CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Krabbe Rules Changes

Rule Number(s): 3701-49-01.1, 3701-55-02, 3701-55-04

Date: 3/01/2016

Rule Type:

- ☐ New
- X Amended
- ☐ 5-Year Review
- ☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   Rule 3701-49-01.1 outlines the fees that the Ohio Department of Heath charges for the services that it provides. This rule is being updated to include the new fees associated with screening for Krabbe disease as required by recent legislation. Rule 3701-55-02 lists the required screenings that are included in the Newborn Screening panel that is performed by the lab on all babies born in the state. This rule is being modified to add Krabbe to the required screening list. Rule 3701-55-04 outlines the notification that is required for hospitals, birthing centers to provide of the newborn screening testing. This rule is being

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modified to provide notification of a parent's option to forgo Krabbe screening and the means to notify the laboratory of the opt out per recent legislation.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**
    a. ORC 3701.221 and 3701.501
3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   No
4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**
    a. Not Applicable
5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**
    a. The ODH laboratory is mandated to provide newborn screening for all babies born in Ohio. Pursuant to recent legislation, the Department must include Krabbe disease screening as a part of the newborn screening panel. The amendments to the rule incorporate the additional required screening, the associated fee and notification consistent with statutory changes.
6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**
    a. Success will be measured by the addition of the Krabbe test to the newborn screening panel. This includes the acquisition of the required instruments, calibration, and validation of the testing protocols. Success will also be measured by the number of Krabbe tests completed in the newborn screening panel.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
    a. Hospitals
    b. Local Health Departments
    c. Midwives/Birthing Centers
    d. Ohio Department of Medicaid

e. Insurance Companies
f. Newborn Screening Advisory Council
g. American Sickle Cell Anemia Association
h. Ohio Hospital Association
i. Association of Ohio Health Plans
j. Medical Professionals

If applicable, please include the date and medium by which the stakeholders were initially contacted.

Stakeholders were notified and provided with a draft of the proposed rules changes via email on March 7, 2016. They were able to provide comments and participate, in person or via webinar, in the stakeholder meeting which was held on March 21, 2016.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

a. Stakeholders asked if the fee increase would still be charged if a parent chose to opt out of the screening. Since the fee is a part of the total fee charger per testing there will be no reduction in cost if a parent opts out of the screening.

b. There were concerns raised about the level of education that hospitals need to provide to the mother. ODH indicated that this is an opt out process, not a opt in process. ODH will provide written materials for hospital use.

c. Stakeholders provided feedback on the best way to communicate the decision to opt of the screening back to the bureau of public health laboratory.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

a. Data was used to determine the fee needed to implement the Krabbe screening. This cost took into account the costs of instruments, reagents, payroll, and associated overhead costs. The cost of the fee increase is only to cover the increase in expenditures required to perform the mandated testing.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

a. ODH is required by statute to conduct Krabbe screening for babies whose parents have not opted out of screening. ODH explored the possibility of outsourcing, but the costs for outsourcing exceed the cost of state operations. The agency has looked at

parsing the costs for efficiencies, however the cost to maintain the testing in the ODH lab is significantly lower than outsourcing.

11. Did the Agency specifically consider a performance-based regulation? Please explain.

a. No. The statute specifically requires that ODH conduct Krabbe screening and limits that screening to the process known as "first tier testing" by mass spectrometry.

Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

a. R.C. 3701.501 authorizes ODH to create rules for screening for the presence of genetic, endocrine, and metabolic disorders. Additionally, ODH completes the 5 year rule review to ensure that all regulations are complete, accurate and not duplicative. ODH also closely reviews all rules proposed and the rule writing language within them.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

a. ODH program staff will be conducting training, calibration, validation, and documentation of the processes required to successfully implement the testing. ODH will also produce a written notice for hospital use to provide to parents. The notice will provide information regarding Krabbe and the parents' option to forgo screening of this disease.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. **Identify the scope of the impacted business community;** the impacted business community includes hospitals, birthing centers, local health departments, and health insurance companies.

b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);** A fee increase for test kits to hospitals, birthing centers, and other entities that purchase the testing kit. Also, the additional time required by the designated person at facilities to provide the required notification and to notify ODH if a parent chooses to opt out of screening for Krabbe. This rule package implements

statutory changes by amending existing rules. The impacts articulated in this section speak directly to the amendments and not the overarching impact of the rules as a whole. The overall impact of newborn screening rules will be directly addressed in the prospective FYR of these rules.

c. **Quantify the expected adverse impact from the regulation.**
The immediate quantification of the adverse impact in the amended rules is the $11 increase to the newborn screening kit. This impact is a direct result of the legislative mandate to include the Krabbe screening; the overall adverse impact of the newborn screening rules will be addressed in the FYR of the rules. The time impact is the number of minutes it takes to properly notify parents of their rights multiplied by 140,000 births per year.
Proficiency tests, equipment purchase, or maintenance costs are estimated by amortizing the cost over the total number of samples tested per time period (one year for maintenance contracts, or the estimated life of the instrument for purchase costs).

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

a. The early identification of diseases provides optimal circumstances for treatment and cures in newborns. This early identification can prevent long term disabilities which, when identified earlier, would lower overall costs of care. These cost savings would far outweigh the cost of performing the additional testing.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The statute and therefore the rules provide options for parents to opt out of the Krabbe screening. The cost however is not mitigated with the absence of screening because the cost is a kit (all inclusive) price. There are no exemptions or alternative methods as this screening is required due to recent legislation. All babies must be tested unless the parent chooses to forgo the screening.

17. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

    There are no fines or penalties associated with OAC 3701-49-01.1, 3701-55-02 or 3701-55-04.

18. **What resources are available to assist small businesses with compliance of the regulation?**

    The laboratory has staff available to assist customers with questions they may have concerning regulations and compliance.

    More specific information is also provided on the website:

    Newborn Screening: http://www.odh.ohio.gov/odhprograms/phl/newbrn/nbfaq1.aspx.