

1 10A NCAC 14C .1402 is proposed as a temporary rule as follows:

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3 **10A NCAC 14C .1402 INFORMATION REQUIRED OF APPLICANT**

4 (a) An applicant proposing to develop a ~~new~~ Level I nursery in the facility for the first time or ~~increase the number~~
5 ~~of~~ new or additional Level II, III or IV neonatal beds shall use the Acute Care Facility/Medical Equipment
6 application form.

7 (b) An applicant proposing to develop a ~~new~~ Level I nursery ~~service~~ in the facility for the first time or ~~to increase~~
8 ~~the number of~~ new or additional Level II, III or IV neonatal beds shall provide the following additional information:

- 9 (1) the current number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds
10 operated by the applicant;
- 11 (2) the proposed number of Level I nursery bassinets, Level II beds, Level III beds and Level IV beds
12 to be operated following completion of the proposed project;
- 13 (3) evidence of the applicant's experience in treating the following patients at the facility during the
14 past twelve months, including:
- 15 (A) the number of obstetrical patients treated at the acute care facility;
- 16 (B) the number of neonatal patients treated in Level I nursery bassinets, Level II beds, Level
17 III beds and Level IV beds, respectively;
- 18 (C) the number of inpatient days at the facility provided to obstetrical patients;
- 19 (D) the number of inpatient days provided in Level II beds, Level III beds and Level IV beds,
20 respectively;
- 21 (E) the number of high-risk obstetrical patients treated at the applicant's facility and the
22 number of high-risk obstetrical patients referred from the applicant's facility to other
23 facilities or programs; and
- 24 (F) the number of neonatal patients referred to other facilities for services, identified by
25 required level of neonatal service (i.e. Level II, Level III or Level IV);
- 26 (4) the projected number of neonatal patients to be served identified by Level I, Level II, Level III and
27 Level IV neonatal services for each of the first three years of operation following the completion
28 of the project, including the methodology and assumptions used for the projections;
- 29 (5) the projected number of patient days of care to be provided in Level I bassinets, Level II beds,
30 Level III beds, and Level IV beds, respectively, for each of the first three years of operation
31 following completion of the project, including the methodology and assumptions used for the
32 projections;
- 33 (6) if proposing to provide Level I or Level II neonatal ~~services;~~ services in the facility for the first
34 time, documentation that at least 90 percent of the anticipated patient population is within 30
35 minutes driving time one-way from the facility;

- 1 (7) if proposing to provide ~~new~~ Level I or Level II neonatal ~~services~~, services in the facility for the
2 first time, documentation of a written plan to transport infants to Level III or Level IV neonatal
3 services as the infant's care requires;
- 4 (8) evidence that the applicant shall have access to a transport service with at least the following
5 components:
- 6 (A) trained personnel;
 - 7 (B) transport incubator;
 - 8 (C) emergency resuscitation equipment;
 - 9 (D) oxygen supply, monitoring equipment and the means of administration;
 - 10 (E) portable cardiac and temperature monitors; and
 - 11 (F) a mechanical ventilator;
- 12 (9) documentation that the proposed service shall be operated in an area organized as a physically and
13 functionally distinct entity with controlled access;
- 14 (10) documentation to show that the new or additional Level I, Level II, Level III or Level IV neonatal
15 services shall be offered in a physical environment that conforms to the requirements of federal,
16 state, and local regulatory bodies;
- 17 (11) a detailed floor plan of the proposed area drawn to scale;
- 18 (12) documentation of direct or indirect visual observation by unit staff of all patients from one or more
19 vantage points; and
- 20 (13) documentation that the floor space allocated to each bed and bassinet shall accommodate
21 equipment and personnel to meet anticipated contingencies.
- 22 (c) If proposing to provide ~~new~~ Level III or Level IV neonatal services in the facility for the first time, the applicant
23 shall also provide the following information:
- 24 (1) documentation that at least 90 percent of the anticipated patient population is within 90 minutes
25 driving time one-way from the facility, with the exception that there shall be a variance from the
26 90 percent standard for facilities which demonstrate that they provide very specialized levels of
27 neonatal care to a large and geographically diverse population, or facilities which demonstrate the
28 availability of air ambulance services for neonatal patients;
 - 29 (2) evidence that existing and approved neonatal services in the applicant's defined neonatal service
30 area are unable to accommodate the applicant's projected need for additional Level III and Level
31 IV services;
 - 32 (3) an analysis of the proposal's impact on existing Level III and Level IV neonatal services which
33 currently serve patients from the applicant's primary service area;
 - 34 (4) the availability of high risk OB services at the site of the applicant's planned neonatal service;
 - 35 (5) copies of written policies which provide for parental participation in the care of their infant, as the
36 infant's condition permits, in order to facilitate family adjustment and continuity of care following
37 discharge; and

- 1 (6) copies of written policies and procedures regarding the scope and provision of care within the
2 neonatal service, including but not limited to the following:
3 (A) the admission and discharge of patients;
4 (B) infection control;
5 (C) pertinent safety practices;
6 (D) the triaging of patients requiring consultations, including the transfer of patients to
7 another facility; and
8 (E) the protocols for obtaining emergency physician care for a sick infant.
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10 *History Note: Authority G.S. 131E-177(1); 131E-183;*
11 *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
12 *becomes effective, whichever is sooner;*
13 *Eff. January 4, 1994;*
14 *Amended Eff. November 1, 1996;*
15 *Temporary Amendment Eff. March 15, 2002;*
16 *Amended Eff. April 1, 2003;*
17 *Temporary Amendment Eff. February 1, 2010.*