

MEMORANDUM

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TO: North Carolina Healthcare Association
FROM: Womble Bond Dickinson (US) LLP
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RE: No Patient Left Alone Act

Summary

The No Patient Left Alone (“NPLAA”) became effective in North Carolina on November 1, 2021 as has the stated aim to ensure that patient visitation rights will not be impacted during declared disasters and emergencies. The North Carolina General Assembly enacted NPLAA in response to complaints that hospital visitation restrictions prevented visits to patients during the current Covid-19 pandemic. The preamble of NPLAA indicates that this law applies to visitation of patients who have not been diagnosed with Covid-19. However, the body of the statute does not distinguish whether it applies only to visits to Covid negative patients or whether it applies to visits for both Covid positive patients and Covid negative patients. To take the most conservative position, the statute should be treated as addressing visits to both types of patients.

As we explain in more detail below, to implement NPLAA, a North Carolina hospitals will need to take the following actions:

- (1) Revise its patient visitation notice to include contact information for the individuals and agencies tasked with investigating violations of hospital patient visitation rights.
- (2) Revise its visitation policies to permit compassionate care visits for both Covid positive and Covid negative patients.
- (3) Ensure hospital visitation policies comply with CMS Conditions of Participation, the applicable CMS Covid Phase guidelines, and NPLAA.

Analysis

I. N.C. Gen. Stat. §131E-79.3(a)

Statutory Language

“Each hospital licensed under this Chapter shall permit patients to receive visitors to the fullest extent permitted under any applicable rules, regulations, or guidelines adopted by either the Centers for Medicare and Medicaid Services or the Centers for Disease Control and Prevention or any federal law.”

Analysis

We interpret N.C. Gen. Stat. §131E-79.3(a) to require NC hospitals' visitation policies to be no more restrictive than the federal rules, regulations or guidelines from the Centers for Medicare and Medicaid Services (“CMS”) or the Centers for Disease Control and Prevention (“CDC”) or any federal law that regulate hospital visitation.

The CMS Phase II guidelines, which are currently in effect and generally apply to visitation for Covid negative patients, states that a hospital may generally preclude visitations. However, the guidelines also permit hospitals to be flexible and make discretionary exceptions to the non-visitiation policy after considering a number of factors, including the prevalence of Covid in the community, staffing levels, the prevalence of Covid in the facility, personal protective equipment supplies, etc. Also, in the CMS Phase II guidelines, CMS urges hospitals to develop visitation plans that consider patient and public health safety as well as the “emotional and care needs of patients and their families who are facing illness or life-events in separation.” The CMS Phase II guidelines also list the following “special circumstances” in which “family/caregiver presence may be especially important to include”:

- a. End of life care, including clergy visitation for end of life care and patients who have elected hospice and are pending discharge.
- b. Labor and Delivery
- c. Pediatric care where parent or legal guardian is required
- d. Inpatient hospice
- e. In person training of caregiver is considered essential, and may permit training more than one caregiver providing social distancing and other precautions are maintained.
- f. Reasonable access to support person(s) for patients with disabilities, for example patients with cognitive or developmental disabilities who require presence of legal guardian.
- g. At the discretion and order of the hospital attending physician where having a family member would be of significant benefit to the patient’s clinical care (for example patients with complex or prolonged hospitalization).

The only comments the CMS Phase II guidelines make about visitation to Covid positive patients is to recognize that there may be considerations that preclude visits to Covid positive patients and

to suggest that virtual visitation may be a way to facilitate visits between family members and Covid positive patients.

Note that CMS may issue new guidelines regarding patient visitation. Until the recent emergence of the Covid-19 omicron variant, it has been anticipated that new guidelines would become less restrictive. There is considerable uncertainty whether the new variant, as well as the recent surge in cases, may result in more restrictive guidelines.

Additionally, the Medicare Conditions of Participation (42 C.F.R. §§482.13(h)) require written policies and procedures for patient visitation and permit any “clinically necessary or reasonable restriction or limitation...” on visitation. The CDC has not issued guidance specific to US hospitals. However, the CDC can issue quarantine and isolation orders in particular situations. See 82 Fed. Reg. 2890 (January 19, 2017).

II. N.C. Gen. Stat. §131E-79.3(b)

Statutory Language

“In the event the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, or any other federal agency finds a hospital has violated any rule, regulation, guidance, or federal law relating to a patient's visitation rights, the Department may issue a warning to the hospital about the violation and give the hospital not more than 24 hours to allow visitation. If visitation is not allowed after the 24-hour warning period, the Department’s shall impose a civil penalty in an amount not less than five hundred dollars (\$500.00) for each instance on each day the hospital was found to have a violation. This civil penalty shall be in addition to any fine or civil penalty that the Centers for Medicare and Medicaid Services or other federal agency may choose to impose.”

Analysis

According to N.C. Gen. Stat. §131E-79.3(b), the North Carolina Department of Health and Human Services (“NC DHHS”) may issue a warning to a hospital if CMS, CDC or any other federal agency finds that the hospital has violated any rule, regulation, guidance, or federal law relating to a patient's visitation rights. Upon issuance of the warning, the hospital will have 24 hours to allow the visitation. If visitation is not allowed within the 24-hour warning period, NC DHHS will impose a civil penalty in an amount not less than five hundred dollars (\$500) for each instance on each day the hospital was found to be in violation.

In addition to the CMS Visitation Guidance, hospitals must also comply with the patient visitation rights requirements under the Condition of Participation (42 C.F.R. §483(h)), which state:

Standard: Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

- (2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.
- (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.
- (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

We anticipate that a violation of N.C. Gen. Stat. §131E-79.3(b) could occur if an individual complains to CMS¹ or NC DHHS that a hospital is violating NPLAA by not allowing the individual to visit a patient. Upon receiving the complaint, NC DHHS will investigate to determine if the hospital is violating NPLAA or any hospital licensure regulations enacted as a result of NPLAA (see below). CMS could also require NC DHHS to conduct an investigation as the delegated Medicare “State Agency” in accordance with the Medicare State Operations Manual to determine if a violation of a hospital’s Conditions of Participation has occurred.

A determination of “immediate jeopardy” could be made if an impermissibly restrictive visitation policy causes “a significant decline in physical, mental, or psychosocial functioning [of a patient] (that is not solely due to the normal progression of a disease or aging process).” Failure to correct the deficiency within the 23-day deadline, could result in a loss of participation in the Medicare program. (SOM Appendix Q Section III).

CMS could also find a violation where a survey (which will be conducted by NC DHHS) did not result in a determination of “immediate jeopardy.” Failure to correct the deficiency within the 90-day deadline, could result in a loss of participation in the Medicare program as well.

Through the above process, NC DHHS will be aware of any federal violation of the Medicare Conditions of Participation. If NC DHHS and CMS does find a violation of Medicare Conditions of Participation, it would then trigger the 24-hour warning period and corresponding penalties if the violation is not remedied within the warning period under N.C. Gen. Stat. §131E-79.3(b). Note that the 24-hour warning period starts when NC DHHS finds a violation. The 23-day and 90-day periods are for the corrective action process following a violation.

To avoid liability under N.C. Gen. Stat. §131E-79.3(b), hospitals should ensure that their visitation notices and policies comply with CMS Phase II or then Guidelines, the Conditions of Participation, and subsections (d) and (e) of NPLAA (see below).

III. N.C. Gen. Stat. §131E-79.3(c)

Statutory Language

“Notwithstanding the provisions of subsection (b) of this section, in the event that circumstances require the complete closure of a hospital to visitors, the hospital shall use its best efforts to develop alternate visitation protocols that would allow visitation to the greatest extent safely

¹ The CDC has not issued guidance specifically applicable to US hospitals. (It has issued guidance for hospitals in foreign countries.)

possible. If those alternate protocols are found by the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, or any other federal agency to violate any rule, regulation, guidance, or federal law relating to a patient's visitation rights, the Department may impose a civil penalty in an amount not less than five hundred dollars (\$500.00) for each instance on each day the hospital was found to have a violation. This civil penalty shall be in addition to any fine or civil penalty that the Centers for Medicare and Medicaid Services or other federal agency may choose to impose.”

Analysis

A hospital may violate N.C. Gen. Stat. §131E-79.3(c) if the alternate visitation protocols it implements upon a complete closure of the hospital to visitors is found to violate federal law, rules, or regulations or CMS or CDC rules or guidance on patient visits. The process of CMS or NC DHHS finding a violation of this subsection (c) is identical to the process CMS or NC DHHS finding a violation under subsection (b). Consequently, to avoid penalties under N.C. Gen. Stat. §131E-79.3(c), hospitals should ensure that their visitation policies comply with CMS Phase II or then current Guidelines, the Conditions of Participation, and subsections (d) and (e) of NPLAA.

IV. N.C. Gen. Stat. §131E-79.3(d)

Statutory language

“Each hospital shall provide notice of the patient visitation rights in this act to patients and, when possible, family members of patients. The required notice shall also include the contact information for the agency or individuals tasked with investigating violations of hospital patient visitation.”

Analysis

Section N.C. Gen. Stat. §131E-79.3(d) requires hospitals to provide notice of the patient visitation rights described in NPLAA. The notice must include the contact information for the agency or individuals tasked with investigating violations of hospital patient visitation. This notice requirement is consistent with the patient notice requirements in the Medicare Conditions of Participation. To comply with this provision, we recommend that hospitals add to their current patient notice regarding hospital visitation the contact information for the individuals or agencies tasked with investigating violations. This would include designated hospital employee(s) responsible for compliance, and the designated individuals at NC DHHS, and the CMS Region IV Office.²

V. N.C. Gen. Stat. §131E-79.3(e)

Statutory language

“Each hospital shall allow compassionate care visits. A hospital may require compassionate care visitors to submit to health screenings necessary to prevent the spread of infectious diseases, and, notwithstanding anything to the contrary in this section, a hospital may restrict a compassionate care visitor who does not pass a health screening requirement or who has tested positive for an infectious disease. A hospital may require compassionate care visitors to adhere to infection control procedures, including wearing personal protective equipment. Compassionate care situations that require visits include, but are not limited to, the following:
(1) End-of-life situations.

² We are requesting information from those agencies about the individuals that should be listed.

- (2) A patient who was living with his or her family before recently being admitted to the facility is struggling with the change in environment and lack of physical family support.
- (3) A patient who is grieving after a friend or family member recently passed away.
- (4) A patient who needs cueing and encouragement with eating or drinking, previously provided by family or caregivers, is experiencing weight loss or dehydration.
- (5) A patient, who used to talk and interact with others, is experiencing emotional distress, seldom speaking, or crying more frequently when the patient had rarely cried in the past.”

The technical correction bill (HB 404) subjects this provision to “... any rules, regulations, or guidelines adopted by either the Centers for Medicare and Medicaid Services or the Centers for Disease Control and Prevention or any federal law...”

Analysis:

Given N.C. Gen. Stat. §131E-79.3(e), the current CMS guidance, and the Conditions of Participation, the default position for compliance with this subsection (e) is to allow visits to both Covid positive and Covid negative patients with infection control precautions in place. While current CMS Phase II guidance *permits* hospitals to preclude visits to Covid positive patients, it does not *require* that hospitals preclude such visits. A state law that expands the types of hospital visitations required or permitted under the federal CMS Phase II guidelines or the CMS Conditions of Participation does not contradict such guidelines, and is thus permissible. Consequently, as a result of the implementation of NPLAA, NC hospitals will have to abide by the NPLAA provisions requiring compassionate care visits, CMS Phase II or then current Guidelines, and CMS Conditions of Participation requirements.

We recommend hospitals revise their patient visitation policies and manuals to permit “compassionate care” visitors to both Covid positive and Covid negative patients. The visitation policies and manuals should also include the list of compassionate care situations enumerated in the statute. For example, the hospital visitation policy may state, “Visits to patients shall be permitted to allow for compassionate care visits, which include, but are not limited to: [list situations noted in subsection (e)] and may be permitted for Covid negative patients for situations involving: [list non-overlapping visitation circumstances listed in #5 of CMS Visitation Guidance]

Notwithstanding the requirement that compassionate care visitors be allowed in the hospital, each hospital may require such visitors to submit to health screenings and may restrict those who fail the health screenings or who test positive for Covid. Additionally, hospitals may require compassionate care visitors to follow its infection control procedures and policies, including requiring visitors to wear personal protection equipment.

We spoke to a representative of the North Carolina Department of Health and Human Services and they confirmed that although, N.C. Gen. Stat. §131E-79.3(e) is subject to CMS and CDC guidelines, when NC DHHS surveys a hospital based upon a complaint of violation of this law, the agency will expect a hospital to comply with both this state law and CMS Conditions of Participation. Therefore, if NC DHHS investigates a potential NPLAA violation, it will be reviewing hospital visitation policies to ensure compliance with CMS Conditions of Participation as well as compliance with NPLAA, including the hospital’s provision of compassionate care visits.

While NPLAA does not specify a penalty for the violation of this subsection (e), a violation under this subsection could also be interpreted as a violation under this statute and of the Hospital Licensure Act and a Class 1 misdemeanor.

VI. N.C. Gen. Stat. §131E-79.3(f)

Statutory Language

"The Commission shall adopt rules necessary to require each hospital to have written policies and procedures for visitation."

Analysis

This subsection (f) makes rulemaking mandatory and thus, the Medical Care Commission is required to issue regulations. The basic patient visit provisions are already in existing regulations, but it is possible that the Medical Care Commission may elaborate on these regulations. It is our understanding that NCHA has had discussions with the Medical Care Commission and the Medical Care Commission has indicated that it may not move forward with rulemaking because it believes the statute may be sufficient.

Conclusion

To comply with NPLAA, North Carolina hospitals should (1) revise their patient visitation notices to include contact information for the individuals and agencies tasked with investigating violations of hospital patient visitation rights, (2) revise their visitation policies to permit compassionate care visits for both Covid positive and Covid negative patients, and (3) continue to ensure hospital visitation policies comply with CMS Conditions of Participation, the applicable CMS Covid Phase guidelines, and NPLAA.

While the visitation policies under the current CMS Phase II guidelines permit visitations under certain conditions, it is uncertain whether these guidelines will become more restrictive on patient visitations given the onset of the Omicron variant and the rising Covid 19 cases across the country. If there is a change in CMS Phase II guidelines, hospitals should revisit how the new guidance will affect its compliance with NPLAA.