SB20 Education and Summary on Operational and Clinical Response

July 28, 2023

Law Overview

When abortion is lawful in North Carolina beginning July 1, 2023

- **At any time, in cases of medical emergency**
- **During first 12 weeks of pregnancy**
  - Must be performed by a qualified physician
  - May be medical abortion or surgical abortion
  - If surgical, must be in an approved location (hospital or approved clinic)
- **After 12th week and through the 20th week in cases of rape or incest**
  - Must be performed by a qualified physician
  - Must be performed in an approved location (hospital or approved clinic)
- **During first 24 weeks if a qualified physician identifies a life-limiting anomaly**

Total ban:

- "Partial birth abortions"
- If person performing the abortion has knowledge that the patient is seeking the abortion, in whole or in part, because of:
  - Actual or presumed race
  - Sex
  - **Presence or presumed presence of T21 (Downs Syndrome)**

Definitions

Medical Abortion & Surgical Abortion

- **What's new:** definition of abortion is split into two – "medical abortion" and "surgical abortion"

Medical abortion	Surgical abortion
The use of any medicine, drug, or substance intentionally to terminate the pregnancy of a woman known to be pregnant with an intention **other than to do any of the following (not considered an abortion if)**: ◦ Increase the probability of a live birth. ◦ Preserve the life or health of the child. ◦ Remove a dead, unborn child who died as a result of (i) natural causes in utero, (ii) accidental trauma, or (iii) a criminal assault of the pregnant woman or her unborn child which causes the premature termination of the pregnancy. ◦ Remove an ectopic pregnancy.	The use or prescription of any instrument or device intentionally to terminate the pregnancy of a woman known to be pregnant with an intention other than to do any of the following **(not considered an abortion if)**: ◦ Increase the probability of a live birth. ◦ Preserve the life or health of the child. ◦ Remove a dead, unborn child who died as a result of (i) natural causes in utero, (ii) accidental trauma, or (iii) a criminal assault of the pregnant woman or her unborn child which causes the premature termination of the pregnancy. ◦ Remove an ectopic pregnancy.

Abortion-Inducing Drug

- **What's new:** Entirely new term

Defined as:

- A medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will, with reasonable likelihood, cause the death of the unborn child.
- Specifically includes off-label use of mifepristone, misoprostol, and methotrexate, prescribed specifically with the intent of causing an abortion, whether or not there exists a diagnosed pregnancy at the time of prescription or dispensing.
- Does not include drugs that may be known to cause an abortion but are prescribed for other medical indications.

Life-limiting Anomaly & Qualified Physician

- **What's new:** Both are entirely new terms
- **Life-limiting Anomaly**
  - Defined as: The diagnosis by a qualified physician of a physical or genetic condition that (i) is defined as a life-limiting disorder by current medical evidence and (ii) is uniformly diagnosable.

- **Qualified Physician**
  - Defined as any of the following:
    - A physician who possesses, or is eligible to possess, board certification in obstetrics or gynecology
    - A physician who possesses sufficient training based on established medical standards in safe abortion care, abortion complications, and miscarriage management
    - A physician who performs an abortion in a medical emergency (as defined in the law)

Medical Emergency

- **What's new:** While definition has not changed, medical emergency is now more relevant after 12 weeks as opposed to 20 weeks.

- Medical Emergency defined as: A condition which, in reasonable medical judgment, so complicates the medical condition of the pregnant woman as to necessitate the immediate abortion of her pregnancy:
  - To avert her death, or
  - For which a delay will create a serious risk of substantial and irreversible physical impairment of a major bodily function.
    * Not including any psychological or emotional conditions
    * No condition shall be deemed a "medical emergency" if based on a claim or diagnosis that the woman will engage in conduct which would result in her death or in a substantial and irreversible physical impairment of a major bodily function

Probable Gestational Age

- **Not new, no changes**
- What, in the judgment of the physician, will, with reasonable probability, be the gestational age of the unborn child at the time the abortion is planned to be performed.

New “Born Alive” Protection Act

What is the Born-Alive Survivors Protection Act?

This is a new provision of North Carolina law that imposes certain requirements on providers in cases where an abortion or attempt to perform an abortion results in a “child born alive.”

What is does “born alive” mean?

“Born alive” is defined in the law as follows: “the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.

What are a providers’ obligations in the situation where an infant is “born alive”?

Any health care practitioner present shall “[e]xercise the same degree of professional skill, care, and diligence to preserve the life and health of the child as a reasonably diligent and conscientious health care practitioner would render to any other child born alive at the same gestational age,” and following the exercise of such skill, care and diligence, “ensure that the child born alive is immediately transported and admitted to a hospital.”

In addition, any practitioner who is aware of failure to exercise appropriate skill, care, and diligence must report the failure to comply to an appropriate State or federal law enforcement agency.

If a fetus was delivered with signs of life, even though an abortion was intended, the fetus must be immediately transported and admitted or resuscitated if it is of a gestational age that would normally warrant resuscitation.

Enforcement

Medical Board Action

- Existing law (NCGS 90-14(a)(2)):
  - The North Carolina Medical Board “shall have the power to” place on probation with or without conditions, impose limitations and conditions on, publicly reprimand, assess monetary redress, issue public letters of concern, mandate free medical services, require satisfactory completion of treatment programs or remedial or educational training, fine, deny, annul, suspend, or revoke a license, or other authority to practice medicine in this State, if the Board determines that the physician has produced or attempted to produce an abortion contrary to law.

- **Additional law, effective July 1, 2023:**
  - **A physician who violates the law regulating abortions in North Carolina “shall be” subject to discipline by the North Carolina Medical Board**

Civil liability (aside from general malpractice)

- **A patient may sue the person who performed the patient's abortion if the person performing the abortion acted in knowing or reckless violation of the law**
  - In wrongful death actions, the patient's personal representative may file suit **(new)**
  - A father of an unborn child that was the subject of an abortion may also sue in these cases
  - If the patient is a minor, the minor's parents may file suit **(new)**
- **Injunctive relief may also be sought to prevent persons who willfully violate the law from performing or inducing further abortions in violation of the law**
  - Injunctive relief may be sought by a patient upon whom an abortion was performed or attempted to be performed in violation of law, or any person who is that patient's spouse, parent, sibling, guardian, current or former licensed health care provider, or Attorney General
- **Attorneys' fees are available**

Criminal liability – longstanding statutes

- “If any person shall willfully administer to any woman, either pregnant or quick with child, or prescribe for any such woman, or advise or procure any such woman to take any medicine, drug or other substance whatever, or shall use or employ any instrument or other means with intent thereby to destroy such child, he shall be punished as a Class H felon.” NCGS 14-44 (no change since 1981)

- “If any person shall administer to any pregnant woman, or prescribe for any such woman, or advise and procure such woman to take any medicine, drug or anything whatsoever, with intent thereby to procure the miscarriage of such woman, or to injure or destroy such woman, or shall use any instrument or application for any of the above purposes, he shall be punished as a Class I felon.” NCGS 14-45 (no change since 1981)

These criminal statutes are caveated by the law which indicates when abortion is lawful (see earlier slides).

Criminal liability – New statute

- **No one within NC may mail, provide, supply, ship or cause to be shipped an abortion-inducing drug directly to a pregnant person without satisfying:**
  - the consent requirement that includes the name of the physician who will prescribe, dispense, or otherwise provide the abortion-inducing drug, and
  - the requirement that the physician prescribing, dispensing, or otherwise providing the drug shall be physically present in the same room as the patient when the first drug is administered
- **Lack of knowledge or intent that the drug will be administered outside the physical presence of a physician is not a defense**
- It is also illegal to advertise, host/maintain a website, or provide an internet service purposefully directed to NC residents when it is known that the purpose of the advertisement, website or internet service is solely to promote the sale of an abortion-inducing drug to be administered in violation of the consent and presence requirements set forth above
- **Violation of this new statute is an infraction (a noncriminal violation of law) and subject to a $5000 fine**

Clinical Management

Clinical Consensus

A group of Departmental Leaders from OBGYN, Family Medicine, Emergency Medicine, Psychiatry, and Peds/Adolescent Medicine formed a Clinical Collaborative to review anticipated clinical scenarios and how to manage them in compliance with the laws.

General consensus was reached on the following (not specified in the law – but the general guidance agreed upon by this leadership group):

Medical Emergencies:

- The law specifically allows for abortion for cases in which a delay in performing abortion will create a serious risk of "substantial or irreversible harm".
- Considering clinical scenarios, the group identified that such a serious risk could be one that is **immediate, or up to days, weeks, or months after recognizing the clinical diagnosis**. What makes a situation an emergency is that the delay in performing the abortion creates a "serious risk" of harm, even in if the harm may not manifest immediately.

Life Limiting Anomalies

- The group recommended deferring the clinical judgement of these scenarios to our Maternal Fetal Medicine colleagues.

Clinical Consensus

Miscarriage Management

- For any situation in which the patient has a missed AB or incomplete or inevitable AB, the group recommended using the term "miscarriage" documentation and using ICD 10 codes for miscarriage rather than abortion, in order to not confuse the clinical diagnosis.

Threatened miscarriage ICD 10 = O20.0

Incomplete miscarriage ICD 10 = O03.4

Spontaneous miscarriage ICD 10 = O03.9 (also codes for “abortion” ie. Spontaneous abortion)

Pregnancy of Unknown Location

- For pregnancy of unknown location, if D&C is to be performed as part of the evaluation for PUL, document using dot phrase for PUL to clearly state D&C is being performed for a pregnancy of unknown location evaluation
- .NCPREGNANCYUNKNOWNLOCATION

Dot Phrase: Use for all related care as follows:

For All Abortion related care use:

.NCABORTION

There will be the picklist options below for all categories. Please select all lists that apply.

For patients refusing Medication Abortion Follow-up Use:

.NCABORTIONFOLLOWUPREFUSAL

For Pregnancy of Unknown location use:

.NCPREGNANCYUNKNOWNLOCATION

For miscarriage care use:

.NCMISCARRIAGE

For fetal demise in utero use:

.NCFETALDEATHINUTERO

For Pharmacist documentation of non abortion use of medications that *can* be used for abortion

.NCPHARMACEUTICAL

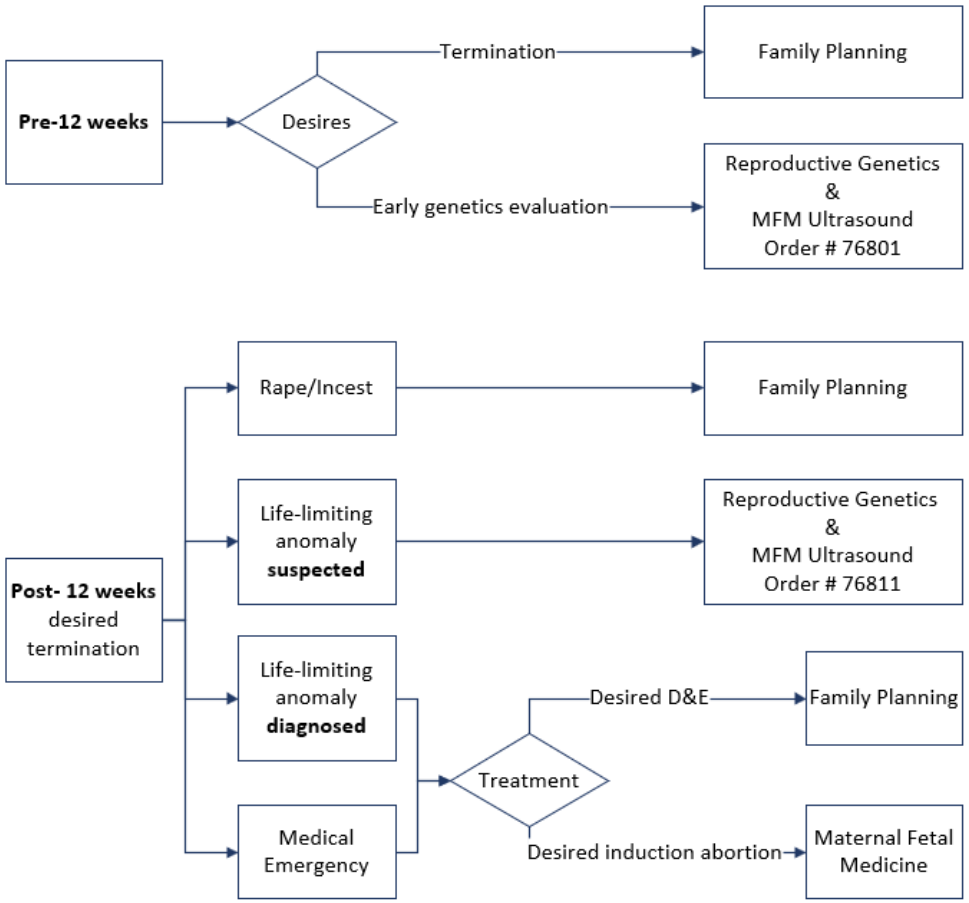
Resources

- All needed resources are available on intranet Sharepoint site
- https://unchcs.sharepoint.com/SitePages/Updates-on-Senate-Bill-20.aspx
  - Includes
    - Bill explanation
    - Description of changes in practice by abortion type and weeks of gestation
    - Reporting requirements
    - All DHHS forms
    - FAQs for providers and staff

    - **Please make sure you READ through ALL the first 5 topics including the FAQs to gain a more complete understanding of the law's implications on clinical management**

Contact Triage for Abortion Care

Contact Triage for Abortion-Related Care



Contacting Family Planning:
Routine Scheduling
Epic Referral

Urgent Scheduling
(<48 hours):
Epic Referral + Phone Call 984-974-8955

After Hours/Weekend
Urgent Clinical Question/Care Concern/Emergent Scheduling:
Family Planning Fellow On Call - One Call Directory

Contacting Maternal Fetal Medicine/Ultrasound:
Routine Scheduling:
Epic Referral

Urgent Scheduling
(<48 hours):
Epic Referral + Phone Call 919-784-6425
"Presence of suspected fetal anomaly"

After Hours/Weekend
Urgent Clinical Question/Care Concern/Emergent Scheduling:
OB Antepartum Attending (24/7 MFM on call)
UNC Transfer Center to page OB Attending on call

How to Send Epic@UNC Referrals:

Referal to Family Planning:
Order Number: REF30 (Gynecology)
Specialty: Gynecology
Referred To Department:
UNC FAMILY PLANNING HILLSBOROUGH

Referal to Maternal Fetal Medicine:
Order Number: REF86
Specialty: Obstetrics
Referred To Department:
UNC MATERNAL FETAL MEDICINE AT VILCOM CENTER
UNC MATERNAL FETAL MEDICINE RALEIGH

Referal to Reproductive Genetics:
Order Number: REF210
Specialty: Obstetrics
Referred To Department:
UNC MATERNAL FETAL MEDICINE AT VILCOM CENTER
UNC MATERNAL FETAL MEDICINE RALEIGH

MFM Ultrasound Orders:
OB IMG US orders- always select UNC for UNC MFM US procedures

***Picking a Referred To Department is A MUST to ensure proper care timeline**

Consent forms

Two forms to complete: The "Consent Form" and "Declaration Form"

Consent form must be completed by **patient** for all abortions **72 hours before abortion, in person.**

- A **qualified professional*** must sign this form (does not have to be physician or physician providing abortion)
  - NCDHHS Medical Abortion Informed Consent - (English/Spanish)
    - **Ultrasound** must be completed **prior** to the Medication Abortion Form being complete
  - NCDHHS Surgical Abortion Informed Consent - (English/Spanish)

Declaration form must be completed by the **physician** on the day of the procedure/medication administration

- NCDHHS Physician Declaration Form - (English/Spanish)
- NCDHHS Abortion Life Limiting Anomaly Consent - (English/Spanish)

**If a minor is being consented, a Physician must obtain the consent*

Consent specifics

- If a minor is being consented, a Physician must obtain the consent
- If procedure is for a Medical Emergency, and documentation is provided for this indication, the 72 hour Consent *and* the Declaration forms are waived.
- If procedure is for a Life-Limiting Anomaly, the “Life Limiting Anomaly Consent” must be completed.

72-hour Consent Tip Sheet

Tipsheet For Referring Providers Completing NC Abortion Consent Forms

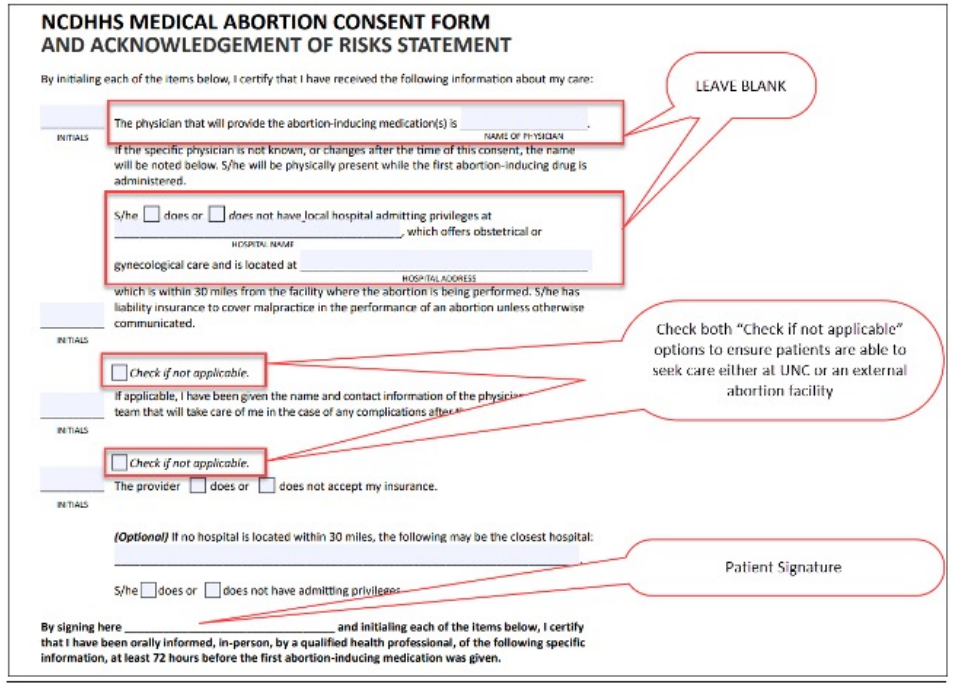
1. First, determine if the patient is obtaining a MEDICAL or SURGICAL abortion and sign the appropriate consent form.
   a. If > 12 weeks gestation, the abortion must be performed surgically.
   b. If ≤ 12 weeks, it is strongly recommended that both forms are signed even if patient is relatively certain which type they will pursue, in order to ensure options aren't limited if situation changes. Of note, typically medication abortion is offered up to 11w0d.

Medication - https://www.ncdhhs.gov/ncdhhs-medical-abortion-informed-consent-english/download

Surgical - https://www.ncdhhs.gov/ncdhhs-surgical-abortion-informed-consent-english/download

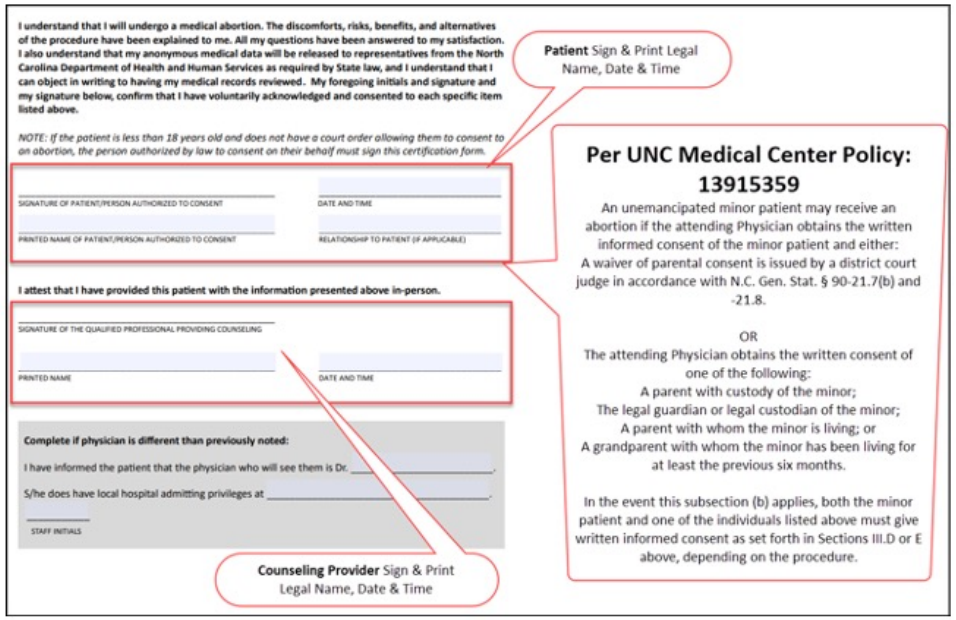
2. Complete patient name and date of birth at the top of the form. **Do NOT use a patient sticker**

3. **PAGE 1**



4. Read the line-by-line provisions in the consent form to the patient
5. Ask the patient to initial **EACH** of the statements in the consent form

6. Ask the patient to print and sign their full name as well as time/date



7. As the counseling provider who has provided the information contained in the consent form, please print and sign your name as well as time/date.

8. Provide patient with a copy of the form regardless of where they will be receiving abortion care and instruct them to bring the form to all upcoming appointments.

9. If the patient might be seeking care at UNC, have the form IMMEDIATELY scanned into the Media tab of Epic entitled "GYN CONSENT" so as not to delay care.

10. If patient expresses confidentiality concerns and is certain not to be receiving abortion services through UNC, consider not scanning into Media tab and just giving patient a copy.

11. Place a referral for family planning in Epic if the care is desired through UNC. Also call Family Planning on-call directly if patient is close to 12 week cut-off (or 20 week cut-off for rape/incest.)
    Order Number REF30 (Referral to Gynecology)
    Specialty: Gynecology
    Referred To Department: UNC FAMILY PLANNING HILLSBOROUGH
    ***This is required in order to avoid patient care delay.**

Reporting Medical and Surgical Abortions

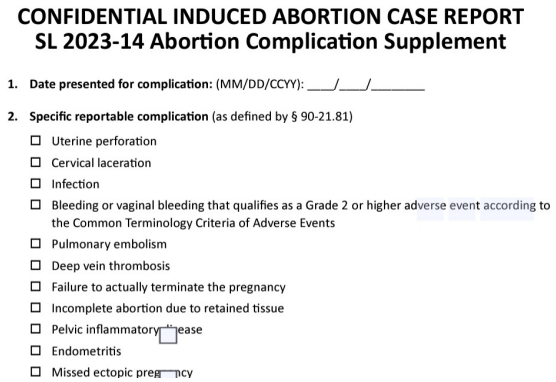
- All abortions must be reported to DHHS within 15 days for adults and within 30 days for minors of med AB follow-up, last encounter from a surgical AB, or the last day of the month in which the abortion was performed (whichever is later).
- Inpatient abortions reporting form will be completed by the attending involved at the time of delivery and hand delivered to a specified collection location.
- Outpatient abortions reporting form will be completed by the attending overseeing the care and follow Family Planning clinic protocol
  - Med AB reports must be initially started at time of medication administration and finalized at time of follow-up visit
- Designated OBGYN staff member will send all completed reports scanned to shared drive monthly to DHHS

- NCDHHS 1891 Abortion Case Report Form - (English/Spanish)

Reporting Complications

Complications are to be reported using this form

- Physician who provided medication abortion or physician diagnosing complication must report within 3 days (Includes non OBGYN as well: ED, Fam Med, Psych physicians as possible reporters)
- If uncertain if true complication exists, please contact the physician who provided the abortion medication before reporting
- Must report Complications listed on Complication Form for surgical AB
- For Med AB report “adverse events” through “Medwatch” FDA portal (follow same standard of reporting as prior).
- NCDHHS Abortion Complications Reporting Supplement 1891a - (English/Spanish)



CONFIDENTIAL INDUCED ABORTION CASE REPORT
SL 2023-14 Abortion Complication Supplement

1. **Date presented for complication:** (MM/DD/CCYY): ____/____/_____
2. **Specific reportable complication** (as defined by § 90-21.81)
   - ☐ Uterine perforation
   - ☐ Cervical laceration
   - ☐ Infection
   - ☐ Bleeding or vaginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria of Adverse Events
   - ☐ Pulmonary embolism
   - ☐ Deep vein thrombosis
   - ☐ Failure to actually terminate the pregnancy
   - ☐ Incomplete abortion due to retained tissue
   - ☐ Pelvic inflammatory disease
   - ☐ Endometritis
   - ☐ Missed ectopic pregnancy

Reporting

Birth/Death Certificate – unchanged

- Per decedent affairs if any signs of life, must complete birth and death certificate >20 weeks.

Induction of Labor Terminations

- We will continue to offer induction of labor terminations that fall within the exceptions provided by the law
- We have hospital and system leadership support to allow providers in consultation with patients to exercise clinical judgement regarding declining resuscitation efforts (compliance with **“Born Alive”** act) based on both Gestational Age and Fetal Condition
  - Specific protocols and review processes have been developed to ensure compliance
    - Standardized internal clinical review process pre-scheduling termination
    - Pre-Induction Termination Huddle with all team members involved to be completed
    - Pre-Induction Termination Huddle Checklist Sheet to be used to ensure all necessary elements covered
    - KCL can be offered according to prior clinical practice

Induction of Labor Terminations

Prior to Admission/Decision for Induction: *Case Review Process*

Patient's responsible provider consults with with (1) UNC MFM faculty and (1) UNC Neonatology faculty

a. Consult can be done by contacting MFM (Antepartum Attending) and UNC Neonatology (Wayne Price or Misty Good) or via E-Consult.
b. MFM and NCCC providers document in maternal medical record regarding life limiting fetal condition using SB20 dot phrases (.NCABORTION)
   - Providers document***
     1) planned neonatal care intensive care vs routine neonatal care and
     2) Type of providers planned to be present at delivery, ie OB nursing, NCCC providers
     ***Above documentation must be present at the time of scheduling case**
c. If a non-emergency condition, must complete SB20 consents with patient.

During Admission: *Pre-Procedure Huddle Process*

a. Pre-procedure huddle
1. Required at Huddle: OB faculty, OB resident, patient primary nurse, L&D charge nurse (NCCC team if planning to be present at delivery)
2. Review
   - Documentation from MFM and NCCC regarding plan of care
   - Complete Huddle Checklist (following slides)
3. Repeat huddle with change in OB faculty, charge nurse, primary nurse

a. Delivery
1. If cardiac motion is present, infant admitted to NCCC, birth certificate created'
2. If no signs of life at delivery, birth certificate is not created
3. Follow plan for neonatal care as outlined in huddle/medical record

Induction Abortion Pre-Procedure Huddle Checklist

For Life-Limiting Anomalies and Medical Emergency 22w0d -24w6d

Induction Abortion Pre-Procedure Huddle Checklist

For Life-Limiting Anomalies and Medical Emergency 22w0d -24w6d

- Huddle and checklist to be completed with all team members involved in patient's care
- Required attendees: OB faculty, OB resident, patient primary nurse, L&D charge nurse (NCCC team if planning to be present at delivery).
- **All must be checked off before induction begins**

	State Forms Review
☐	NCDHHS Patient Consent obtained (Not applicable for medical emergency.)
☐	72 hours since consent has passed (Not applicable for medical emergency.)
☐	Physician Declaration Form Signed

	Procedure
☐	Review diagnosis/indication for induction and fetal management plan documented by MFM and Perinatal/Neonatal Medicine Faculty (clearly review plan for resuscitative/palliative care efforts).
☐	Physician conducted and documented a physical exam, independent verification pregnancy exists, and verified probable gestational age.
☐	Reviewed and documented Iron/H&H, Rh status and any medically indicated tests ordered to determine if patient has heightened risk for complications
☐	Patient has active Type and Screen
☐	Patient screened for coercion or abuse
☐	Patient was informed they may see the remains of the infant in the process of completing the abortion
☐	Planned Procedure ☐Mifepristone/misoprostol induction ☐Misoprostol induction ☐Oxytocin Induction
☐	Planned provider teams present at delivery ☐OB RN ☐OB L&D Provider ☐Pediatric Team

	Post Delivery Efforts
☐	Does clinical judgment support declining neonatal intensive care if fetus delivers with signs of life? ☐Yes ☐No
☐	Physician scheduled/offered a follow-up visit at approximately 7-14 days after delivery and documented in medical record
☐	OB delivery provider completes NCDHHS Reporting Form immediately following delivery and places in designated location.

Escalation of Urgent Questions

Urgent Clinical Questions Affecting Care Decisions:

- Review Sharepoint site https://unchcs.sharepoint.com/SitePages/Updates-on-Senate-Bill-20.aspx
- Review Education Slide Deck
  - If answer unclear, contact Medical or Nursing Director
  - If remains unclear, escalate to Executive Medical Director or Division Director
  - If questions remain, Contact Legal Via On-Call Pager one One-Call Directory