

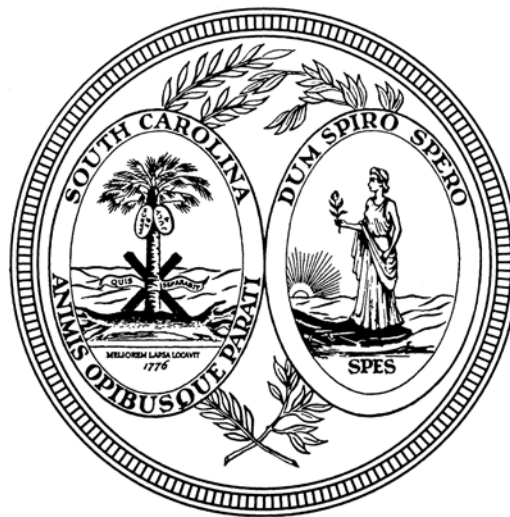


SOUTH CAROLINA GENERAL ASSEMBLY

Legislative Audit Council

May 2015

A REVIEW OF THE S.C. DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL'S REGULATION OF ABORTION CLINICS



LEGISLATIVE AUDIT COUNCIL

1331 Elmwood Ave., Suite 315
Columbia, SC 29201
(803) 253-7612 VOICE
(803) 253-7639 FAX

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Introduction and Background

Audit Objectives

Members of the General Assembly requested that we conduct an audit to determine if the S.C. Department of Health and Environmental Control (DHEC) properly regulates abortion clinics, as required by state law and regulation. Our audit objectives are listed below.

- Determine how DHEC regulates abortion clinics to ensure that the facilities are in compliance with state law and regulation.
- Identify improvements which can be implemented in policy, regulation, or state law regarding the regulation of abortion clinics.

Scope and Methodology

We reviewed the operations of the S.C. Department of Health and Environmental Control, only as they pertain to the regulation of abortion clinics. The period of our review was generally 2011 through 2014, with consideration of earlier and more recent periods when relevant. To conduct this audit, we used a variety of sources of evidence, including the following:

- State laws, regulations, and agency policies.
- Interviews of DHEC employees, employees of other state agencies, and private individuals.
- DHEC inspection forms, staff training records, vital statistic records, incident/accident data, and complaint investigations.
- Information from DHEC's website, in addition to websites of agencies in other states which regulate abortion clinics.
- Documentation from agencies in other states that regulate abortion clinics.

Criteria used to measure performance included state laws, agency policies, and best practices of other states. We used samples, which are described in the audit report. We reviewed internal controls in several areas, including DHEC's systems for managing inspection data, abortion data, and complaint data. Our findings are detailed in the report.

We interviewed staff regarding the various information systems used by DHEC. We determined how the data was maintained and what the various levels of control were. The use of computerized data was not central to our audit objectives. We also accompanied a DHEC inspector during an annual licensing renewal inspection of one of the state's three abortion clinics.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those generally accepted government auditing standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

In South Carolina, abortion is legal during the first trimester, with the consent of the pregnant woman and during the second trimester with the woman's consent in a certified clinic or hospital. South Carolina law makes a legal presumption that viability, the stage of development when the fetus is potentially able to live outside the womb, occurs no sooner than 24 weeks. Therefore, abortion is legal in the third trimester only if performed in a hospital and only if the abortion is necessary to preserve the life or health of the woman.

Although hospitals are certified by DHEC to perform abortions in South Carolina, 99% of all abortions are performed in one of three clinics throughout the state. DHEC regulates these clinics through a licensing process that involves annual, onsite inspections aimed at monitoring compliance with state law and regulation.

We reviewed South Carolina laws and regulation to determine the specific requirements for abortion clinics, the specific actions DHEC is required to take in regulating abortion clinics, and what the clinics are required to do in order to be compliant with state law. DHEC Regulation 61-12 covers the construction, renovation, operation, and maintenance of abortion clinics, as well as the procedures for caring for patients and reporting requirements.

S.C. Regulation 61-12 defines an abortion clinic as any facility, other than a hospital, which is licensed by DHEC to perform abortions and which performs any second trimester abortions or at least five first trimester abortions per month. DHEC's Bureau of Health Facilities Licensing is responsible for licensing and inspecting abortion facilities, along with responding to complaints and investigating incidents. DHEC's Division of Fire and Life Safety and its Bureau of Drug Control might also be involved during the construction of new facilities and investigating alleged violations of drug laws and regulations, respectively.

DHEC's Responsibilities

DHEC is legally responsible for:

- Promulgating and enforcing regulations for licensing and certifying abortion clinics and certifying hospitals as suitable facilities for performing abortions.
- Enforcing regulations governing sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reports, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, and information on and access to follow-up care.

Abortion Clinics' Responsibilities

Abortion clinics are legally responsible for:

- Providing patients with information mandated under state law (e.g., the probable gestational age of the fetus, the right to view an ultrasound, and her right to view materials describing fetal development).
- Receiving signed confirmation from the patient that she has received this mandated information or been afforded an opportunity to review it.
- Receiving all required signatures consenting to the procedure.
- Informing the woman of the gestational age of the fetus and confirming the age before performing an abortion.
- Confirming that at least 24 hours have passed between the time the woman accesses information pursuant to the Woman's Right to Know Act and the abortion procedure.
- Informing the woman of her right to view an ultrasound, if one is performed.
- Reporting the procedure within seven days to DHEC.

Access to Information and Waiting Periods

State law requires that patients be provided with certain information and that they indicate with their signatures that they have been informed. DHEC must provide information on its website on the risks associated with abortion procedures and carrying a pregnancy to term; information on services that pregnant women may access before, during, and after pregnancy; information on child development; and information on calculating gestational age. After accessing this information from DHEC's website, which must be programmed to provide a date and time stamp on the information when accessed, the patient must wait 24 hours before the abortion procedure may be performed. The facility must retain, for three years, the patient's written verification that the information was provided or offered.

If an ultrasound is performed, the patient must wait 60 minutes before the procedure. Also, the physician must inform the woman that she has the opportunity to review it, but she is not required to review it.

The woman must sign and date a form, presented by her physician, that contains a statement informing her of her right to review a list of printed materials prepared by the state describing fetal development, a list of agencies offering alternatives to abortion, and medical assistance benefits which may be available for prenatal, childbirth, and postnatal care.

Materials must be available from DHEC upon request and “in appropriate number” to any person, facility, or hospital and must be available for printing from DHEC’s website. The website must permit the user to print the date and time it was downloaded and must have links to websites of providers who offer free ultrasounds and who have requested to have their links posted to DHEC’s website.

Consent Requirements

State law requires that:

- A woman give her consent before any abortion procedure.
- If married and living with her husband, the consent of her husband is also required for third trimester abortions.
- If married and mentally incompetent, consent must be obtained from her husband or legal guardian.
- If unmarried and mentally incompetent, consent be obtained from at least one parent or legal guardian.
- If less than 17 years of age and not emancipated, consent be secured from the pregnant minor and at least one parent, legal guardian, grandparent, or a person acting in loco parentis for at least sixty days.
- If less than 17 years of age, not emancipated, and unable to get the consent of a parent, grandparent, legal guardian, or someone acting in loco parentis for at least 60 days, consent must come from the minor and an order of the court affirming her right to an abortion.
- If the minor is emancipated, the minor must give her consent.

No consent is required if the physician determines that a medical emergency exists, including the life or grave physical injury to the pregnant woman or if the pregnancy is the result of incest.

Reporting Requirements

All abortions must be reported to DHEC within seven days. The names of the physician and the patient are prohibited from being reported, but the form used must indicate from whom consent was obtained or any circumstances for which consent was not required.

Chapter 1
Introduction and Background

Audit Results

Abortion Clinic Inspections

The S.C. Department of Health and Environmental Control (DHEC) has not consistently inspected abortion clinics annually, as required by state law. In addition, we found shortcomings that could, if not addressed, result in serious problems for patients.

- Of the 42 annual inspections which should have been conducted for the three abortion clinics currently licensed to operate from 2001–2014, DHEC could only provide 33 inspection reports.
- Inspectors are allowed to rely on a review of as few as three patient files during an annual inspection in order to determine compliance with state law.
- In reviewing inspection reports from 2011–2014, we found “start” and “completion” times indicating the lengths of the inspections that were questionable.
- DHEC does not approve each facility’s statement of patient rights.
- DHEC inspectors do not confirm with DHEC Public Health Statistics and Information Services that all abortions are reported.
- Facilities are providing corrective action plans for violations found during inspections, but DHEC does not validate the implementation of those plans until the next annual inspection.

Inconsistent Annual Inspections

DHEC could only provide 33 of the 42 annual inspection reports for these abortion clinics from 2001–2014. We were unable to document that the inspections were done for those facilities for which reports were unavailable. Two of the missing reports are recent, one from 2012 and one from 2013. Attempts to access them using DHEC’s website also yielded no results.

We reviewed the inspection process and DHEC’s enforcement of Regulation 61-12. We examined available inspection reports from 2001–2014. There are three licensed abortion clinics in South Carolina — one in the Upstate, one in the Midlands, and one in the Lowcountry.

The total number of inspection reports we collected for this period for these three facilities was 33. Nine inspection reports were missing or inaccessible. Since 2011, DHEC inspectors have entered inspection data into an information system (STETON) from which officials are able to generate computerized reports detailing which inspection items were reviewed and whether the facility was in or out of compliance. Available inspection reports prior to that period were not computerized.

Number of Patient Files Reviewed

According to a DHEC official, during annual inspections, a minimum of three patient files are to be reviewed for each abortion clinic. If the facility has records of minors, at least one of the files should be that of a minor. The number of patient files reviewed is not always noted in the report. In one case where we were able to determine the number of files reviewed from all patient files that year, the inspector reviewed 6 patient files from a population of 1,887. However, the six files represent only 0.32% of the files for an entire year.

Patient files are not always organized by clinic administrators in a way that allows the inspector to select, in a timely manner, a sample representing a cross-section of patients of varying ages and gestation periods. Only if the inspector specifically writes notes referencing the number of patient files reviewed would that information be available.

The total number of abortions performed for each facility since 2009 is reported in Table 2.1. Inspectors use paper checklists to record their observations during an inspection, including observations from the patient record reviews. However, once the inspector enters the inspection data into DHEC's information system, the paper checklists are destroyed. They are not retained for subsequent retrieval or review. Reviewing a larger number of patient files that is more representative of the total population will provide greater assurance that clinics are conforming to state law.

**Table 2.1: Number of Abortions,
2009 – 2014**

YEAR	LOWCOUNTRY	UPSTATE	MIDLANDS	OTHER*	TOTAL
2009	2,516	2,191	2,161	43	6,911
2010	2,367	2,066	1,969	62	6,464
2011	2,243	2,108	1,971	57	6,379
2012	2,122	2,039	1,863	60	6,084
2013	1,928	2,064	1,805	81	5,878
2014	1,887	2,108	1,645	68	5,708

* Refers to hospitals and physicians' offices; however, during this period, none were reported from physicians' offices.

Source: DHEC Public Health Statistics and Information Services, March 2015

In only 2 of 33 inspection reports (2014 inspection of the Lowcountry clinic and 2003 inspection of the Midlands clinic) was it possible to determine from the comments in the reports the number of patient files examined. In the remaining inspections, there is no indication of the number of patient files reviewed, if any, or whether the patients were minors.

Section 44-41-31(A) of the S.C. Code of Laws requires that, in the case of a pregnant minor, the physician secures the informed consent of the pregnant minor and one parent of the minor, or a legal guardian of the minor, or a grandparent of the minor, or any person standing in loco parentis for a period of not less than 60 days. If the minor is emancipated, only the consent of the emancipated minor is required. Under other circumstances, the physician must have the informed consent of the pregnant minor and a court order.

Determining whether a facility is in compliance with these and other provisions requires that the inspector review all patient files or a statistically-representative sample.

There is no requirement that clinic staff organize each year's files with a single list of every patient record to include an identifier, patient date of birth, and gestation length. Doing so would allow the inspector to retrieve, much more quickly, a larger and more representative sample of the entire population of patients for the year under review in order to determine compliance with state law.

We found that Alabama, Georgia, Mississippi, and North Carolina typically send two inspectors to conduct inspections. Alternatively, allotting additional time coupled with reallocating staff and other strategies determined by DHEC could result in more time to review a larger sample of patient files and conduct a more thorough inspection and extensive reviews of other documentation.

Incomplete Inspections

Inspection reports from 2011–2014 record the time of day when an inspection was started and when it was completed. In reviewing inspection reports from 2011–2014, we found “start” and “completion” times that were questionable. We were able to review 10 inspection reports from 2011–2014. Eight of these 10 inspection reports had “start” and “completion” times that were distinct. In one of the other two, the “start” and “completion” times were recorded as the same time; in the other, they differed by one minute. In five of the remaining eight inspection reports, the time allotted to the inspection was less than four hours; and in each of those, we found examples of inspection items that were not observed.

We found inspection reports from 2011–2014 where inspection items appear in reports as “not observed,” with no explanation as to the significance of that code other than to conclude that the inspection items were, in fact, not observed by the inspector.

The following are other examples of incomplete inspections and the amount of time reported as having been spent conducting the inspection:

2013 UPSTATE CLINIC [3 HRS 40 MIN]

No violations were found, and the inspection documents show that significant items were reportedly not observed at all, including anything regarding the quality improvement plan.

2012 MIDLANDS CLINIC [3 HRS 13 MIN]

Although the report indicates that three violations were found, certain inspection items were reportedly not observed, including a review of the quality improvement plan.

2012 LOWCOUNTRY CLINIC [2 HRS]

No violations were found and certain inspection items were reportedly not observed, including indicators dealing with the quality improvement program.

2011 LOWCOUNTRY CLINIC [3 HRS 15 MIN]

No violations were found, and certain inspection items were reportedly not observed, including indicators dealing with the quality improvement program.

2011 UPSTATE CLINIC [2 HRS 21 MIN]

Inspection report indicates that most of the inspection items were not observed. Inspector appears to have reviewed staff files and found no violations. However, other administrative items, patient records, and walk-through items were not observed, including any indicators dealing with the quality improvement plan.

Patient Rights

DHEC does not approve each facility's statement of patient rights, which is to include information about filing complaints. Section 209 of S.C. Regulation 61-12 states that these rights must be approved by the licensee. Each facility must display a copy of the patient rights in a conspicuous place, and a copy signed by the patient is to be included in the patient's medical record. Failure to post a patient's statement of rights is a violation, and in one case, an inspector noted that the information on the statement was incorrect. The facility was cited with a violation.

There is, however, no single statement of patient rights that all facilities must use. Having a consistent template would ensure that the information is complete and accurate. While regulation mandates that all patients must sign a copy to be included in their patient files, regulation is silent about requiring clinics to include a copy in each patient's discharge packet so that the patient may have access to this information.

Legal Requirements for Reporting Abortions to DHEC Vital Records

DHEC inspectors do not confirm with Public Health Statistics and Information Services that all abortions are reported as required by §44-41-60 of the S.C. Code of Laws and Regulation 61-12. Regulation 61-12 requires that all abortions, including, but not limited to those performed in abortion clinics, be reported by the performing physician on the standard form for reporting abortions to Public Health Statistics and Information Services, within seven days of the procedure. State law prohibits patient names and physician names from being reported, but the form must indicate from whom consent was obtained, if legally required, or the circumstances for waiving consent. During a routine, annual inspection, the inspector is required to review documentation that the clinic administrator has satisfied the reporting requirements. All three abortion clinics make their reports online.

We compared a report obtained from one abortion clinic containing the total number of abortions from 2009-2013 to a report obtained from DHEC which included annual totals for abortions for that clinic from 2009-2013. The clinic's own data shows that its physicians performed more abortions each year during those years than appear on the report provided by DHEC. DHEC did not have a record of 471 abortions for those 5 years.

Table 2.2: Difference in Clinic and DHEC Data in Reporting Abortions, 2009 – 2013

YEAR	CLINIC DATA	DHEC DATA	DIFFERENCE BETWEEN CLINIC TOTALS AND DHEC TOTALS
2009	2,613	2,516	+97
2010	2,443	2,367	+76
2011	2,288	2,243	+45
2012	2,239	2,122	+117
2013	2,064	1,928	+136
TOTAL	11,647	11,176	+471

Source: Lowcountry Clinic and Department of Health and Environmental Control

Comparing the totals from each year would at least provide a level of assurance that all procedures are being reported. Inconsistencies could be investigated and resolved to ensure that abortion data is valid. Section 403 of S.C. Regulation 61-12 requires that abortions be reported within seven days of the procedure. Failure to substantiate reporting and failing to, at least, reconcile annual totals, invalidates the integrity of DHEC's database containing abortion data.

Violations and Corrective Action Plans

When violations during inspections were found, facilities provided corrective action plans. However, DHEC does not validate the implementation of those plans until the next annual inspection. We found that DHEC has not imposed any penalties against abortion clinics other than for an expired license.

The most cited violations involved:

- Maintenance and housekeeping issues, such as broken equipment, failure to document equipment preventative maintenance and equipment testing, broken ceiling tiles, dust and occasional dead bugs, broken or inaudible alarms, and burned-out bulbs.
- Personnel issues, such as failure to document tuberculosis testing, training, or job descriptions in staff files.
- Expired medications and supplies.
- Failure to keep current records.
- Inconsistencies between the contents of emergency kits and the content lists.

This could suggest that inspectors, lacking in medical experience and training, have emphasized relatively easy-to-detect violations.

We reviewed inspection reports and found cases where facilities responded with descriptions of corrective actions. In two cases where violations were noted as repeat violations, there was no evidence that the facilities had been penalized, and DHEC officials advised that no penalties had been assessed to an abortion facility over the past five years. For example, in one instance, the inspector cited a repeat violation of expired medications, a class II violation, the monetary penalty for which can range from \$200–\$1,000 for a second offense. In another instance, the inspector cited a repeat violation for failing to dispose of medications properly, another class II violation. Class II violations are those DHEC believes to have direct or immediate relationship to the health, safety, or well-being of the patients.

Section 103 (E) of Regulation 61-12 states that DHEC will consider various factors in imposing a penalty, such as the specific conditions and their impact or potential impact on health, safety, and well-being. When inspections lead to findings of repeat violations, especially those involving medications, equipment, or treatment procedures, the potential for patient harm is increased beyond what it would normally be. Given that inspections occur annually, barring special circumstances that result in a more immediate inspection, there is no way to know how long the violation has existed. Failure to impose a sanction, despite repeat violations, risks undermining the credibility of the inspection process and provides facilities with disincentives to take necessary correction action to avoid future violations.

Recommendations

1. The S.C. Department of Health and Environmental Control should conduct all annual inspections, as required by state law.
2. The S.C. Department of Health and Environmental Control should review a statistically-representative sample of patient files based on a percentage of total files and ensure that all files for minors are reviewed.
3. The S.C. Department of Health and Environmental Control should take steps to amend S.C. Regulation 61-12 to require that abortion clinics organize patient files in such a way as to allow for easy identification of the files of patients who are minors.
4. The S.C. Department of Health and Environmental Control should enforce a system of graduated penalties on clinics with repeat violations.
5. The S.C. Department of Health and Environmental Control should develop a standardized statement of patient rights which includes consistent and correct information about how patients may file complaints and requires all licensed clinics to post this statement in a conspicuous location, maintain a copy signed by each patient in the patient's medical record, and include a copy with the patient's discharge documents.
6. The S.C. Department of Health and Environmental Control should ensure that its inspectors verify that the total number of abortions performed by each facility conforms to the number reported to DHEC's Public Health Statistics and Information Services.

Complaints

We reviewed DHEC's complaint process and found that DHEC needs to improve this process. We found DHEC's Bureau of Health Facilities Licensing:

- Has not maintained adequate documentation of complaints against abortion clinics.
- Does not have a policy for forwarding complaints which are not under its purview to other agencies for investigation.
- Had two positions in its complaint section which did not have defined roles or responsibilities.

- Does not have a policy to ensure that all of the complaint allegations are investigated by the inspectors prior to the completion of their investigations.
- Does not maintain all revisions of its policies.
- Does not have adequate controls for assuring that patients are informed of how to file complaints.
- Did not maintain adequate access to all complaint tracking systems.
- Does not have adequate controls to ensure patients are informed of the right to file a complaint.
- Does not provide a toll-free telephone number for filing complaints.

Although the public has the option of sending DHEC complaints via telephone, fax, e-mail, or online, there is no toll-free telephone number provided. We contacted Alabama, Florida, Georgia, Mississippi, and North Carolina and found that these states have toll-free numbers specifically for filing complaints. A toll-free telephone number would better assist those members of the public who do not have internet or free long-distance telephone service. This service will better serve the public by allowing for greater access to DHEC and eliminate the cost of contacting DHEC to file a complaint.

Recommendation

7. The S.C. Department of Health and Environmental Control should establish a toll-free number for reporting complaints against abortion clinics.

Inaccurate Information About Complaints

DHEC officials initially provided us with inaccurate information concerning the number of complaints filed against abortion clinics. We requested documentation of all complaints filed against abortion clinics. DHEC officials informed us that they had no documentation or knowledge of any complaints ever being filed. However, we discovered documentation of a complaint investigation of the Lowcountry abortion clinic from 2005 conducted by DHEC. Our ability to verify how many other complaints

DHEC had received against abortion clinics was impeded because DHEC officials initially stated that they no longer had access to complaint records prior to January 7, 2015. During our preliminary exit, DHEC produced copies of its previous complaint tracking systems which included the Lowcountry abortion clinic complaint investigation. However, these records date back to only 2005. DHEC also produced documentation of one more complaint filed in 2009 against the same clinic.

We contacted officials with the S.C. Department of Labor, Licensing, and Regulation (LLR) to determine if there had been complaints against abortion clinics reviewed by that office. LLR officials stated that they had no documentation of any complaints forwarded to them for investigation from DHEC, nor do they have documentation of sending DHEC any complaints. Officials with DHEC confirmed that they do not have a policy for forwarding complaints DHEC receives, that are not under its purview, to other agencies for investigation.

DHEC should retain information for tracking purposes, including information from inactive systems, to ensure that complaints are tracked and followed-up on, if necessary. This would also assist inspectors and management by having documentation of repeat violations, or successive complaints of the same nature.

Recommendations

8. The S.C. Department of Health and Environmental Control should maintain access to previous records of all complaint tracking systems for abortion clinics used by the agency.
9. The S.C. Department of Health and Environmental Control should establish a policy for forwarding complaints involving abortion clinics it receives, that are not under its purview, to other agencies for investigation.

Complaint Policy

DHEC officials could not provide us with dates of when its complaint-related policies were first implemented or documentation of how long they had been in effect. Therefore, we could not establish that DHEC had any policies regarding the in-take, triage, or investigation of complaints prior to January 21, 2015.

We also reviewed DHEC's new complaint tracking log, which was implemented January 7, 2015. This log is managed by the complaint oversight nurse, who is also responsible for in-taking and triaging complaints. Triaging includes evaluating the circumstances of a complaint to determine the urgency with which an investigation should occur. Officials confirmed that, prior to the employment of the complaint oversight nurse on May 2, 2014, the Bureau of Health Facilities Licensing did not have a nurse review or triage complaints it received for investigation.

We found that the policy for inputting information into the log was last reviewed on October 7, 2014, and addresses inputting information into a number of different areas. We found, however, that numerous data entry fields, which were present with the new system, were not mentioned in DHEC's policies. During the exit process, DHEC provided an updated policy, dated March 2015, which corrected the data entry fields we identified.

The benefits from the implementation of these policies could be reduced waste of resources, elimination of redundancies, and could serve as a reference for evaluating the need for additional positions within the bureau.

Recommendations

10. The S.C. Department of Health and Environmental Control should continue to update, in a timely manner, its complaint policies regarding abortion clinics to reflect its current systems and operations.
11. The S.C. Department of Health and Environmental Control should maintain histories of all revisions to its abortion clinic policies.

Review of Inspectors' Reports

We found that DHEC does not have a policy to review inspectors' investigative reports to ensure that all of the allegations submitted to DHEC for investigation were thoroughly investigated. DHEC officials confirmed that there is no policy for following up on investigations if the inspector failed to investigate all of the complainant's allegations and no policy for informing field inspectors of allegations DHEC receives under its purview that it decides not to process as formal complaints for investigation. This would also help to mitigate future problems and complaints that may require a subsequent investigation on the same allegation(s).

Recommendations

12. The S.C. Department of Health and Environmental Control should implement a policy for reviewing the inspectors' investigation reports of abortion clinics prior to their completion.
13. The S.C. Department of Health and Environmental Control should establish a policy for communicating allegations under its purview that are not processed as formal complaints to field inspectors.

Other States' Complaint Notification to Patients

North Carolina requires that the telephone number to register complaints with its public health department be provided by the abortion clinics to the patients, prior to the abortions. Also, Alabama requires that a number to file a complaint be provided to the patient prior to discharge. S.C. Regulation 61-12 requires only that abortion clinics have a written policy to assure that the patient has the right to register complaints with DHEC and that this policy is approved by the abortion clinic licensee.

There is no requirement in S.C. Regulation 61-12 that requires the abortion clinic to provide any specific or standardized information to patients regarding filing a complaint with DHEC. Additionally, there is no stipulation that DHEC must approve the policies or forms provided to the patients. DHEC's inspection walkthrough checklist (Form 1645), which is used by DHEC inspectors when conducting inspections, only has documentation of checking that the information is posted conspicuously. There is no documentation that the inspectors check to ensure that accurate information for filing a complaint with DHEC is provided to the patients.

Recommendation

14. The S.C. Department of Health and Environmental Control should revise its policies to ensure that abortion clinic inspectors check the accuracy of the information for filing a complaint during their inspections.

Unassigned Positions

We reviewed DHEC's organizational chart and found two positions which were not documented in any of the policies submitted to us — Complaint Intake Nurse (RN) and Nurse (LPN). These positions are shown as subordinate to the Complaint Oversight Nurse, who manages the Bureau of Health Facilities Licensing's complaint section. DHEC officials confirmed that these positions were both filled on January 20, 2015; however, officials could not initially inform us of their roles and responsibilities when requested. During our exit process, DHEC produced position descriptions for these two employees.

Recommendation

15. The S.C. Department of Health and Environmental Control should update its policies to address what functions all positions will perform.

Standard Operating Procedures

DHEC has no formal procedures for handling reports of accidents or incidents at abortion clinics, and it only developed standard operating procedures (SOPs) for conducting annual inspections of abortion clinics during our audit. We requested copies of SOPs for conducting inspections, responding to complaints against abortion clinics and staff, including physicians, and investigating reports of accidents. DHEC provided 11 procedures; two apply to inspection of abortion clinics:

ABORTION CLINIC INSPECTION STANDARD OPERATING PROCEDURE
Reviewed October 24, 2014. This procedure document has no specific bureau designation.

GENERAL/RENEWAL INSPECTION PROCESS STANDARD OPERATING PROCEDURE
Reviewed January 29, 2015. This procedure is designated BHFL-06.

DHEC advised that BHFL-06 was the effective document for all health facilities. DHEC is implementing specific SOPs for individual types of facilities. The procedure for inspecting abortion clinics was last updated on October 24, 2014. It had no bureau identification number, leading us to question whether it has been formally adopted for use by inspectors.

We requested earlier versions of SOPs governing inspections and were told that the agency had them back to 2011. Subsequently, DHEC officials informed us that they were mistaken but that one was found in a DHEC operating manual from 2004. DHEC submitted the operating manual which included information on inspection procedures. During the exit process, DHEC discovered six operating manuals in addition to the one dated July 2004. We reviewed each one. While each had a section on conducting inspections, none contained a statement of policies and procedures for inspecting abortion clinics, exclusively. None contained documentation citing specific revision dates, and none contained any statement or change log informing the user of the changes in the current version of the operating manual that superseded a specific provision found in the prior version. The manuals that were submitted lacked documentation that would have allowed us to validate their use during the specific period of time they were purportedly in force.

Standard operating procedures are necessary to ensure that inspections and investigations are conducted consistently and in accordance with state law. Having multiple standard operating procedures for the same activity is needlessly duplicative and confusing for inspectors and for facility administrators and staff.

Recommendations

16. The S.C. Department of Health and Environmental Control should approve, implement, and update as necessary, all standard operating procedures for regulating abortion clinics, including a standard operating procedure for responding to accidents and incidents at abortion clinics.
17. The S.C. Department of Health and Environmental Control should incorporate these standard operating procedures for abortion clinics into its operating manual.
18. The S.C. Department of Health and Environmental Control should incorporate standard operating procedures for conducting inspections, responding to complaints, and investigating accidents reported by abortion facilities into the training for inspectors.

Staffing and Training

There are no policies and procedures governing how training for inspectors of abortion clinics is to be performed, by whom, and for how long. We found that the training for inspectors, including those inspecting abortion clinics, relies heavily on field training with experienced inspectors. There is no assessment tool to determine an inspector's competency level, and no plans for follow-up or refresher training. Training for inspectors is especially important because inspectors can come from a variety of backgrounds and are not required to have medical training, education, or experience when hired.

There are 20 inspectors working in the Bureau of Health Facilities Licensing. Four of those are assigned to the Health Facility Oversight Division — the division responsible for inspecting abortion clinics. However, according to DHEC, only one individual, someone not normally assigned as an inspector of abortion clinics, has been scheduled to conduct these inspections because of her nursing background and expertise.

Beginning in 2014, the bureau began revising its training for inspectors. DHEC hired a training coordinator whose background and experience is in a field other than healthcare. New inspectors are to begin classroom training before going out into the field with an experienced inspector. However, at this point, there are no policies and procedures governing training. In response to our inquiry, DHEC submitted a training manual dated December 2014.

According to DHEC, training for inspectors is now being enhanced with a training manual and in-class and field training. Two of the four inspectors assigned to the section that does inspections of abortion clinics are being trained pursuant to this new format. The other two worked at DHEC prior to the new training initiative and have experience in conducting inspections.

There is no test or assessment tool that is used to determine if an inspector is ready to proceed with field training. No assessment tool is administered once an inspector has completed classroom and field training under the direction of an experienced inspector. Therefore, except for the impression of inspection staff and management, there is no objective measure of competency that DHEC can use to determine that its inspectors are ready to inspect an abortion facility or any other health facility on their own.

According to DHEC, the training manual will be continuously updated. The training coordinator will continue to create presentations and other instructional aids and tests. DHEC could possibly add staff to assist in this training process. DHEC's goal is to develop an e-Learning system. There is no expected date of completion.

Education and Skill Requirements to Become an Inspector

We reviewed the position descriptions of four inspectors assigned to the Health Facility Oversight Division. We found that the minimum requirement for an inspector position is a bachelor's degree, preferably in healthcare administration, business administration, public health administration, computer science, physical science, natural science, or a related field.

Since August 2014, DHEC has assigned a registered nurse to inspect abortion clinics. However, there is nothing in policy or procedures to require similar credentials for abortion clinic inspectors.

We reviewed the requirements for inspectors in Alabama, Florida, Georgia, Mississippi, and North Carolina. We found that, with the exception of Florida, all these states require a registered nurse to be present during an inspection of an abortion clinic. Additionally, the states of Alabama and Georgia require their inspectors, with the consent of the patient, to observe patient clinical abortion procedures as part of their inspection process, a requirement that makes such a clinical background especially relevant. Because inspectors in South Carolina do not necessarily have a healthcare background or clinical experience, training is especially important.

Although inspectors can be trained on the specific legal requirements of DHEC regulation, inspectors also interact with healthcare professionals in the field. It is important that inspectors possess a level of knowledge that allows them to apply the law correctly and consistently while commanding the respect of those health professionals with whom they are charged with regulating.

DHEC has subsequently submitted a training manual, updated March 2015. It mirrors the version submitted to us during our audit but contains items that were missing from the 2014 version. Trainees will be tested at the conclusion of each training phase and must pass a final examination with a grade of 80%.

Recommendations

19. The S.C. Department of Health and Environmental Control should continue to revise its training program for inspectors and amend its policies and procedures, as necessary, to reflect changes in how training is to be performed, by whom, duration, assessment tools, and continuing education and training.
20. The S.C. Department of Health and Environmental Control should ensure that those who conduct training are qualified by virtue of educational background and experience to train persons who will be inspecting healthcare facilities and interacting with trained medical professionals in the field.
21. The S.C. Department of Health and Environmental Control should not allow an inspector to inspect an abortion clinic without the assistance of an experienced inspector unless the employee has successfully completed a valid assessment test aimed at measuring competency in, at a minimum, the regulations, medications, medical procedures, and terminology.
22. The S.C. Department of Health and Environmental Control should actively recruit and give priority to candidates for the job of inspector to individuals with clinical experience.

Website Accessibility

We reviewed the accessibility of information on DHEC's website with specific attention given to the ease of access to DHEC's online database of inspection report results. We found that there was not a logical path for the user to follow in order to locate the inspection reports. We were only able to locate the inspection report webpage via the search field on DHEC's website. We found that the database is cumbersome and not user-friendly. The website provides limited instruction to the user for performing queries.

Once the inspection results were retrieved, we observed that it required scrolling to view all of the available data, which is very limited. Only the name of the facility, facility license number, date of the inspection, type of inspection, quoted section of S.C. Regulation 61-12 that was in violation, and whether or not the violation was a repeat are displayed. The inspection reports do not provide enough information to allow patients to be properly informed. For example, there are no specific explanations of what constitutes a certain violation or its severity.

Alabama and Florida provide searchable databases to the public. In contrast to South Carolina's inspection report results database, both Alabama and Florida allow the public to view the inspectors' actual inspection reports, without identifying patient information, in addition to what sections of law and/or regulation were found to be out of compliance. Unlike DHEC's report results, both Alabama and Florida provide their reports in an easily downloadable and printable format.

Recommendations

23. The S.C. Department of Health and Environmental Control should provide a prominent link to abortion clinic inspection report results on its home page and ensure the reports can be viewed in a user-friendly format.
24. The S.C. Department of Health and Environmental Control should provide its full abortion clinic inspection reports, without patient identifying information, on its website to users in a easily downloadable and printable format.

Availability of Inspection Reports

DHEC's website states that inspection report results are generally available 30 days after an inspection. However, none of the three 2014 inspections were available for review on DHEC's website as of April 15, 2015. According to an official with the Bureau of Health Facilities Licensing, "There is not a timeframe or procedures for uploading results of inspection to DHEC's website. The posting of reports of visit on the website is not a completed project and a completion date is not known."

Recommendation

25. The S.C. Department of Health and Environmental Control should establish and implement a policy to allow for uploading abortion clinic inspection results to its website within 30 days of each inspection.

Complaint Investigation Results

In addition to the inspection reports, we found that DHEC also does not have a policy on posting complaint investigation results. A DHEC official stated, "At this time, the website does not provide results of complaint investigations. The posting of reports of visit on the website is not a completed project and a completion date is not known." Both Alabama and Florida have this information on their websites.

We also found that DHEC does not post the status of a facility's license on its website. Both Alabama and Florida's websites display the statuses of the facilities' licenses. The public can easily determine if a facility's license has been suspended, revoked, terminated, etc. Florida posts information regarding fines, administrative orders, and administrative penalties for the public to view on this same website.

Recommendation

26. The S.C. Department of Health and Environmental Control should modify its website to include complaint investigation results, facility license status information, and any penalties levied against abortion clinics.

Woman's Right to Know Act

The Woman's Right to Know Act (WRTK), §44-41-310 *et seq.* of the S.C. Code of Laws, requires DHEC to make available certain information on its website to women seeking abortions. We reviewed DHEC's list of free ultrasound providers and found inaccuracies.

The WRTK requires DHEC to provide a geographical listing of providers offering free ultrasounds. We found that the information listed under DHEC's webpage "Free Obstetric Ultrasound Provider Listing" contained several prominent errors and omissions among the 11 providers listed whose information we evaluated. Specifically, we found that the listing contained:

- An invalid address for one provider in the Lowcountry. The provider's staff confirmed that the address has been invalid for approximately four years. Section 44-41-340(A)(6) of the S.C. Code of Laws mandates that DHEC update this list annually before September 1.
- An invalid website for one provider in Sumter, South Carolina. We called the provider and obtained its valid website, which was not documented on DHEC's website. Section 44-41-340(D)(2) of the S.C. Code of Laws requires DHEC to provide a link to the website maintained by the provider.
- An incorrect name for one provider in Sumter, South Carolina. The provider's staff informed us that the facility's name had officially changed to a substantially different name in 2012.
- One provider in the Upstate that had closed and was no longer providing services.

In addition, DHEC's website does not provide the hours of operation for the providers listed. We confirmed with DHEC officials that users must go to each provider's website to access this information. Section 44-41-340(A)(6) of the S.C. Code of Laws requires DHEC to document the hours of operation on its website.

The Division of Children's Health at DHEC is charged with managing the information pertaining to the Woman's Right to Know Act on DHEC's website. A DHEC official stated that the information is checked for accuracy by a designated staff member and updated more frequently than the annual requirement prescribed by state law; however, there is no policy or procedure for verifying the accuracy of the information on the website. Although the hours of operation for the providers are contained on each provider's specific website, we found the information difficult to locate for the majority of the providers listed.

Recommendations

27. The S.C. Department of Health and Environmental Control should comply with state law by updating its list of providers annually.
28. The S.C. Department of Health and Environmental Control should comply with state law by documenting the hours of operation for the ultrasound providers on DHEC's website.

Other States' WRTK

We reviewed the information available on other states' websites that provide information related to the Woman's Right to Know Act. Georgia and North Carolina provide the information to the user in an easily-downloadable and printable format. South Carolina does not provide information related to the Woman's Right to Know Act in an easily downloadable format as per the requirements of §44-41-340(D)(1) of the S.C. Code of Laws.

Recommendation

29. The S.C. Department of Health and Environmental Control should comply with state law and add an option to its website for the user to download the materials in an easily downloadable and printable format.

Use of Ultrasounds

South Carolina state law does not specify guidelines, parameters, or requirements relating to why an ultrasound is to be performed. State law does stipulate requirements that must be met if an ultrasound is performed under §44-41-330(A)(1) of the S.C. Code of Laws. However, state law does not denote that the ultrasound should always be used in determining the gestational age of the fetus.

Currently, S.C. Regulation 61-12 allows the physician to establish the gestational age of the fetus from a bimanual physical examination and the date of the woman's last menstrual period, the latter of which is provided by the patient. These methods do not provide for objective information regarding the gestational age for the purpose of verifying compliance with state law. Additionally, if the bimanual physical examination and clinical evidence is inconclusive as to the gestational age of the fetus, S.C. Regulation 61-12 does not require that an ultrasound be performed. We found that other states require a pre-abortion ultrasound for all abortions.

S.C. Regulation 61-12 lists requirements that are not reflected in state law:

SECTION 302. Limitation of Services Offered by Abortion Clinics (I)

A. Abortions performed in abortion clinics shall be performed only on patients who are within 18 weeks from the first day of their last menstrual period. Those beyond 18 weeks shall be performed in a hospital. A licensed ambulatory surgical facility that is also licensed as an abortion clinic may perform abortions on patients who are up to 26 weeks after the first day of their last menstrual period.

B. Clinics performing abortions beyond 14 weeks from the first day of the last menstrual period must meet the requirements of Section 309.

Section 309 of S.C. Regulation 61-12 mandates an ultrasound on all pregnant patients who are estimated to be beyond 14 weeks from the first day of the last menstrual cycle. Additionally, Section 301.C.2 requires abortion clinics to establish and adhere to a policy that an ultrasound shall be recommended when the gestational age of the fetus is estimated to be at 12 weeks or more and required at 14 weeks or more.

However, regulation does not specify whether the ultrasound must be done before or after the abortion. Ultrasounds done before the abortion are to determine the gestational age of the fetuses. Those conducted after the abortions are to ensure that all of the birth material has been removed from the patient. Additionally, S.C. Regulation 61-12 is not clear for what purpose the ultrasound is required to be performed.

We reviewed the laws and regulations of the states of Alabama, Florida, Georgia, Mississippi, and North Carolina to identify best practices in the regulation of abortion clinics. We found that, with the exception of Georgia, which does not have abortion clinics, these states have laws requiring an ultrasound prior to all abortions in order to establish the gestational age of the fetus. Additionally, we reviewed several articles on the accuracy of ultrasound as a method for establishing the gestational age of the fetus. These articles conclude that ultrasonography is more accurate than establishing the gestational age of the fetus by means of the woman's last menstrual period and/or bimanual examination by a physician.

By requiring an ultrasound prior to the abortion, the physician can be assured a greater degree of accuracy in determining the gestational age of the fetus. The documentation of this test should be maintained in each patient's record for DHEC inspectors to check to verify compliance with state law.

Recommendation

30. The General Assembly should amend state law to require a pre-abortion ultrasound to determine the gestational age of the fetus for all abortions.
-

Licensing, Inspection, and Report Fees

We reviewed DHEC's management of its abortion clinic inspection fees and found no material problems. DHEC assesses inspection fees on healthcare facilities, including abortion clinics. Section 44-7-270 of the S.C. Code of Laws requires that applicants for a license to operate a health facility, as defined in §44-7-260, should pay a license fee. An abortion facility is defined as any facility where a second trimester or five or more first trimester abortions are performed per month. DHEC has authority to assess an inspection fee for each facility. The license is issued annually and each applicant shall pay a license fee prior to issuance. The license fee of \$500 is for new licenses and for renewals.

We also reviewed inspection fees for abortion clinics. DHEC implemented annual inspection fees effective March 15, 2014. Within two weeks of completing an inspection, DHEC sends an invoice to the facility for the appropriate fee amount. The inspection fee for an annual routine or a follow-up inspection is \$350 plus \$25 for each procedure room. The fee for follow-up inspections and for an annual inspection related to a unit increase or service modification is \$200 plus \$25 per procedure room. We found that Alabama, Florida, Georgia, Mississippi, and North Carolina do not charge inspection fees.

We reviewed invoices for licensing renewals from 2010–2014 and for inspection fees since the fee was implemented in 2014. We confirmed that invoices were sent and fees were paid. In 2012, a Midlands clinic was also assessed a late fee of \$125 for failure to renew its license upon expiration. The facility paid the late fee. We were unable to access financial data prior to 2010. According to DHEC, the retention schedule for invoices is three closed years plus the current fiscal year.

Clinic Report on
Physicians Conducting
Abortions

We also reviewed compliance with Proviso 34.56 of the FY 14-15 appropriations act, which directed abortion clinics to file a report with DHEC that provides the number of physicians that performed an abortion at the facility between July 1, 2014, and December 31, 2014, who did not have admitting privileges at a local certified hospital, and staff privileges to replace on-staff physicians at the certified hospital and the percentage of these physicians in relation to the overall number of physicians who performed abortions at the facility. Each facility is required to remit a \$25 filing fee to DHEC for this report. We found that each of the three licensed clinics submitted the report and paid the fee.

Southeastern States' Regulation of Abortion Clinics

	ALABAMA	FLORIDA	GEORGIA**	MISSISSIPPI	NORTH CAROLINA	SOUTH CAROLINA
Send a registered nurse to all routine inspections	Yes	No	Yes	Yes	Yes	No*
Typically send at least two inspectors to each inspection	Yes	No	Yes	Yes	Yes	No
Provide a toll-free telephone number for filing complaints	Yes	Yes	Yes	Yes	Yes	No
Charge a fee for inspections	No	No	No	No	No	Yes
Require ultrasounds for all abortions	Yes	Yes	No	Yes	Yes	No
Provide inspection reports online	Yes	Yes	No	No	No	Yes
Provide complaint investigation reports online	Yes	Yes	No	No	No	No

* Currently, a registered nurse is assigned to inspect abortion clinics; however, agency policy does not require similar credentials for abortion clinic inspectors.

** In Georgia, abortion clinics are licensed as ambulatory surgical centers.

Source: Interviews with state officials, state laws, and state government websites, February 2015.

Agency Comments



W. Marshall Taylor Jr., Acting Director

Promoting and protecting the health of the public and the environment

The South Carolina Department of Health and Environmental Control (“Department” or “DHEC”) appreciates the effort of the Legislative Audit Council (“LAC”) in formulating its report entitled *A Review of the S.C. Department of Health and Environmental Control’s Regulation of Abortion Clinics* (“Report”) and will consider implementing many of the recommendations therein. However, the Report presents a narrow view of the Department’s regulation of abortion facilities, particularly in its omission of findings in the context of the Department’s ongoing quality improvement measures, substantial focus on reference literature over actual execution of duties protecting patient health and safety, and minimization or disregard of Department submissions in response to specific alleged findings. This includes, but is not limited to, the following:

- Framing findings as overview of static DHEC processes and capabilities, as opposed to a snapshot of the Department’s ongoing quality enhancements yielding improved organization and implementation of duties charged by the General Assembly;
- Advancing an inaccurate number of annual inspections conducted by the Department despite submissions indicating otherwise;
- Disregarding submissions, including emails and manager position description, indicating weekly managerial review of investigative reports to advance a finding that such duties do not appear in DHEC policy reference material;

- Conceding the Department has an inspector competency test requirement in its latest policies immediately after contending the Department lacks a test or assessment to determine inspector competency; and
- Disregarding email submissions evidencing instances of DHEC forwarding complaints to other agencies with appropriate jurisdiction to advance a finding of there being no policy dictating such action.

The Department appreciates the work undertaken by the LAC in the interest of improving implementation of executive duties. Moreover, the Department appreciates this opportunity to highlight that multiple DHEC submissions presented during the audit process and after viewing an initial draft of the Report, along with the ongoing quality improvement process, have not been adequately considered to present a more complete appraisal of the subject at issue. The following constitutes the Department's response to the Report.

I. Ongoing DHEC Quality Improvement

As described to the LAC in response to the initial draft Report, the Department's Bureau of Health Facilities Licensing ("Bureau" or "BHFL") has been in the midst of a quality improvement effort. In June of 2013, upon recognizing program deficiencies, newly hired or promoted DHEC personnel participated in drafting a proposal of program needs for the Bureau. The December 2013 revision of this document specifically identified regulatory oversight needs associated with abortion clinics. This proposal, along with hiring of new management, established the foundation for change. Implementation of the improvement process could only begin after instituting inspection fees to overcome budget-related constraints. The Department implemented fees in March 2014 and, with additional resources, began updating its standard operating procedures.

Because quality improvement was and continues to be ongoing, the LAC did not obtain a final product but only a snapshot of a work-in-progress. This multiyear plan continues to take shape and evolve in response to the newly implemented fee structure, technology modifications, and staff transition and turnover. The Department did not suspend the restructuring and process improvements upon commencement of the LAC audit. DHEC continues to implement new processes as part of the plan originally proposed in June 2013 and intends to incorporate recommendations of the Audit Report, as applicable, into the plan. Prior to the audit, the Department had also recognized the need to update Regulation 61-12, Standards for Licensing Abortion Clinics, and included the revision in its internal regulation promulgation schedule. Regulation 61-12 has not been revised since it was first promulgated in 1996. The upcoming revision will seek to improve health and safety-focused processes in accordance with governing statutory authority.

Overall, a substantial portion of the Report centers on updating policies and procedures. The audit fieldwork included accompanying a DHEC inspector on an abortion facility inspection, and, notably, the Audit Results present no deficiency observed during that inspection. The Department certainly recognizes the importance of and will emphasize maintaining up-to-date reference literature; however, it places greatest importance on actual execution of duties directly protecting patient health and safety. A complete appraisal of the Department's regulation of abortion clinics should incorporate the absence of deficiency observed during the inspection, which is among the most vital and functional execution of DHEC's regulatory responsibilities.

II. Abortion Clinic Inspections

On page 7 of the Report, the LAC concludes the Department has failed to consistently inspect abortion clinics by presenting a count of 33 total inspections conducted from 2001-2014. In actuality, the Department presented 36 inspection reports during the audit fieldwork and in response to the initial draft of the Report. The Department will continue to emphasize the inspection process as its quality improvement effort continues. This includes determining an adequate quantity of patient files necessary to conduct a meaningful inspection. The Department will also consider a means by which it can efficiently obtain a representative sample of records for pregnant minors. Implementation may require amendments to R.61-12 with respect to facilities' organization of files.

Page 10 of the Report mentions questionable timeframes marked on inspection reports and instances of inspection items being "not observed." These are not indicative of "incomplete inspections." Instead, according to the Department's review of this issue, some inspection reports reflect the times of data entry, as opposed to the times the inspector was actually onsite at the abortion clinic. Furthermore, in many cases the inspector considered "not observed" as "no violation was observed," as opposed to being an indication of not observing the item at issue. These are certainly errors on the part of the inspector with respect to entry of inspection data. The Department is addressing improved inspector training under the individual newly hired to take on this duty and the overall quality improvement effort.

As part of the ongoing quality improvement effort, the Department shall also consider means for incorporating the LAC's analysis of patient rights statements and reporting abortions to the Department's Public Health Statistics and Information Services, appearing on pages 11 and 12 of the Report. This may require amendments to R.61-12. The Department shall also consider enhanced scrutiny of repeat violations cited during inspections, as discussed on page 13 of the

Report. However, the Department takes issue with the LAC's speculation that most commonly cited violations involve maintenance and housekeeping issues because "inspectors, lacking in medical experience and training, have emphasized relatively easy-to-detect violations." The DHEC inspector conducting all abortion clinic inspections is a Registered Nurse who is certainly well equipped to notice care-related violations.

III. Complaints

Page 15 of the Report states "DHEC officials provided us with inaccurate information concerning the number of complaints filed against abortion clinics." This verbiage misrepresents the Department's efforts to cooperate and provide requested information as quickly as possible based on LAC deadlines. According to the Report, when inquired, Department officials indicated they had no knowledge of any filed complaints. This does not amount to provision of inaccurate information. Instead, current personnel were merely unaware of the requested information. The LAC's subsequent discovery of such documentation at a Lowcountry abortion clinic does little to question the accuracy of the Department's response, as the Department did not present a zero tally of complaint investigations. Again, Department personnel only indicated they were not aware of such information at the particular time of inquiry. Additional time for response may have yielded a more complete answer, as evidenced by the fact that DHEC ultimately provided more complaint documentation.

Page 16 of the Report states the Department should forward complaints outside of the Department's purview to the appropriate agency. The LAC apparently advances this finding despite receiving email submissions from the Department reflecting instances of DHEC forwarding complaints outside its purview to the S.C. Department of Labor, Licensing and Regulation. These were not abortion clinic complaints because the Department has not received

any abortion clinic complaints outside its purview. Nonetheless, the submission clearly demonstrates Department practice of forwarding complaints to the appropriate agency.

Page 17 of the Report also disregards the Department's submission of a BHFL manager's review of a sampling of investigative reports of abortion clinics prior to completion of the reports and the manager's position description indicating such role. The Report instead takes issue with the role not being present in the Department's policy reference material. As mentioned above, the Department certainly recognizes the importance of and will emphasize maintaining up-to-date reference literature but places greatest importance on actual execution of duties directly protecting patient health and safety.

The Department shall consider means for incorporating the LAC's analysis, appearing on Report page 18, of assuring patients are more aware of their right to file complaints to DHEC. This may require amendments to R.61-12.

IV. Standard Operating Procedures

During the audit investigation, the Department submitted Operations Manuals from 2005 to 2014 showing the processes and procedures for responding to accidents and incidents in licensed facilities. These processes and procedures are not unique to abortion clinics but rather apply to all facilities under DHEC's purview. The Department submitted a draft copy of the standard operating procedure ("SOP") for abortion clinic inspections, last reviewed October 2014, which outlines the inspection process for abortion clinics. As part of the ongoing quality improvement effort, the Department is currently in the process of creating facility-specific SOPs for all types of licensed facilities and the abortion clinic SOP will therefore be incorporated into the Operations Manual upon completion of this project. However, it would be duplicative to include processes

and procedures for responding to accidents and incidents in abortion clinics as these procedures are not unique to abortion clinics and are covered in the Operations Manual.

V. Staffing and Training

The training process for inspectors is an important part of the ongoing quality improvement effort currently in progress at DHEC. During the audit investigation, DHEC submitted a BHFL Inspector Training Manual, dated November 2014, evidencing the Department's efforts to improve and update inspector training protocols. The training manual has since been completed as evidenced by the Department's submission of the BHFL Inspector Training Manual, dated March 2015. Moreover, as evidenced by the March 2015 BHFL Inspector Training Manual, trainees are tested at the completion of each training phase and must pass a final examination with a score of at least eighty percent (80%), thus ensuring the trainee is qualified to competently perform the duties required of inspectors. This is contrary to the Report's contention on page 21 that "[t]here is no assessment tool to determine an inspector's competency level[.]" Additionally, the individual hired to conduct training has a wealth of experience in a wide variety of fields as evidenced by the Department's submission to the LAC of this individual's employment application and associated position description. This individual's years of experience, coupled with the resources of the Department, makes her more than qualified to conduct training.

The Department also recognizes the importance of having inspectors with clinical experience. DHEC ensures an inspector with qualifications as a Registered Nurse conducts all abortion clinic inspections. The Department submitted this individual's employment application and accompanying position description to the LAC showing her twenty-two (22) years of experience in healthcare as a Registered Nurse. Moreover, this individual's employment application documents more than twenty (20) years clinical experience in neonatal intensive care

and high risk deliveries. Page 22 of the Report concedes “DHEC has assigned a registered nurse to inspect abortion clinics” but finds “there is nothing in policy or procedures to require similar credentials for abortion clinic inspectors. As mentioned above, the Department certainly recognizes the importance of and will emphasize maintaining up-to-date reference literature but places greatest importance on actual execution of duties directly protecting patient health and safety.

VI. Website Accessibility

The Department shall consider means for incorporating the LAC’s analysis of its website accessibility beginning on Report page 24.

VII. Woman’s Right to Know Act

As part of its quality improvement effort and in conjunction with the Division of Children’s Health, the Department is in the process of updating the information provided on the website required by the Woman’s Right to Know Act (“WRTK”). This process includes updating or correcting outdated or broken hyperlinks.

The information required by the WRTK is provided on the DHEC website in a manner best suited to ensure the prospective patient proceeds through all of the information as opposed to offering all of the information in a single downloadable document. The information is organized on separate pages requiring the user to progress through each one ultimately ending at the patient statement page. The patient statement page instructs the prospective patient to print and sign the statement attesting that she has had the opportunity to review the required WRTK information. Moreover, the patient statement is date- and time-stamped, as required by statute. Overall, the Department appreciates the LAC’s recommendations on this issue.

VIII. Use of Ultrasounds

As mentioned above, the Department will commence in the process of revising and updating R.61-12, *Standards for Licensing Abortion Clinics* in the coming months. However, the Department is restricted to the bounds of the statute authorizing the regulation of abortion clinics. If the General Assembly elects to amend the statute for abortions, thus requiring an ultrasound prior to having an abortion, the Department will update Regulation 61-12 accordingly.

IX. Conclusion

The Department appreciates the work undertaken by the LAC and the opportunity to comment on the Report. While much of the Report provides helpful input warranting consideration, it does not portray systematic failures by the Department reflecting imminent harm to patient health or safety. The Department credits the ongoing quality improvement effort and proceeds in its commitment to protecting the health of the citizens of South Carolina.



Lauren A. Shuster
Director of Public Health
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

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