CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: The Ohio Department of Health

Regulation/Package Title: 3701-45 Ohio Hearing Aid Assistance Program

Rule Number(s): 3701-45-01; 3701-45-02; 3701-45-03; 3701-45-04;

Date: November 8, 2013

Rule Type:

- √ **New**
- □ **5-Year Review**
- □ **Amended**
- □ **Rescinded**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.

   The 130th General Assembly earmarked funds to assist families with the purchase of hearing aids for children under age 21 with a hearing impairment. Assistance is limited to those families with incomes below 400 % of the Federal Poverty Level. These rules develop criteria for family applications, along with a sliding scale fee schedule, and criteria for audiology providers who apply for funding for audiology services and hearing aids for eligible children in eligible families.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

Ohio Revised Code, Section 3701.285.20. Mothers and Children Safety Net Services

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.

These rules do not implement a federal requirement. However, they do complement the Ohio Universal Newborn Hearing Screening (UNHS) mandate, requiring birthing hospitals to screen newborns hearing prior to hospital discharge. When the newborn who fails a hearing screening receives further evaluation and a permanent hearing loss is confirmed, an eligible child in an eligible family could apply for assistance with the purchase of hearing aids through this program.

In Ohio, infants with a confirmed hearing loss are eligible for early intervention services though the federally funded Part C program (Help Me Grow) implementing the Individuals with Disabilities Education Act (34 CFR part 303). The Part C program funds Early Intervention for families of infants and toddlers up to age three with developmental delays or disabilities.

The Health Resources and Services Administration and Centers for Disease Control both provide federal funds to Ohio via a competitive grant process to assist Ohio with identifying and tracking infants and toddlers with a hearing loss and enrolling them in early intervention.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Nothing in the state mandate governing UNHS or in federal regulation provides for the purchase of hearing aids for children with a permanent hearing loss. These proposed rules are for a safety net program for families that are not eligible for Medicaid or for Bureau for Children with Medical Handicaps (BCMH) services but may not have the financial resources or insurance coverage for hearing aids.

Both state and federal programs operating in Ohio track and identify infants and toddlers with hearing impairment and the need for early intervention. Families eligible for Medicaid and families eligible for BCMH (currently with incomes up to 200% of the Federal Poverty Guidelines) may purchase hearing aids through those programs. This earmark is intended to address the needs of families with income up to 400% of the Federal Poverty Guidelines who have no insurance, inadequate insurance coverage, or insurance with such high copayments and deductibles that it is very difficult for the family to pay for a child's hearing aids and affiliated services.

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)?**

The Ohio Department of Health (ODH), in response to Ohio Revised Code, Section 3701.285.20. Mothers and Children Safety Net Services, has developed regulations to provide a structure for application for and disbursement of earmarked funds. These rules provide clear criteria for families' and providers' applications and processes to follow for requesting assistance for the purchase of hearing aids with these funds.

3701-45-01 provides definitions of key terms in the chapter.
3701-45-02 provides instructions for administrative responsibility for the program and identifies providers who may apply for assistance for families through this program.
3701-45-03 outlines requirements for eligibility and application by eligible families.
3701-45-04 outlines requirements for providers who may identify eligible families and submit application for assistance for them under this program.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

ODH will monitor the applications for assistance and track the number of eligible families that have applied, the number of eligible children provided with hearing aids, and the number of providers who have applied for assistance for eligible families. Records of each of the referenced markers will also be tracked based on geographic location to determine general disbursement of funds within Ohio.

Records will also be kept of applications that were rejected in order to determine the need for better guidance for providers and families, improved forms, more clarification, etc. Finally, records will be kept of applications that were made but the program was unable to fund because all funds had already been expended when the application was received.

Initially, success will be determined by appropriate family application and prompt fitting of eligible child. Parameters will be developed for timeliness of response to a completed application, timeliness of delivery of requested hearing aid(s), and payment for provider services. Another measure of success will be whether our promotion of the program results in potential providers being knowledgeable about the program and referring eligible families through it so that all earmarked funds are used for their intended purpose.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
If applicable, please include the date and medium by which the stakeholders were initially contacted.

Initial stakeholders were the members of the UNHS Advisory Subcommittee of the Medical Advisory Committee. The Advisory Subcommittee includes stakeholders from an array of

professions: audiologists, speech-language pathologist, parents of a hearing-impaired child, geneticists, epidemiologist, otolaryngologist, neurologist, pediatrician, adults who are dear or hearing impaired, representative from an organization for the deaf or hearing impaired, nurses from well-baby & NICU, teacher of the deaf working with infants and toddlers, representative of the health insurance industry, Ohio Hospital Association, Bureau for Children with Medical Handicaps, Ohio Department of Education, the Ohio Department of Job and Family Services, Ohio Board Speech Language Pathology & Audiology, Regional Infant Hearing Program Project Director, and educational audiologists. Their role is to advise the Infant Hearing Program, make recommendations regarding challenges and policies, and to advise and make recommendations regarding program development and implementation related to Early Hearing Detection and Intervention.

Members of the Subcommittee were instrumental in enacting the earmark. There were discussions in person with the members of this group on May 10, 2013, August 2, 2013, and November 1, 2013. A smaller workgroup of Subcommittee members and ODH representatives held a video conference on June 12, 2013 and met in person on August 14, 2013.

There were seven face-to-face meetings in August, September, and October with key staff at ODH who could provide assistance with developing administrative guidelines, setting fee schedules, and developing forms and processes including staff from BCMH, School Health, Legislative Affairs, Legal Counsel, and Senior BCDSHN Managers. Numerous email consultations were exchanged among these staffs regarding details related to definitions, processes, format, forms, quality control, administration, and rules development.

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

As noted above, many stakeholders were engaged throughout the process of drafting and refining these rules. Stakeholders were involved in determining how the provider eligibility and responsibilities should be determined. They helped define covered services. They made recommendations for appropriate fees and co-payments. Stakeholders assisted in identifying family eligibility criteria and requirements for application.

The input of the stakeholders helped to clarify the requirements for program operation, brought recommended services and suggested fees into alignment with existing practices, and helped provide structure to the initial concept for a hearing aid safety net program.

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?**

The rules were developed with the recommendation that providers follow the standards for appropriate clinical practice as outlined in "American Academy of Audiology Clinical Practice Guidelines, Pediatric Amplification," June 2013, http://www.audiology.org/resources/documentlibrary/Documents/PediatricAmplificationGuidelines.pdf. These standards outline current state-of-the-art practice for providers who will be fitting eligible children.

Staff also considered the existing Infant Hearing Program UNHS rules, Chapter 3701-40, for congruency with definitions and recommendations from the Joint Committee on Infant Hearing, the *"Year 2007 Position Statement; Principles and Guidelines for Early Hearing Detection and Intervention Programs*, http://pediatrics.aappublications.org/cntent/120/4/898.full and the American Speech Hearing Association's "*Guidelines for the Audiologic Assessment of Children From Birth to 5 Years of Age"*, http://www.asha.org/Practice-Portal/Clinical-Topics/Permanent-Childhood-Hearing-Loss/ which also recommend best practices for diagnosing and fitting children with permanent hearing loss.

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?

ODH staff considered utilizing the BCMH program for application for hearing aids and for disbursement of funds under this new safety net provision. However, the existing BCMH program is not staffed and no guidelines are in place, to review or collect co-payments from eligible families when applicable. It was not deemed cost-effective to try to incorporate this small program with its differing income requirements for assistance and the sliding scale co-payment criteria into BCMH.

Dispensing audiologists in this safety net program, as a payer of last resort, will be asked to direct all BCMH or Medicaid eligible families to those programs. The program will be developed and monitored through the Genetics Section, Infant Hearing Program, which is focused on identifying infants and toddlers with hearing loss and ensuring they receive early intervention. This earmark program covers children up to age 21 so there will be additional coordination between the Infant Hearing Program and the School and Adolescent Heath program at ODH to publicize the program for eligible children within school settings.

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

ODH took every opportunity to specify and clarify performance measures, simplify applications, and still provide quality outcome for eligible children. The General Assembly outlined specific criteria for the use of the funds and it would be difficult to administer if

each provider were to develop a process and format for application to ODH for disbursement of funds. ODH staffs have attempted to balance the need for simple guidelines and standardization with the needs of the providers to fit the program into their existing practices with minimal disruption.

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

    ODH conducted a review of existing rules. There are no known regulations governing a program for providing assistance with the purchase of hearing aids and related audiology services for families that are not eligible for BCMH or Medicaid.

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.**

    After the rules are approved, ODH will publicly promote the program to pediatric audiologists throughout Ohio. Information, forms, and contact information will be placed on the Infant Hearing website so that it is readily available to professionals and families. Information will also be provided for School and Adolescent Health staff for distribution to school health professionals and through direct linkage on their website to the Infant Hearing web-based information. Technical assistance will be available through ODH to answer questions consistently about the application forms and processes.

    ODH staffs anticipate that a contract for a single statewide administrator to run the program will be developed, awarded, and implemented. There will be guidelines in the contract for implementation and training for contractor staff. To ensure the regulations are applied consistently throughout Ohio, ODH will monitor key points and timelines for processing applications in any contract as well as periodically reviewing geographic distribution of services and financial disbursements.

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;**
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
    c. **Quantify the expected adverse impact from the regulation.**
    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.

(a) These rules will have an impact on dispensing audiologists, primarily pediatric audiologists, who apply for assistance for eligible children under this program. ODH estimates approximately 100 pediatric audiologists could potentially be impacted (one per child served) although it is more likely that large audiology practices in urban or suburban areas will apply for assistance under this program simply because they see more patients and interact with more potentially eligible families.

(b) Several geographically-dispersed audiology practices were consulted about the safety net programs they provided for children. ODH used the information they provided to develop a definition of covered services and a fee schedule to assist in defraying basic costs of audiology providers. OHD also took their input, and that of the BCMH program, into consideration when determining appropriate subsidization of the hearing aids.

Using the earmarked funds, ODH will pay up to $2,000 for an eligible child with a binaural hearing loss under this program in state fiscal year 2014. This amount covers both the basic audiology services fee and the hearing aids. Earmark funding of $200,000 per year would enable up to 100 families to receive assistance under this program.

(c) ODH has estimated it will take an average of 2 hours for the dispensing audiology practice to explain the application to the family, collect their application form, complete the provider request for the hearing aids, gather supporting documentation, and email or fax the application forms to the administrator. For eligible families, the audiologist is ensured payment of a set amount to cover their costs for fitting the aid and the hearing aids are provided to them for the child.

On the reverse side of the ledger, if this family has no or poor insurance coverage, and is not eligible for BCMH or Medicaid, what does the dispensing audiologist currently do? Is the family offered a payment plan, and then the audiologist must spend time trying to collect full payment? Is the family turned away until they can come up with the money to cover the cost of the hearing aids? Does the audiologist provide the service and then later take a tax write-off of the cost of fitting the hearing aids and of the hearing aids or of some portion of that cost if the payment cannot be collected?

While there is time cost to the dispensing audiologist to apply, the benefit of a definite payment to cover both basic services and the hearing aids for a family that otherwise could not pay for them would seem to tip the balance in favor of "no adverse impact" or at least to a neutral balance point.

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

These new rules were created to have minimal impact upon the dispensing audiologists while meeting the requirements of Amended Substitute House Bill Number 59, Section 285.20 of the 130th General Assembly requiring ODH set forth rules for distributions of the appropriations designated to assist Ohio families with children under twenty-one years of age with a permanent hearing loss in purchasing hearing aids.

Regulatory Flexibility

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

There are no exemptions or alternative means of compliance for small businesses under these new rules. However, there is no requirement for any small business to participate in this program. The business is free to use any other sources of funds that may be available to them for their patients. The business, without penalty, may decide the reimbursement for services and the hearing aids under this program are not something they want to pursue for their patients. This program, governed by these rules, are simply intended to provide another source of funds available to dispensing audiologists for providing services and hearing aids to eligible families.

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?

These rules do not impose fines or civil penalties. For those providers that choose to participate in the program, technical assistance will be available if there are questions about the application or the selection of the hearing aids, or incomplete applications are submitted and information is needed to verify family eligibility and/or to process the purchase of hearing aids.

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

ODH will be promoting the program on-line through the Help Me Grow, Infant Hearing Program, website including email and telephone contact information for program consultation and technical assistance. The Board of Speech-Language Pathology and Audiology has agreed to publicize the program to their members and the School and Adolescent Health program will be asked to publicize the program and to link to the Infant Hearing site. ODH anticipates awarding a contracting for administration and the contract

will also include a requirement to make available a contact person for questions from professionals.