

Impact Analysis for Rule 10A NCAC 41A .0212 Handling and Transportation of Bodies

Agency:	North Carolina Commission for Public Health Department of Health and Human Services Division of Public Health Epidemiology Section Communicable Disease Branch
Rule Citation(s):	10A NCAC 41A .0212 Handling and Transportation of Bodies
Agency Contact:	Jean-Marie Maillard, MD, MSc Medical Director, Communicable Disease Branch NCDHHS, Division of Public Health Jean-marie.maillard@dhhs.nc.gov 919-546-1650
	Virginia Niehaus Rulemaking Coordinator, Commission for Public Health Director of Regulatory and Legal Affairs NCDHHS, Division of Public Health Virginia.niehaus@dhhs.nc.gov 919-707-5006
Rulemaking Authority:	G.S. 130A-144, 130A-146
Impact Summary:	State Government: Yes Local Government: No Private Sector: Yes Substantial Impact: No

Introduction and Purpose

Rule 10A NCAC 41A .0212 is being amended for the purpose of establishing control measures related to the prevention of infection in the handling and transportation of the bodies of persons infected with COVID-19. COVID-19, a novel coronavirus, was identified as the cause of an emerging infectious disease outbreak in December 2019 in Wuhan, Hubei Province, China. This novel coronavirus causes respiratory illness ranging in severity from mild illness to death. As of April 7, 2021, over 131,837,500 confirmed cases and 2,862,600 deaths had been reported from 216 countries, including the United States (U.S.).¹

The first U.S. case was reported in a traveler returning from Wuhan on January 21, 2020 in Washington State. As of April 7, 2021, over 30,596,830 cases and 554,420 deaths had been reported in the U.S.,² and over 924,810 cases and 12,212 deaths had been reported in North

¹ World Health Organization, "Coronavirus (COVID-19) Dashboard," available at: <https://covid19.who.int/>.

² United States Centers for Disease Control and Prevention, "COVID Data Tracker," available at: <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

Carolina.³ The North Carolina Division of Public Health (DPH) is working closely with the United States Centers for Disease Control and Prevention (CDC) to monitor and respond to this pandemic in North Carolina.

On June 18, 2020, the North Carolina Commission for Public Health (CPH) received a petition for rulemaking from the North Carolina Board of Funeral Service, requesting that CPH consider amending rule 10A NCAC 41A .0212 to set out the proper precautions to prevent infection in the handling and transportation of the bodies of persons infected with COVID-19 and require notification of those precautions. Pursuant to G.S. 150B-20, CPH fully considered and granted the petition at its meeting on August 5, 2020. At a special meeting on September 15, 2020, CPH adopted an amendment to 10A NCAC 41A .0212 under emergency procedures and simultaneously proposed to amend 10A NCAC 41A .0107 under temporary procedures. The temporary amendment was adopted on November 4, 2020. The permanent rulemaking process is now being undertaken to ensure that the important amendments made during the emergency and temporary rulemaking processes do not expire from the Administrative Code.

Description of Proposed Rule

The purpose of rule 10A NCAC 41A .0212 is to reduce the risk of transmission of certain communicable diseases from the body of a deceased individual to persons handling the body by providing notice to persons handling the body to ensure that proper precautions are taken. This permanent amendment:

- Adds a new paragraph (a) to require that all persons handling the body of a person who has died comply with standard precautions published by the CDC;
- Adds a notification requirement for when a person dies and is known to be infected with COVID-19;
- Allows for greater flexibility in who is required to make the notification by including physician assistants, nurse practitioners, and designated representatives, in addition to physicians, and in the method of reporting, by including verbal and electronic notifications in addition to written;
- Sets out more specifically who is required to be notified, which would now include the funeral service director, funeral service worker, or body transporter;
- Adds a new paragraph (c) for medical examiner notifications when a person dies and is known to be infected with COVID-19; and
- Adds a new paragraph (f), which contains the precautions to be followed by funeral home workers handling the body of a person who has died to prevent transmission of COVID-19 infections, in alignment with CDC guidance.

Impact Analysis

This analysis focuses on the economic impact that is expected to arise as a result of the amendments to rule 10A NCAC 41A .0212 as described in the preceding section. At present, the number of COVID-19 cases and deaths appear to be declining, which may be due to the increasing availability and administration of COVID-19 vaccines, advances in COVID-19 treatment, and the continuation of mitigation measures (such as wearing masks and social

³ North Carolina Department of Health and Human Services, "COVID-19 North Carolina Dashboard," available at: <https://covid19.ncdhhs.gov/dashboard>.

distancing); however, these shifting conditions, as well as the emergence of variant strains of the virus, make it challenging to predict future trends. Therefore, for the purpose of this impact analysis, the period of reference used is the time between September 25, 2020 (the date on which the emergency rule became effective) and February 28, 2021, a period of approximately 5 months. During that time, 8,236 COVID-19 deaths were reported in North Carolina. This figure is used in the calculations described herein as a best estimate of the economic impact of the proposed rule.

As noted in the preceding section, rule 10A NCAC 41A .0212 has been amended to include a new Paragraph (a) that mandates compliance with the standard precautions for all patient care that are published by the CDC. Although new to this rule, this is not a new requirement for health systems, funeral homes, emergency services, and others who handle decedents, as these individuals are separately required to use comparable standard precautions under their professional licenses, in accordance with Occupational Safety and Health Administration (OSHA) requirements, and pursuant to the requirements of 21 NCAC 34B .0704, to prevent the transmission of communicable diseases. In addition, this reference aligns with existing language in rule 10A NCAC 41A .0201, which specifies that control measures for communicable diseases that do not have a specific control measure rule are aligned with guidelines and recommended actions published by the CDC, which are incorporated by reference. The addition of standard precaution language in rule 10A NCAC 41A .0212(a) is intended to reinforce and remind our regulated public about these existing requirements. For this reason, there is not expected to be a fiscal impact associated with the new Paragraph (a). Fiscal impacts from other changes are discussed below.

State and Local Government Impact

The main anticipated economic impact to state and local government stems from the new requirement included in 10A NCAC 41A .0212(c) for medical examiners with jurisdiction over the body of someone who died and was known to be infected with COVID-19 to provide verbal, written, or electronic notice to the funeral service director, funeral service worker, or body transporter at the time that the body is removed from medical examiner custody of the proper precautions to prevent infection, which are specified in Paragraph (f) of the rule. The duty to notify shall be considered met if performed by a designated representative of the medical examiner.

The North Carolina Medical Examiner (ME) System is a network of medical doctors and allied health professionals throughout North Carolina who investigate deaths in North Carolina that result from injury or violence, as well as natural deaths that are suspicious, unusual, or unattended by a medical professional. The ME System is led by the Office of the Chief Medical Examiner (OCME), which is housed in DPH. The MEs in North Carolina typically investigate 12-13% of the total number of deaths that occur in North Carolina every year.⁴ As part of an ME's death investigation, the ME may receive medical records and other information about the deceased patient in the ME's care; however, the amount of information available varies on case-by-case basis and may not always include information about whether the deceased is infected with COVID-19. The ME may also not conduct a test to determine if the deceased is infected with COVID-19, if such a test is not indicated for the death investigation.

⁴ In the four years preceding the COVID-19 pandemic (2015-2018), the average number of deaths per year in North Carolina was 92,578.

In accordance with the requirements set forth in the emergency and temporary rules, MEs across the state have provided notification on approximately 55 occasions between September 25, 2020 and February 28, 2021. Based on feedback we have received from the OCME and members of the ME System, it is estimated that it takes a ME approximately 10 minutes to provide notification in satisfaction of the rule.

As county MEs are paid fees for services rendered in accordance with G.S. 130A-387, the additional notification time would be absorbed under these fees and is not an additional cost. MEs at OCME are paid by the state and the time it takes to make this notification would be considered an opportunity cost to state government. Conservatively, this fiscal note treats all 55 notifications as an opportunity cost to the state and quantifies the impact below.

In addition, the Chief Medical Examiner also spent time reviewing the rule to understand its practical application to the ME System and developing educational materials on the new notification requirement established under the emergency and temporary rules, as MEs had previously not been required give notification under the rule. The Chief Medical Examiner spent 18 hours on this review and education work. The 359 MEs across the state were provided a 15-minute training on the rule, given by the Chief Medical Examiner on multiple occasions.

Numerous factors inform the number of individuals in the next five months who will be known to be infected with COVID-19 at the time of death, as well as the number of those deceased individuals whose death will be subject to investigation by the ME System, which makes it challenging to determine the precise economic impact of the amended rule on State government going forward. The information provided by the OCME for the time period from September 25, 2020 and February 28, 2021 is therefore used as a proxy for our calculations in Table 1 below. The total cost to state government reflected in Table 1 is a high-end estimate, as the continued roll out of COVID-19 vaccinations, increased access to testing, and adherence to mitigation measures (mask wearing, social distancing) may reduce the number of COVID-19 cases in the coming months.

Table 1. State Government Impact (5 Month Projection)			
Number of Notifications Provided by MEs	Time in Hours Spent to Provide Notification as Required by Rule	Hourly Average Salary of Medical Examiner ⁵	Total Cost
55	0.17	\$50.20	\$469.37
Time in Hours Spent by Chief Medical Examiner to Review Rule and Develop Education Materials	Time in Hours Spent by Chief Medical Examiner to Provide Educational Presentation to North Carolina MEs	Hourly Salary of Chief Medical Examiner ⁶	Total Cost
12	6	\$130.55	\$2,349.90

⁵ Calculated based estimated annual salary of a ME (\$104,419), as estimated by the OCME.

⁶ Calculated based estimated annual salary of the Chief Medical Examiner (\$271,543).

Number of MEs in North Carolina	Time in Hours Spent Receiving Training on Rule and Notification Requirement	Hourly Average Salary of Medical Examiner ⁷	Total Cost
359	.25	\$50.20	\$4,505.45
Total Cost to State Government			\$7,324.72

The amendments to rule 10A NCAC 41A .0212 are not expected to have a fiscal impact on local governments.

Private Sector Impact

The main cost to the private sector relates to the physicians, physician assistants, nurse practitioners, or their designated representatives who now, under the amended rule, are required to provide notification in instances where an individual dies and is known to be infected with COVID-19. Training for these individuals is not needed, as physicians were already required to give notice for other diseases and conditions specified in the rule and in many instances those physicians were already delegating this notification.

Below are estimates for costs to the private sector resulting from this new notification requirement. It is estimated that it takes a physician, physician assistant, nurse practitioner, or designated representative approximately 10 minutes to provide notification as required under the rule in instances where the decedent is known to have COVID-19 (this is the same amount of time that it is estimated to take a ME to provide similar notice). The salaries of physicians, physician assistants, nurse practitioners, and the staff who could serve as their designees are expected to vary considerably; therefore, to avoid skewing our calculations in any one direction, we have estimated an hourly salary rate by averaging the typical salaries of a physician, physician assistant, and nurse practitioner in North Carolina.⁸

Table 2 shows these costs, using death data from September 25, 2020 through February 28, 2021 as a proxy and noting that, due to the reasons discussed above, it is challenging to project the number of notifications that will be needed in the future.

It should also be noted that there is an expected benefit to the private sector due to this rule change. Under the amended rule, transporters and funeral service personnel will be notified of the precautions to take when a decedent who was known to be infected with COVID-19 is released into their care. This will allow transporters and funeral service personnel to take steps to better protect themselves against COVID-19, potentially avoiding transmission of the disease and accompanying costs, such as health care expenses, lost wages, and lost productivity. These cost savings are difficult to quantify as it is not possible to know how often disease transmission and/or serious illness are avoided. Not all individuals who contract COVID-19 exhibit symptoms.

⁷ Calculated based estimated annual salary of a ME (\$104,419), as estimated by the OCME.

⁸ The average annual salary for a Physician in NC is \$235,890, or \$113.41 hourly; the average annual salary for a Physician Assistant in NC is \$104,150, or \$50.07 hourly; and the average annual salary for Nurse Practitioner in NC \$106,162, or \$51.04 hourly. The average hourly salary of these three professional groups in NC is \$71.51.

Table 2. Private Sector Impact (5 Month Projection)			
Number of Reported COVID-19 Deaths	Time in Hours Spent to Provide Notification as Required by Rule	Hourly Average Salary of Person Providing Notice ⁹	Total Cost
8,236	0.17	\$71.51	\$100,122.58
Benefits derived for avoiding disease transmission			Total Benefit
			Unquantifiable
Total Cost to Private Sector			\$100,122.58

Summary

Rule 10A NCAC 41A .0212 is being amended to prevent infection in the handling and transportation of bodies of person infected with COVID-19 by ensuring that individuals handling the body are notified of communicable disease control measures and follow standard precautions. The amended rule will result in an impact to state government that largely stems from costs associated with MEs having to provide notifications, as well as initial review by the Chief Medical Examiner and development and delivery of training. Required notifications will also have an impact on private healthcare providers, although there is expected to be an unquantifiable benefit to individuals who, due to this notification, are able to take additional steps to protect against transmission. The total expected impact of this rule amendment is set out in Table 3 below.

Table 3. Total Impact (5 Month Projection)	
Total Cost to State Government	\$7,324.72
Total Cost to Local Government	\$0
Total Cost to Private Sector	\$100,122.58
Total Cost	\$107,447.30
Total Benefit.....	Unquantifiable

⁹ Calculated based estimated annual salary of a ME (\$104,419), as estimated by the OCME.

Appendix: Proposed Rule Text

10A NCAC 41A .0212 HANDLING AND TRANSPORTATION OF BODIES

(a) Persons handling the body of any person who has died shall comply with the standard precautions for all patient care published by the United States Centers for Disease Control and Prevention, which are hereby incorporated by reference, including any subsequent amendments and editions, and available free of charge at: <https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html>.

~~(a)~~(b) It shall be the duty of the ~~physician~~ physician, physician assistant, or nurse practitioner attending to any person who dies and is known to be infected with HIV, plague, ~~or~~ hepatitis B, or COVID-19 or any person who dies and is known or reasonably suspected to be infected with smallpox, rabies, severe acute respiratory syndrome (SARS), or Jakob-Creutzfeldt to provide ~~written~~ written, verbal, or electronic notification to ~~all~~ individuals handling the body of the proper precautions to prevent ~~infection~~. infection, as set forth in Paragraphs (d), (e), and (f) of this Rule. This ~~written~~ written, verbal, or electronic notification shall be provided to the funeral service director, funeral service worker, or body transporter ~~personnel~~ at the time the body is removed from any hospital, nursing home, or other health care facility. When the patient dies in a location other than a health care facility, the ~~attending physician~~ physician, physician assistant, or nurse practitioner shall notify the funeral service director, funeral service worker, or body transporter ~~personnel~~ verbally of the precautions required as soon as the ~~physician~~ physician, physician assistant, or nurse practitioner becomes aware of the death. These precautions are noted in Paragraphs ~~(b)~~(d), (e), and ~~(e)~~-(f) of this Rule. The duty to notify shall be considered met if performed by one of the following individuals:

- (1) the physician, physician assistant, or nurse practitioner attending to the person who died; or
- (2) a designated representative of the physician, physician assistant, or nurse practitioner.

(c) It shall also be the duty of a medical examiner with jurisdiction pursuant to G.S. 130A-383 over the body of any person who dies and is known to be infected with COVID-19 to provide written, verbal, or electronic notification to the funeral service director, funeral service worker, or body transporter at the time the body is removed from medical examiner custody of the proper precautions to prevent ~~infection~~. infection, as set forth in Paragraph (f) of this Rule. These precautions are noted in Paragraph (f) of this Rule. The duty to notify shall be considered met if performed by a designated representative of the medical examiner.

~~(b)~~(d) The body of any person who died and is known or reasonably suspected to be infected with smallpox or severe acute respiratory syndrome (SARS) or any person who died and is known to be infected with plague shall not be embalmed. The body shall be enclosed in a strong, tightly sealed outer case ~~which~~ that will prevent leakage or escape of odors as soon as possible after death and before the body is removed from the hospital room, home, building, or other premises where the death occurred. This case shall not be reopened except with the consent of the local health director. Nothing in this Paragraph shall prohibit cremation.

~~(e)~~(e) Persons handling the body of any person who died and is known to be infected with HIV or hepatitis B or any person who died and is known or reasonably suspected to be infected with Jakob-Creutzfeldt or rabies shall be provided ~~written~~ written, verbal, or electronic notification to observe blood and body fluid precautions.

(f) Persons handling the body of any person who died and is known to be infected with COVID-19 shall be provided written, verbal, or electronic notification to observe the COVID-19 guidance for funeral home workers published by the United States Centers for Disease Control and Prevention, which is hereby incorporated by reference, including

any subsequent amendments or editions, and available free of charge at: <https://www.cdc.gov/coronavirus/2019-ncov/community/funeral-faqs.html>.

History Note: Authority G.S. 130A-144; 130A-146;
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Recodified from 15A NCAC 19A .0204 Eff. June 11, 1991;
Temporary Amendment Eff. November 1, 2003;
Amended Eff. April 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Emergency Amendment Eff. September 25, 2020;
Temporary Amendment Eff. December 1, 2020.