



Senate Public Health & Welfare Committee
Senate Abortion Bills Hearing
Testimony from Dr. Eli N. Avila
Wednesday, April 13, 2011

Opening Remarks

Good afternoon Chairman Vance, Chairman Kitchen and members of the Senate Public Health & Welfare Committee. As most of you now know, I am the Department's Acting Secretary, Eli N. Avila. I value the opportunity to again speak before the Committee and am pleased that our discussion today will be focused around solutions.

Since first speaking before you on March 1 regarding the deplorable events concerning the Women's Medical Society and Dr. Kermit Gosnell, you and your fellow committee members have done a commendable job in introducing six Senate bills to further ensure that such a public health breakdown does not occur again in our Commonwealth. As you are all aware, many of the legislative changes proposed are already being implemented by my Department, including annual abortion facility inspections with additional random inspections, a process to investigate complaints, an online complaint mechanism, posting in the facilities of a toll-free number to take complaints, and information sharing with the Department of State.

I would now like to further discuss with you what the Department has already done and will continue to do to make sure the health and safety of women is not compromised.

The Department currently has the authority to monitor and regulate facilities that are approved to perform abortions and to deny or revoke that approval for cause. Governor Corbett and I are committed to thorough oversight and regulation of abortion facilities

under current law. As the Governor stated in his press conference on February 15, the Department of Health has adopted new procedures to inspect abortion facilities on a regular basis, to investigate all complaints promptly, and to take many other steps to protect the interests and welfare of women and premature infants born alive in the course of an abortion procedure.

Plan of Action

As outlined by Governor Corbett, the following are specific actions the Department of Health will take - or has taken already:

Inspections:

- In terms of process, abortion clinics are now held to a higher level of scrutiny with a systemic approach to ensure patient safety.
- Inspections are done annually, with additional random inspections conducted unannounced, including during weekends and evenings. The practical effect of this requirement is that the facilities may end up having three or more inspections in any given year. We are returning to facilities to ensure that required corrections are implemented.
- Inspectors from the Division of Acute and Ambulatory Care (DAAC) within the Bureau of Facility Licensure & Certification conduct these inspections.
- This Division is also responsible for inspecting Pennsylvania's hospitals and out-patient surgery facilities.
- The Bureau previously responsible for these clinics was the Division of Home Health that surveys and licenses home health and hospices.
- The inspectors, who are registered nurses within the Department, are trained to inspect these types of facilities to maintain quality assurance and enforce regulations.
- This plan for inspections has already proven its effectiveness. Following the closure of the Women's Medical Society, the former Secretary of Health ordered the Department's Quality Assurance physician, along with a registered nurse, to inspect all 24 of the free standing abortion clinics in Pennsylvania. This resulted in Notices of Deficiencies being issued to 15 facilities. A physician who operated two

of these facilities retired from the practice of medicine and closed his facilities within 10 days of the inspections.

- The remaining Notices of Deficiency for the 13 facilities addressed clinical deficiencies –
 - ✓ Expired medications
 - ✓ No antidote/reversal drugs for certain anesthetic medications
 - ✓ Lack of resuscitative equipment
 - ✓ Inappropriate oxygen sources
 - ✓ Failure to follow manufacturer recommendations for equipment maintenance
 - ✓ **No** deficiencies rose to the level of Gosnell
- Facilities with these deficiencies were asked to correct them *immediately* before performing subsequent procedures
- Some facilities: deficient in performing urine protein and sugar testing
- Some facilities: deficient in documenting tissue examination
- Some facilities: had inappropriate medical documentation of monitoring recovery room vital signs
- Some facilities: failed to have an RN or appropriate supervision of an LPN

All cited facilities responded to the notice, and all submitted their Plans of Correction to the Department for review and evaluation. I want to assure you that allowing these facilities to remain open did not and will not compromise the health and safety of women.

And as I have told you before, I am joining the inspectors on subsequent inspections. I believe my presence conveys the message of just how seriously this Administration and my Department are taking our responsibilities.

Monitoring:

- Abortion facilities are now included in the same Department computer system used to monitor hospitals and other medical facilities to ensure inspections are done in a timely fashion and standards are met.
- The computerized system tracks complaints, serious events and investigations.

- New Notices of Deficiencies and Plans of Correction from abortion facilities are available and searchable on-line within approximately 41 to 45 days of the completion of the inspections.
 - Deficiency notices and correction plans currently are available and searchable regarding hospitals, ambulatory surgery facilities, and nursing care facilities.

Deficiencies:

- If a deficiency is found, Plans of Correction will be required within 10 days, submitted online, and made available to the public on the Department's website.
- A facility's Plan of Correction must identify the proposed date by which the facility will have corrected the identified deficiencies and be in compliance with the regulation.
- The Plan of Correction must be approved by the surveyor, who will be specifically trained to assess abortion facilities.
 - Failure to comply in submitting a Plan of Correction will result in another on-site inspection.
 - Failure to file a second Plan of Correction within a second 10-day period will result in an immediate suspension of the facility.
- Any Facility that fails to report a serious event - either to the state or the patient - will be subject to a fine of up to \$1,000 a day until it files the required report.

Training:

- The Department held an all-day training for the currently operating abortion facilities on March 21.
- This mandatory training reviewed the current regulations, the survey process and plans of correction, reporting requirements, and the serious event and complaint processes.
- The session included training from the Patient Safety Authority and the Department of State.

- This training was well received and met with positive feedback from the abortion facility providers. The overall consensus was that the training was not only helpful, but long overdue.

Communicating with the Department of State:

- Finally, the Department has been working closely with the Department of State to establish a framework for sharing monthly reports between the two agencies, including reports of complaints, serious events, complications, and deaths.
- The two departments have established a process for joint investigations whereby both agencies will work in a coordinated manner.
- During the course of an investigation conducted by the Department, or the Department of State, that involves a facility providing abortions, each agency notifies or otherwise involves the other agency.
- It is the intent of both agencies to monitor and track the progress of any matter brought to the agencies' attention.
- Complaint and report sharing is already taking place, and the agencies will periodically review the reporting process to ensure its efficiency.
- We have named the Acting Deputy Secretary for Quality Assurance, Melanie Waters, and a representative of our Office of Legal Counsel, as our points of contact to avoid confusion and ensure institutional continuity.

Conclusion

The Department's primary responsibility under the Abortion Control Act is to protect the health and safety of women having abortions and of premature infants born alive. The Department's plan of action, as I outlined above, is to carry out this mandate, including the inspection of abortion facilities, to determine whether they are satisfying the regulatory requirements the Department has imposed upon them.

Governor Corbett and I are 100 percent committed to fulfilling the Commonwealth's obligation to protect the health and safety of women who use these services. I will continue to do everything in my power and the power of the Department to see that we carry out this responsibility we have to the Commonwealth. The elements I have

outlined are the critical parts to our core function of quality assurance for all providers that we regulate. I look forward to working with you.

I will now take any questions you may have.