parameters of pilot studies.

(b) The Department shall contact the county department of health where the patient resides and provide the following information:

- (1) The name and address of the registered caregiver.
- (2) Identifying information contained on the caregiver registration card.

**"§ 90-113.103. Registration of pilot studies and neurologists.**

(a) A neurologist seeking to conduct a pilot study pursuant to this Article shall submit an application to the Department providing all of the following information:

- (1) The name of the pilot study.
- (2) The affiliated research institution.
- (3) The scientific and clinical parameters of the study.
- (4) The protocols established to ensure patient safety.
- (5) The name and address of the one or more neurologists associated with the pilot study.
- (6) Any other information deemed necessary by the Department to determine the safety and evidence-based nature of the pilot study.

(b) The Department shall examine applications received pursuant to subsection (a) of this section and register in the database the proposed pilot studies that the Department certifies follow minimal scientific methods and protect patient safety.

(c) The Department may monitor registered pilot studies to ensure continued adherence to patient safety protocols and the scientific parameters of the study.

**"§ 90-113.104. Caregiver registration card; application; fees.**

(a) The Department shall, in coordination with recommendations from the Department of Public Safety, establish the form and content of caregiver registration cards to be issued to individuals who satisfy the requirements set forth in this section.

(b) The Department shall issue a caregiver registration card, valid for a period of one year from issuance, to an individual who satisfies all of the following criteria:

- (1) Is at least 18 years of age.
- (2) Is a resident of North Carolina.
- (3) Provides the Department with a statement signed by a neurologist conducting a pilot study that satisfies all of the following:
  - a. Demonstrates that a patient in the caregiver's care satisfies all of the following criteria:
    1. Has been examined and is under the care of the neurologist.
    2. Suffers from intractable epilepsy.
    3. May benefit from treatment with hemp extract.
    4. Is eligible for inclusion in the registered pilot study.
  - b. Contains a recommendation for the use of hemp extract for treatment of intractable epilepsy as part of a registered pilot study.
  - c. Is consistent with records received from the neurologist, concerning the patient, contained in the database described in G.S. 90-113.102.

- (4) Pays the Department a fee, not to exceed fifty dollars (\$50.00), established by the Department under G.S. 90-113.106.
- (5) Submits an application to the Department that contains all of the following:
  - a. The caregiver's name and address.
  - b. The patient's name and address.
  - c. A copy of the caregiver's valid government-issued photo identification.
  - d. Any additional information the Department finds necessary to implement this Article.

(c) The Department shall renew a caregiver registration card upon certification from the caregiver and the neurologist that all information initially provided to the Department under subsection (b) of this section is current or has been updated to reflect any changes. The Department shall charge a fee for renewal of a caregiver registration card, not to exceed twenty-five dollars (\$25.00), established under G.S. 90-113.106.

**"§ 90-113.105. Immunity for neurologists; medical records.**

(a) On a case-by-case basis, neurologists conducting a registered pilot study may approve of dispensation to a registered caregiver, as approved by this Article, hemp extract acquired from another jurisdiction.

(b) A neurologist shall not be subject to arrest or prosecution, penalized or disciplined in any manner, or denied any right or privilege for approving or recommending the use of hemp extract or providing a written statement or health records to the Department for the use of hemp extract pursuant to this Article.

(c) A neurologist conducting a registered pilot study who signs a statement as described in G.S. 90-113.104(b)(3) shall do the following:

- (1) Keep a record of the evaluation and observation of a patient under the neurologist's care, including the patient's response to hemp extract treatment.
- (2) Transmit the record described in subdivision (1) of this subsection to the Department upon request.

(d) All medical records received or maintained by the Department pursuant to this Article are confidential and may not be disclosed to the public. Nothing in this Article is intended to alter the provisions of G.S. 8-53 or G.S. 8-53.1.

**"§ 90-113.106. Rule making.**

The Department shall adopt rules in accordance with Article 2A of Chapter 150B of the General Statutes to implement the provisions of this Article."

**SECTION 3.** Article 5 of Chapter 90 of the General Statutes is amended by adding a new section to read:

**"§ 90-94.1. Exemption for use or possession of hemp extract.**

(a) As used in this section, "hemp extract" means an extract from a cannabis plant, or a mixture or preparation containing cannabis plant material, that has all of the following characteristics:

- (1) Is composed of less than three-tenths of one percent (0.3%) tetrahydrocannabinol by weight.
- (2) Is composed of at least ten percent (10%) cannabidiol by weight.
- (3) Contains no other psychoactive substance.

(b) Notwithstanding any other provision of this Chapter, an individual may possess or use hemp extract, and is not subject to the penalties described in this Chapter, if the individual satisfies all of the following criteria:

- (1) Possesses or uses the hemp extract only to treat intractable epilepsy, as defined in G.S. 90-113.101.
- (2) Possesses, in close proximity to the hemp extract, a certificate of analysis that indicates the hemp extract's ingredients, including its percentages of tetrahydrocannabinol and cannabidiol by weight.
- (3) Has a current hemp extract registration card issued by the Department of Health and Human Services under Article 5G of Chapter 90 of the General Statutes.

(c) Notwithstanding any other provision of this Chapter, an individual who possesses hemp extract lawfully under this section may administer hemp extract to another person under the individual's care and is not subject to the penalties described in this Chapter for administering the hemp extract to the person if both of the following conditions are satisfied:

(1) The individual is the person's caregiver, as defined in G.S. 90-113.101.

(2) The individual is registered with the Department of Health and Human Services to administer hemp extract under G.S. 90-113.103."

**SECTION 4.** No later than October 1, 2014, the Department of Health and Human Services shall establish and adopt temporary rules to implement the provisions of this act.

**SECTION 5.** Section 3 of this act becomes effective upon adoption of rules pursuant to Section 4 of this act. The remainder of this act is effective when it becomes law.

In the General Assembly read three times and ratified this the 26<sup>th</sup> day of June, 2014.

s/ Philip E. Berger  
President Pro Tempore of the Senate

s/ Justin P. Burr  
Presiding Officer of the House of Representatives

s/ Pat McCrory  
Governor

Approved 9:08 a.m. this 3<sup>rd</sup> day of July, 2014

## REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services

RULE CITATION: All Rules

**DEADLINE FOR RECEIPT: Tuesday, December 16, 2014**

**NOTE WELL:** *This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

*On the form, box 5, line g, please delete the effective date of December 19, 2014, as G.S. 150B-21.1(b) and G.S. 150B-21.3 controls and the date could not be this Friday, December 19, 2014.*

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

Abigail M. Hammond  
Commission Counsel

Date submitted to agency: Monday, December 15, 2014



# **TEMPORARY RULE-MAKING FINDINGS OF NEED**

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

<b>1. Rule-Making Agency:</b> NC Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services
<b>2. Rule citation &amp; name:</b> 10A NCAC 26E .0701, Scope
<b>3. Action:</b> <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
<b>4. Was this an Emergency Rule:</b> <input type="checkbox"/> Yes                      Effective date: <input checked="" type="checkbox"/> No
<b>5. Provide dates for the following actions as applicable:</b> a. Proposed Temporary Rule submitted to OAH: October 3, 2014 b. Proposed Temporary Rule published on the OAH website: October 10, 2014 c. Public Hearing date: October 21, 2014 d. Comment Period: October 10, 2014 - October 31, 2014 e. Notice pursuant to G.S. 150B-21.1(a3)(2): October 3, 2014 f. Adoption by agency on: November 24, 2014 g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: December 19, 2014 h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]:
<b>6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.</b>  <div style="margin-left: 20px;"> <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare.  <input checked="" type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress.              Cite: S.L. 2014-53              Effective date: July 3, 2014  <input type="checkbox"/> A recent change in federal or state budgetary policy.              Effective date of change:  <input type="checkbox"/> A recent federal regulation.              Cite:              Effective date:  <input type="checkbox"/> A recent court order.              Cite order:  <input type="checkbox"/> State Medical Facilities Plan.  <input type="checkbox"/> Other:         </div> <p><b>Explain:</b> : S.L. 2014-53 created an intractable epilepsy alternative treatment pilot study program and registry for the scientific investigation of the safety and efficacy of hemp extract treatment for intractable epilepsy. The act required the Department of Health and Human Services to adopt temporary rules to implement the provisions thereof no later than October 1, 2014.</p>



**7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?**

Per G.S. 90-113.100 the General Assembly found that "there are children in this State suffering from intractable epilepsy for which currently available treatment options have been ineffective; hemp extract shows promise in treating children with intractable epilepsy; and additional study of the use of hemp extract for the treatment of intractable epilepsy should be undertaken, and the medical research universities of the State of North Carolina are well-suited for this type of clinical exploration". S.L. 2014-53 created an intractable epilepsy alternative treatment pilot study program and registry for the scientific investigation of the safety and efficacy of hemp extract treatment for intractable epilepsy. The act required the Department of Health and Human Services to adopt temporary rules to implement the provisions thereof no later than October 1, 2014. The General Assembly had the interest of those suffering from intractable epilepsy in mind when requiring the adoption of temporary rules. Adherence to the notice and hearing requirements of the permanent rulemaking process would have been contrary to the legislative intent for more immediate adoption of the rules and as well as the public interest given that the rules set forth the requirements for registering neurologists who will conduct the pilot studies specified in the legislation and well as the requirements for issuing a caregiver registration card.

Alternatively, the General Assembly expressly dictated the use of temporary rules to implement S.L. 2014-53, so the findings otherwise required by 150B-21.1(a) before adopting temp rules are not necessary and have been waived by the General Assembly. In other words, it was the intent of the General Assembly to make hemp oil extract legally available to children suffering from intractable epilepsy without delay, so they chose to bypass the time consuming procedures for permanent rule making.

**8. Rule establishes or increases a fee? (See G.S. 12-3.1)**

☐ Yes

Agency submitted request for consultation on:  
Consultation not required. Cite authority:

☒ No

**9. Rule-making Coordinator: W. Denise Baker**

Phone: 919-715-2780

E-Mail: denise.baker@dhhs.nc.gov

**Agency contact, if any:**

Phone:

E-Mail:

**10. Signature of Agency Head\*:**



\* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Courtney M. Cantrell, Ph.D.

Title: Director, Division of MH/DD/SAS

E-Mail: courtney.m.cantrell@dhhs.nc.gov

**RULES REVIEW COMMISSION USE ONLY**

Action taken:

Submitted for RRC Review:

☐ Date returned to agency:



## North Carolina Department of Health and Human Services

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

October 1, 2014

Ms. Molly Masich  
Director, APA Services  
Office of Administrative Hearings  
1711 New Hope Church Road  
Raleigh, NC 27609

Dear Ms. Masich:

This letter will serve as notice that the Department of Health and Human Services has delegated the rulemaking authority of the Department set out in Session Law 2014-53 to the Director of the Department's Division of Mental Health, Developmental Disabilities and Substance Abuse Services.

Sincerely,

A handwritten signature in cursive script, appearing to read "Wos".

Aldona Wos, M. D.  
Secretary

OFFICE OF  
ADMIN HEARINGS

2014 DEC 15 PM 1:36

FILED

[www.ncdhhs.gov](http://www.ncdhhs.gov)

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Mailing Address: 2001 Mail Service Center • Raleigh, NC 27699-2001

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1 10A NCAC 26E .0701 is adopted as a temporary rule with changes as follows:

2  
3 SECTION .0700 INTRACTABLE EPILEPSY ALTERNATIVE TREATMENT PILOT STUDY

4  
5 **10A NCAC 26E .0701 SCOPE**

6 (a) The purpose of the rules in this Section is to set forth the requirements for registering neurologists who conduct  
7 scientific research on hemp extract development, production, and the efficacy of hemp extract treatment for  
8 intractable epilepsy.

9 (b) These rules also set forth the requirements for issuance of a caregiver registration card to a parent, legal  
10 guardian, or custodian of a patient diagnosed with intractable epilepsy.

11  
12 *History Note:* Authority [~~S.L. 2014 53;~~]G.S. 90-113.106;

13 Temporary Adoption Eff. November 21, 2014.

## REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services

RULE CITATION: 10A NCAC 26E .0702

**DEADLINE FOR RECEIPT: Tuesday, December 16, 2014**

***NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

*This rule is an adoption, with changes after publication. To make the changes more evident, please remove the underlining from all text that was published and not changed, as set forth in [26 NCAC 02C .0405\(b\)\(1\)](#). Please see this example:*

<http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20changes%20for%20Publication%20in%20the%20NCAC.pdf>

*Line 9, replace "must" with "shall"*

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

Abigail M. Hammond  
Commission Counsel  
Date submitted to agency: Monday, December 15, 2014

1 10A NCAC 26E .0702 proposed and published on the OAH website as 10A NCAC 26E .0703 is adopted as a  
2 temporary rule with changes as follows:

3  
4 **10A NCAC 26E .0702 REGISTERING STUDIES AND NEUROLOGISTS**

5 (a) Prior to submitting an application to the Department, each neurologist ~~[must]~~ shall obtain a Drug Enforcement  
6 Administration Controlled Substance Registration Certificate and a North Carolina Department of Health and  
7 Human Services Controlled Substance Registration Certificate for ~~[research, as well as any other license or~~  
8 ~~registration required by state or federal law to conduct research with Hemp Extract.]~~ research.

9 (b) Each application must include the University's approval of the study's protocols, including documentation that  
10 the study meets ~~[minimal]~~ scientific methods and protects patient safety.

11 (c) Each neurologist shall notify the Department when a patient's participation in ~~[their]~~ the pilot study has  
12 concluded.

13  
14 History Note: Authority ~~[S.L. 2014-53;]~~ G.S. 90-113.103; 90-113.106;

15 Temporary Adoption Eff. November 21, 2014

## REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services

RULE CITATION: 10A NCAC 26E .0703

**DEADLINE FOR RECEIPT: Tuesday, December 16, 2014**

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

Abigail M. Hammond  
Commission Counsel  
Date submitted to agency: Monday, December 15, 2014

1 10A NCAC 26E .0703 proposed and published on the OAH website as 10A NCAC 26E .0704 is adopted as a  
2 temporary rule with changes as follows:

3  
4 **10A NCAC 26E .0703 CAREGIVER REGISTRATION CARDS**

5 (a) To request a Caregiver Registration Card, a caregiver ~~[must]~~ shall submit the application required by the  
6 Department in accordance with ~~[S.L. 2014 53;]~~ G.S. 90-113.104.

7 ~~[(b) No registered caregiver shall knowingly obtain, seek to obtain, or possess, individually or collectively, hemp  
8 extract that was not approved by the patient's neurologist.]~~

9 ~~[(c)]~~ (b) A registered caregiver shall notify the Department of any change in application information within 10 days  
10 after the change occurs.

11 ~~[(d)]~~ (c) A registered caregiver who loses his or her caregiver registration card shall notify the Department of this  
12 loss within 10 days of becoming aware the card has been lost.

13 ~~[(e)]~~ (d) The Department may revoke a caregiver registration card for any of the following reasons:

14 (1) ~~Submission~~ submission of misleading, incorrect, false, or fraudulent information in the application  
15 or renewal application; ~~or~~

16 ~~[(2) Fraudulent use of the registry identification card; or]~~

17 ~~[(3)]~~ (2) ~~[Failure]~~ failure to notify the Department of any change in application information within 10 days;  
18 or

19 ~~[(4) Failure to notify the Department within 10 days of becoming aware their card has been lost; or]~~

20 ~~[(5) Selling, distributing, transferring in any manner, or giving hemp extract to any unauthorized  
21 person; or]~~

22 ~~[(6)]~~ (3) ~~[Tampering]~~ tampering with, falsifying, altering, modifying, or duplicating a registration card.

23 ~~[(f)]~~ (e) No cost shall be charged for initial, ~~[renewal]~~ renewal, or replacement registration cards.

24 *History Note:* Authority ~~[S.L. 2014 53;]~~ G.S. 90-113.104; G.S. 90-113.106;

25 Temporary Adoption Eff. November 21, 2014.