AN ACT relating to freestanding birthing centers.

***Be it enacted by the General Assembly of the Commonwealth of Kentucky:***

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 216B IS CREATED TO READ AS FOLLOWS:

***(1) As used in this section, "freestanding birthing center" means any health facility, place, or institution which is not a hospital, is not in a hospital or a private residence, and is established to provide care for labor, delivery, the immediate postpartum period, and the newborn immediately following delivery.***

***(2) The cabinet shall establish licensure standards for freestanding birthing centers that:***

***(a) Require accreditation by the Commission for the Accreditation of Birth Centers;***

***(b) Delineate requirements for medical malpractice insurance;***

***(c) Require location within thirty (30) miles of a hospital. If a hospital located within thirty (30) miles of a freestanding birthing center ceases operations after a freestanding birthing center has been established, the requirement of this paragraph shall not apply to the affected freestanding birthing center;***

***(d) Do not prohibit a hospital from owning or operating a freestanding birthing center that complies with the requirements of this section; and***

***(e) Include any other requirements deemed necessary by the cabinet that are not inconsistent with the other requirements of this section.***

***(3) (a) A freestanding birthing center shall have a medical director who is a licensed physician who has, at a minimum, the following functions:***

***1. Participation in approval of criteria that would exclude a client or newborn from receiving care at the freestanding birthing center; and***

***2. Participation in the quality review functions of the freestanding birthing center, including review of transfers and sentinel events.***

***(b) The cabinet shall establish a timeline for a freestanding birthing center to fill the position of medical director if the position becomes vacant.***

***(4) A freestanding birthing center shall obtain written informed consent for each client receiving care. The written informed consent shall include:***

***(a) A description of the benefits, risks, and eligibility requirements for receiving care at the freestanding birthing center;***

***(b) A description of the education and credentials of practitioners providing clinical care at the freestanding birthing center;***

***(c) Instructions for obtaining a copy of the administrative regulations promulgated pursuant to this section;***

***(d) Instructions for filing a complaint relating to the freestanding birthing center with the cabinet;***

***(e) A summary of a written protocol for emergencies, including transfer to a higher level of care;***

***(f) Disclosure of professional liability insurance held by health care providers at the freestanding birthing center; and***

***(g) A summary of procedures established by the freestanding birthing center for professional collaboration with other care providers.***

***(5) (a) A freestanding birthing center shall have a written patient transfer agreement with a hospital that provides obstetric services. The cabinet shall establish minimum requirements for the patient transfer agreement which shall include:***

***1. Specifying the responsibilities that a freestanding birthing center and a hospital assume in the transfer of a patient; and***

***2. Establishing the freestanding birthing center's responsibility for:***

***a. Notifying the receiving hospital promptly of the impending transfer of a patient; and***

***b. Arranging for appropriate and safe transportation.***

***(b) The cabinet shall establish a process and criteria by which the requirement of paragraph (a) of this subsection may be waived if a freestanding birthing center submits to the cabinet evidence of a failure by a hospital that provides obstetric services to enter into a written patient transfer agreement with the freestanding birthing center.***

***(6) (a) A freestanding birthing center shall have a written patient transfer agreement with a licensed emergency medical transportation service.***

***(b) The cabinet shall establish a process and criteria by which the requirement of paragraph (a) of this subsection may be waived if a freestanding birthing center submits to the cabinet evidence of a failure by a licensed emergency medical transportation service to enter into a written patient transfer agreement with the freestanding birthing center.***

***(7) A certificate of need shall not be required to establish and license a freestanding birthing center with no more than four (4) beds.***

***(8) (a) Nothing in this section is intended to expand or limit the liability of a health care provider, health care facility, or freestanding birthing center.***

***(b) In the event of an action for injury or death due to any act or omission of a health care provider rendering services at a freestanding birthing center from which an injured patient is transferred to any other licensed health care provider or licensed health care facility:***

***1. The liability of the subsequent licensed health care provider or licensed health care facility shall be limited to their own negligent acts and omissions that violate their standards of care according to existing law, except as provided in subparagraph 2. of this paragraph; and***

***2. If the subsequent licensed health care provider or licensed health care facility owns, operates, or provides care at the freestanding birthing***

***center from which the injured patient was transferred, then the licensed health care provider or licensed health care facility shall be liable for acts or omissions that violate their standards of care and that occurred at the freestanding birthing center.***

***(9) In accordance with KRS 311.772, no person shall perform an abortion in a freestanding birthing center.***

➔Section 2. KRS 216B.015 is amended to read as follows:

Except as otherwise provided, for purposes of this chapter, the following definitions shall apply:

(1) "Abortion facility" means any place in which an abortion is performed;

(2) "Administrative regulation" means a regulation adopted and promulgated pursuant to the procedures in KRS Chapter 13A;

(3) "Affected persons" means the applicant; any person residing within the geographic area served or to be served by the applicant; any person who regularly uses health facilities within that geographic area; health facilities located in the health service area in which the project is proposed to be located which provide services similar to the services of the facility under review; health facilities which, prior to receipt by the agency of the proposal being reviewed, have formally indicated an intention to provide similar services in the future; and the cabinet and third-party payors who reimburse health facilities for services in the health service area in which the project is proposed to be located;

(4) (a) "Ambulatory surgical center" means a health facility:

1. Licensed pursuant to administrative regulations promulgated by the cabinet;

2. That provides outpatient surgical services, excluding oral or dental procedures; and

3. Seeking recognition and reimbursement as an ambulatory surgical center

from any federal, state, or third-party insurer from which payment is sought.

(b) An ambulatory surgical center does not include the private offices of physicians where in-office outpatient surgical procedures are performed as long as the physician office does not seek licensure, certification, reimbursement, or recognition as an ambulatory surgical center from a federal, state, or third-party insurer.

(c) Nothing in this subsection shall preclude a physician from negotiating enhanced payment for outpatient surgical procedures performed in the physician's private office so long as the physician does not seek recognition or reimbursement of his or her office as an ambulatory surgical center without first obtaining a certificate of need or license required under KRS 216B.020 and 216B.061;

(5) "Applicant" means any physician's office requesting a major medical equipment expenditure exceeding the capital expenditure minimum, or any person, health facility, or health service requesting a certificate of need or license;

(6) "Cabinet" means the Cabinet for Health and Family Services;

(7) "Capital expenditure" means an expenditure made by or on behalf of a health facility which:

(a) Under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance or is not for investment purposes only; or

(b) Is made to obtain by lease or comparable arrangement any facility or part thereof or any equipment for a facility or part thereof;

(8) "Capital expenditure minimum" means the annually adjusted amount set by the cabinet. In determining whether an expenditure exceeds the expenditure minimum, the cost of any studies, surveys, designs, plans, working drawings, specifications,

and other activities essential to the improvement, expansion, or replacement of any plant or any equipment with respect to which the expenditure is made shall be included. Donations of equipment or facilities to a health facility which if acquired directly by the facility would be subject to review under this chapter shall be considered a capital expenditure, and a transfer of the equipment or facilities for less than fair market value shall be considered a capital expenditure if a transfer of the equipment or facilities at fair market value would be subject to review;

(9) "Certificate of need" means an authorization by the cabinet to acquire, to establish, to offer, to substantially change the bed capacity, or to substantially change a health service as covered by this chapter;

(10) "Certified surgical assistant" means a certified surgical assistant or certified first assistant who is certified by the National Surgical Assistant Association on the Certification of Surgical Assistants, the Liaison Council on Certification of Surgical Technologists, or the American Board of Surgical Assistants. The certified surgical assistant is an unlicensed health-care provider who is directly accountable to a physician licensed under KRS Chapter 311 or, in the absence of a physician, to a registered nurse licensed under KRS Chapter 314;

(11) "Continuing care retirement community" means a community that provides, on the same campus, a continuum of residential living options and support services to persons sixty (60) years of age or older under a written agreement. The residential living options shall include independent living units, nursing home beds, and either assisted living units or personal care beds;

(12) "Formal review process" means the ninety (90) day certificate-of-need review conducted by the cabinet;

(13) "Health facility" means any institution, place, building, agency, or portion thereof, public or private, whether organized for profit or not, used, operated, or designed to provide medical diagnosis, treatment, nursing, rehabilitative, or preventive care and

includes alcohol abuse, drug abuse, and mental health services. This shall include but shall not be limited to health facilities and health services commonly referred to as hospitals, psychiatric hospitals, physical rehabilitation hospitals, chemical dependency programs, nursing facilities, nursing homes, personal care homes, intermediate care facilities, assisted living communities, family care homes, outpatient clinics, ambulatory care facilities, ambulatory surgical centers, emergency care centers and services, ambulance providers, hospices, community mental health centers, home health agencies, kidney disease treatment centers and freestanding hemodialysis units, ***freestanding birthing centers as defined in Section 1 of this Act,*** and others providing similarly organized services regardless of nomenclature;

(14) "Health services" means clinically related services provided within the Commonwealth to two (2) or more persons, including but not limited to diagnostic, treatment, or rehabilitative services, and includes alcohol, drug abuse, and mental health services;

(15) "Independent living" means the provision of living units and supportive services, including but not limited to laundry, housekeeping, maintenance, activity direction, security, dining options, and transportation;

(16) "Intraoperative surgical care" includes the practice of surgical assisting in which the certified surgical assistant or physician assistant is working under the direction of the operating physician as a first or second assist, and which may include the following procedures:

(a) Positioning the patient;

(b) Preparing and draping the patient for the operative procedure;

(c) Observing the operative site during the operative procedure;

(d) Providing the best possible exposure of the anatomy incident to the operative procedure;

(e) Assisting in closure of incisions and wound dressings; and

(f) Performing any task, within the role of an unlicensed assistive person, or if the assistant is a physician assistant, performing any task within the role of a physician assistant, as required by the operating physician incident to the particular procedure being performed;

(17) "Major medical equipment" means equipment which is used for the provision of medical and other health services and which costs in excess of the medical equipment expenditure minimum. In determining whether medical equipment has a value in excess of the medical equipment expenditure minimum, the value of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of the equipment shall be included;

(18) "Nonsubstantive review" means an expedited review conducted by the cabinet of an application for a certificate of need as authorized under KRS 216B.095;

(19) "Nonclinically related expenditures" means expenditures for:

(a) Repairs, renovations, alterations, and improvements to the physical plant of a health facility which do not result in a substantial change in beds, a substantial change in a health service, or the addition of major medical equipment, and do not constitute the replacement or relocation of a health facility; or

(b) Projects which do not involve the provision of direct clinical patient care, including but not limited to the following:

1. Parking facilities;

2. Telecommunications or telephone systems;

3. Management information systems;

4. Ventilation systems;

5. Heating or air conditioning, or both;

6. Energy conservation; or

7. Administrative offices;

(20) "Party to the proceedings" means the applicant for a certificate of need and any affected person who appears at a hearing on the matter under consideration and enters an appearance of record;

(21) "Perioperative nursing" means a practice of nursing in which the nurse provides preoperative, intraoperative, and postoperative nursing care to surgical patients;

(22) "Person" means an individual, a trust or estate, a partnership, a corporation, an association, a group, state, or political subdivision or instrumentality including a municipal corporation of a state;

(23) "Physician assistant" means the same as the definition provided in KRS 311.550;

(24) "Record" means, as applicable in a particular proceeding:

(a) The application and any information provided by the applicant at the request of the cabinet;

(b) Any information provided by a holder of a certificate of need or license in response to a notice of revocation of a certificate of need or license;

(c) Any memoranda or documents prepared by or for the cabinet regarding the matter under review which were introduced at any hearing;

(d) Any staff reports or recommendations prepared by or for the cabinet;

(e) Any recommendation or decision of the cabinet;

(f) Any testimony or documentary evidence adduced at a hearing;

(g) The findings of fact and opinions of the cabinet or the findings of fact and recommendation of the hearing officer; and

(h) Any other items required by administrative regulations promulgated by the cabinet;

(25) "Registered nurse first assistant" means one who:

(a) Holds a current active registered nurse licensure;

(b) Is certified in perioperative nursing; and

(c) Has successfully completed and holds a degree or certificate from a

recognized program, which shall consist of:

1. The Association of Operating Room Nurses, Inc., Core Curriculum for the registered nurse first assistant; and
2. One (1) year of postbasic nursing study, which shall include at least forty-five (45) hours of didactic instruction and one hundred twenty (120) hours of clinical internship or its equivalent of two (2) college semesters.

A registered nurse who was certified prior to 1995 by the Certification Board of Perioperative Nursing shall not be required to fulfill the requirements of paragraph (c) of this subsection;

(26) "Secretary" means the secretary of the Cabinet for Health and Family Services;

(27) "Sexual assault examination facility" means a licensed health facility, emergency medical facility, primary care center, or a children's advocacy center or rape crisis center that is regulated by the Cabinet for Health and Family Services, and that provides sexual assault examinations under KRS 216B.400;

(28) "State health plan" means the document prepared triennially, updated annually, and approved by the Governor;

(29) "Substantial change in a health service" means:

(a) The addition of a health service for which there are review criteria and standards in the state health plan; or

(b) The addition of a health service subject to licensure under this chapter;

(30) "Substantial change in bed capacity" means the addition or reduction of beds by licensure classification within a health facility;

(31) "Substantial change in a project" means a change made to a pending or approved project which results in:

(a) A substantial change in a health service, except a reduction or termination of a health service;

(b) A substantial change in bed capacity, except for reductions;

(c) A change of location; or

(d) An increase in costs greater than the allowable amount as prescribed by regulation;

(32) "To acquire" means to obtain from another by purchase, transfer, lease, or other comparable arrangement of the controlling interest of a capital asset or capital stock, or voting rights of a corporation. An acquisition shall be deemed to occur when more than fifty percent (50%) of an existing capital asset or capital stock or voting rights of a corporation is purchased, transferred, leased, or acquired by comparable arrangement by one (1) person from another person;

(33) "To batch" means to review in the same review cycle and, if applicable, give comparative consideration to all filed applications pertaining to similar types of services, facilities, or equipment affecting the same health service area;

(34) "To establish" means to construct, develop, or initiate a health facility;

(35) "To obligate" means to enter any enforceable contract for the construction, acquisition, lease, or financing of a capital asset. A contract shall be considered enforceable when all contingencies and conditions in the contract have been met. An option to purchase or lease which is not binding shall not be considered an enforceable contract; and

(36) "To offer" means, when used in connection with health services, to hold a health facility out as capable of providing, or as having the means of providing, specified health services.

➔Section 3. KRS 216B.020 is amended to read as follows:

(1) The provisions of this chapter that relate to the issuance of a certificate of need shall not apply to abortion facilities as defined in KRS 216B.015; any hospital which does not charge its patients for hospital services and does not seek or accept Medicare, Medicaid, or other financial support from the federal government or any

state government; assisted living residences; family care homes; state veterans' nursing homes; services provided on a contractual basis in a rural primary-care hospital as provided under KRS 216.380; community mental health centers for services as defined in KRS Chapter 210; primary care centers; rural health clinics; private duty nursing services operating as health care services agencies as defined in KRS 216.718; group homes; licensed residential crisis stabilization units; licensed free-standing residential substance use disorder treatment programs with sixteen (16) or fewer beds, but not including Levels I and II psychiatric residential treatment facilities or licensed psychiatric inpatient beds; outpatient behavioral health treatment, but not including partial hospitalization programs; end stage renal disease dialysis facilities, freestanding or hospital based; swing beds; special clinics, including but not limited to wellness, weight loss, family planning, disability determination, speech and hearing, counseling, pulmonary care, and other clinics which only provide diagnostic services with equipment not exceeding the major medical equipment cost threshold and for which there are no review criteria in the state health plan; nonclinically related expenditures; nursing home beds that shall be exclusively limited to on-campus residents of a certified continuing care retirement community; home health services provided by a continuing care retirement community to its on-campus residents; the relocation of hospital administrative or outpatient services into medical office buildings which are on or contiguous to the premises of the hospital; the relocation of acute care beds which occur among acute care hospitals under common ownership and which are located in the same area development district so long as there is no substantial change in services and the relocation does not result in the establishment of a new service at the receiving hospital for which a certificate of need is required; the redistribution of beds by licensure classification within an acute care hospital so long as the redistribution does not increase the total licensed bed capacity of the hospital;

residential hospice facilities established by licensed hospice programs; ***freestanding birthing centers as defined in Section 1 of this Act;*** the following health services provided on site in an existing health facility when the cost is less than six hundred thousand dollars ($600,000) and the services are in place by December 30, 1991: psychiatric care where chemical dependency services are provided, level one (1) and level two (2) of neonatal care, cardiac catheterization, and open heart surgery where cardiac catheterization services are in place as of July 15, 1990; or ambulance services operating in accordance with subsection (6), (7), or (8) of this section. These listed facilities or services shall be subject to licensure, when applicable.

(2) Nothing in this chapter shall be construed to authorize the licensure, supervision, regulation, or control in any manner of:

(a) Private offices and clinics of physicians, dentists, and other practitioners of the healing arts, except any physician's office that meets the criteria set forth in KRS 216B.015(5) or that meets the definition of an ambulatory surgical center as set out in KRS 216B.015;

(b) Office buildings built by or on behalf of a health facility for the exclusive use of physicians, dentists, and other practitioners of the healing arts; unless the physician's office meets the criteria set forth in KRS 216B.015(5), or unless the physician's office is also an abortion facility as defined in KRS 216B.015, except no capital expenditure or expenses relating to any such building shall be chargeable to or reimbursable as a cost for providing inpatient services offered by a health facility;

(c) Outpatient health facilities or health services that:

1. Do not provide services or hold patients in the facility after midnight; and

2. Are exempt from certificate of need and licensure under subsection (3)

of this section;

(d) Dispensaries and first-aid stations located within business or industrial establishments maintained solely for the use of employees, if the facility does not contain inpatient or resident beds for patients or employees who generally remain in the facility for more than twenty-four (24) hours;

(e) Establishments, such as motels, hotels, and boarding houses, which provide domiciliary and auxiliary commercial services, but do not provide any health related services and boarding houses which are operated by persons contracting with the United States Department of Veterans Affairs for boarding services;

(f) The remedial care or treatment of residents or patients in any home or institution conducted only for those who rely solely upon treatment by prayer or spiritual means in accordance with the creed or tenets of any recognized church or religious denomination and recognized by that church or denomination; and

(g) On-duty police and fire department personnel assisting in emergency situations by providing first aid or transportation when regular emergency units licensed to provide first aid or transportation are unable to arrive at the scene of an emergency situation within a reasonable time.

(3) The following outpatient categories of care shall be exempt from certificate of need and licensure on July 14, 2018:

(a) Primary care centers;

(b) Special health clinics, unless the clinic provides pain management services and is located off the campus of the hospital that has majority ownership interest;

(c) Specialized medical technology services, unless providing a State Health Plan service;

(d) Retail-based health clinics and ambulatory care clinics that provide nonemergency, noninvasive treatment of patients;

(e) Ambulatory care clinics treating minor illnesses and injuries;

(f) Mobile health services, unless providing a service in the State Health Plan;

(g) Rehabilitation agencies;

(h) Rural health clinics; and

(i) Off-campus, hospital-acquired physician practices.

(4) The exemptions established by subsections (2) and (3) of this section shall not apply to the following categories of care:

(a) An ambulatory surgical center as defined by KRS 216B.015(4);

(b) A health facility or health service that provides one (1) of the following types of services:

1. Cardiac catheterization;

2. Megavoltage radiation therapy;

3. Adult day health care;

4. Behavioral health services;

5. Chronic renal dialysis;~~[~~

~~6. Birthing services;]~~ or

***6.***~~[7.]~~ Emergency services above the level of treatment for minor illnesses or injuries;

(c) A pain management facility as defined by KRS 218A.175(1);

(d) An abortion facility that requires licensure pursuant to KRS 216B.0431; or

(e) A health facility or health service that requests an expenditure that exceeds the major medical expenditure minimum.

(5) An existing facility licensed as an intermediate care or nursing home shall notify the cabinet of its intent to change to a nursing facility as defined in Public Law 100-203. A certificate of need shall not be required for conversion of an intermediate

care or nursing home to the nursing facility licensure category.

(6) Ambulance services owned and operated by a city government, which propose to provide services in coterminous cities outside of the ambulance service's designated geographic service area, shall not be required to obtain a certificate of need if the governing body of the city in which the ambulance services are to be provided enters into an agreement with the ambulance service to provide services in the city.

(7) Ambulance services owned by a hospital shall not be required to obtain a certificate of need for the sole purpose of providing non-emergency and emergency transport services originating from its hospital.

(8) (a) As used in this subsection, "emergency ambulance transport services" means the transportation of an individual that has an emergency medical condition with acute symptoms of sufficient severity that the absence of immediate medical attention could reasonably be expected to place the individual's health in serious jeopardy or result in the serious impairment or dysfunction of the individual's bodily organs.

(b) A city or county government that has conducted a public hearing for the purposes of demonstrating that an imperative need exists in the city or county to provide emergency ambulance transport services within its jurisdictional boundaries shall not be required to obtain a certificate of need for the city or county to:

1. Directly provide emergency ambulance transport services as defined in this subsection within the city's or county's jurisdictional boundaries; or
2. Enter into a contract with a hospital or hospitals within its jurisdiction, or within an adjoining county if there are no hospitals located within the county, for the provision of emergency ambulance transport services as defined in this subsection within the city's or county's jurisdictional boundaries.

(c) Any license obtained under KRS Chapter 311A by a city or county for the provision of ambulance services operating under a certificate of need exclusion pursuant to this subsection shall be held exclusively by the city or county government and shall not be transferrable to any other entity.

(d) Prior to obtaining the written agreement of a city, an ambulance service operating under a county government certificate of need exclusion pursuant to this subsection shall not provide emergency ambulance transport services within the boundaries of any city that:

1. Possesses a certificate of need to provide emergency ambulance services;
2. Has an agency or department thereof that holds a certificate of need to provide emergency ambulance services; or
3. Is providing emergency ambulance transport services within its jurisdictional boundaries pursuant to this subsection.

(9) (a) Except where a certificate of need is not required pursuant to subsection (6), (7), or (8) of this section, the cabinet shall grant nonsubstantive review for a certificate of need proposal to establish an ambulance service that is owned by a:

1. City government;
2. County government; or
3. Hospital, in accordance with paragraph (b) of this subsection.

(b) A notice shall be sent by the cabinet to all cities and counties that a certificate of need proposal to establish an ambulance service has been submitted by a hospital. The legislative bodies of the cities and counties affected by the hospital's certificate of need proposal shall provide a response to the cabinet within thirty (30) days of receiving the notice. The failure of a city or county legislative body to respond to the notice shall be deemed to be support for the

proposal.

(c) An ambulance service established under this subsection shall not be transferred to another entity that does not meet the requirements of paragraph (a) of this subsection without first obtaining a substantive certificate of need.

(10) Notwithstanding any other provision of law, a continuing care retirement community's nursing home beds shall not be certified as Medicaid eligible unless a certificate of need has been issued authorizing applications for Medicaid certification. The provisions of subsection (5) of this section notwithstanding, a continuing care retirement community shall not change the level of care licensure status of its beds without first obtaining a certificate of need.

(11) An ambulance service established under subsection (9) of this section shall not be transferred to an entity that does not qualify under subsection (9) of this section without first obtaining a substantive certificate of need.

(12) (a) The provisions of subsections (7), (8), and (9) of this section shall expire on July 1, 2026.

(b) All actions taken by cities, counties, and hospitals, exemptions from obtaining a certificate of need, and any certificate of need granted under subsections (7), (8), and (9) of this section prior to July 1, 2026, shall remain in effect on and after July 1, 2026.

➔Section 4. KRS 196.173 is amended to read as follows:

(1) Except as provided in subsection (2) of this section, an inmate housed in a jail, penitentiary, or local or state correctional or detention facility, residential center, or reentry center who is known to be pregnant shall be restrained solely with handcuffs in front of her body unless further restraint is required to protect herself or others.

(2) (a) Except in an extraordinary circumstance, no inmate who is known to be pregnant shall be restrained during labor, during transport to a medical facility

or ***freestanding*** birthing center for delivery, or during postpartum recovery.

(b) As used in this subsection, "extraordinary circumstance" means that reasonable grounds exist to believe the inmate presents an immediate and credible:

1. Serious threat of hurting herself, staff, or others; or
2. Risk of escape that cannot be reasonably minimized through any method other than restraints.

➔Section 5. KRS 211.122 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall, in cooperation with maternal and infant health and mental health professional societies:

(a) Develop written information on perinatal mental health disorders and make it available on its website for access by ***freestanding*** birthing centers, hospitals that provide labor and delivery services, and the public; and

(b) Provide access on its website to one (1) or more evidence-based clinical assessment tools designed to detect the symptoms of perinatal mental health disorders for use by health care providers providing perinatal care and health care providers providing pediatric infant care.

(2) The Cabinet for Health and Family Services shall establish the Kentucky Maternal and Infant Health Collaborative. The collaborative shall be composed of the following members appointed by the secretary of the Cabinet for Health and Family Services:

(a) Four (4) representatives of health care facilities that provide obstetrical, newborn, maternal, and infant health care, one (1) of whom shall be a member of the Kentucky Chapter of the American College of Obstetricians and Gynecologists;

(b) Two (2) providers of maternal mental health care;

(c) Two (2) representatives of university mental health training programs;

(d) Two (2) maternal health advocates;

(e) Three (3) women, each of whom shall have experience living with at least one (1) of the following:

1. Perinatal mental health disorders;

2. Substance use disorder; and

3. Intimate partner violence;

(f) One (1) public health director of a local health department in the Commonwealth; and

(g) The commissioner of the Department for Public Health or his or her designee.

(3) The purposes of the collaborative shall be:

(a) Improving the quality of prevention and treatment of perinatal mental health disorders;

(b) Promoting the implementation of evidence-based bundles of care to improve patient safety;

(c) Identifying unaddressed gaps in service related to perinatal mental health disorders that are linked to geographic, racial, and ethnic inequalities; lack of screenings; and insufficient access to treatments, professionals, or support groups; and

(d) Exploring grant and other funding opportunities and making recommendations for funding allocations to address the need for services and supports for perinatal mental health disorders.

(4) The collaborative shall annually review the operations of the Kentucky Maternal Psychiatry Access Program established in KRS 211.123.

(5) The objectives set forth in subsection (3) of this section may be achieved by incorporating the collaborative's findings and recommendations into other programs administered by the Cabinet for Health and Family Services that are intended to improve maternal health care quality and safety.

(6) On or before November 1 of each year, the collaborative shall submit a report to the Interim Joint Committee on Families and Children, the Interim Joint Committee on Health Services, and the Advisory Council for Medical Assistance describing the collaborative's work and any recommendations to address identified gaps in services and supports for perinatal mental health disorders.

➔Section 6. KRS 211.647 is amended to read as follows:

(1) The office, on receipt of an auditory screening report of an infant from a hospital or ***freestanding*** ~~[alternative]~~ birthing center in accordance with KRS 216.2970 shall review each auditory screening report that indicates a potential hearing loss. The office shall contact the parents to schedule follow-up evaluations or make a referral for evaluations within three (3) business days.

(2) The office shall secure information missing from birth certificates or hospital referral reports which is relevant to identifying infants with a hearing loss.

(3) The office shall establish standards for infant audiological assessment and diagnostic centers based on accepted national standards, including but not limited to the "Guidelines for the Audiologic Assessment of Children From Birth to 5 Years of Age" as published by the American Speech-Language-Hearing Association (ASHA) and the "Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs" as published by the Joint Committee on Infant Hearing (JCIH). The office may promulgate administrative regulations in accordance with KRS Chapter 13A to establish the standards for the centers.

(4) The office shall maintain a list of approved infant audiological assessment and diagnostic centers that meet the standards established by the office. An audiological assessment and diagnostic center included on the list shall meet the standards established by the office. An approved center may voluntarily choose not to be included on the list.

(5) An approved audiology assessment and diagnostic center shall agree to provide requested data to the office for each infant evaluated and on any newly identified children ages birth to three (3) years with a permanent childhood hearing loss within forty-eight (48) hours and make a referral to the Kentucky Early Intervention System point of entry in the service area of the child's residence for services under KRS 200.664. A center shall submit documentation to the office of a referral made to the Kentucky Early Intervention System. A referral received by the Kentucky Early Intervention System from a center shall be considered a referral from the office.

(6) If the audiological evaluation performed by the office contains evidence of a hearing loss, within forty-eight (48) hours the office shall:

(a) Contact the attending physician and parents and provide information to the parents in an accessible format as supplied by the Kentucky Commission on the Deaf and Hard of Hearing; and

(b) Make a referral to the Kentucky Early Intervention System point of entry in the service area of the child's residence for services under KRS 200.664.

(7) The office shall forward a report of an audiological evaluation that indicates a hearing loss, with no information that personally identifies the child, to:

(a) The Kentucky Commission on the Deaf and Hard of Hearing for census purposes; and

(b) The Kentucky Birth Surveillance Registry for information purposes.

(8) Cumulative demographic data of identified infants with a hearing loss shall be made available to agencies and organizations including but not limited to the Cabinet for Health and Family Services and the Early Childhood Advisory Council, requesting the information for planning purposes.

➔Section 7. KRS 211.660 is amended to read as follows:

(1) The Department for Public Health shall establish and maintain a Kentucky birth

surveillance registry that will provide a system for the collection of information concerning birth defects, stillbirths, and high-risk conditions. The system may cover all or part of the Commonwealth.

(2) In establishing the system, the department may review vital statistics records, and shall also consider expanding the current list of congenital anomalies and high-risk conditions as reported on birth certificates.

(3) (a) The department may require general acute-care hospitals licensed under KRS Chapter 216B to maintain a list of all inpatients and voluntarily to maintain a list of all outpatients up to the age of five (5) years with a primary diagnosis of a congenital anomaly or high-risk condition as defined by the department upon the recommendation of the appointed advisory committee. Hospital participation regarding its outpatients shall be voluntary and subject to the discretion of each hospital.

(b) The department may require medical laboratories licensed under KRS Chapter 333 to maintain medical records for all persons up to the age of five (5) years with a primary diagnosis of or a laboratory test result indicating congenital anomaly or high-risk condition as defined by the department upon the recommendation of the appointed advisory committee.

(4) Each licensed ***freestanding***~~[free-standing]~~ birthing center, general acute-care hospital licensed under KRS Chapter 216B, and medical laboratory licensed under KRS Chapter 333 shall grant, if required or otherwise participating voluntarily under the provisions of subsection (3) of this section, to any Kentucky Birth Surveillance Registry personnel or his or her designee, upon presentation of proper identification, access to the medical records of any patient meeting the criteria in subsection (3) of this section. If the department's agent determines that copying of the medical records is necessary, associated costs shall be borne by the Department for Public Health at the rate pursuant to KRS 422.317.

(5) No liability of any kind, character, damages, or other relief shall arise or be enforced against any licensed ***freestanding***~~[free-standing]~~ birthing center, general acute-care hospital, or medical laboratory by reason of having provided the information or material to the Kentucky Birth Surveillance Registry.

(6) The Department for Public Health may implement the provisions of KRS 211.651 to 211.670 through the promulgation of administrative regulations in accordance with the provisions of KRS Chapter 13A.

➔Section 8. KRS 213.046 is amended to read as follows:

(1) A certificate of birth for each live birth which occurs in the Commonwealth shall be filed with the state registrar within five (5) working days after such birth and shall be registered if it has been completed and filed in accordance with this section and applicable administrative regulations. No certificate shall be held to be complete and correct that does not supply all items of information called for in this section and in KRS 213.051, or satisfactorily account for their omission except as provided in KRS 199.570(3). If a certificate of birth is incomplete, the state registrar shall immediately notify the responsible person and require that person to supply the missing items, if that information can be obtained.

(2) When a birth occurs in ***a health facility***~~[an institution]~~ or en route thereto, the person in charge of the ***health facility***~~[institution]~~ or that person's designated representative, shall obtain the personal data, prepare the certificate, secure the signatures required, and file the certificate as directed in subsection (1) of this section or as otherwise directed by the state registrar within the required five (5) working days. The physician***, midwife,*** or other person in attendance shall provide the medical information required for the certificate and certify to the fact of birth within five (5) working days after the birth. If the physician***, midwife,*** or other person in attendance does not certify to the fact of birth within the five (5) working day period, the person in charge of the ***health facility***~~[institution]~~ shall complete

and sign the certificate.

(3) When a birth occurs in a ***health facility***~~[hospital]~~ or en route thereto to a woman who is unmarried, the person in charge of the ***health facility***~~[hospital]~~ or that person's designated representative shall immediately before or after the birth of a child, except when the mother or the alleged father is a minor:

(a) Meet with the mother prior to the release from the ***health facility***~~[hospital]~~;

(b) Attempt to ascertain whether the father of the child is available in the ***health facility***~~[hospital]~~, and, if so, to meet with him, if possible;

(c) Provide written materials and oral, audio, or video materials about paternity;

(d) Provide the unmarried mother, and, if possible, the father, with the voluntary paternity form necessary to voluntarily establish paternity;

(e) Provide a written and an oral, audio, or video description of the rights and responsibilities, the alternatives to, and the legal consequences of acknowledging paternity;

(f) Provide written materials and information concerning genetic paternity testing;

(g) Provide an opportunity to speak by telephone or in person with staff who are trained to clarify information and answer questions about paternity establishment;

(h) If the parents wish to acknowledge paternity, require the voluntary acknowledgment of paternity obtained through the ***health facility-based***~~[hospital-based]~~ program be signed by both parents and be authenticated by a notary public;

(i) Upon both the mother's and father's request, help the mother and father in completing the affidavit of paternity form;

(j) Upon both the mother's and father's request, transmit the affidavit of paternity to the state registrar; and

(k) In the event that the mother or the alleged father is a minor, information set forth in this section shall be provided in accordance with Civil Rule 17.03 of the Kentucky Rules of Civil Procedure.

If the mother or the alleged father is a minor, the paternity determination shall be conducted pursuant to KRS Chapter 406.

(4) The voluntary acknowledgment of paternity and declaration of paternity forms designated by the Vital Statistics Branch shall be the only documents having the same weight and authority as a judgment of paternity.

(5) The Cabinet for Health and Family Services shall:

(a) Provide to all public and private ***health facilities offering obstetric or midwifery services*** ~~[birthing hospitals]~~ in the state written materials in accessible formats and audio or video materials concerning paternity establishment forms necessary to voluntarily acknowledge paternity;

(b) Provide copies of a written description in accessible formats and an audio or video description of the rights and responsibilities of acknowledging paternity; and

(c) Provide staff training, guidance, and written instructions regarding voluntary acknowledgment of paternity as necessary to operate the ***health services-based*** ~~[hospital-based]~~ program.

(6) When a birth occurs outside ***a health facility*** ~~[an institution]~~, verification of the birth shall be in accordance with the requirements of the state registrar and a birth certificate shall be prepared and filed by one (1) of the following in the indicated order of priority:

(a) The ***health care provider*** ~~[physician]~~ in attendance at or immediately after the birth; or, in the absence of such a person,

(b) A midwife or any other person in attendance at or immediately after the birth; or, in the absence of such a person,

(c) The father, the mother, or in the absence of the father and the inability of the mother, the person in charge of the premises where the birth occurred or of the ***health facility***~~[institution]~~ to which the child was admitted following the birth.

(7) No physician, midwife, or other attendant shall refuse to sign or delay the filing of a birth certificate.

(8) If a birth occurs on a moving conveyance within the United States and the child is first removed from the conveyance in the Commonwealth, the birth shall be registered in the Commonwealth, and the place where the child is first removed shall be considered the place of birth. If a birth occurs on a moving conveyance while in international waters or air space or in a foreign country or its air space and the child is first removed from the conveyance in the Commonwealth, the birth shall be registered in the Commonwealth, but the certificate shall show the actual place of birth insofar as can be determined.

(9) The following provisions shall apply if the mother was married at the time of either conception or birth or anytime between conception and birth:

(a) If there is no dispute as to paternity, the name of the husband shall be entered on the certificate as the father of the child. The surname of the child shall be any name chosen by the parents; however, if the parents are separated or divorced at the time of the child's birth, the choice of surname rests with the parent who has legal custody following birth;

(b) If the mother claims that the father of the child is not her husband and the husband agrees to such a claim and the putative father agrees to the statement, a three (3) way affidavit of paternity may be signed by the respective parties and duly notarized. The state registrar of vital statistics shall enter the name of a nonhusband on the birth certificate as the father and the surname of the child shall be any name chosen by the mother; and

(c) If a question of paternity determination arises which is not resolved under paragraph (b) of this subsection, it shall be settled by the District Court.

(10) The following provisions shall apply if the mother was not married at the time of either conception or birth or between conception and birth or the marital relationship between the mother and her husband has been interrupted for more than ten (10) months prior to the birth of the child:

(a) The name of the father shall not be entered on the certificate of birth. The state registrar shall upon acknowledgment of paternity by the father and with consent of the mother pursuant to KRS 213.121, enter the father's name on the certificate. The surname of the child shall be any name chosen by the mother and father. If there is no agreement, the child's surname shall be determined by the parent with legal custody of the child;

(b) If an affidavit of paternity has been properly completed and the certificate of birth has been filed accordingly, any further modification of the birth certificate regarding the paternity of the child shall require an order from the District Court;

(c) In any case in which paternity of a child is determined by a court order, the name of the father and surname of the child shall be entered on the certificate of birth in accordance with the finding and order of the court; and

(d) In all other cases, the surname of the child shall be any name chosen by the mother.

(11) If the father is not named on the certificate of birth, no other information about the father shall be entered on the certificate. In all cases, the maiden name of the gestational mother shall be entered on the certificate.

(12) Any child whose surname was restricted prior to July 13, 1990, shall be entitled to apply to the state registrar for an amendment of a birth certificate showing as the surname of the child, any surname chosen by the mother or parents as provided

under this section.

(13) The birth certificate of a child born as a result of artificial insemination shall be completed in accordance with the provisions of this section.

(14) Each birth certificate filed under this section shall include all Social Security numbers that have been issued to the parents of the child.

(15) Either of the parents of the child, or other informant, shall attest to the accuracy of the personal data entered on the certificate in time to permit the filing of the certificate within five (5) days prescribed in subsection (1) of this section.

(16) When a birth certificate is filed for any birth that occurred outside ***a health facility*** ~~[an institution]~~, the Cabinet for Health and Family Services shall forward information regarding the need for an auditory screening for an infant and a list of options available for obtaining an auditory screening for an infant. The list shall include the Office for Children with Special Health Care Needs, local health departments as established in KRS Chapter 212, ***health facilities*** ~~[hospitals]~~ offering obstetric ***or midwifery*** services, ~~[alternative birthing centers required to provide an auditory screening under KRS 216.2970, ]~~audiological assessment and diagnostic centers approved by the Office for Children with Special Health Care Needs in accordance with KRS 211.647 and licensed audiologists, and shall specify the hearing methods approved by the Office for Children with Special Health Care Needs in accordance with KRS 216.2970.

***(17) As used in this section, "health facility" has the same meaning as in Section 2 of this Act.***

➔Section 9. KRS 214.155 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall operate a newborn screening program for heritable and congenital disorders that includes but is not limited to procedures for conducting initial newborn screening tests on infants twenty-eight (28) days or less of age and definitive diagnostic evaluations provided by a state

university-based specialty clinic for infants whose initial screening tests resulted in a positive test. The secretary of the cabinet shall, by administrative regulation promulgated pursuant to KRS Chapter 13A:

(a) Prescribe the times and manner of obtaining a specimen and transferring a specimen for testing;

(b) Prescribe the manner of procedures, testing specimens, and recording and reporting the results of newborn screening tests; and

(c) Establish and collect fees to support the newborn screening program.

(2) The administrative officer or other person in charge of each ***health facility***~~[institution]~~ caring for infants twenty-eight (28) days or less of age and the person required in pursuance of the provisions of KRS 213.046 shall register the birth of a child and cause to have administered to every such infant or child in~~[ its or]~~ his***, her, or the facility's*** care tests for heritable disorders, including but not limited to phenylketonuria (PKU), sickle cell disease, congenital hypothyroidism, galactosemia, medium-chain acyl-CoA dehydrogenase deficiency (MCAD), very long-chain acyl-CoA deficiency (VLCAD), short-chain acyl-CoA dehydrogenase deficiency (SCAD), maple syrup urine disease (MSUD), congenital adrenal hyperplasia (CAH), biotinidase disorder, cystic fibrosis (CF), 3-methylcrotonyl-CoA carboxylase deficiency (3MCC), 3-OH 3-CH3 glutaric aciduria (HMG), argininosuccinic acidemia (ASA), beta-ketothiolase deficiency (BKT), carnitine uptake defect (CUD), citrullinemia (CIT), glutaric acidemia type I (GA I), Hb S/beta-thalassemia (Hb S/Th), Hb S/C disease (Hb S/C), homocystinuria (HCY), isovaleric acidemia (IVA), long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCAD), methylmalonic acidemia (Cbl A,B), methylmalonic acidemia mutase deficiency (MUT), multiple carboxylase deficiency (MCD), propionic acidemia (PA), trifunctional protein deficiency (TFP), tyrosinemia type I (TYR I), spinal muscular atrophy (SMA), and krabbe disease. The listing of tests for heritable

disorders to be performed shall include all conditions consistent with the recommendations of the American College of Medical Genetics.

(3) The administrative officer or other person in charge of each ***health facility***~~[institution]~~ caring for infants twenty-eight (28) days or less of age and the person required in pursuance of the provisions of KRS 213.046 shall register the birth of a child and cause to have administered to every such infant or child in~~[ its or]~~ his***, her, or the facility*** care a screening for critical congenital heart disease (CCHD) prior to discharge unless CCHD has been ruled out or diagnosed with prior echocardiogram or prenatal diagnosis of CCHD.

(4) Each health care provider of newborn care shall provide an infant's parent or guardian with information about the newborn screening tests required under subsections (2) and (3) of this section. The ***health facility***~~[institution]~~ or health care provider shall arrange for appropriate and timely follow-ups to the newborn screening tests, including but not limited to additional diagnoses, evaluation, and treatment when indicated.

(5) Nothing in this section shall be construed to require the testing of any child whose parents are members of a nationally recognized and established church or religious denomination, the teachings of which are opposed to medical tests, and who object in writing to the testing of his or her child on that ground.

(6) The cabinet shall make available the names and addresses of health care providers, including but not limited to physicians, nurses, and nutritionists, who may provide postpartum home visits to any family whose infant or child has tested positive for a newborn screening test.

(7) A parent or guardian shall be provided information by the ***health facility***~~[institution]~~ or health care provider of newborn care about the availability and costs of screening tests not specified in subsections (2) and (3) of this section. The parent or guardian shall be responsible for costs relating to additional screening

tests performed under this subsection, and these costs shall not be included in the fees established for the cabinet's newborn screening program under subsection (1) of this section. All positive results of additional screening of these tests shall be reported to the cabinet by the ***health facility***~~[institution]~~ or health care provider.

(8) (a) For the purposes of this subsection, a qualified laboratory means a clinical laboratory not operated by the cabinet that is accredited pursuant to 42 U.S.C. sec. 263a, licensed to perform newborn screening testing in any state, and reports its screening results using normal pediatric reference ranges.

(b) The cabinet shall enter into agreements with public or private qualified laboratories to perform newborn screening tests if the laboratory operated by the cabinet is unable to screen for a condition specified in subsection (2) of this section.

(c) The cabinet may enter into agreements with public or private qualified laboratories to perform testing for conditions not specified in subsection (2) of this section. Any agreement entered into under this paragraph shall not preclude ***a health facility***~~[an institution]~~ or health care provider from conducting newborn screening tests for conditions not specified in subsections (2) and (3) of this section by utilizing other public or private qualified laboratories.

(9) The secretary for health and family services or his or her designee shall apply for any federal funds or grants available through the Public Health Service Act and may solicit and accept private funds to expand, improve, or evaluate programs to provide screening, counseling, testing, or specialty services for newborns or children at risk for heritable disorders.

(10) ***As used in this section, "health facility" has the same meaning as in Section 2 of this Act.***

***(11)*** This section shall be cited as the James William Lazzaro and Madison Leigh Heflin

Newborn Screening Act.

➔Section 10. KRS 214.565 is amended to read as follows:

As used in KRS 214.565 to 214.571:

(1) "Department" means the Department for Public Health in the Cabinet for Health and Family Services;

(2) ***"Health care provider" means a licensed provider who has the care of pregnant women within his or her professional scope of practice; and***

***(3)*** "Health facility" has the same meaning as in KRS 216B.015~~[; and~~

~~(3) "Physician" means any person licensed to practice medicine under KRS Chapter 311~~].

➔Section 11. KRS 214.567 is amended to read as follows:

(1) The department shall make available to the public on its ***website***~~[Web site]~~ educational resources regarding the incidence of congenital cytomegalovirus, including information about:

(a) The transmission of congenital cytomegalovirus before and during pregnancy;

(b) Birth defects caused by congenital cytomegalovirus;

(c) Methods of diagnosing congenital cytomegalovirus;

(d) Available preventive measures; and

(e) Resources available to the family of an infant born with congenital cytomegalovirus.

(2) The department may solicit and accept the assistance of relevant medical associations or community resources to develop, promote, and distribute the public educational resources.

(3) A health facility or ***health care provider***~~[physician]~~ providing obstetric or prenatal services shall provide pregnant women or women who may become pregnant with the information listed in subsection (1) of this section or provide the patients with a link to the ***website***~~[Web site]~~ described in subsection (1) of this section.

➔Section 12. KRS 214.569 is amended to read as follows:

Every infant in this state who is given an auditory screening test described in KRS 216.2970, and fails the initial two (2) screenings or has other risk factors associated with congenital cytomegalovirus, shall be tested for congenital cytomegalovirus not later than twenty-one (21) days after the date of birth by the health facility or ***health care provider***~~[physician]~~ providing services to the infant, unless the parents or guardians of the infant opt out of testing.

➔Section 13. KRS 216.2920 is amended to read as follows:

As used in KRS 216.2920 to 216.2929, unless the context requires otherwise:

(1) "Ambulatory facility" means an outpatient facility, including an ambulatory surgical facility, ~~[freestanding birth center, ]~~freestanding or mobile technology unit, or an urgent treatment center, that is not part of a hospital and that provides one (1) or more ambulatory procedures to patients not requiring hospitalization;

(2) "Cabinet" means the Cabinet for Health and Family Services;

(3) "Charge" means all amounts billed by a hospital or ambulatory facility, including charges for all ancillary and support services or procedures, prior to any adjustment for bad debts, charity contractual allowances, administrative or courtesy discounts, or similar deductions from revenue. However, if necessary to achieve comparability of information between providers, charges for the professional services of hospital-based or ambulatory-facility-based physicians shall be excluded from the calculation of charge;

(4) "Facility" means any hospital, health care service, ***freestanding birthing center,*** or other health care facility, whether operated for profit or not;

(5) "***Health care***~~[Health care]~~ provider" or "provider" means any pharmacist as defined pursuant to KRS Chapter 315, and any of the following independent practicing practitioners:

(a) Physicians, osteopaths, and podiatrists licensed pursuant to KRS Chapter 311;

(b) Chiropractors licensed pursuant to KRS Chapter 312;

(c) Dentists licensed pursuant to KRS Chapter 313;

(d) Optometrists licensed pursuant to KRS Chapter 320;

(e) Physician assistants regulated pursuant to KRS Chapter 311;

(f) Nurse practitioners licensed pursuant to KRS Chapter 314; and

(g) Other health-care practitioners as determined by the Cabinet for Health and Family Services by administrative regulation promulgated pursuant to KRS Chapter 13A;

(6) "Hospital" means a facility licensed pursuant to KRS Chapter 216B as either an acute-care hospital, psychiatric hospital, rehabilitation hospital, or chemical dependency treatment facility;

(7) "Procedures" means those surgical, medical, radiological, diagnostic, or therapeutic procedures performed by a provider, as periodically determined by the cabinet in administrative regulations promulgated pursuant to KRS Chapter 13A as those for which reports to the cabinet shall be required. "Procedures" also includes procedures that are provided in hospitals or other ambulatory facilities, or those that require the use of special equipment, including fluoroscopic equipment, computer tomographic scanners, magnetic resonance imagers, mammography, ultrasound equipment, or any other new technology as periodically determined by the cabinet;

(8) "Quality" means the extent to which a provider renders care that obtains for patients optimal health outcomes; and

(9) "Secretary" means the secretary of the Cabinet for Health and Family Services.

➔Section 14. KRS 216.2970 is amended to read as follows:

(1) As a condition of licensure or relicensure, all ***health facilities***~~[hospitals]~~ offering obstetric ***or midwifery*** services ~~[and alternative birthing centers with at least forty (40) births per year ]~~shall provide an auditory screening for all infants using one (1) of the methods approved by the Office for Children with Special Health Care Needs

by administrative regulation promulgated in accordance with KRS Chapter 13A.

(2) An auditory screening report that indicates a finding of potential hearing loss shall be forwarded by the ***health facility***~~[hospital or alternative birthing center]~~ within twenty-four (24) hours of receipt to the:

(a) Attending physician or health care provider;

(b) Parents;

(c) Office for Children with Special Health Care Needs for evaluation or referral for further evaluation in accordance with KRS 211.647; and

(d) Audiological assessment and diagnostic center approved by the office if a follow-up assessment has been scheduled prior to the infant's discharge from the hospital.

(3) An auditory screening report that does not indicate a potential hearing loss shall be forwarded within one (1) week to the Office for Children with Special Health Care Needs with no information that personally identifies the child.

➔Section 15. KRS 216.2921 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall collect, pursuant to KRS 216.2925, analyze, and disseminate information in a timely manner on the cost, quality, and outcomes of health services provided by health facilities and ***health care***~~[health care]~~ providers in the Commonwealth. The cabinet shall make every effort to make health data findings that can serve as a basis to educate consumers and providers for the purpose of improving patient morbidity and mortality outcomes available to the public, and state and local leaders in health policy, through the cost-effective and timely use of the media and the internet and through distribution of the findings to health facilities and ***health care***~~[health care]~~ providers for further dissemination to their patients.

(2) The secretary of the Cabinet for Health and Family Services shall serve as chief administrative officer for the health data collection functions of KRS 216.2920 to

216.2929.

(3) Neither the secretary nor any employee of the cabinet shall be subject to any personal liability for any loss sustained or damage suffered on account of any action or inaction of under KRS 216.2920 to 216.2929.

➔Section 16. KRS 216.2923 is amended to read as follows:

(1) For the purposes of carrying out the provisions of KRS 216.2920 to 216.2929, the secretary may:

(a) Appoint temporary volunteer advisory committees, which may include individuals and representatives of interested public or private entities or organizations;

(b) Apply for and accept any funds, property, or services from any person or government agency;

(c) Make agreements with a grantor of funds or services, including an agreement to make any study allowed or required under KRS 216.2920 to 216.2929; and

(d) Contract with a qualified, independent third party for any service necessary to carry out the provisions of KRS 216.2920 to 216.2929; however, unless permission is granted specifically by the secretary a third party hired by the secretary shall not release, publish, or otherwise use any information to which the third party has access under its contract.

(2) For the purposes of carrying out the provisions of KRS 216.2920 to 216.2929, the secretary shall:

(a) Periodically participate in or conduct analyses and studies that relate to:

1. Health-care costs;

2. Health-care quality and outcomes;

3. ***Health care***~~[Health-care]~~ providers and health services; and

4. Health insurance costs;

(b) Promulgate administrative regulations pursuant to KRS Chapter 13A that

relate to its meetings, minutes, and transactions related to KRS 216.2920 to 216.2929; and

(c) Prepare annually a budget proposal that includes the estimated income and proposed expenditures for the administration and operation of KRS 216.2920 to 216.2929.

(3) The cabinet may promulgate administrative regulations pursuant to KRS Chapter 13A that impose civil fines not to exceed five hundred dollars ($500) for each violation for knowingly failing to file a report as required under KRS 216.2920 to 216.2929. The amount of any fine imposed shall not be included in the allowed costs of a facility for Medicare or Medicaid reimbursement.

➔Section 17. KRS 216.2925 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall establish by promulgation of administrative regulations pursuant to KRS Chapter 13A those data elements required to be submitted to the cabinet by all hospitals and ambulatory facilities, including a timetable for submission and acceptable data forms. Each hospital and ambulatory facility shall be required to report on a quarterly basis information regarding the charge for and quality of the procedures and health-care services performed therein, and as stipulated by administrative regulations promulgated pursuant to KRS Chapter 13A. The cabinet shall accept data that, at the option of the provider, is submitted through a third party, including but not limited to organizations involved in the processing of claims for payment, so long as the data elements conform to the requirements established by the cabinet. The cabinet may conduct statistical surveys of a sample of hospitals, ambulatory facilities, or other providers in lieu of requiring the submission of information by all hospitals, ambulatory facilities, or providers. On at least a biennial basis, the cabinet shall conduct a statistical survey that addresses the status of women's health, specifically including data on patient age, ethnicity, geographic region, and payor sources. The

cabinet shall rely on data from readily available reports and statistics whenever possible.

(2) The cabinet shall require for submission to the cabinet by any group of providers, except for physicians providing services or dispensaries, first aid stations, or clinics located within business or industrial establishments maintained solely for the use of their employees, including those categories within the definition of provider contained in KRS 216.2920 and any further categories determined by the cabinet, at the beginning of each fiscal year after January 1, 1995, and within the limits of the state, federal, and other funds made available to the cabinet for that year, and as provided by cabinet promulgation of administrative regulations pursuant to KRS Chapter 13A, the following:

(a) A list of medical conditions, health services, and procedures for which data on charge, quality, and outcome shall be collected and published;

(b) A timetable for filing information provided for under paragraph (a) of this subsection on a quarterly basis;

(c) A list of data elements that are necessary to enable the cabinet to analyze and disseminate risk-adjusted charge, quality, and outcome information, including mortality and morbidity data;

(d) An acceptable format for data submission that shall include use of the uniform:

1. Health claim form pursuant to KRS 304.14-135 or any other universal health claim form to be determined by the cabinet if in the form of hard copy; or

2. Electronic submission formats as required under the federal Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. sec. 300gg et seq., in the form of magnetic computer tape, computer diskettes, or other electronic media through an electronic network;

(e) Procedures to allow ***health care***~~[health care]~~ providers at least thirty (30) days to review information generated from any data required to be submitted by them, with any reports generated by the cabinet to reflect valid corrections by the provider before the information is released to the public; and

(f) Procedures pertaining to the confidentiality of data collected.

(3) The cabinet shall coordinate but not duplicate its data-gathering activities with other data-collection activities conducted by the Department of Insurance, as well as other state and national agencies that collect health-related service, utilization, quality, outcome, financial, and health-care personnel data, and shall review all administrative regulations promulgated pursuant to KRS 216.2920 to 216.2929 to prevent duplicate filing requirements. The cabinet shall periodically review the use of all data collected under KRS 216.2920 to 216.2929 to assure its use is consistent with legislative intent.

(4) The cabinet shall conduct outcome analyses and effectiveness studies and prepare other reports pertaining to issues involving health-care charges and quality.

(5) The cabinet may independently audit any data required to be submitted by providers as needed to corroborate the accuracy of the submitted data. Any audit may be at the expense of the cabinet and shall, to the extent practicable, be coordinated with other audits performed by state agencies.

(6) The cabinet may initiate activities set forth in subsection (1) or (2) of this section at any time after July 15, 1996.

(7) The Cabinet for Health and Family Services shall collect all data elements under this section using only the uniform health insurance claim form pursuant to KRS 304.14-135, the Professional 837 (ASC X12N 837) format, the Institutional 837 (ASC X12N 837) format, or its successor as adopted by the Centers for Medicare and Medicaid Services.

➔Section 18. KRS 216.2927 is amended to read as follows:

(1) The following types of data shall be deemed as relating to personal privacy and, except by court order, shall not be published or otherwise released by the cabinet or its staff and shall not be subject to inspection under KRS 61.870 to 61.884:

(a) Any data, summary of data, correspondence, or notes that identify or could be used to identify any individual patient or member of the general public, unless the identified individual gives written permission to release the data or correspondence;

(b) Any correspondence or related notes from or to any employee or employees of a provider if the correspondence or notes identify or could be used to identify any individual employee of a provider, unless the corresponding persons grant permission to release the correspondence; and

(c) Data considered by the cabinet to be incomplete, preliminary, substantially in error, or not representative, the release of which could produce misleading information.

(2) ***Health care***~~[Health-care]~~ providers submitting required data to the cabinet shall not be required to obtain individual permission to release the data, except as specified in subsection (1) of this section, and, if submission of the data to the cabinet complies with pertinent administrative regulations promulgated pursuant to KRS Chapter 13A, shall not be deemed as having violated any statute or administrative regulation protecting individual privacy.

(3) (a) No less than sixty (60) days after the annual report or reports are published and except as otherwise provided, the cabinet shall make all aggregate data which does not allow disclosure of the identity of any individual patient, and which was obtained for the annual period covered by the reports, available to the public.

(b) Persons or organizations requesting use of the data shall agree to abide by a public-use data agreement and by HIPAA privacy rules referenced in 45

C.F.R. Part 164. The public-use data agreement shall include, at a minimum, a prohibition against the sale or further release of data, and guidelines for the use and analysis of the data released to the public related to provider quality, outcomes, or charges.

(4) Collection of data about individual patients shall include information commonly used to identify an individual for assigning a unique patient identifier. Upon assigning a unique patient identifier, all direct identifying information shall be stripped from the data and shall not be retained by the cabinet or the cabinet's designee.

(5) All data and information collected shall be kept in a secure location and under lock and key when specifically responsible personnel are absent.

(6) Only designated cabinet staff shall have access to raw data and information. The designated staff shall be made aware of their responsibilities to maintain confidentiality. Staff with access to raw data and information shall sign a statement indicating that the staff person accepts responsibility to hold that data or identifying information in confidence and is aware of penalties under state or federal law for breach of confidentiality. Data which, because of small sample size, breaches the confidence of individual patients, shall not be released.

(7) Any employee of the cabinet who violates any provision of this section shall be fined not more than five hundred dollars ($500) for each violation or be confined in the county jail for not more than six (6) months, or both, and shall be removed and disqualified from office or employment.

➔Section 19. The Cabinet for Health and Family Services shall promulgate updated administrative regulations in accordance with KRS Chapter 13A to implement the requirements of Section 1 of this Act by December 1, 2025.

➔Section 20. This Act may be cited as the Mary Carol Akers Birth Centers Act.