February 17, 2016

Hon. Casey Cox
Indiana State Representative
200 West Washington Street
Indianapolis, IN 46204

Representative Cox:

I received your letter regarding the Indiana State Department of Health’s (ISDH) report on newborn safety incubators, as required by HEA 1016 (2015). The law required the ISDH to make recommendations concerning this issue after considering a number of factors. We did consider those factors and have made recommendations concerning this issue. I can assure you the ISDH took the responsibility of evaluating all factors necessary to make recommendations regarding standards and protocols very seriously. Ultimately, we came to the conclusion that standards couldn’t be recommended for newborn safety incubators given their unprecedented use in the US and the medical device regulations that must be considered to ensure the safety and wellbeing of a newborn. Know that I admire and share your heart for the most vulnerable among us, and I hope we can continue to work together to promote the dignity and sanctity of life.

The task force on Infant Mortality and Child Health under the Commission on Improving the Status of Children (the Commission) was also assigned the topic of studying newborn safety incubators by HEA 1016. This group represents multiple agencies and considered the topic thoughtfully from multiple angles in order to make recommendations not only to the Commission, but also to the ISDH and the Department of Child Services (DCS).

At its meeting on November 18, 2015, the Commission ultimately recommended against advancing the use of newborn safety incubators. During the discussion, Commission members raised many concerns including the cost, installation, and effectiveness of newborn safety incubators. The Commission instead voted to recommend that additional resources be put toward improving awareness of Indiana’s existing Safe Haven Law.

As the ISDH completed its own report on newborn safety incubators, we certainly took the Commission’s recommendations into consideration as we evaluated the items specified in HEA 1016. ISDH also utilized the task force’s literature review of prior practices regarding the use (and non-use) of newborn safety incubators and the use of Safe Haven Laws.

After considering all the factors outlined in the law, ISDH found that there were no specifications or function requirements that could be created that would ensure the safety and security of children placed in such a device. There are currently no standards – either internationally or here in the United States – for the design, manufacturing, and maintenance of material housing for abandoned children. If such a device were to be used, it would be imperative that industry professionals provide recommendations on how to best conform to the local standards that hospital systems and other Safe Haven sites across the state would be able to support. Additionally, as a medical device, any device designed to house an abandoned baby should undergo certification and testing to standards set by the US Food and Drug Administration (FDA), the International Electrotechnical Commission, or other agencies as appropriate. Consequently, our recommendation is that this avenue be pursued by the Vendor.
The ISDH also could not issue guidelines on a device for which we do not have any inspection or oversight authority. The ISDH is the state licensing and federal Medicare certification agency for twenty-eight types of acute care providers and four types of long-term care providers. These entities are regulated under state licensing rules or federal certification regulations. When it comes to building design, standards are developed from the Guidelines for the Design and Construction of Hospitals and Outpatient Facilities from the Facilities Guidelines Institute and the National Fire Protection Association’s Life Safety Code. These standards are derived from experts in healthcare architectural design and fire and building safety. It is a significant concern that neither of these sources include design standards for a device to house an abandoned baby. This reiterates the ISDH’s apprehension that no standards exist—either internationally or domestically—for the design, implementation, and maintenance for material housing for abandoned children.

Even if the ISDH were given regulatory authority and performed routine inspections of newborn safety incubators, we could not ensure an infant’s safety. There are no standards or protocols that could ensure a device would not malfunction, which could potentially result in the harm of an infant. Indiana’s babies are too precious to take this risk.

In closing, the safety, security, health, and wellbeing of our children is too important to jeopardize with the use of an unregulated product for which no international or domestic standards exist. Rather, we believe the best way to ensure the safety and wellbeing of our most vulnerable children is to recommend increased promotion of Indiana’s existing Safe Haven Law. We welcome your continued partnership as we work to protect and promote the dignity of human life.

Sincerely,

Jerome Adams, MD
JEROME M. ADAMS, MD, MPH
STATE HEALTH COMMISSIONER