NICU FAQs

1. We are starting a new NICU and do not have a provisional license, can we start treating patients once I initiate the license application process?

Your provisional license must be issued prior to treating patients.

2. We want to increase our NICU levels of care, for instance a Level II to a Level III, can we treat patients at the new level of care?

Your provisional license must be issued prior to treating patients at the upgraded level of care.

3. Can we send in fees with the application?

No. You will receive an invoice once the application has been processed.

4. What will happen to the current Certificate of Need Process?

Effective December 1, 2025, a Certificate of Need will not be required for the initiation of NICU services. The CON requirement will be eliminated. Hospitals that are currently operating or initiating new NICU services must apply for initial licensure specific to the operation of NICU services. This includes licensed hospitals with CON approved NICUs operating prior to December 1, 2025. All NICUs Level II-IV must obtain the required provisional license effective December 1, 2025.

5. Where can I find the NICU application?

The application is located at the following link: https://www.tn.gov/hfc/quality-service-license.html

- 6. What is the application process?
 - a. Beginning December 1, 2025, NICU service lines must submit a licensure application to the Health Facilities Commission (HFC).
 - *A licensing fee schedule is listed at the end of the application.
 - b. Please complete the entire application responding to each applicable field. All applications must be signed by an authorized representative. Incomplete or unsigned applications will be returned which may delay the processing of the application.
 - c. All applications will need to be emailed to hfc.service@tn.gov. An email will be sent to the applicant within two (2) business days of receipt verifying that the application was received.
 - d. Any hospital seeking to initiate a new NICU service line that was previously not licensed, or seeks to modify NICU (Level II-IV services, must submit architectural plans to Plans review through the online portal at https://apps.tn.gov/tnhcf/

- e. If a hospital is modifying an existing NICU service line (e.g. renovations, increasing a NICU level, or increasing bed capacity), the hospital must submit architectural plans to Plans Review as well.
- f. If an initial service is being implemented, after Plans Review has been completed and approved, a Life Safety Inspector will be sent out within ten (10) days. Within thirty (30) to forty-five (45) days, a health licensure surveyor will be sent out to determine approval.
- g. If the application is for a new NICU service, after the Plans Review approval, a HFC surveyor will conduct an on-site review for the initial occupancy approval.
- h. Upon receipt of the application, HFC staff will review the application for completeness. Once determined to be complete, a service license number will be assigned, and an invoice will be sent to the listed billing contact. The requested license fee will need to be submitted to Health Facilities Commission, following the invoice instructions, by listed due date on the invoice.
- i. Once the license fees have been received, a provisional approval letter will be sent to the Administrator. When complete, the application will then be presented to the Commission at the next regularly scheduled Commission meeting for ratification.
- j. If the Commission ratifies the application, the license certificate will then be created and mailed to the licensee. You should receive the physical license in ten (10) to fourteen (14) days.
- k. If the Commission does not ratify the initial approval of your application, a letter will be mailed to you providing an explanation and specific instructions as to any actions you may take to have the decision reviewed, at which time this authorization shall cease to be effective.

7. When will the NICU obtain a full license?

To obtain full licensure each NICU will need to undergo a verification site review within three years of issuance of the provisional license.

8. Who should sign the application?

Other than the CEO or Administrator of the facility/organization, anyone who has the authority to sign for the facility/organization.

9. We have satellite campuses, are the satellites to submit an application separately from the host?

Each satellite campus must submit a separate application for their services located on the satellite's campus. The host location will submit their application separate from the satellites.

10. How often will the NICU program need to be relicensed?

Each license to operate a facility shall expire annually on the anniversary date of its original issuance and shall become invalid on that date unless renewed. A licensee may renew its license within sixty (60) days following the license expiration date upon payment of the renewal fee in addition to a late penalty established by the commission for each month or fraction of a month that payment for renewal is late; provided, that the late penalty shall not exceed twice the renewal fee. TCA 68-11-206(a)(8)

11. What is designation?

Neonatal Intensive Care Unit (NICU) Designation is a formal process that recognizes a hospital's NICU for meeting standards of care for newborns, especially those who are born early, small, or with medical complications.

Hospitals are designated as different levels of NICU care based on the types of services they can safely provide. NICU designation helps ensure that each newborn receives the right level of care in the right place. It also gives families and healthcare providers confidence that the facility is held to clear, high standards for safety and quality.

12. What is the purpose of neonatal levels of care?

Neonatal levels of care are a way to make sure that newborn babies get the right care based on how sick they are or how early they were born.

Hospitals are grouped into levels — from Level I to Level IV — based on the type of care they can provide:

The goal is to keep babies safe by making sure they're cared for in hospitals that have the right doctors, nurses, equipment, and support for their needs. If a baby needs more care than a hospital can provide, the baby must be transferred to a higher-level facility. This system helps improve health outcomes for babies, especially those born too soon or with serious medical conditions.

13. What is the earliest a NICU can undergo a site review?

It is anticipated that the earliest designation site reviews will be conducted between October and December of 2026. Initial scheduling of site reviews is projected to occur in the late spring of 2026. Further updates will be provided to licensed facilities and additional contacts as they become available.

14. Which levels will the state survey?

Level II's will undergo a site review by a team of state-contracted clinicians. Site reviews for Level III and Level IV facilities are expected to be conducted by approved third-party organizations.

Additional Level II site reviewer requirements will be posted at a later date.

15. How will third-party organizations be identified?

Third-party verification site review organizations are expected to be solicited and approved in Spring of 2026. Updates to scheduling protocols will be provided once third-party organizations are identified.

16. How will third party verification site reviews for Level III and IV NICUs differ from Level II site reviews?

All verification site reviews performed will evaluate a hospital's capacity and performance relative to its designated level of care according to the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing, and Facilities 2020 Edition. The same standards for reviewer procedures, documentation and reporting will be applied across all verification site reviewer teams whether they are performed by third-party organizations or state-contracted clinician teams. These standards will be established through the Tennessee NICU Site Review Process Operations Guide with a published target date on the HFC website in the Spring 2026.

17. Will the State accept American Academy of Pediatrics (AAP) NICU Designation reciprocally?

Yes, if a hospital chooses to pursue AAP designation independently from these state requirements and processes for designation site reviews, it will be accepted as proof of compliance with state verification.

18. After December 1, 2025, will site reviews be conducted on the 2020 Perinatal Care System guidelines, or the new 2025 guidelines?

Site reviews will be conducted on the 2020 Perinatal Care System Guidelines which are incorporated into the current rules. The 2025 updated Perinatal Care System guidelines will be required to go through a future rulemaking process.

19. What are the guidelines or recommendations for transitioning levels of care?

On December 1, 2025, you will designate your level of care. After that date, to transition levels of care, a hospital with a NICU will need to resubmit the initial application, as well as the appropriate fees.

20. Will there be a list of NICU's and their designated levels of care posted to a public website?

Yes. HFC will publish a list of NICU's and their levels of care that they have self-designated at, and it will show verified once they have undergone a verification site-review.

21. Where can I find the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing, and Facilities 2020 Edition and other associated guidelines published by the Tennessee Department of Health.

All publications and updates can be found at Reports and Publications.

22. Where are the Regional Perinatal Centers located?

East Tennessee Regional Perinatal Center

The University of Tennessee Medical Center at Knoxville

Knoxville, Tennessee L&D: (865) 305-9830

Maternal Referrals: 1-800-422-9301 or 865-305-9300

Neonatal Consult/Transport: 1-800-732-7295 or (865) 305-9834

NICU: (865) 305-9834

Middle Tennessee Regional Perinatal Center

Vanderbilt University Medical Center/Monroe Carell, Jr. Children's Hospital at Vanderbilt

Nashville, Tennessee L&D: (615) 322-2555

OB Consults/Referrals: 1-888-636-8863 (1-888-MFM-VUMC)

OB consults/referrals: 615-343-0976 (Transfer Center)

Neonatal Consult / Transport: 1-800-288-8111

NICU: (615) 322-0963

Northeast Tennessee Regional Perinatal Center

Johnson City Medical Center Hospital

Johnson City, Tennessee

Perinatal Center office: (423) 431-6640

L&D: (423) 431-6437 Referrals: 1-800-365-5262

Neonatal Consult/Transport: (423) 431-6671

NICU: (423) 431-6671

Southeast Tennessee Regional Perinatal Center

Erlanger Health System/T.C. Thompson Children's Hospital

Chattanooga, Tennessee

L&D: (423) 778-7956

OB Consults / Referrals: (423) 778-8100 or 1-866-4HI-RISK

Neonatal Consult/Transport: (423) 778-6438

NICU: (423) 778-6438

West Tennessee Regional Perinatal Center

Regional Medical Center at Regional One Health

Memphis, Tennessee L&D: (901) 545-7345

OB Inpatient Transport: (901) 545-8181 Neonatal Consult/Transport: (901) 545-7366

NICU: (901) 545-7366

23. What is the link to the Health Facilities Commission public meetings and where is it posted?

Meetings are public and information can be found at the following link: <u>TN Health Facilities</u> Commission Meeting Information.

24. Can we submit one application for Burn Centers, NICU, and MRI/PET on the same application and all services will be licensed under the hospital's license?

Yes. You can submit on application for Burn Centers, NICU, and MRI/PET on one application. Each service will receive a separate license, or provisional license, number.

25. For hospitals that will be applying for Level II (for the first time) – will there be an initial provisional verification survey or will you be granted a provisional license via committee and later verified?

Hospitals applying for Level II to IV NICUs will initially be granted provisional license. They will then have to undergo a verification site review either by the AAP or a state conducted site review in order to obtain a full license.

26. Will the license/verification process repeat every so often?

Licensure applications will need to be renewed annually. Verification will be once every three vears.

27. Will verification site reviews be a separate focused site review, unannounced, or perhaps combined with other hospital surveys?

Verification site reviews will be performed separately from other surveys and will have to be scheduled on a first-come first-served basisi.

28. Do we have to wait until the survey to begin providing care for the request Level of Care on the application (example: moving to Level II, we can care for the patients while waiting for the survey next October-December 2026)?

A NICU II to IV can provide care corresponding to the requested level on the application once the provisional license has been issued.

29. Is there an email list for information we can receive? I received this information through TIPQC. How do we get into the email list?

You can receive notifications by emailing us at hfc.service@tn.gov.

30. Will this be incorporated into the Acute Care Hospital Licensure Application in the future?

Yes. However, the development of a new application portal is in the very early stages of development.

31. If you have had a CON for a Level III for a certain number of beds, can you add bed capacity for that same Level of Care?

Yes. You can add beds; however, you will want to contact us to verify if a Plans Review Survey will need to be conducted.