STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION EMERGENCY TELECONFERENCE MEETING
DIVISION OF HEALTH SERVICE REGULATION
809 RUGGLES DRIVE
RALEIGH, NORTH CAROLINA 27603
CONFERENCE ROOM #026A – EDGERTON BUILDING

Teams Video Conference Link
Click here to join the meeting

Or

Dial-In Number: 1-984-204-1487 / Passcode: 23608305#

WEDNESDAY, DECEMBER 9, 2020
11:30 A.M.

AGENDA

I. **Meeting Opens and Comments**……..……..……..…….……..…..Dr. John Meier

II. **Public Meeting Statement**…….....Dr. John Meier

This meeting of the Medical Care Commission is open to the public but is not a public hearing. Therefore, any discussion will be limited to members of the Commission and staff unless questions are specifically directed by the Commission to someone in the audience.

III. **Ethics Statement**……...…Dr. John Meier

The State Government Ethics Act requires members to act in the best interest of the public and adhere to the ethical standards and rules of conduct in the State Government Ethics Act, including the duty to continually monitor, evaluate, and manage personal, financial, and professional affairs to ensure the absence of conflicts of interest.

IV. **Old Business** (Discuss Rules, fiscal note, and comments submitted) (Action Items)

A. Rules for Adoption

1. Adult Care Home & Family Care Home Rules..…….……Nadine Pfeiffer & Megan Lamphere

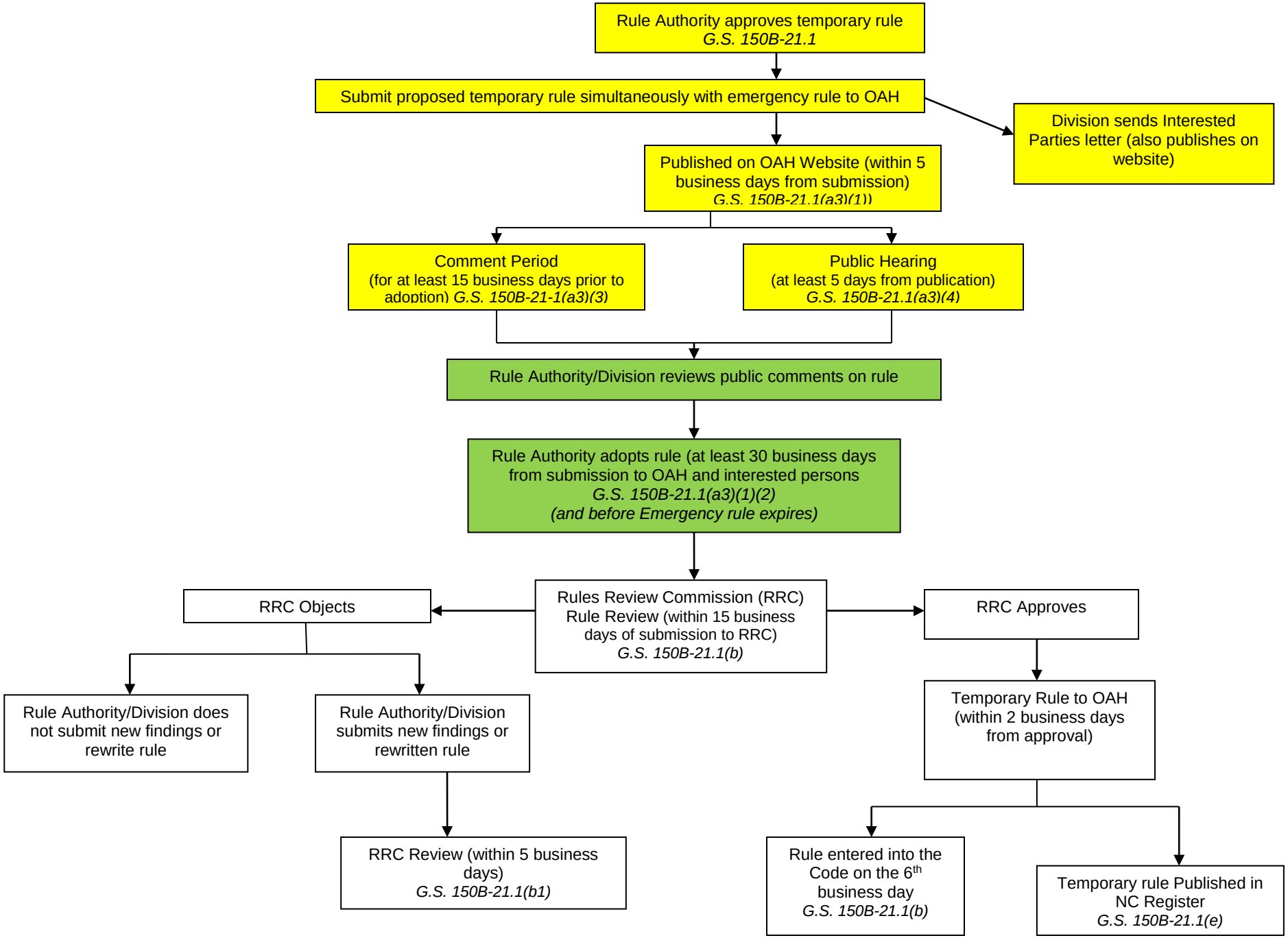
Temporary rulemaking for infection prevention policies and procedures, communicable disease reporting due to COVID-19. (Four Rules)

- 10A NCAC 13F .1801, and .1802, 10A NCAC 13G .1701, and .1702 **(See Exhibits A thru A/3)**

V. **Meeting Adjournment**

Temporary Rulemaking Process

Exhibit A



10A NCAC 13F .1801 is adopted under temporary procedures with changes as follows:

SECTION .1800 - INFECTION PREVENTION AND CONTROL

10A NCAC 13F .1801 INFECTION PREVENTION AND CONTROL PROGRAM

(a) In accordance with Rule 13F .1211 of this Subchapter and G.S. 131D-4.4A(b)(1), the facility shall establish and implement a comprehensive infection prevention and control program (IPCP) consistent with the federal Centers for Disease Control and Prevention (CDC) published guidelines on infection prevention and control.

~~(b) The facility shall ensure implementation of the facility's IPCP, related policies and procedures, and guidance or directives issued by the CDC, the local health department, and/or the North Carolina Department of Health and Human Services.~~

~~(c)~~ (b) The facility shall assure the following policies and procedures are established and implemented consistent with the federal CDC published guidelines on infection control and addresses ~~at least~~ the following:

(1) Standard and transmission-based precautions, for which guidance can be found on the CDC website at https://www.cdc.gov/infectioncontrol/basics, including:
   (A) respiratory hygiene and cough etiquette;
   (B) environmental cleaning and disinfection;
   (C) reprocessing and disinfection of reusable resident medical equipment;
   (D) hand hygiene;
   (E) accessibility and proper use of personal protective equipment (PPE);
   (F) types of transmission-based precautions and when each type is indicated, including contact precautions, droplet precautions, and airborne precautions:

(2) When and how to report to the local health department when there is a suspected or confirmed reportable communicable disease case or condition, or communicable disease outbreak in accordance with Rule 13F .1802 of this Section:

(3) Resident care when there is suspected or confirmed communicable disease in the facility, including, when indicated, isolation of infected residents, limiting or stopping group activities and communal dining, and based on the mode of transmission, use of source control as tolerated by the residents. Source control includes the use of face coverings for residents when the mode of transmission is through a respiratory pathogen:

(4) Procedures for screening visitors to the facility and criteria for restricting visitors who exhibit signs of illness, as well as posting signage for visitors regarding screening and restriction procedures;

(5) Procedures for screening facility staff and criteria for restricting staff who exhibit signs of illness from working;

(6) Procedures and strategies for addressing staffing issues and ensuring staffing to meet the needs of the residents during a communicable disease outbreak:

(7) The annual review of the facility's IPCP and update of the IPCP as necessary; and

(8) a process for updating policies and procedures to reflect guidelines and recommendations by the CDC, local health department, and North Carolina Department of Health and Human Services (NCDHHS) during a public health emergency as declared by the United States and that applies to North Carolina or a public health emergency declared by the State of North Carolina.

(c) When a communicable disease outbreak has been identified at the facility or there is an emerging infectious disease threat, the facility shall ensure implementation of the facility's IPCP, related policies and procedures, and published guidance issued by the CDC; however, if guidance or directives specific to the communicable disease outbreak or emerging infectious disease threat have been issued by the NCDHHS or local health department, the specific guidance or directives shall be implemented by the facility.

(d) In accordance with Rule 13F .1211 of this Subchapter, the facility shall ensure all staff are trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs ~~(c)(1)~~ (b)(1) through (5) of this Rule. Training on Parts ~~(c)(1)(D)~~ (b)(1)(D) and (E) of this Rule shall include hands-on demonstration by a trained instructor and return demonstration by the staff person.

(e) The facility shall ensure that, prior to administration, all staff responsible for administering tests to residents for the diagnosis of a communicable disease or condition shall be trained on the proper use of testing devices and materials consistent with manufacturer's specifications.

(f) The facility shall ensure staff employed in a management or supervisory role in the facility are trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs ~~(c)(1)~~ (b)(1) through (6) of this Rule.

(g) The policies and procedures listed in Paragraph ~~(c)~~ (b) of this Rule shall be maintained in the facility and accessible to staff working at the facility.

(h) The ~~facility shall ensure that the IPCP is incorporated into the~~ facility's emergency preparedness disaster plan ~~and updated as needed to~~ shall address any emerging infectious disease threats to protect the residents during a shelter-in-place or emergency evacuation event.

History Note: *Authority G.S. 131D-2.16; 131D-4.4A; 131D-4.5; 143B-165;*
Emergency Adoption Eff. October 23, ~~2020;~~2020;
Temporary Adoption Eff. December 30, 2020.

10A NCAC 13F .1802 is adopted under temporary procedures with changes as follows:

10A NCAC 13F .1802 REPORTING AND NOTIFICATION OF A SUSPECTED OR CONFIRMED COMMUNICABLE DISEASE OUTBREAK

(a) The facility shall report suspected or confirmed communicable diseases and conditions within the time period and in the manner determined by the Commission for Public Health as specified in Rules 10A NCAC 41A .0101 and 10A NCAC 41A .0102(a)(1) through (a)(3), including subsequent amendments and editions.

~~(b) The facility shall implement recommendations to the greatest extent practicable provided by the local health department in response to a suspected or confirmed communicable disease case or condition or communicable disease outbreak.~~

~~(c)~~ (b) The facility shall inform the residents and their representative(s) and staff within 24 hours following confirmation by the local health department of a communicable disease outbreak, or one or more confirmed cases of COVID-19 among any resident or staff person. The facility, in its notification to residents and their representative(s), shall:

(1) not disclose any personally identifiable information of the residents or staff;

(2) provide information on the measures the facility is taking to prevent or reduce the risk of transmission, including whether normal operations of the facility will change;

(3) provide weekly updates until the communicable illness within the facility has resolved, as determined by the local health department; and

(4) provide education to the resident(s) concerning measures they can take to reduce the risk of spread or transmission of infection.

History Note: *Authority G.S. 131D-2.16; 131D-4.4B; 131D-4.5; 143B-165;*
Emergency Adoption Eff. October 23, ~~2020.~~ 2020;
Temporary Adoption Eff. December 30, 2020.

10A NCAC 13G .1701 is adopted under temporary procedures with changes as follows:

SECTION .1700 - INFECTION PREVENTION AND CONTROL

10A NCAC 13G .1701 INFECTION PREVENTION AND CONTROL PROGRAM

(a) In accordance with Rule 13G .1211 of this Subchapter and G.S. 131D-4.4A(b)(1), the facility shall establish and implement a comprehensive infection prevention and control program (IPCP) consistent with the federal Centers for Disease Control and Prevention (CDC) published guidelines on infection prevention and control.

~~(b) The facility shall ensure implementation of the facility's IPCP, related policies and procedures, and guidance or directives issued by the CDC, the local health department, and/or the North Carolina Department of Health and Human Services.~~

~~(c)~~ (b) The facility shall assure the following policies and procedures are established and implemented consistent with the federal CDC published guidelines on infection control and addresses ~~at least~~ the following:

(1) Standard and transmission-based precautions, for which guidance can be found on the CDC website at https://www.cdc.gov/infectioncontrol/basics, including:
   (A) respiratory hygiene and cough etiquette;
   (B) environmental cleaning and disinfection;
   (C) reprocessing and disinfection of reusable resident medical equipment;
   (D) hand hygiene;
   (E) accessibility and proper use of personal protective equipment (PPE);
   (F) types of transmission-based precautions and when each type is indicated, including contact precautions, droplet precautions, and airborne precautions:

(2) When and how to report to the local health department when there is a suspected or confirmed reportable communicable disease case or condition, or communicable disease outbreak in accordance with Rule 13G .1702 of this Section:

(3) Resident care when there is suspected or confirmed communicable disease in the facility, including, when indicated, isolation of infected residents, limiting or stopping group activities and communal dining, and based on the mode of transmission, use of source control as tolerated by the residents. Source control includes the use of face coverings for residents when the mode of transmission is through a respiratory pathogen:

(4) Procedures for screening visitors to the facility and criteria for restricting visitors who exhibit signs of illness, as well as posting signage for visitors regarding screening and restriction procedures;

(5) Procedures for screening facility staff and criteria for restricting staff who exhibit signs of illness from working;

(6) Procedures and strategies for addressing staffing issues and ensuring staffing to meet the needs of the residents during a communicable disease outbreak:

(7) The annual review of the facility's IPCP and update of the IPCP as necessary; and

(8) a process for updating policies and procedures to reflect guidelines and recommendations by the CDC, local health department, and North Carolina Department of Health and Human Services (NCDHHS) during a public health emergency as declared by the United States and that applies to North Carolina or a public health emergency declared by the State of North Carolina.

(c) When a communicable disease outbreak has been identified at the facility or there is an emerging infectious disease threat, the facility shall ensure implementation of the facility's IPCP, related policies and procedures, and published guidance issued by the CDC; however, if guidance or directives specific to the communicable disease outbreak or emerging infectious disease threat have been issued by the NCDHHS or local health department, the specific guidance or directives shall be implemented by the facility.

(d) In accordance with Rule 13G .1211 of this Subchapter, the facility shall ensure all staff are trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs ~~(c)(1)~~ (b)(1) through (5) of this Rule. Training on Parts ~~(c)(1)(D)~~ (b)(1)(D) and (E) of this Rule shall include hands-on demonstration by a trained instructor and return demonstration by the staff person.

(e) The facility shall ensure that, prior to administration, all staff responsible for administering tests to residents for the diagnosis of a communicable disease or condition shall be trained on the proper use of testing devices and materials consistent with manufacturer's specifications.

(f) The facility shall ensure staff employed in a management or supervisory role in the facility are trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs ~~(c)(1)~~ (b)(1) through (6) of this Rule.

(g) The policies and procedures listed in Paragraph ~~(c)~~ (b) of this Rule shall be maintained in the facility and accessible to staff working at the facility.

(h) The ~~facility shall ensure that the IPCP is incorporated into the~~ facility's emergency preparedness disaster plan ~~and updated as needed to~~ shall address any emerging infectious disease threats to protect the residents during a shelter-in-place or emergency evacuation event.

History Note: *Authority G.S. 131D-2.16; 131D-4.4A; 131D-4.5; 143B-165;*
Emergency Adoption Eff. October 23, ~~2020;~~ 2020;
Temporary Adoption Eff. December 30, 2020.

10A NCAC 13G .1702 is adopted under temporary procedures with changes as follows:

10A NCAC 13G .1702 REPORTING AND NOTIFICATION OF A SUSPECTED OR CONFIRMED COMMUNICABLE DISEASE OUTBREAK

(a) The facility shall report suspected or confirmed communicable diseases and conditions within the time period and in the manner determined by the Commission for Public Health as specified in Rules 10A NCAC 41A .0101 and 10A NCAC 41A .0102(a)(1) through (a)(3), including subsequent amendments and editions.

~~(b) The facility shall implement recommendations to the greatest extent practicable provided by the local health department in response to a suspected or confirmed communicable disease case or condition or communicable disease outbreak.~~

~~(c)~~ (b) The facility shall inform the residents and their representative(s) and staff within 24 hours following confirmation by the local health department of a communicable disease outbreak, or one or more confirmed cases of COVID-19 among any resident or staff person. The facility, in its notification to residents and their representative(s), shall:

(1) not disclose any personally identifiable information of the residents or staff;

(2) provide information on the measures the facility is taking to prevent or reduce the risk of transmission, including whether normal operations of the facility will change;

(3) provide weekly updates until the communicable illness within the facility has resolved, as determined by the local health department; and

(4) provide education to the resident(s) concerning measures they can take to reduce the risk of spread or transmission of infection.

History Note: *Authority G.S. 131D-2.16; 131D-4.4B; 131D-4.5; 143B-165;*
Emergency Adoption Eff. October 23, ~~2020.~~ 2020;
Temporary Adoption Eff. December 30, 2020.

Adult Care Home & Family Care Home Temporary Rules Public Comments
10A NCAC 13F .1801 & .1802; 10A NCAC 13G .1701 & .1702
Comment Period 10/23/20 – 11/16/20

Introduction:

Three individuals submitted comments during the public comment period on the temporary adoption rules 10A NCAC 13F .1801 & .1802; 10A NCAC 13G .1701 & .1702. Of these comments, one person made statements during the public hearing conducted on November 4, 2020. The comments were submitted by representatives from the following: N.C. Senior Living Association, and the N.C. Assisted Living Association (public hearing and written comments. A summary of all comments received on this rule is below:

1) Listing of Comments Received and Agency's Consideration of Comments for Rule 13F .1801 – Infection Prevention And Control Policies And Procedures:

Commenter	Comment Summary
1) N.C. Senior Living Association (NCSLA) (public hearing comment)	Paragraph (b) has three different agencies, the CDC, the local health department, and North Carolina DHHS that the providers must keep track of for directives, policies, and guidance issued for everything providers do. To ask adult care homes to do this and to stay on top of this all the time is setting them up for failure because it's an impossible task. Sometimes the directives and guidance issued by the CDC, the local health department and the North Carolina Department of Health and Human Services conflict with each other. When that happens what does a provider do? The Agency should specifically state which directives issued by the CDC and maybe NC DHHS that providers are to comply with. The Agency should do due diligence to determine if there's any conflict between those different agencies before putting this in rule. Our members say it depends on the health department from which county you're in on what kind of instructions, guidance, or directives you get. It's all over the map. One county will give directives one way, another county will give directives another way in terms of testing, how to respond to the pandemic, etc. It will be very confusing for providers to stay on top of the guidance and directives issued by these three government agencies to decide what's coming out, reconcile conflicting ones, and decide which one to go with, and then also put them into policies procedures, and training staff on them. It's an impossible task. Request: the Agency should explicitly state in the rule which guidance or directives by each of these bodies provider compliance is expected and to be certain of no conflicts between the guidance and directives of those different governmental agencies.
2) N.C. Senior Living Association (NCSLA)	Paragraph (b) creates the same type of ambiguity that providers experienced when cited by DHSR for not following guidelines and recommendations from the CDC, DHHS, and the local health departments.

Commenter	Comment Summary
(written comment)	Requiring providers to constantly check, reconcile differences, revise policies and procedures, and train staff based on guidance or directives issued by three agencies is difficult, if not impossible to achieve. Following local health department guidance or directives depends on which county your facility happens to be located. The direction varies widely by county during the pandemic. Request: Commission remove any reference to local health departments in the proposed rules, explicitly tell providers in rule which specific CDC or DHHS guidance or directives to follow, and to focus guidance and directives that are unlikely to change during the time the temporary rules are in effect. With input from Division of Public Health and others in DHHS, easier rules for providers to navigate and comply can be generated.

DHSR Response to Comments Above:

The agency has worked collaboratively with stakeholders (including the associations that provided comment above) to clarify the language in (b), which is now (c) in rule 13F .1801. The new language clarifies that a facility should follow CDC guidance and its own infection control policies and procedures unless more specific guidance or directives have been issued by NCDHHS or the local health department, in which case, the facility shall implement the specific guidance and directives. CDC guidance is issued nationally and serves as a basis, or foundation, for infection prevention and control in long term care facilities. However, it can be reasonably expected that states or local health departments may issue specific guidance or directives based on the special circumstances within each state, county, or even each facility.

In regard to the comments that the associations believe that the temporary rules should not become permanent rules, these comments are not relevant to the current proceedings. The issue before the agency at this time is the adoption of temporary rules to take the place of the emergency rules that will expire in January 2020. While the agency does intend to pursue permanent rulemaking for these rules, that is a separate process during which the agency will continue to engage all relevant stakeholders and will include another public comment period and opportunities to make changes to the rules. Additionally, the permanent rulemaking process will include an analysis of the fiscal impact of the rules on all relevant parties. For now, both associations have purported to the agency that they are in support of temporary rules and the agency has been transparent throughout the temporary rulemaking process and made several modifications to the rules based on their feedback.

The agency believes that it is imperative for the health and safety of residents in adult care homes, not just during a pandemic but for everyday operations, that facilities have clear requirements for the development and implementation of effective infection prevention and control practices in the facility. Adult care home residents are increasingly older, more medically complex, and at a higher risk of complications due to various infectious diseases. Residing in a congregate living setting also increases their risk. Additionally, adult care homes are typically not staffed with clinical professionals who have the education and training to understand, recognize and evaluate situations that pose significant risks to residents. The rules before the Medical Care Commission seek to strengthen the existing rules and statues for infection prevention and control, which are currently vague and lack specific guidance to facilities on preventing communicable diseases. Equally important, the new rules set forth requirements for reporting suspected outbreaks to the appropriate agency, as well as informing residents, their

families, and staff when an outbreak occurs. The temporary rules before the Commission, after consideration and incorporation of feedback from stakeholders, are recommended by the agency for final adoption.

2) Listing of Comments Received and Agency's Consideration of Comments for Rule 13G .1701 – Infection Prevention And Control Policies And Procedures:

Commenter	Comment Summary
1) N.C. Senior Living Association (NCSLA) (public hearing comment)	Paragraph (b) has three different agencies, the CDC, the local health department, and North Carolina DHHS that the providers must keep track of for directives, policies, and guidance issued for everything providers do. To ask adult care homes to do this and to stay on top of this all the time is setting them up for failure because it's an impossible task. Sometimes the directives and guidance issued by the CDC, the local health department and the North Carolina Department of Health and Human Services conflict with each other. When that happens what does a provider do? The Agency should specifically state which directives issued by the CDC and maybe NC DHHS that providers are to comply with. The Agency should do due diligence to determine if there's any conflict between those different agencies before putting this in rule. Our members say it depends on the health department from which county you're in on what kind of instructions, guidance, or directives you get. It's all over the map. One county will give directives one way, another county will give directives another way in terms of testing, how to respond to the pandemic, etc. It will be very confusing for providers to stay on top of the guidance and directives issued by these three government agencies to decide what's coming out, reconcile conflicting ones, and decide which one to go with, and then also put them into policies procedures, and training staff on them. It's an impossible task. Request: the Agency should explicitly state in the rule which guidance or directives by each of these bodies provider compliance is expected and to be certain of no conflicts between the guidance and directives of those different governmental agencies.
2) N.C. Senior Living Association (NCSLA) (written comment)	Paragraph (b) creates the same type of ambiguity that providers experienced when cited by DHSR for not following guidelines and recommendations from the CDC, DHHS, and the local health departments. Requiring providers to constantly check, reconcile differences, revise policies and procedures, and train staff based on guidance or directives issued by three agencies is difficult, if not impossible to achieve. Following local health department guidance or directives depends on which county your facility happens to be located. The direction varies widely by county during the pandemic.

Commenter	Comment Summary
	Request: Commission remove any reference to local health departments in the proposed rules, explicitly tell providers in rule which specific CDC or DHHS guidance or directives to follow, and to focus guidance and directives that are unlikely to change during the time the temporary rules are in effect. With input from Division of Public Health and others in DHHS, easier rules for providers to navigate and comply can be generated.

DHSR Response to Comments Above:

The agency has worked collaboratively with stakeholders (including the associations that provided comment above) to clarify the language in (b), which is now (c) in rule 13G .1701. The new language clarifies that a facility should follow CDC guidance and its own infection control policies and procedures unless more specific guidance or directives have been issued by NCDHHS or the local health department, in which case, the facility shall implement the specific guidance and directives. CDC guidance is issued nationally and serves as a basis, or foundation, for infection prevention and control in long term care facilities. However, it can be reasonably expected that states or local health departments may issue specific guidance or directives based on the special circumstances within each state, county, or even each facility.

In regard to the comments that the associations believe that the temporary rules should not become permanent rules, these comments are not relevant to the current proceedings. The issue before the agency at this time is the adoption of temporary rules to take the place of the emergency rules that will expire in January 2020. While the agency does intend to pursue permanent rulemaking for these rules, that is a separate process during which the agency will continue to engage all relevant stakeholders and will include another public comment period and opportunities to make changes to the rules. Additionally, the permanent rulemaking process will include an analysis of the fiscal impact of the rules on all relevant parties. For now, both associations have purported to the agency that they are in support of temporary rules and the agency has been transparent throughout the temporary rulemaking process and made several modifications to the rules based on their feedback.

The agency believes that it is imperative for the health and safety of residents in family care homes, not just during a pandemic but for everyday operations, that facilities have clear requirements for the development and implementation of effective infection prevention and control practices in the facility. Family care home residents are increasingly older, more medically complex, and at a higher risk of complications due to various infectious diseases. Residing in a congregate living setting also increases their risk. Additionally, family care homes are typically not staffed with clinical professionals who have the education and training to understand, recognize and evaluate situations that pose significant risks to residents. The rules before the Medical Care Commission seek to strengthen the existing rules and statues for infection prevention and control, which are currently vague and lack specific guidance to facilities on preventing communicable diseases. Equally important, the new rules set forth requirements for reporting suspected outbreaks to the appropriate agency, as well as informing residents, their families, and staff when an outbreak occurs. The temporary rules before the Commission, after consideration and incorporation of feedback from stakeholders, are recommended by the agency for final adoption.

3) Listing of Comments Received and Agency's Consideration of General Comments:

Commenter	Comment Summary
1) N.C. Senior Living Association (NCSLA) (public hearing comment)	Emergency rules were effective 10/23/20 due to the coronavirus. The Agency is moving to make temporary rules using the emergency rules' basis for that. Understands the rules were in response to the coronavirus pandemic and why doing temporary rules. But would expect the temporary to expire and not become permanent rules in any way. Reason being these rules were to address the coronavirus pandemic and its effect on ACHs and FCHs. These rules have a significant financial impact for facilities to develop the policies procedures, implement those, train staff on them, etc. To have these as temporary rules, or even before it could ever be considered for permanent rule, a lot of discussion and due diligence on the part of the Agency is needed regarding the fiscal impact and whether facilities can even comply with these rules.
2) N.C. Assisted Living Association (NCALA)	Rules would impose permanent infection control procedures on NC ACHs and FCHs. When rules were first proposed in early Oct. '20 during the COVID pandemic, NCALA worked with and supported the Department for developing and implementing temporary rules for the public health emergency. The rules were developed quickly because of the pandemic. We do not support these same rules becoming permanent rules because more time and input is needed in developing appropriate infection control rules to govern providers during times of both public health emergency and non-emergency operation periods. We support the development and implementation of permanent rules governing infection control policies and procedures, programs, and reporting obligations for ACH and FCH, but not the adoption of the current temporary rules as permanent rules. Permanent rules should be developed outside the context of a public health emergency, with full participation of all affected stakeholders, and when they have time to offer input and have discussions about the substance of such rules. We believe permanent rules should be developed as quickly as possible, but also believe sufficient time should be dedicated to the development of the rules and with participation of affected stakeholders.
3) N.C. Senior Living Association (NCSLA) (written comment)	DHSR and the Commission are in the process of making the emergency infection control rules as temporary rules. The emergency rules were passed in response to COVID-19, and it appears DHSR and Commission are on track to make permanent infection control rules. Our association together with NCALA, worked with DHSR in October when the rules were first being considered. We appreciate the need for rules to address certain standards for providers to protect residents and staff during the pandemic. We do not support making these rules permanent due to the increased costs of compliance, especially for ACH and FCH receiving fixed public funding from state/county special assistance for room and board and Medicaid for personal care services. Without increases in public reimbursement, many facilities receiving funding from public sources (majority of facilities), would be set up for failure. Prior to the pandemic, infection control

Commenter	Comment Summary
	statutes and rules were in place for ACH and FCH such as G.S. 131D-4.4A, 10A NCAC 13F .1004(n) and 10A NCAC 13G .1004(n), and 10A NCAC 13F .1211(a)(4) and 10A NCAC 13G .1211(a)(4). The above rules were working well for ACH and FCH prior to the pandemic and continue to work well. If DHSR and the Commission want to add additional infection control regulatory requirements as permanent rules, it needs to be done after the pandemic has ended, not in response to the pandemic, and with a complete and thorough fiscal impact evaluation before being approved. The emergency and temporary rules were in response, in part, to our concern that DHSR was citing facilities during the pandemic for not complying with CDC, DHHS, and local health department guidelines and recommendations. These citations not only lacked authority, but was seen as ambiguous and unreasonable since the guidelines and recommendations continue to change and evolve as the pandemic has unfolded. DHSR determined emergency rules were needed. We believe that was the correct decision to provide further requirements for providers during the pandemic; however, the developed rules and the temporary rules fall short in several areas.

DHSR Response to Comments Above:

The agency has worked collaboratively with stakeholders (including the associations that provided comment above) to clarify the language in (b), which is now (c) in rules 13F .1801 and 13G .1701. The new language clarifies that a facility should follow CDC guidance and its own infection control policies and procedures unless more specific guidance or directives have been issued by NCDHHS or the local health department, in which case, the facility shall implement the specific guidance and directives. CDC guidance is issued nationally and serves as a basis, or foundation, for infection prevention and control in long term care facilities. However, it can be reasonably expected that states or local health departments may issue specific guidance or directives based on the special circumstances within each state, county, or even each facility.

In regard to the comments that the associations believe that the temporary rules should not become permanent rules, these comments are not relevant to the current proceedings. The issue before the agency at this time is the adoption of temporary rules to take the place of the emergency rules that will expire in January 2020. While the agency does intend to pursue permanent rulemaking for these rules, that is a separate process during which the agency will continue to engage all relevant stakeholders and will include another public comment period and opportunities to make changes to the rules. Additionally, the permanent rulemaking process will include an analysis of the fiscal impact of the rules on all relevant parties. For now, both associations have purported to the agency that they are in support of temporary rules and the agency has been transparent throughout the temporary rulemaking process and made several modifications to the rules based on their feedback.

The agency believes that it is imperative for the health and safety of residents in adult care homes, not just during a pandemic but for everyday operations, that facilities have clear requirements for the development and implementation of effective infection prevention and control practices in the facility. Adult care home residents are increasingly older, more medically complex, and at a higher risk of complications due to various infectious diseases. Residing in a congregate living setting also increases their risk. Additionally, adult care homes are typically not staffed with clinical professionals who have the education and training to

understand, recognize and evaluate situations that pose significant risks to residents. The rules before the Medical Care Commission seek to strengthen the existing rules and statues for infection prevention and control, which are currently vague and lack specific guidance to facilities on preventing communicable diseases. Equally important, the new rules set forth requirements for reporting suspected outbreaks to the appropriate agency, as well as informing residents, their families, and staff when an outbreak occurs. The temporary rules before the Commission, after consideration and incorporation of feedback from stakeholders, are recommended by the agency for final adoption.