

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: The Ohio Department of Health

Regulation/Package Title: 3701-8 Help Me Grow

Rule Number(s): Amend 3701-8-01; 3701-8-03; 3701-8-04; 3701-8-06; 3701-8-06.1; 3701-8-07; 3701-8-07.1; 3701-8-08.1; 3701-8-09; Rescind 3701-8-08 and replace with new 3701-8-08

Date: December 31, 2013

Rule Type:

☒ **New**

☐ **5-Year Review**

☒ **Amended**

☒ **Rescinded**

The Common Sense Initiative was established by Executive Order 2011-001K 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 rule package outlines regulations for participants and providers in Help Me Grow, which includes Ohio's statewide prenatal to age three Home Visiting and Early Intervention programs administered by the Department of Health. The Help Me Grow Early Intervention program for infants and toddlers with disabilities fulfills Part C of the Individuals with Disabilities Education Act and carries with it the federally mandated regulations for early intervention service

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providers which are included in this rule package. The package also includes regulations for the statewide Help Me Grow Home Visiting program, supported by state general revenue funds.

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

Revised Code Section 3701.61

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.

The rules within this package related to Help Me Grow Early Intervention implement federal requirements under Part C of the Individuals with Disabilities Education Act [Public Law 105-17 (20 USC 1437(a))], which is the federal law for the Early Intervention Program for Infants and Toddlers with Disabilities. The regulations for this federal law (34 CFR part 303) were revised and re-issued on September 28, 2011. These rules are required to comply with federal law and to maintain federal Part C funding in Ohio no later than June 30, 2014. The updated federal regulations for Part C of the Individuals with Disabilities Education Act, as well as Ohio-specific feedback on already established rules from the US Department of Education, require clarified definitions and expectations for state early intervention lead agencies specifically around the use of public and private insurance, personally identifiable information, and the frequency of, and mandated participants for Individualized Family Service Plan (IFSP) meetings.

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

Section 3701.61 of the Ohio Revised Code requires the Director of the Ohio Department of Health to adopt the rules necessary and proper to implement the Help Me Grow program, which includes both Help Me Grow Home Visiting and Help Me Grow Early Intervention. While there are no federal regulations pertaining to the Home Visiting program, there are for the Early Intervention program. The proposed Early Intervention rules are aligned with the federal law for Early Intervention and include the following instances when the rule exceeds federal regulations:

3701-8-04: Follow up information is provided to professional referral sources. Although not required in federal regulations, the federal regulations require the state to provide a “comprehensive, coordinated system” for children in Early Intervention. Via public comment, ODH has heard from medical and service providers that they make referrals into Help Me Grow and never hear back about the result of their referral. While protecting confidentiality, this requirement was included to help referral sources know that their referrals were received by

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HMG service providers. The revised HMG Referral Follow-up form, as revised, allows for parents to consent for information sharing at the time of referral; therefore addressing the concern of stunted follow-up to providers as well as ensuring informed consent.

3701-8-07 and 3701-8-06.1: Requires a nutrition screening be done with children, unless they are receiving Women, Infants, and Children (WIC) services, have a nutrition-linked condition, or had a comparable screening within the past ninety calendar days. This requirement goes beyond the federal regulations, but it is recognized as necessary and important because of the known link between nutrition deficits and developmental delays, and because nutrition services are one of the seventeen early intervention service types required by federal law.

This rule package also includes regulations for the home visiting program as established in state statute, but not federal law.

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 public purpose for this regulation is to provide program grantees and contractors with standards, requirements and minimum expectations for delivery of the program services. These regulations are necessary to implement the federal provisions of the Individuals with Disabilities Education Act for infants and toddlers in Ohio. More specifically, Help Me Grow Early Intervention provides a statewide comprehensive, coordinated, multidisciplinary, interagency system of supports and services to infants and toddlers with disabilities and/or developmental delays and their families.

The regulations are also necessary to implement the Help Me Grow statewide Home Visiting program as established in state statute and funded by the Ohio General Assembly. Help Me Grow Home Visiting provides a program to first time pregnant women and first time parents of infants and toddlers. This programs goal is to increase healthy pregnancies, increase the confidence and competence of parents to raise very young children, make meaningful needs-based referrals to community supports, and to transition children to a development-enhancing program by the time they are three years old.

These rules establish the standards for both Help Me Grow programs and are designed to assure the achievement of the goal-related outcomes for the participants. For example, the rules require all providers to enter information into a centralized database so that outcomes can be measured, the impact of the program can be evaluated, and the return on the investment can be calculated.

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

ODH will monitor the Help Me Grow Home Visiting contractors for compliance with the standards set forth in these rules. Success will be measured by using the statewide web-based data system which includes participant outcomes, technical assistance staff, monthly professional development calls with providers, and reporting the results of performance-based monitoring. Success of the Early Intervention program will be measured in the same way, but also will include 14 indicators of federal compliance and performance-based outcomes as set forth by the federal Office of Special Education Programs within the U.S. Department of Education.

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.*

Numerous stakeholders have been meeting in person quarterly and by conference call monthly since March 2013. The table in Appendix 1 provides the list of invited participants.

The draft rules are being posted for public comment (inclusive of this document) for a minimum of 60 calendar days December 2013 – February 2014. Each time the rules package was posted, emails alerted interested parties of the timeline and method to provide public comment.

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 have been engaged throughout the revision process. As public comment is collected, it will be analyzed, summarized, and either result in further rule revision or not. Each comment will be considered thoroughly and an explanation will be provided to the public.

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?

For Early Intervention, the rules were developed using the federal law and regulations provided September 28, 2011. Other documents which reflect the state of the science on early childhood development and provided by the US Department of Education's Office of Special Education Programs (USDOE/OSEP), the National Early Childhood Technical Assistance Center (NECTAC), the Infant and Toddler Coordinator's Association (ITCA), Early Intervention Family Alliance (EIFA),

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Early Childhood Outcomes Center (ECO), and the Data Accountability Center (DAC), were also used.

For Home Visiting, the rules were developed using the research literature on home visiting as well as federal guidance provided by the U.S. Department of Health and Human Services including, The Design Options for Maternal, Infant, and Early Childhood Home Visiting Evaluation (DOHVE) Technical Assistance (TA) Team, and the scientific data provided by the Nurse-Family Partnership and Healthy Families America.

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?

Many alternatives were considered. Some examples include: various models of home visiting, including variations in visit schedule, criteria for inclusion as a provider; caseload and supervision requirements; diagnoses included on the Early Intervention conditions list and the whole of the criteria for eligibility (an entire workgroup was convened to consider alternatives to the existing criteria). Drafted rules fulfill the requirements of the federal Individuals with Disabilities Education Act, Part C and maintain the home visiting standards put into place in July 2010 with the new Help Me Grow Home Visiting program. More flexibility was added, but the model of home visiting maintained is the same to maximize consistency in order to evaluate the effectiveness across time. The inclusion of stakeholders throughout the revision process has allowed for the rule package to be discussed with various alternatives considered and debated.

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.*

Yes, the ODH did consider performance-based regulations throughout the proposed rule package. Specific examples include outlining the activities required by the federal law for service coordinators in Early Intervention without mandating a maximum caseload of children to each service coordinator and eliminating the minimum number of supervision hours required for service coordinators and home visitors. The ODH took every opportunity to specify and clarify the exact performance measures it is held to by the federal law for Early Intervention without inserting additional proxies for quality outcome measures. This new approach focuses more on outcomes than process.

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

The ODH conducted a review of existing rules and included representatives from other state agencies in the monthly stakeholder meetings. This rule package does not duplicate existing Ohio regulation because it is specific to Help Me Grow.

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.

Once the rules are final, the ODH will provide training on the new rules for all interested parties, including service providers, parents, and referral sources. The agency will host a statewide meeting for providers in June 2014 where the rules will be presented by contractor type which will allow for pre-implementation questions and answers. In addition to this burst of training using a variety of electronic and in-person methods of delivery, the ODH will update its Home Visiting Program manual and create an Early Intervention Program manual; as well as update its website with applicable guidance and training related to these revisions in rule.

To ensure that the regulation is applied consistently throughout all 88 Ohio counties, the ODH will continue its technical assistance using four Early Intervention and five Home Visiting program consultants. New this year are three additional Early Intervention program consultants employed with Part C federal funds at the Ohio Department of Developmental Disabilities. All program consultants are available by phone and email for program-related technical assistance, as well as for local provider-requested on-site training and technical assistance visits. The program's data and monitoring teams will continue to provide guidance in meeting program outcomes and data quality procedures. Through the use of program-specific reports, consultants help service providers identify areas of non-compliance or obstacles to implementation and use improvement plans to strategize solutions.

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.

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- (a) In addition to local governmental agencies, businesses that may enter into a contractual relationship to provide Help Me Grow services include, but are not limited to, non-profit agencies; for-profit entities or licensed professionals that provide early childhood health, social or education services, and hospitals.
- (b) These rules establish standards for entering into a voluntary contractual relationship with the Ohio Department of Health to carry out services in the HMG programs. In this coming year, ODH anticipates approximately 90 governmental agencies will participate in the HMG program through a grant or agreement relationship. ODH also anticipates approximately 90 businesses will participate in HMG through contract with the ODH. These rules set forth requirements that the contractors must meet in order to maintain a contract with ODH. In addition, the rules list remedies ODH may take if ODH determines the contractor does not comply with these rules and the terms of the contract, including a corrective action plan, attendance at mandatory training, compensating families in early intervention for failure to provide services under federal early intervention; return of ODH funds or withholding future funds; and suspension or termination of contract. The ODH has analyzed and responded to each assertion of a negative business impact and believes that the impact is minimal. With the explanation of the allocation table out to potential providers, the ability to sub-contract services, and the reimbursement for services structure, the ODH has anticipated and provided for concerns expressed about transitioning families, providing services before reimbursement is available, affiliating with an evidence-based home visiting model, the potential delay in receiving funds and being able to get those funds into sub-contracts, as well as forecasting counts of referrals and children served in the most generous possible way based on actual performance over the past two years.

Moreover, while the relationship is voluntary, the ODH acknowledges the impact on businesses regarding submission of reports. Quarterly fiscal and program reports, while not burdensome, impact personnel time in preparation and submission. The requirements are justified because quarterly reporting holds contractors accountable for their use and documentation of use of public funds for the purpose and intent they were allocated. The reports also assist the ODH with monitoring contractors for potential fiscal or programmatic red flags.

- (c) For those businesses that seek and are approved for a contract or grant, the rules require an investment of time to comply with these regulations and the terms of the contract or grant. Agencies that demonstrate that they can comply with the rules and then choose to enter into a contract or grant with ODH to provide Home Visiting or Early Intervention services will have to employ or subcontract with qualified staff that can provide the defined service, enter accurate data into the centralized system, ensure parent's rights, etc. These standards define a more standardized service that also means higher accountability for reporting and fiscal bookkeeping, billing, applications, and training. The ODH has continued to respond with funds to Home

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Visiting providers in order to work toward model affiliation, train staff, and seek and find referrals for the program.

In addition, ODH trainings are provided at no cost, other than the trainees' travel and time, and technical assistance is provided directly to the service providers.

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

These rules have minimal adverse impact to businesses due to the voluntary nature of the relationship. The rules are justified given that the Ohio Revised Code Section 3701.61 sets forth the requirements for ODH to administer the Help Me Grow programs and develop rules to monitor the dissemination of public money to local communities throughout the state through contract, grant, or subsidy agreement. Furthermore, the requirements applicable to the early intervention program are necessary for Ohio to continue receiving federal funding under Part C of the Individuals with Disabilities Education Act (IDEA).

Regulatory Flexibility

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

Under the federal IDEA, Part C law and regulations, the state of Ohio must enforce minimum requirements and provide assurances of written policies which uphold the law and allow the state to monitor and sanction local service providers when non-compliant. The federal law and regulations require the state's lead agency, the ODH, to collect consistent, valid and reliable data with which to report in the required annual performance report to the U.S. Department of Education. However, wherever there was room for flexibility, the drafted rules preserve and provide decision making to service providers. There are instances where a policy or process is required, rather than specifying a required form, because retaining flexibility was an important goal of these rules.

The money to administer and serve families in Help Me Grow is distributed through grants, subsidy agreements, or contracts which are voluntary. There are no requirements in these rules which prohibit small businesses from conducting their business without the money distributed by the ODH.

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. The federal law mandates the documentation needed for Early Intervention such that when data is examined for compliance with the federal law (which, the ODH must do and report on an annual basis), data is always verified by requesting and examining actual records of program participants. Therefore, requiring paperwork is a requirement of the Office of Special Education Programs at the U.S. Department of Education, which funds Early Intervention and is aligned with what social workers and nurses must do as licensed practicing professionals. The rules state explicitly that providers of services will be notified of identified non-compliance and will be provided technical assistance (TA) to remedy the problems or issues related to paperwork violations. The ODH is committed to working with service providers in this way, through corrective action plans and providing TA as well as training before taking further action like withholding money from a contractor, suspending or terminating a contract.

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

The ODH has already planned for training (both on-line and in-person) local providers statewide, providing technical assistance and program consultation on these new rules. Monthly update and informational calls already exist and are planned to continue for service providers to ask questions about rules, procedures, and expectations. There will also be training and follow up on what the new rules mean, how to implement them, timelines for implementation, and reporting and monitoring requirements.

In addition to the resources provided by the program staff at the ODH, there are numerous national resources which we have, and will continue to use for ourselves and local service providers, especially in the area of fulfilling the federal Part C of IDEA law and regulations, including the National Early Childhood Technical Resource Center (NECTAC) and the North Central Regional Resource Center (NCRRC), the Evidence-Based Home Visiting Center; and in-state resources like Ohio Train (for on-line trainings) and the Ohio Professional Development Network registry (for individual credentialing in HMG).

Finally, the ODH employs individuals within the programs who monitor the adherence to federal and state rule, where applicable. Utilizing the web-based statewide data system, program consultants, researchers, and monitoring personnel work together to identify areas of non-compliance with rule and once it is identified, work with local service personnel to resolve the issues. This monitoring is continual and ever evolving; service providers use strategies for self-monitoring, working to self-correct before a problem, habit, or misunderstanding of program rule becomes systemic.

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Appendix 1: Rule Revision (3701-8) Stakeholder Involvement

Early Intervention Stakeholders Includes HMG Early Intervention Advisory Council March 2013 – Currently meeting once/month	
Name	Organization
Michelle Albast	Child Care/Ohio Department of Job & Family Serv.
Melissa Arnold	Ohio Association of American Pediatrics
Ronni Bowyer	Parent of children with disabilities
Kellie Brown	County Board of Developmental Disabilities
Peg Burns	Ohio Council of Behavioral Health Providers Association: Mental Health
Katrina Bush	Ohio Department of Developmental Disabilities
Joyce Calland	Ohio Family & Children First
Brenda George Brodbeck	EI Prof. Dev. Occupational Therapy, OSU
Kim Christensen	EI Professional Development, BGSU
Tom Dannis	Ohio Department of Education; Homeless youth
Cindy Davis	Family & Children First Coordinators Association
Margaret Demko	Family & Children First Coordinator
Robert Denhard	Ohio Department of Insurance
Laurie Dinnebeil	EI Professional Development, Univ. Toledo
Sandi Domoracki	Service Provider/RIHP
Verline Dotson	HMG EI Advisory Council
John Duby	EI Provider Pediatrician
Denielle Ell-Rittinger	Child Welfare/ Ohio Department of Job & Family Services (CAPTA)
Marilyn Espe-Sherwindt	EI Service Provider Akron Children's Hospital/ Family & Child Learning Center
Sharon Gibbs	HMG Contract Manager
Wendy Grove	Ohio Department of Health

Name	Organization
Kim Hauck	Ohio Department of Developmental Disabilities
Earnestine Hargett	Disability Rights Ohio
Esther Borders	EI Service Provider: County Board of Developmental Disabilities
Shawn Henry	Ohio Center for Autism and Low Incidence
Karen Hughes	Ohio Department of Health/Title V
Terry Jones	Ohio Department of Mental Health
Monica Juenger	Governor's Office of Health Transformation
Jennifer Justice	Child Welfare/ Ohio Department of Job & Family Services (CAPTA)
Vicki Kelly	EI Service Provider: Community
Alicia Leatherman	Child Care/ Race to the Top: Early Learning Challenge Grant
Urvia LeSure	Head Start
Julie Litt	EI Service Provider: County Board of Developmental Disabilities
Melissa Manos	HMG EI Service Coordination Contract Manager
Leslie McClain/Dustin McKee	Ohio Association of County Boards
Deb Moscardino	Ohio Department of Medicaid
Nancy Neely	County Boards of Developmental Disabilities Superintendents
Kristie Pretti-Frontczak	EI Professional Development, B2K
Ilka Riddle	University Centers of Excellence/Cincinnati
Paula Rabidoux	Professional Development, Speech-Language Pathology, OSU
Angel Rhodes	Governor's Office, Early Learning
Amanda Runyon-Lynch	Parent of a child with disabilities
Angela Sausser-Short	Ohio Family & Children First

Name	Organization
Stephanie Siddens	Early Learning Education/ Race to the Top: Early Learning Challenge Grant
Pam Stephens	EI Service Providers: County Board of Developmental Disabilities
Yolanda Talley	Ohio Department of Medicaid
Gary Tonks	ARC
Sheila Torio	HMG EI Advisory Council
Kim Travers	Parent of children with disabilities/HMGAC Co-chair
Kay Treanor	Ohio Developmental Disabilities Council
Barb Weinberg	Part B IDEA 619/Ohio Department of Education
Jane Whyde	Family & Children First Coordinators Association
Jennifer Wissinger	Professional Development, Physical Therapy
Sharon Woodrow	County Boards of Developmental Disabilities Superintendents