

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 4, 2015

() ACTION/DECISION

(X) INFORMATION

I. TITLE: Administrative Orders and Consent Orders issued by Health Regulation.

II. SUBJECT: Administrative Orders and Consent Orders issued by Health Regulation for the period of August 1, 2015, through September 30, 2015.

III. FACTS: For the period of August 1, 2015, through September 30, 2015, Health Regulation issued one (1) Administrative Order and two (2) Consent Orders with a total of fourteen thousand, four hundred and seventy-nine dollars (\$14,479.00) in assessed monetary penalties.

Program Area	Health Care Facility or Provider	Administrative Orders	Consent Orders	Assessed Penalties
Bureau of Radiological Health	X-Ray Facility	0	1	\$1,729
Bureau of Health Facilities Licensing	Ambulatory Surgical Facility	0	1	\$10,000
	Abortion Clinic	1	0	\$2,750
TOTAL		1	2	\$14,479.00

Approved By:

Shelly Bezanson Kelly
Director of Health Regulation

HEALTH REGULATION ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 4, 2015

Bureau of Radiological Health

1. Lifeworks Chiropractic (Chiropractic X-Ray Facility) – Charleston, South Carolina

Investigation: DHEC conducted general inspections of Lifeworks (“the Registrant”) on December 17, 2008, April 8, 2012, and April 15, 2015 and as a result of these inspections, DHEC found multiple violations of Regulation 61-64, *X-Rays (Title B)*.

Violations: The Registrant had repeated violations of R.61-64, Sections 4.2.16.1 and 4.2.16.1.3.2 for failing to complete Equipment Performance Testing on each x-ray unit on an annual basis. The Registrant also had repeated violations of R.61-64, Section 4.2.8 for failing to ensure the lead aprons (x-ray protective apparel) were tested for adequacy on an annual basis and that this assessment of the effectiveness of the x-ray protective apparel was documented. In addition, the Registrant had stored the lead apron in a folded position, and folding a lead apron can compromise the effectiveness of the lead and the protection that it provides.

Enforcement Action: On June 17, 2015, DHEC and Lifeworks participated in an enforcement conference where the parties reached an agreement on how to resolve this matter. On August 20, 2015, the parties executed the Consent Order, which requires the Registrant to pay an assessed monetary penalty in the amount of \$1,729. As a term of the Consent Order, Lifeworks paid \$430 of the assessed penalty within the first 30 days of executing the Consent Order. The remainder of the assessed penalty is stayed upon a 24-month period of substantial compliance with Regulation 61-64.

Prior Sanctions: None.

X-Ray Facilities in South Carolina	TOTAL
Registered X-Ray Facilities in South Carolina	3,869
Registered Chiropractic X-Ray Facilities in South Carolina	493
Registered X-Ray Tubes in South Carolina	11,922

Bureau of Health Facilities Licensing

2. Carolina Colonoscopy Center (Ambulatory Surgical Facility) – Columbia, South Carolina

Investigation: DHEC conducted a general inspection and a complaint investigation of South Carolina Medical Endoscopy Center d/b/a Carolina Colonoscopy Center (“CCC”) on April 10, 2015, and a follow-up inspection on May 5, 2015. As a result of these visits, DHEC determined CCC was in violation of Regulation 61-91, *Standards for Licensing Ambulatory Surgical Facilities*.

Violations: CCC had violations and repeated violations of Regulation 61-91 related to sanitation and infection control, staffing and supervision, and documentation. CCC staff failed to follow facility policies and procedures for cleaning endoscopy equipment post-procedure. CCC failed to clean and disinfect equipment in accordance with the manufacturer’s instructions. CCC failed to designate staff to serve in absence of the administrator. CCC failed to have a registered nurse on duty or enough licensed nurses on duty. CCC failed to have documentation of staff training on in-service training requirements. CCC failed to ensure staff in contact with patients had a health assessment within 12 months of contact. CCC failed to document physician orders for colonoscopies performed on four patients. CCC failed to have nursing staff supervise seven patients post-operation and/or -procedure. CCC failed to issue written discharge instructions to four patients. CCC failed to have the drugs in its emergency kit correspond with the contents listed on the kit’s inventory list. CCC failed to document staff vaccinations. Finally, CCC failed to ensure staff received a two-step TB skin test in accordance with Regulation 61-91.

Enforcement Action: The parties met on July 9, 2015, and agreed to settle this matter by consent order. The parties then executed the Consent Order on September 3, 2015, with an assessed monetary penalty of \$10,000, which CCC has paid.

Prior Sanctions: None.

Ambulatory Surgical Facilities (“ASF”) in South Carolina	TOTAL
Licensed ASF in South Carolina	75
Operating Rooms, Endoscopy Rooms, and Procedure Rooms in Licensed ASF	285
Endoscopy Rooms in Licensed ASF	75
Endoscopy Rooms in Carolina Colonoscopy Center (“CCC”)	2

Bureau of Health Facilities Licensing (cont'd.)

3. Greenville Women’s Clinic (Abortion Clinic) – Greenville, South Carolina

Investigation: DHEC conducted a general inspection and a complaint investigation of Greenville Women’s Clinic (“GWC” or “the Facility”) on September 2, 2015. As a result, DHEC determined GWC was in violation of Regulation 61-12, *Standards for Licensing Abortion Clinics*.

Violations: GWC violated the Woman’s Right to Know Act (WRKA) because records showed that an abortion was performed sooner than 60 minutes following completion of the ultrasound. GWC failed to have the drugs in its emergency kit correspond with the contents listed on the kit’s inventory list. GWC failed to manage the products of conception resulting from abortion procedures in accordance with the requirements for pathological waste pursuant to Regulation 61-105, *South Carolina Infectious Waste Management*. Of the 12 minors whose records were reviewed, GWC failed to include the name of the minor’s father on eight of the records. GWC failed to document an abortion procedure was reported to DHEC’s Office of Vital Records. Finally, GWC failed to ensure infectious waste was managed in accordance with Regulation 61-105.

Enforcement Action: On September 11, 2015, DHEC executed the Administrative Order against Greenville Women’s Clinic. DHEC suspended the license of Greenville Women’s Clinic and imposed a \$2,750 monetary penalty, which the Facility has paid in full. DHEC stipulated in the Administrative Order that it would lift the Facility’s suspension upon the following conditions being met: (1) GWC’s payment of the imposed monetary penalty; (2) GWC’s timely submission of a plan of correction addressing corrective actions taken, preventative actions taken, and the date of those actions taken in regard to violations contained in DHEC’s reports of visit on September 2, 2015; and (3) GWC’s evidence of training all employees and volunteers in the Facility’s policies and procedures, the WRKA requirements, and all in-service training requirements. GWC satisfied all of the conditions set forth in the Administrative Order in a timely manner, and therefore, DHEC lifted the Facility’s suspension.

Prior Sanctions: None.

Abortion Clinics in South Carolina	TOTAL
Licensed Abortion Clinics in South Carolina	3