

**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 NC 27603
EDGERTON BUILDING
CONFERENCE ROOM - 026A**

Via Microsoft TEAMS video-conference ([Click here to join the meeting](#))

Or

Dial-in: +1 984-204-1487 (ID#: 184704620#)

March 10, 2021

11:30 A.M.

AGENDA

I. Meeting Opens – Roll Call

II. Chairman’s Comments.....Dr. John Meier

III. 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.

IV. 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.

V. New Business

A. Rules for Initiating Rulemaking Approval (Discuss rules & fiscal note)

1. Adult Care Home & Family Care Home Rules.....N. Pfeiffer & M. Lamphere

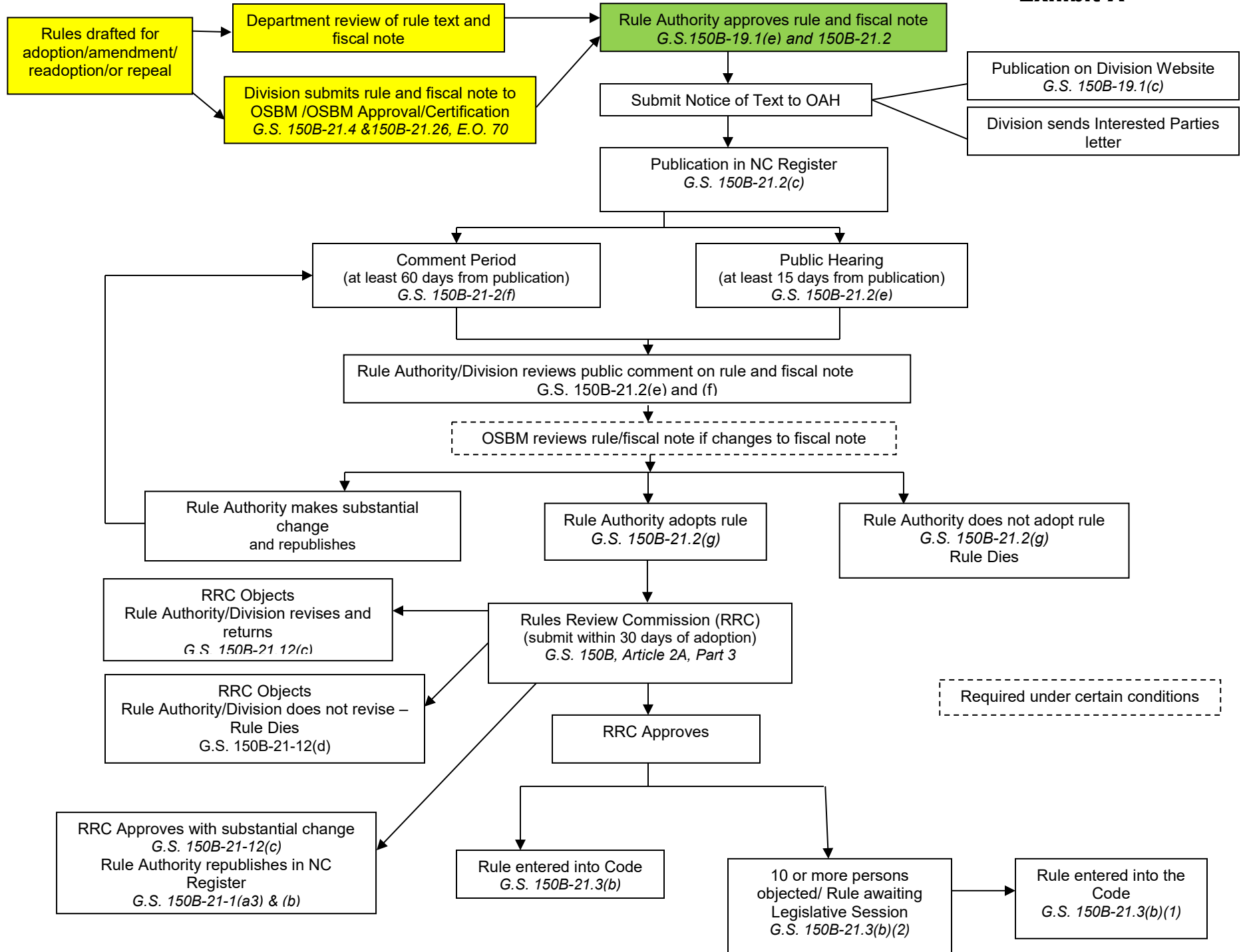
Permanent adoption of four rules for infection prevention policies and procedures, communicable disease reporting

- Rules: 10A NCAC 13F .1801, .1802, .1701 & .1702 (See Exhibits A thru A/3)

VI. Meeting Adjournment

Process for Medical Care Commission to Initiate Rulemaking

Exhibit A



1 10A NCAC 13F .1801 is proposed for adoption as follows:
2

3 **SECTION .1800 - INFECTION PREVENTION AND CONTROL**
4

5 **10A NCAC 13F .1801 INFECTION PREVENTION AND CONTROL PROGRAM**

6 (a) In accordance with Rule .1211(a)(4) of this Subchapter and G.S. 131D-4.4A(b)(1), the facility shall establish and
7 implement an infection prevention and control program (IPCP) consistent with the federal Centers for Disease Control
8 and Prevention (CDC) published guidelines on infection prevention and control.

9 (b) The facility shall assure the following policies and procedures are established and implemented consistent with
10 the federal CDC published guidelines, which are hereby incorporated by reference including subsequent amendments
11 and editions, on infection control that are accessible at no charge online at <https://www.cdc.gov/infectioncontrol>, and
12 addresses the following:

13 (1) Standard and transmission-based precautions, for which guidance can be found on the CDC website
14 at <https://www.cdc.gov/infectioncontrol/basics>, including:

15 (A) respiratory hygiene and cough etiquette;

16 (B) environmental cleaning and disinfection;

17 (C) reprocessing and disinfection of reusable resident medical equipment;

18 (D) hand hygiene;

19 (E) accessibility and proper use of personal protective equipment (PPE); and

20 (F) types of transmission-based precautions and when each type is indicated, including contact
21 precautions, droplet precautions, and airborne precautions;

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

25 (3) Measures the facility should consider taking in the event of a communicable disease outbreak to
26 prevent the spread of illness, such as isolating infected residents; limiting or stopping group
27 activities and communal dining; limiting or restricting outside visitation to the facility; screening
28 staff, residents and visitors for signs of illness; and use of source control as tolerated by the residents.

29 (4) Strategies for addressing potential staffing issues and ensuring staffing to meet the needs of the
30 residents during a communicable disease outbreak;

31 (c) When a communicable disease outbreak has been identified at the facility or there is an emerging infectious disease
32 threat, the facility shall ensure implementation of the facility's IPCP, related policies and procedures, and published
33 guidance issued by the CDC; however, if guidance or directives specific to the communicable disease outbreak or
34 emerging infectious disease threat have been issued in writing by the North Carolina Department of Health and Human
35 Services or local health department, the specific guidance or directives shall be implemented by the facility.

1 (d) In accordance with Rule .1211 of this Subchapter and G.S. 131D-4.4A(b)(4), the facility shall ensure all staff are
2 trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs (b)(1) through (2)
3 of this Rule.

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

6
7 *History Note: Authority G.S. 131D-2.16; 131D-4.4A; 143B-165;*
8 *Emergency Adoption Eff. October 23, 2020;*
9 *Temporary Adoption Eff. December 30, ~~2020~~; 2020;*
10 *Adopted Eff. October 1, 2021.*

1 10A NCAC 13F .1802 is proposed for adoption as follows:

2

3 **10A NCAC 13F .1802 REPORTING AND NOTIFICATION OF A SUSPECTED OR CONFIRMED**
4 **COMMUNICABLE DISEASE OUTBREAK**

5 (a) The facility shall report suspected or confirmed communicable diseases and conditions within the time period and
6 in the manner determined by the Commission for Public Health as specified in 10A NCAC 41A .0101 and 10A NCAC
7 41A .0102(a)(1) through (a)(3), which are hereby incorporated by reference, including subsequent amendments.

8 (b) The facility shall inform the residents and their representative(s) and staff within 24 hours following confirmation
9 by the local health department of a communicable disease outbreak. The facility, in its notification to residents and
10 their representative(s), shall:

- 11 (1) not disclose any personally identifiable information of the residents or staff;
- 12 (2) provide information on the measures the facility is taking to prevent or reduce the risk of
13 transmission, including whether normal operations of the facility will change;
- 14 (3) provide weekly updates until the communicable illness within the facility has resolved, as
15 determined by the local health department; and
- 16 (4) provide education to the resident(s) concerning measures they can take to reduce the risk of spread
17 or transmission of infection.

18

19 *History Note: Authority G.S. 131D-2.16; 131D-4.4B; 131D-4.5; 143B-165;*
20 *Emergency Adoption Eff. October 23, 2020;*
21 *Temporary Adoption Eff. December 30, ~~2020~~ 2020;*
22 *Adopted Eff. October 1, 2021.*

1 10A NCAC 13G .1701 is proposed for adoption as follows:

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3

SECTION .1700 - INFECTION PREVENTION AND CONTROL

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

6 (a) In accordance with Rule .1211(a)(4) of this Subchapter and G.S. 131D-4.4A(b)(1), the facility shall establish and
7 implement an infection prevention and control program (IPCP) consistent with the federal Centers for Disease Control
8 and Prevention (CDC) published guidelines on infection prevention and control.

9 (b) The facility shall assure the following policies and procedures are established and implemented consistent with
10 the federal CDC published guidelines, which are hereby incorporated by reference including subsequent amendments
11 and editions, on infection control that are accessible at no charge online at <https://www.cdc.gov/infectioncontrol>, and
12 addresses the following:

13 (1) Standard and transmission-based precautions, for which guidance can be found on the CDC website
14 at <https://www.cdc.gov/infectioncontrol/basics>, including:

15 (A) respiratory hygiene and cough etiquette;

16 (B) environmental cleaning and disinfection;

17 (C) reprocessing and disinfection of reusable resident medical equipment;

18 (D) hand hygiene;

19 (E) accessibility and proper use of personal protective equipment (PPE); and

20 (F) types of transmission-based precautions and when each type is indicated, including contact
21 precautions, droplet precautions, and airborne precautions;

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

25 (3) Measures the facility should consider taking in the event of a communicable disease outbreak to
26 prevent the spread of illness, such as isolating infected residents; limiting or stopping group
27 activities and communal dining; limiting or restricting outside visitation to the facility; screening
28 staff, residents and visitors for signs of illness; and use of source control as tolerated by the residents.

29 (4) Strategies for addressing potential staffing issues and ensuring staffing to meet the needs of the
30 residents during a communicable disease outbreak;

31 (c) When a communicable disease outbreak has been identified at the facility or there is an emerging infectious disease
32 threat, the facility shall ensure implementation of the facility's IPCP, related policies and procedures, and published
33 guidance issued by the CDC; however, if guidance or directives specific to the communicable disease outbreak or
34 emerging infectious disease threat have been issued in writing by the North Carolina Department of Health and Human
35 Services or local health department, the specific guidance or directives shall be implemented by the facility.

1 (d) In accordance with Rule .1211 of this Subchapter and G.S. 131D-4.4A(b)(4), the facility shall ensure all staff are
2 trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs (b)(1) through (2)
3 of this Rule.

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

6
7 *History Note: Authority G.S. 131D-2.16; 131D-4.4A; 143B-165;*
8 *Emergency Adoption Eff. October 23, 2020;*
9 *Temporary Adoption Eff. December 30, ~~2020~~; 2020;*
10 *Adopted Eff. October 1, 2021.*

1 10A NCAC 13G .1702 is proposed for adoption as follows:

2

3 **10A NCAC 13G .1702 REPORTING AND NOTIFICATION OF A SUSPECTED OR CONFIRMED**
4 **COMMUNICABLE DISEASE OUTBREAK**

5 (a) The facility shall report suspected or confirmed communicable diseases and conditions within the time period and
6 in the manner determined by the Commission for Public Health as specified in 10A NCAC 41A .0101 and 10A NCAC
7 41A .0102(a)(1) through (a)(3), which are hereby incorporated by reference, including subsequent amendments.

8 (b) The facility shall inform the residents and their representative(s) and staff within 24 hours following confirmation
9 by the local health department of a communicable disease outbreak. The facility, in its notification to residents and
10 their representative(s), shall:

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

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

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

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

18

19 *History Note: Authority G.S. 131D-2.16; 131D-4.4B; 131D-4.5; 143B-165;*
20 *Emergency Adoption Eff. October 23, 2020;*
21 *Temporary Adoption Eff. December 30, ~~2020~~ 2020;*
22 *Adopted Eff. October 1, 2021.*

DHSR Adult Care Licensure Section
Fiscal Impact Analysis
Permanent Rule Adoption with Substantial Economic Impact

Agency: North Carolina Medical Care Commission

Contact Persons: Nadine Pfeiffer, DHSR Rules Review Manager, (919) 855-3811
Megan Lamphere, Adult Care Licensure Section Chief, (919) 855-3784
Tichina Hamer, Director of Programs, (919) 855-3782

Impact:

Federal Government: No
State Government: Yes
Local Government: No
Private Entities: Yes
Substantial Impact: Yes

Titles of Rule Changes and N.C. Administrative Code Citation

Rule Adoption (*See proposed text of these rules in Appendix*)

10A NCAC 13G .1701	Infection Prevention and Control Program
10A NCAC 13G .1702	Reporting and Notification of a Suspected or Confirmed Communicable Disease Outbreak
10A NCAC 13F .1801	Infection Prevention and Control Program
10A NCAC 13F .1802	Reporting and Notification of a Suspected or Confirmed Communicable Disease Outbreak

Authorizing Statutes: G.S. 131D-2.16; G.S. 131D-4.4; 143B-165

Introduction:

In North Carolina, assisted living facilities are defined by law as “adult care homes.” There are over 1100 licensed adult care homes licensed by the Adult Care Licensure Section (ACLS) and approximately 39,000 licensed beds. There are two main categories of Adult Care Homes (ACHs)—family care homes and adult care homes. Family care homes (FCHs) are facilities with a licensed capacity of two to six residents. Due to the facility’s licensed capacity, the number of staff working at the facility may be limited to one to two staff per shift depending upon the assessed needs of the residents. Staff may also be live-in staff.

Adult care homes are larger facilities with a licensed capacity of seven or more residents. Currently, 14% of licensed adult care homes have a licensed capacity of 100 or more residents.¹ The facility with the highest capacity has 201 beds. The majority of licensed adult care facilities

¹ (2020 Adult Care Homes data from Long Term Care Safety Initiative System)

have a capacity between 60-99 residents (47%).¹ These facilities can receive a special designation as a Special Care Unit licensed to serve residents with certain diagnoses, such as Alzheimer’s disease or dementia. Forty-two percent of adult care facilities have licensed special care units.² Facilities are required to provide sufficient staff to provide care and supervision based on the facility’s census and assessed needs of the residents. Residents admitted to adult care homes (and family care homes) must be at least 18 years old. Based on the 2020 ACLS Facility License Renewal data, 61% of the resident population was at least 65 years old. Residents ages 75 and older make up 63% of the total resident population. Almost 20% of residents are over the age of 85.

Most of the rules for both types of ACHs are the same with the primary exception of staffing and physical plant requirements since they serve the same population based on need for care and services. From this point onward in this report, the term “adult care home (ACH)” refers in general to both types of facilities—adult care homes and family care homes.

Adult care homes provide 24-hour care and services for residents who need assistance with various tasks such as personal care, medication administration, food and nutrition services, health care referral, housekeeping and laundry, social and recreational activities, and supervision for safety. These services are provided based on a resident’s assessed needs. Most residents require assistance with personal care tasks such as bathing, dressing, feeding, toileting and ambulation with devices such as a wheelchair or walker. Assessed health care needs may include wound care, medication administration through injections, use of oxygen and collecting and testing fingerstick blood samples. These assessed needs, along with others referenced in 10A NCAC 13F .0903 and 10A NCAC 13G .0903, are considered “licensed health professional support (LHPS)” tasks and require a registered nurse to assess each resident who requires these tasks on a quarterly basis, provide guidance to the staff on caring for the resident, and identify any issues unable to be assessed by the facility’s unlicensed staff and need to be communicated to the resident’s physician.

Adult care homes employ unlicensed staff to provide personal care, administer medications and supervise residents. Regulations require staff to be at least 18 years old, have a high school diploma or general education degree (GED), and no substantiated listing on the Healthcare Personnel Registry for findings such as resident abuse, neglect and misappropriation of property. ACHs may employ individuals with no work history and no prior work experience in a healthcare setting.

Staff hired in positions that involve providing direct care to residents, such as Personal Care Aides or Medication Aides, are required by General Statutes and rules, at a minimum, to attend classroom training and have certain skills validated by a registered nurse who observes staff performing the tasks.

The purpose of licensure rules is to establish the minimum standards for adult care homes to ensure the health, safety and well-being of residents. For adult care homes in particular, licensure rules establish requirements for training unlicensed individuals who are caring for a vulnerable population with medical and cognitive impairments that place them at greater risk for abuse, neglect, exploitation, harm or even death.

² Data from Adult Care Homes 2020 Facility License Renewal Applications

The Need for Infection Control Rules:

Although there are several reasons why infection control rules are needed for ACHs, the primary reasons are: the unique vulnerabilities of a congregate living setting, the health conditions and age of residents, and the limitations of unlicensed staff who provide care to the residents in these settings. But most obviously, in settings where hands-on health care services are being provided to people, basic infection prevention and control practices protect people by reducing the transmission of disease and can potentially save lives.

First, ACHs are congregate living settings where residents share dining room space during meals, living room space for activities, bathrooms and share living space with another resident as roommates. Residents freely move throughout the facility to visit other residents. While residents are encouraged to interact and talk with each other during activities and dining, infectious diseases, including but not limited to, influenza, norovirus, and coronavirus, can quickly spread among residents due to the close contact with each other, as well as among roommates.

Second, residents in ACHs are at greater risk of experiencing complications and negative outcomes from exposure to various communicable diseases and bloodborne pathogens. Individuals who live in ACHs typically have physical disabilities, chronic illness, mental or behavioral health conditions, or a combination of these conditions. Residents have a range of medical and cognitive diagnoses which includes diabetes, hypertension, obesity, heart disease, stroke, chronic obstructive pulmonary disease (COPD), and dementia. In an article published by Healio, Dr. Keith Kaye reveals, “older adults become more susceptible to infections due to several factors. As people get older, it is more frequent that they have comorbid conditions, such as diabetes, renal insufficiency and arthritis. Many comorbid conditions, both the number and type of comorbid conditions, predispose people to infections”.³

Individuals move into ACHs for assistance because of these various needs and conditions. Staff in facilities provide this personal, close contact care to many residents throughout the day. Staff are within close proximity to residents and other staff members for prolonged periods of time and touching many of the same surfaces and reusing various equipment to carry out their work. All of these factors make transmission of viruses and communicable diseases more likely to occur in this environment, and sound infection prevention and control practices are critical to maintaining the health and safety of residents and staff.

Another challenge in these congregate living settings is the difficulty in effectuating some recommended environmental controls when there is an outbreak. ACHs typically serve as a resident’s home for the long term, and therefore, facilities have limited space and room availability to properly quarantine, isolate, and cohort residents if they become ill. This can make it hard for facilities to manage an outbreak once a virus has entered a facility.

³ (Healio News, 2011) “Comorbidities, metabolic changes make elderly more susceptible to infection”

North Carolina Public Health Communicable Disease Outbreak Report Summary for 2015-2018⁴ revealed 73% of reported communicable disease outbreaks were from the state’s long-term care facilities, including nursing homes and adult care homes. Over this 4-year span, communicable disease reports in long-term care facilities have doubled. Of all the reports from every setting, 49% were respiratory causes with influenza being 93% of those illnesses reported; 41% were gastrointestinal causes with norovirus being 80% of those types of illnesses reported; and 10% of reports were related to other causes such as scabies.

Generally, the most common communicable disease is influenza, or “the flu.” The influenza virus can be spread between residents, staff and visitors. The Centers for Disease Control and Prevention (CDC) estimates, in recent years, “that between 70 percent and 85 percent of seasonal flu-related deaths have occurred in people 65 years and older, and between 50 percent and 70 percent of seasonal flu-related hospitalizations have occurred among people in this age group”.⁵ The flu, for example, can worsen certain medical conditions, such as diabetes, by raising a person’s blood sugar or increase the risk of serious complications.⁶

Worst Case Scenario: A Global Pandemic – COVID-19 and Its Impact on ACHs

Congregate living settings present unique challenges in infection control of communicable diseases. The coronavirus pandemic has hit long-term care residents particularly hard. “Since the start of the pandemic, 100,033 residents and staff at long-term care facilities have died from COVID-19 as of November 24, 2020.”⁷ In North Carolina, residential care facilities account for 10,493 cases, 743 deaths, and there have been 273 outbreaks.⁸ This represents over 1/10th of the total deaths in North Carolina.⁹ There have been 20,978 cases, 2,280 deaths, and 303 outbreaks at nursing homes. As this data shows, highly communicable diseases can be especially deadly in congregate living situations, which is why infection control practices are an essential part of care of residents in adult and family care homes. The pandemic has highlighted and enhanced a need that previously existed which was to improve the quality of policies and training around IPC.

COVID-19 represents a worst-case scenario for assisted living settings and the impact of a communicable disease. COVID-19, is a new coronavirus that “spreads through respiratory droplets or small particles, such as those in aerosols, produced when an infected person coughs, sneezes, sings, talks, or breathes”.¹⁰ COVID-19, has killed more than 500,000 people as a result of the infection in 2020-2021, in comparison to the flu which 22,000 people

⁴ Outbreak Report Summary: 2015-2018, NC DHHS Epidemiology Communicable Disease Reports. Data retrieved 1/7/2021. https://epi.dph.ncdhhs.gov/cd/figures/aggregate_outbreak_data_2015_2018.pdf

⁵ (CDC, 2020) Seasonal Influenza (Flu) Who is at High Risk for Complications

⁶ (WedMD.com) “6 Health Problems to Watch For”

⁷ Kaiser Family Foundation, “COVID-19 Has Claimed the Lives of 100,000 Long-Term Care Residents and Staff,” <https://www.kff.org/policy-watch/covid-19-has-claimed-the-lives-of-100000-long-term-care-residents-and-staff/>.

⁸ Outbreaks and Clusters, NC DHHS COVID Dashboard. Data retrieved 1/7/2021.

<https://covid19.ncdhhs.gov/dashboard/> outbreaks-and-clusters

⁹ NCDHHS’ COVID-19 Response. Data retrieved 12/17/2020. <https://covid19.ncdhhs.gov/>

¹⁰ (CDC, 2021)Frequently Asked Questions <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Basics>

died in 2019-2020. The flu is also a communicable disease spread through similar mode of transmission as COVID-19.

Although infectious diseases occur in both nursing homes and ACHs, unlike nursing homes, ACHs do not have the advantage of being staffed with licensed health care professionals. ACHs are not required to have a registered nurse on duty or onsite to provide clinical assessment and monitoring of residents' conditions or to oversee unlicensed personnel and implementation of infection control measures. ACHs also do not have medical directors to direct or guide facility infection prevention and control programs. In a recent survey conducted by the Division of Health Service Regulation Adult Care Licensure Section, 59% of facilities reported they do not employ a registered nurse on duty. Therefore, for the safety of residents and staff and to prevent and reduce the spread of communicable diseases in ACHs, well-defined regulations requiring comprehensive infection prevention and control policies and procedures are warranted to ensure unlicensed staff have guidelines and proper training to prevent and limit spread the spread of communicable diseases and bloodborne pathogens.

Administrators are responsible for the overall operation of the facility and often develop the policies and procedures that direct how staff are to respond to and handle incidents and accidents, emergencies and infection control. As part of improving the quality of care and services and the overall management of the facility, administrators may earn continuing education credits towards their biennial re-certification for course work related to infection control.

Facility staff have many and varied duties within ACHs, depending on the facility. They are responsible for performing multiple tasks for residents which include administering medications, meal preparation, assistance with activities of daily living, housekeeping and laundry, nutrition and food services, and ensuring safety. The lack of ongoing staff education related to infection prevention and control and the facility's policies and procedures on implementing these critical measures contributes to the increased rates of transmission of communicable diseases in this setting. Research from Walden University, studied the impact of hospital-acquired infections (HAIs) on staff and associated costs to patients and staff.¹¹ (Debesai, 2019) This research focused on "reprocessing medical devices to prevent HAIs".¹¹ The research reveals that the CDC and the Food and Drug Administration issued a health advisory that focused on ensuring adequate training for personnel involved in reprocessing medical devices to prevent HAIs", which recommended training "upon hire and at least one year after the initial hiring date".¹¹ This research drew a correlation between staff training and infection control measures which reduced HAIs by 70% "when employees and providers were aware of infections and had adequate training in infection prevention".¹¹ It was noted in the report that healthcare workers should adhere to the standards and wearing PPE.¹¹ Although the research was focus on HAIs, the conclusion can be drawn that providing training to adult care facility staff routinely on how to use PPE and staff adherence to wearing PPE may prevent or reduce the spread of infectious diseases.

As mentioned previously, staff working in ACHs have frequent and direct contact with residents and do not have clinical training or backgrounds. The most common qualifications that employees

¹¹ (Debesai, Strategies Healthcare Managers Use to Reduce, 2019)
<https://scholarworks.waldenu.edu/cgi/viewcontent.cgi?article=7694&context=dissertations>

of adult care homes have are completion of personal care aide training and medication aide certificates. Personal care aides must complete 80 hours of training and competency evaluation completed by a registered nurse. Personal Care aides receive basic training in infection control and universal precautions. Medication aides are unlicensed staff who administer medications to residents independently and not under the supervision of a licensed professional. N.C. Gen. Stat. § 131D-4.5B requires medication aides to complete 15 hours of training, one-time clinical skills evaluation by a registered nurse, and pass an exam. Medication aides, as part of their training, are evaluated by a registered nurse on infection control skills related to administering medications.

Lastly, based on infectious outbreak data and recent and past compliance data, there is a need for the state licensing agency to have the clear authority to enforce regulations with infection prevention and control standards and guidance for the protection of residents. Providers are required to report to public health officials per N.C. Gen. Stat. §131D-4.4B, but not required to implement written strategies that would reduce the risk of spreading infectious diseases to other residents. Current rules are vague and, as evidenced by the COVID-19 pandemic, detailed requirements are needed to promote better understanding and prevention of communicable diseases and bloodborne pathogens and implementation of safe practices to prevent harm and transmission of illness. The proposed rules ensure that basic infection prevention and control standards of care are applied consistently adult in care facilities across the state. The rules set forth clearly defined minimum requirements of IPC and provide ACLS the ability enforcement those requirements, and as a result will reduce the transmission of infectious diseases.

III. Baseline

Adult care homes have been required to comply with basic infection control standards related to bloodborne pathogens since January 1, 2012, based on N.C. Gen. Stat. § 131D-4.4A. The statute requires ACHs to develop written infection control policies consistent with CDC guidelines to prevent the spread of blood borne pathogens. The statute also requires providers to monitor the facility's compliance with IC policies and update the policies as necessary to prevent transmission. The facility is required to have a staff person on-site who is knowledgeable of the CDC infection control guidelines.

Since the adoption of current rules in 2005, facilities have been required to maintain infection control policies in accordance with 10A NCAC 13F .1211 and 13G .1211; however, the rules as written provide no specific criteria indicating what should be included in the IC policies and procedures nor measures facilities should take if there is a suspected communicable disease case or outbreak.

Although current general statutes and rules both address infection control and staff training, these requirements are limited. In 2018 and 2019, N.C. Gen. Stat. § 131D-4.4A was cited 40 times against adult care homes for reasons including medication aides using a single glucometer for multiple residents, and not following infection control policies. In the seven months prior to COVID-19 (September 2019– March 2020), 48 citations were issued to adult care homes for failure to provide training to medication aides which includes infection control training.

Infection prevention and control emergency rules were implemented effective October 23, 2020 through December 30, 2020. Since the implementation of the emergency rules, 13F .1801 and 13G

.1701, ACLS identified non-compliance in both adult care and family care homes related infection prevention and control. As a result, of the 56 facilities surveyed, adult care facilities were cited at a rate of 48.6% for non-compliance with rule 13F .1801, and family care homes were cited for non-compliance with rule 13G .1701 at a rate of 68.4%. However, these rates are based on surveys that were done primarily as a response to complaints received by the licensing agency and do not represent the overall population of adult care homes and family care homes that are expected to need to implement additional infection control procedures above those that they normally do.

Review of Proposed Rules: Infection Prevention and Control Program 10A NCAC 13F .1801 and 13G .1701

The proposed permanent rules were developed to give ACHs specific requirements to address in infection prevention and control policies and procedures and compel facilities to implement recommendations from the CDC, NCDHHS and the local health department when necessary for the health and safety of residents and staff. The rules are the minimum standards that facilities should have as part of the written IPC policies and procedures. The requirement for facilities to have IPC policies and procedures is not a new standard. Providers are currently required to comply with N.C. Gen. Stat. 131D-4.4A and 10A NCAC 13F/13G .1211 which requires infection control policies dealing specifically with bloodborne pathogens to be consistent with CDC guidelines.

It should be noted that the proposed rules apply to any communicable disease that may impact residents living at ACHs irrespective of a global pandemic. The focus of implementation of the rules will be addressed from the perspective of “normal” or “non-pandemic” events with diseases that typically impact ACHs each year, such as the influenza, norovirus and bloodborne pathogens. While COVID-19 has certainly had an incredible impact on ACHs this past year and cannot be discounted, it is not a typical or common occurrence in these facilities and will be addressed separately at the conclusion of this report.

Proposed Rule 13F .1801(a)/13G .1701(a)

The rule requires providers to establish and implement IPC programs and IC policies in accordance with CDC guidelines. It should be noted that this rule is not a new requirement. ACHs are currently required to comply with N.C. Gen. Stat. 131D-4.4A and 10A NCAC 13F/13G .1211 which require ACHs to have infection control policies and infection control policies related to bloodborne pathogens to be consistent with CDC guidelines. The proposed rule was added to provide clarity regarding the minimum requirements of the ACH’s infection control policy and present a cohesive set of rules, making it easier for providers to access and follow and improve consistency across the state.

Proposed Rule 13F .1801(b)/13G .1701(b)

Rules (b)(1) through (b)(4) provide define the areas that are to be included in a facilities’ IPC policies and procedures. These areas are the very basic foundation of infection prevention and control in a long-term care congregate living setting. The rule directs providers to assure that the policies and procedures developed are consistent with CDC guidelines. This rule provides the CDC website where providers can locate the latest information and resources, including toolkits, where are available at no cost, for provider to address the components listed in rule (b)(1)(a-f), which

requires providers, at a minimum, to address standard and transmission-based precautions. The IPC policies and procedures should specifically address the following:

- respiratory hygiene and coughing etiquette,
- environmental cleaning and disinfection,
- reprocessing and disinfection of reusable resident medical equipment;
- hand hygiene;
- accessibility and proper use of personal protective equipment (PPE);
- types of transmission-based precautions and when each type is indicated, including contact precautions, droplet precautions, and airborne precautions.

The CDC website provides detailed information and some toolkits for providers to reference regarding each item required to be included in the IPC policies and procedures. These are basic, evidence-based practices employed in all health care settings to prevent the spread of illness between residents and staff. It should be noted providers are currently required to comply with U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) regulations when occupational hazards are assessed by facilities. While OSHA requirements are focused on worker safety, there are some of these requirements that overlap with the proposed rules for resident safety. Also, to assist their members with implementation of this requirement, the N.C. Senior Living Association and N.C. Assisted Living Association collaborated to develop a template of policies and procedures and have provided those to their member facilities. Providers are required to have IPC policies and procedures. Any fiscal impact of updating the policies is expected to be due to ensuring that the ACH's policies discuss the minimum infection control standards. As the providers have templates and CDC information readily available, the time needed to do this should be minimal.

Rule (b)(2) requires providers to ensure policies address when and how to notify the local health department for suspected reportable communicable disease or outbreak. Providers have been required to report communicable outbreaks since 2011, when N.C. Gen. Stat. § 131D-4.4B was established. ACHs should have a procedure for staff to follow when there is a suspected or confirmed reportable communicable disease condition. Staff should be aware of what these conditions are and how and where to report. In accordance with the law, the Department established the process for ACHs to report suspected communicable disease outbreaks to local health departments by telephone within 24 hours of when the outbreak reasonably suspected to exist. There is no additional burden on facilities. ACHs will need to ensure that this process is included in their policies and procedures.

Rule (b)(3) provides guidance to ACH providers of common considerations or steps to take to mitigate and reduce the spread of a suspected or known outbreak of a communicable disease. The measures listed in the rule, including isolating infected residents, limiting or stopping group activities or communal dining, conduct screenings of staff, residents and visitors, and limit visitation are measures commonly issued in CDC guidance for long term care facilities to prevent further spread and are typically included in the recommendations given by local health departments to facilities when there is an outbreak. These measures listed in the rule can be critical to preventing

further spread when implemented in a timely manner. These standard measures are not new and are ordinarily included in CDC guidance for influenza and norovirus outbreaks in LTC settings, and are also recommended protections against COVID-19 and other diseases. This rule requires the ACHs to update current IPC policies and procedures to include these measures to be considered by staff when there is illness identified in the facility.

Rule (b)(4) requires ACHs to update current IPC policies and procedures by developing a plan to address potential staffing shortages due to an illness or an outbreak. Planning for staffing issues during an outbreak is critical as oftentimes staff also fall ill or so do their family members for whom they may have personal obligations to care for. This rule compels ACHs to coordinate staff and provide procedures for facility managers and supervisors on how to ensure there is adequate staffing to meet the needs of the residents during an outbreak. Examples may include contacting a staffing agency, using staff from a sister facility or developing a pool of on-call staff. ACHs are currently required to meet staffing requirements according to 10A NCAC 13F .0600 and 13G .0600. Therefore, the impact of this rule is updating the IPC policies and procedures to reflect staffing strategies.

Rule (c) requires ACHs to implement IPC policies and procedures when a communicable disease outbreak has been identified at the facility or there is an emerging infectious disease threat. The rule is to help prevent and mitigate the spread of communicable diseases within the facility and has a direct impact on the health and safety of residents. The rule requires ACHs to follow more specific written guidance or directives when issued from the local health department or NCDHHS in response to what may be occurring in our state, in the ACHs' geographic area, or the facility itself. It is important to note that while state and local public health agencies follow guidance issued by the CDC, these agencies may also have recommendations specific to the facility, the area impacted by the infectious disease, resources available, or other factors. The rule directs facilities to follow CDC guidance, but to follow the guidance and recommendation of state and local public health officials if there is more specific guidance provided. This rule resolves any conflict between sources of guidance and requires ACHs to follow public health guidance.

Rule (d) requires ACHs to provide annual IPC training to all staff. The intent is to ensure all staff working at ACHs know and understand the facility's policies and procedures for IPC to protect residents and staff and prevent the transmission of communicable diseases and bloodborne pathogens. Per existing rule (13F/G .1211) and law (GS 131D-4.4A(b)(4)), all staff are required to be trained within 30 days of hire on the facility's policies and procedures to ensure they are able to implement these practices as they carry out their duties. The requirement for this training to be conducted annually is a new requirement and will have a fiscal impact on facilities to provide this training each year.

Rule (e) requires ACHs to ensure IPC policies and procedures are readily accessible for facility staff for reference and guidance. This is a current requirement according to 13F .1211 and 13G .1211, therefore there is no fiscal impact.

Review of Proposed Rules: 10A NCAC 13F .1802/.1702 Reporting and Notification of a Suspected or Confirmed Communicable Disease Outbreak

Rule (a) requires ACHs to report suspected or confirmed reportable communicable diseases in accordance with rules adopted by the Commission for Public Health. Since 2011, ACHs have been required to report suspected communicable disease outbreaks based on N.C. Gen. Stat. § 131D-4.4B.

Rule (b) requires ACHs to notify residents, staff and family members within 24 hours following confirmation by the local health department of a communicable disease outbreak. This is a new requirement. The intent of providing notification to residents, staff and family members within 24 hours is to mitigate the risk and spread of a confirmed communicable disease outbreak and ensure residents, staff and families are kept informed of outbreaks in the facility without sharing confidential information. Having awareness of a confirmed communicable disease outbreak prepares staff and residents for the implementation of IPC policies and procedures and keeps families abreast of possible changes in visitation.

The facility has discretion regarding how individuals are notified, such as by email, text message, or other means. If the ACH does not have an email account, letters or flyers may be considered as notification. Information to be shared may be how many residents or staff are infected, and any changes to facility policies such as visitation.

Fiscal Impact

Time Required to Update Policies and Procedures

Rules 10A NCAC 13F .1801 and 13G .1701 require ACHs to make updates to current IPC policies and procedures. The fiscal impact is based on the administrator, who is responsible for the management and operations of the facility, updating the IPC policies and procedures using the CDC resources available at no cost.

Based on a previous survey conducted by ACLS, the average administrator's salary is approximately \$55,542. On average, salary and wages account for 70% of private industry worker compensation costs for employers, with benefits accounting for 30%.¹² Using this ratio, benefits would cost an additional \$23,766 for a total annual cost of \$79,218 and hourly cost of \$38.08. Although the actual amount of time needed to update IPC policies is unknown, estimating 5 hours of research using information provided by the CDC and policy development, the cumulative cost of the administrator's time is estimated \$190.40. It is also unknown how many adult care homes whose policies would need to be updated to match the proposed rules versus those whose policies would already meet the requirements. Potentially if CDC guidance changes again in the future, there would be additional time needed to update the procedures but it is unknown when this might happen and how much time would be needed. Although ACH administrators serve as administrator for multiple facilities and use the same policies, the total cost of \$214,771 is based on each one administrator per facility.

Time Required to Provide Staff Training

There is a fiscal impact to provide annual training to staff as it is currently not required. The estimated cost is based on the number of staff required in accordance with the facility's licensed capacity, environmental services staff and food service for adult care homes. Medication aides

¹² Employer Costs for Employee Compensation – June 2020. BLS. <https://www.bls.gov/news.release/pdf/ecec.pdf>

and personal care aides' average hourly rate ranges between \$10-\$12 per hour or \$24,480 annually.^{13,14} Considering the employee's compensation and benefits for a total salary of \$34,972, the cost of providing annual infection prevention and control training to direct care staff and auxiliary support staff, such as custodians and dietary staff, the estimated cost would be \$18.25 per hour of training per staff. The number of staff varies as it is based on the company's operational structure and facility census. Based on minimum staffing chart and the average licensed capacity of 60 residents in facilities, the estimated cost of training 30 adult care employees and 5 family care home employees is approximately \$365,380.00.

Time for ACLS Staff to Spend on Enforcement of these Rules

Review of infection prevention and control practices is currently part of the ACLS survey process. The review for compliance with infection control has been part of the survey process prior to the implementation of N.C. Gen. Stat. § 131D-4.4A. Observing infection prevention and control measures includes observing medication administration, personal care, feeding assistance and the use of PPE. Non-compliance identified requires ACLS staff to document findings in a written format. There is no change in the process for ACLS staff and no additional surveyors will need to be hired to enforce these rules. The proposed rules merely provide clarification and authority to appropriately enforce non-compliance identified. The average staff hourly rate with benefits is \$44.26. The amount of time spent on enforcement includes observations, interviewing staff and residents, record reviews and documenting non-compliance. The average number of staff per survey is approximately 3 for adult care homes and 1 for family care homes. Although there is no data for the amount of time spent solely on reviewing compliance with infection control during for non-pandemic surveys, the estimated cost of enforcement is \$265.56 for three hours spent conducting the survey process. Based on the number of surveys referenced in Table 2, the estimated cost is \$32,132.76.

Time Required to Notify Resident or Representatives

It is anticipated that this requirement will have a minimal impact on ACHs. With technology today, communicating information to large groups of people can be simplified by using tools like email, phone messaging systems, or texting apps. The expectations of this rule is that ACHs notify residents and their responsible person, as well as their staff, when they become aware that there is a communicable disease outbreak in the facility. ACHs may send these groups an email or text providing notice of an outbreak at the facility. Based on ACLS data, 99% of licensed facilities reporting having an email address. Based on the average licensed capacity of 60 residents for facilities, adult care providers could create an email distribution list of families, residents, and/or staff for purposes of sharing information such as outbreaks or other emergencies. The estimated cost for an administrator to spend 15 minutes drafting and sending an email to comply with the rule to notify families and staff is an approximate total of \$9.52 for each weekly notification.

¹³ Personal care aide salary in North Carolina (careerexplorer.com)

¹⁴ Medication Aide Salary in North Carolina (indeed.com)

Cost to Comply with CDC Guidance

There is a fiscal impact to implement Rule .1801(c) and .1701(c). The cost is based on the requirement of the facility to comply with CDC guidance. Under normal circumstances, outside of a global pandemic, most facilities' current practice is to adhere to CDC guidance and OSHA regulations, such as the cost to practice hand hygiene, cleaning and disinfecting surfaces and equipment, purchasing the necessary PPE, and paper products for food service. The cost to implement this rule comes from the increase in complying with CDC guidelines (primarily PPE) from the subset of the adult care homes who do not currently comply with CDC guidance. Implementation of these new requirements will have a positive impact on ACHs ability to carry out appropriate infection prevention and control practices. As the regulations require specific measures to be a part of a facility's policies and procedures, and for staff to be trained annually on those procedures, it serves to impress upon the facility and staff the importance of taking these precautions. In addition, the regulations set forth the expectation that "guidance" or "recommendations" from the CDC, NCDHHS or the local health department are not optional and shall be followed to the greatest extent possible. The agencies are the subject matter experts on infectious disease and best practices for preventing or stopping the spread of illnesses that can be harmful to long-term care residents. They have expertise of not only how to utilize standard and transmission-based precautions, but also can assist facilities with implementing environmental controls to ensure the daily operations of the facility are not contributing to the spread of illness. The rules also clarify procedures for when there seems to be different recommendations coming from these various agencies. While all of these agencies base their recommendations off of CDC protocols, NCDHHS and local health departments may provide direction to ACHs that is more specific and geared toward a facility's unique situation, such as the resident population, local community factors, staffing issues, facility layout, etc. Given that these rules provide more concrete and specific direction to ACHs than current regulations, it is reasonable to believe that it will be easier for ACHs to implement infection prevention and control measures, follow recommendations given by public health experts, and be better prepared when there is an outbreak of an illness.

Facilities routinely purchase PPE for staff for regular infection prevention, such as gloves, to assist residents with hands-on tasks such as eating, bathing and toileting. Providers will need to supply additional PPE required when there is an outbreak of a communicable disease that is above the baseline of normal PPE usage. There is minimal data to determine the baseline of normal PPE usage in ACHs. Due to the pandemic, NCDHHS assisted providers with purchasing PPE. Based on daily burn rate data provided for gloves, in December 2020, facilities who requested PPE reported a daily burn rate as follows: as follows:

Gloves	217 pairs
Goggles	15
N-95 masks	13
"Procedural" Masks	45
Gowns	37

However, the rate of PPE usage will be dependent upon the residents and their specific conditions and any infectious diseases that residents may have at certain times, so the rate of PPE

usage will fluctuate based on these conditions. Although the size of the adult care homes that requested PPE varied greatly (capacity of 60-120), the December 2020 data reflects the adult care homes that requested PPE had an average licensed capacity of 82 residents. Family care homes licensed capacity a maximum of 6 residents.

The chart below represents some current vendors' prices for PPE.

Type of PPE	Supplier	Average Cost/Unit
Goggles	RB Medical Supply	\$5.75
Facemask	RB Medical Supply	\$7.00 (box of 50)
Nonsterile, disposable patient isolation gowns	Grainger	\$1.44
Nonsterile gloves	Grainger	\$17.50 (box of 100)
N95 respirators	RB Medical Supply	92.50 (box of 50)

Based on these prices, the average daily cost of PPE for the average PPE burn rate above would total \$207.86. However, many times goggles can be reused, so this estimate would overstate the total cost and provides a conservative estimate. This amount also reflects December 2020 usage, which was during one of the largest COVID-19 case surges and before mass vaccination in congregate living situations. In general, the overall cost of PPE would be lower without the impact of COVID-19.

Cost of Provider Violations

There is also a cost incurred by facilities as a result of violations cited by ACLS for noncompliance with implementing IPC procedures. In accordance with N.C. Gen. Stat. § 131D-34, civil penalty amounts vary based on the type of penalty and license type. The initial violation for a Type A1 for a family care home may range from \$500 to \$20,000, and an adult care may range from \$1,000 to \$20,000. Factors surrounding the violation cited will impact the penalty amount imposed. As COVID-19 became more prevalent in ACH facilities, complaints regarding infection control increased as well as the amount of non-compliance identified for failure to comply with infection control measures.

Based on ACLS data (Table 2), surveys conducted between May 2020 and October 2020, found 41% of facilities surveyed during this period were non-compliant with infection prevention and control measures. Of the facilities cited, 94% of non-compliance identified were violations. The potential cost of violations is estimated at \$25,500.

(Table 2)

ACLS Survey Data – Compliance with Infection Control May 2020-October 2020	
Number of Surveys May-October 2020	121
Number of facilities – infection control - compliant	71
Number of facilities – infection control non-compliant	50
• Adult Care facilities	34
• Family Care facilities	16

Number of facilities cited for violations (A1, A2, UA, B, UB)	47
Number of facilities cited for standard deficiencies	3

In 2020, violations cited for infection control included lack of staff training, lack of supplies for norovirus, and failure to wear proper PPE.

Fiscal Impact of COVID-19 on Proposed Rules

Currently, during the COVID-19 global pandemic, ACHs have incurred additional costs particularly for PPE (face shields, larger gown supply, thermometers) in which ACHs have received additional financial support through the passage of appropriations and temporary increased Medicaid rates.

As a result of COVID-19 and its deadly impact, the N.G. General Assembly passed the Coronavirus Relief Act 3.0, providing \$20,000,000 to licensed facilities with residents receiving Special Assistance funds to offset the increased cost of caring for residents during the pandemic. Personal Care Service rates increased for facilities with Medicaid recipients by approximately 83% from \$4.10 per unit to \$7.50 per unit to assist ACHs with the cost associated with providing personal care to residents.¹⁵ Additionally, another \$9,667,539 was appropriated to the N.C. Assisted Living Association and N.C. Senior Living Association to purchase COVID-19 tests for residents, staff and visitors in adult care homes.

Also, Session Law 2020-4, the 2020 COVID-19 Recovery Act, allocated \$7,500,000.00 to the N.C. Senior Living Association for “(i) the purchase of supplies and equipment necessary for life safety, health, and sanitation, such as ventilators, touch-free thermometers, gowns, disinfectant, and sanitizing wipes, and (ii) the purchase of personal protective equipment that meets the federal standards and guidelines from the Centers for Disease Control and Prevention, such as surgical and respiratory masks and gloves.”

Due to the advancement of vaccines, it is likely that the cost for providers to comply with coronavirus specific precautions will be decreasing and will not extend into perpetuity.

Benefits Related to Reduction of Infectious Disease Transmission & Avoidance of Disease

Non-compliance cited due to failure or refusal of a facility to implement CDC, NCDHHS and/or local public health recommendations to prevent the spread of COVID-19, has many other associated costs as well. Some of these are: increased cost for additional PPE to the facility as the virus spreads and impacts more residents and staff; cost of staff who call out sick; cost of treatment and hospitalizations of residents and staff who contracted the virus; and the cost of resident and staff lives lost from COVID-19.

There are numerous benefits that would result from decreasing the transmission of infectious diseases to both residents and healthcare workers. As the COVID-19 pandemic represents somewhat of a worst-case scenario, the discussion of benefits also runs the gamut depending on

¹⁵ (NC Division of Health Benefits, 2020) <https://medicaid.ncdhhs.gov/blog/2020/05/06/special-bulletin-covid-19-82-expedited-hardship-advances-and-retroactive-targeted>

the scale of outbreak and type of infectious disease. Decreased incidence of disease could potentially have the following benefits:

- Decrease in emergency room visits and hospitalizations for both residents and healthcare workers: According to Healthcare Finance, the average cost of a COVID-19 hospitalization for insured patients over the age of 60 was \$40,208. For an uninsured patient over 60, the cost spiked to \$77,323.¹⁶ The average cost of an influenza-related inpatient hospital stay between 2006-2016 was \$16,000.¹⁷
- Decreased occurrence of long-term impacts/reduction of risk for long-term impacts: Long-term impacts of COVID-19 infections are more likely in older people and those with many serious medical conditions. They include fatigue, shortness of breath, cough, joint pain, chest pain, muscle pain/headache, tachycardia, loss of smell or taste, memory, concentration, or sleep problems, rash, and hair loss. Heart, lung, and brain damage is also possible as are blood clots and blood vessel problems that lead to liver and kidney problems.¹⁸
- Reduction of risk of death: While we cannot necessarily say that a death would be avoided, but using CDC recommended infection practices would reduce the risk of death. The central VSL estimate for 2021 according to HHS is \$10.3M in 2014 dollars. This amount is not the value of saving an individual's life with certainty, but rather represents the amount that an individual would be willing to pay for a defined change in his or her own risk.
- Decrease in PPE costs: Reduced risk of transmission can lead to fewer residents with infections where staff need to use transmission precautions to determine appropriate PPE. This can decrease the overall cost of PPE if an outbreak is confined instead of spreading through the entire home.
- Decrease in sick call outs for employees: Reduced risk of transmission could lead to fewer sick day call outs from employees. This benefits the administration by leading to less time spent dealing with making sure there are enough staff to cover all of the residents. Absences may equate to approximately 5.7% of a provider's payroll in overtime for staff coverage.¹⁹
- A study of 161 hospitals in Pennsylvania involving 7,076 nurses who treated patients with urinary tract infections (UTIs) and surgical site infections (SSIs) focused on the impact of increasing the number of patients and patient care. The study revealed by "increasing [the] nurse workload by one patient resulted in an increase of UTIs and SSIs, resulting in 1,351 additional infections in the study population. Similarly, decreasing nurse burnout from an average of 30% to 10% could result in preventing 4,160 infections, leading to cost savings of \$41 million in the Pennsylvania hospitals (Cimiotti et al., 2012)".¹¹ "Hall, Johnson, Watt, Tsipa, and O'Connor (2016) included 46 research studies in their review and found that poor patient safety associated with moderate to high burnout and poor wellbeing of healthcare professionals. Of those 30 studies on burnout, 83.3% had a direct connection between healthcare professional burnout and poor patient safety; similarly, 88.9% of the studies on wellbeing had a direct correlation between poor wellbeing and

¹⁶ <https://www.healthcarefinancenews.com/news/average-cost-hospital-care-covid-19-ranges-51000-78000-based-age>

¹⁷ <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb253-Influenza-Hospitalizations-ED-Visits-2006-2016.jsp>

¹⁸ <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351>

¹⁹ https://www.shrm.org/hr-today/news/hr-magazine/documents/kronos_us_executive_summary_final.pdf

poor patient safety (Hall et al., 2016).¹¹ Although the study takes place at a hospital setting, the impact of staff shortage or staff call outs can have similar impacts when providing care to multiple residents.

- Better quality of care for residents due to less staffing issues: A study shows that the number of care hours per resident per day delivered by NAs is an important contributor to residents' quality of care in LTC homes.²⁰ If there are too many call-outs among staff due to infections or the need to quarantine after exposure, staff to resident ratios rise and quality of care may suffer.

Benefits of implementing effective infection prevention and control are reduction of staff call-outs, staff burnout and better care provided to residents. Practicing good infection prevention may reduce the number of staff getting from infected residents and co-workers. Staff infected with COVID-19 may be absent from work for several days and based on medical advice.²¹ Practicing infection prevention and control reduces violations cited by ACLS for non-compliance with rules.

Alternatives Considered

The proposed permanent rules were preceded by emergency and temporary rules. The emergency and temporary infection prevention and control rules for adult care homes and family care homes included language and requirements that addressed specific COVID-19 related issues that have been prevalent in facilities during the time of the pandemic. An alternative to the current proposed permanent rules would be to keep the rules the same as the emergency and temporary rules, making no changes. However, because it is expected that the impacts of COVID-19 will continue to lessen and no longer be as great a threat to resident and staff health and safety, this language would become overly burdensome to providers and may eventually become outdated. The current proposed permanent rules are a better alternative as they lay the foundation for a basic infection prevention and control program with ACHs and help to ensure facilities are prepared for and can respond to any type of illness or transmittable disease that may impact the facility. The rules ensure that policies and procedures are based on evidence and standard practice, that staff are adequately trained, and that there is good communication between the facility and others who need to be involved.

A second alternative that could be considered in lieu of the proposed rules would be to adopt the infection prevention and control regulations for nursing homes, which are established by the federal Centers for Medicare & Medicaid Services (CMS). The CMS State Operations Manual, which governs the implementation of nursing home regulations, sets for the requirements for §483.80(a),(e),(f) and states, *“The facility must establish and maintain an IPCP (Infection Prevention and Control Program) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. This program must include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, and visitors. The IPCP must follow national standards and guidelines.”* Since nursing home

²⁰ Boscart, V. M., Sidani, S., Poss, J., Davey, M., d'Avernas, J., Brown, P., Heckman, G., Ploeg, J., & Costa, A. P. (2018). The associations between staffing hours and quality of care indicators in long-term care. *BMC health services research*, 18(1), 750. <https://doi.org/10.1186/s12913-018-3552-5>

²¹ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html>

residents are typically more medically complex and susceptible to illness and rapid changes in condition, nursing homes are required to employ a myriad of clinical staff to oversee their care, including a Medical Director, Director of Nursing, and Registered Nurses. To comply with CMS regulation §483.80(b), nursing homes must also employ an “Infection Preventionist” at least part-time. The Infection Preventionist must, “*have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field; and have completed specialized training in infection prevention and control.*” This staff person must also serve on the facility’s quality assurance team and report out on any infection control related issues identified in the facility. Again, this alternative was not considered because ACHs do not generally care for residents with as high acuity as nursing homes, and they do not employ clinical staff that could oversee an IPCP such as Medical Director or Registered Nurses. Adopting CMS regulation for ACHs would be unduly burdensome and costly.

Lastly, another alternative would be to require the administrator of an adult care home to complete the “Infection Control in Long Term Care Facilities” course offered by the University of Chapel Hill’s SPICE (Statewide Program for Infection Control and Epidemiology) program. The cost of this program is \$465.00 per person. This three-day program held every spring and fall is designed to provide participants with current and practical information for the recognition and management of common infection prevention issues in non-acute care facilities, with an emphasis on long term care. Basic statistics for surveillance and antibiotic stewardship are new additions to the course. This alternative is not the most effective at this time as the course is very clinical in nature and geared toward nursing home managers and infection control nurses in those settings. The training would not be appropriate for direct care staff and ancillary staff in ACHs. SPICE does, however, offer a number of free infection prevention and control web-based trainings for all types of long-term care facilities, including adult care homes.

Conclusion

Rule Impacts	Known Costs/Benefits
Time Required to Update Policies and Procedures	\$214,771 (initial cost, changes to CDC and other public health guidance would require additional time in the future)
Time Required to Provide Staff Training	\$365,380 annually (based on average of 30 adult care home employees and 5 family care home employees)
Time for ACLS Staff to Spend on Enforcement of these Rules	\$265.56 per survey (2 ACLS staff; three hours spent conducting the survey process)
Time Required to Notify Resident or Representatives	\$9.52 for each weekly notification (\$2,380 based on 2018 Aggregate Outbreak data)
Average Cost of PPE/Day for an Average ACH During an Outbreak	\$207.86 (based on average requests from adult care homes that requested PPE in Dec 2020)
Cost of Provider Violations	Estimated \$25,500

Benefits	\$25,500 reduction in violations; unquantifiable benefits discussed above
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Because of the high transmission and death rate, COVID-19 has highlighted a greater need for providers to have systems in place to mitigate the spread of communicable diseases within congregate living settings, such as adult care and family care homes. The proposed permanent rules establish minimum requirements for an infection prevention and control (IPC) plan based on sound public health practices, require on-going training of unlicensed staff, set forth reporting requirements to the local health department, and identifies for facilities when to implement more specific guidance for communicable disease control outbreaks or emerging infectious disease threats. The rules also ensure that residents, families and staff are kept informed of outbreak conditions in a facility so that they can act as necessary to protect the health and safety of themselves or their loved ones. When these IPC policies and procedures are implemented, ACHs will be able to mitigate and reduce the spread of communicable diseases, whether during a pandemic or the seasonal flu and prevent further harm and loss of life to residents and staff.

APPENDIX

10A NCAC 13F .1801 is proposed for adoption as follows:

SECTION .1800 - INFECTION PREVENTION AND CONTROL

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

(a) In accordance with Rule .1211(a)(4) of this Subchapter and G.S. 131D-4.4A(b)(1), the facility shall establish and implement an 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 assure the following policies and procedures are established and implemented consistent with the federal CDC published guidelines, which are hereby incorporated by reference including subsequent amendments and editions, on infection control that are accessible at no charge online at <https://www.cdc.gov/infectioncontrol>, and addresses 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); and
 - (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 .1802 of this Section:
- (3) Measures the facility should consider taking in the event of a communicable disease outbreak to prevent the spread of illness, such as isolating infected residents; limiting or stopping group activities and communal dining; limiting or restricting outside visitation to the facility; screening staff, residents and visitors for signs of illness; and use of source control as tolerated by the residents.
- (4) Strategies for addressing potential staffing issues and ensuring staffing to meet the needs of the residents during a communicable disease outbreak:

(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 in writing by the North Carolina Department of Health and Human Services or local health department, the specific guidance or directives shall be implemented by the facility.

(d) In accordance with Rule .1211 of this Subchapter and G.S. 131D-4.4A(b)(4), the facility shall ensure all staff are trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs (b)(1) through (2) of this Rule.

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

*History Note: Authority G.S. 131D-2.16; 131D-4.4A; 143B-165;
Emergency Adoption Eff. October 23, 2020;
Temporary Adoption Eff. December 30, ~~2020~~; 2020;
Adopted Eff. October 1, 2021.*

10A NCAC 13F .1802 is proposed for adoption 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 10A NCAC 41A .0101 and 10A NCAC 41A .0102(a)(1) through (a)(3), which are hereby incorporated by reference, including subsequent amendments.

(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. 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;
Temporary Adoption Eff. December 30, ~~2020~~, 2020;
Adopted Eff. October 1, 2021.*

10A NCAC 13G .1701 is proposed for adoption as follows:

SECTION .1700 - INFECTION PREVENTION AND CONTROL

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

(a) In accordance with Rule .1211(a)(4) of this Subchapter and G.S. 131D-4.4A(b)(1), the facility shall establish and implement an 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 assure the following policies and procedures are established and implemented consistent with the federal CDC published guidelines, which are hereby incorporated by reference including subsequent amendments and editions, on infection control that are accessible at no charge online at <https://www.cdc.gov/infectioncontrol>, and addresses 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); and
 - (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 .1702 of this Section;
- (3) Measures the facility should consider taking in the event of a communicable disease outbreak to prevent the spread of illness, such as isolating infected residents; limiting or stopping group activities and communal dining; limiting or restricting outside visitation to the facility; screening staff, residents and visitors for signs of illness; and use of source control as tolerated by the residents.
- (4) Strategies for addressing potential staffing issues and ensuring staffing to meet the needs of the residents during a communicable disease outbreak;

(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 in writing by the North Carolina Department of Health and Human Services or local health department, the specific guidance or directives shall be implemented by the facility.

(d) In accordance with Rule .1211 of this Subchapter and G.S. 131D-4.4A(b)(4), the facility shall ensure all staff are trained within 30 days of hire and annually on the policies and procedures listed in Subparagraphs (b)(1) through (2) of this Rule.

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

*History Note: Authority G.S. 131D-2.16; 131D-4.4A; 143B-165;
Emergency Adoption Eff. October 23, 2020;
Temporary Adoption Eff. December 30, ~~2020~~; 2020;
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10A NCAC 13G .1702 is proposed for adoption 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 10A NCAC 41A .0101 and 10A NCAC 41A .0102(a)(1) through (a)(3), which are hereby incorporated by reference, including subsequent amendments.

(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. 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;
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