July 3, 2018

Emily Caudill, Regulations Compiler  
Legislative Research Commission  
029, Capitol Annex  
702 Capitol Avenue  
Frankfort, Kentucky 40601

Dear Regulations Compiler:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 20:016, the Cabinet for Health and Family Services, Office of Inspector General proposes the attached agency amendment to 902 KAR 20:016.

Sincerely,

Brandon James Smith  
Executive Director  
Office of Legislative and Regulatory Affairs

Attachments  
BJS/sbb
Agency Amendment

Cabinet for Health and Family Services
Office of Inspector General
Division of Health Care

902 KAR 20:016. Hospitals; operations and services.

Page 1
RELATES TO
Line 12
After “412.22(c),” insert the following:
412.92, 413.65, 482.12(c), 489.25.

Line 13
After “45 C.F.R.”, insert “Part”.
After “160,” insert “Part”.
After “1320d-8,” insert “1395u(b)(18)(C),”.
After “1395x(r)(2)-(5),” insert “1395dd”.

Lines 13-14
After “1395x(r)(2)-(5),” delete “, 1395u(b)(18)(C),”.

Page 21
Section 3(10)(h)
Line 14
After “40 C.F.R.”, insert “Part”.

Page 57
Section 4(12)(j)
Line 2
Before “(j),” insert “(f).”
Delete “(j),”.

Page 59
Section 6(2)
Line 15
After “services],” insert the following:
Section 7. Off-campus, Kentucky Hospital-Owned Freestanding Emergency Department (FSED).
(1) A hospital licensed pursuant to this administrative regulation may provide off-campus emergency services in a hospital-owned FSED. For purposes of this section, “off-campus” shall mean a location:
(a) Off the campus of the parent hospital that owns the FSED; and
(b) At least thirty-five (35) miles from an existing hospital that is:
1. Licensed pursuant to this administrative regulation; and
2. Designated as a sole community hospital pursuant to 42 C.F.R. 412.92.
(2) If a Kentucky-licensed hospital owns and operates an ambulatory care clinic licensed under 902 KAR 20:073 prior to July 15, 2018, or holds a certificate of need for an ambulatory care clinic that is not licensed by that date, the hospital shall notify the cabinet no later than ninety (90) days from the effective date of this administrative regulation of the clinic’s scope of operations. The hospital’s notification shall inform the cabinet whether the clinic will:

(a) Operate as an FSED, in which case the facility shall:
1. Be designated as provider-based pursuant to 42 C.F.R. 413.65;
4. Not be required to obtain a new certificate of need; and
(b) Provide services that are limited to treatment for minor injury or illness, in which case the clinic shall hold itself out to the public as an emergency treatment center or use similar terminology that expresses or implies that emergency medical service is offered at the clinic. This paragraph shall not prohibit the clinic from holding itself out to the public as an urgent treatment center.

(3) A Kentucky-licensed hospital that seeks to establish an FSED under circumstances not covered under subsection (2)(a) of this section shall obtain a certificate of need.

(4) An FSED shall:
(a) Be owned by an accredited Kentucky hospital licensed under this administrative regulation;
(b) Be included under the same license and accreditation as the parent hospital;
(c) Meet the requirements of and be certified by the Centers for Medicare and Medicaid Services as a provider-based entity under 42 C.F.R. 413.65;
(d) Pay a fee in the amount of $1,000 for the FSED location at the time of annual renewal of the hospital’s license;
(e) Operate twenty-four (24) hours per day, seven (7) days per week;
(f) Comply with the provisions of Section 4(8) of this administrative regulation governing emergency services;
(g) Be under the direction of a licensed physician who is a member of the parent hospital’s organized medical staff;
(h) Ensure that nursing personnel are assigned to or designated to cover the emergency service at all times;
(i) Comply with the Emergency Medical Treatment and Labor Act (42 U.S.C. 1395dd) and 42 C.F.R. 489.24;
(j) Have facilities sufficient to assure prompt diagnosis, treatment, and stabilization of injuries and trauma;
(k) Have a written patient transportation agreement with a local emergency medical services (EMS) provider; and
(l) Maintain compliance with applicable federal, state, and local laws.

(5) An FSED shall cease to operate under this administrative regulation if the:
(a) Cabinet finds that there has been substantial failure by the facility to comply with the provisions of KRS Chapter 216B or this administrative regulation; and
(b) Facility fails to submit and implement an acceptable plan of correction or amended plan of correction in accordance with 902 KAR 20:008, Section 2(13).

(6) If an FSED receives notice to cease operations in accordance with subsection (5) of this section, the parent hospital may file a request in writing for a hearing pursuant to KRS 216B.105.