ACTION: Final



Common Sense

DATE: 11/08/2023 8:20 AM

Initiative

Mike DeWine, Governor Jon Husted, Lt. Governor Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: OHIO DEPT. OF AGING			
Rule Contact Name and Contact Information: Tom Simmons rules@age.ohio.gov			
Regulation/Package Title (a general description of the rules' substantive content): OLDER AMERICANS ACT NUTRITION PROGRAM: DIET ORDERS Chapter 173-3 of the Administrative Code establishes requirements to include in, or exclude from, AAA-provider agreements (i.e., contracts) that are paid, in whole or in part, with Older Americans Act funds.			
Rule Number(s): 173-4-05 and 173-4-06			
Date of Submission for CSI Review: July	20, 2023		
Public Comment Period End Date: August 2, 2023 at 11:59PM.			
Rule Type/Number of Rules: New/# rules	□ No Change/# rules (FYR? □)		
✓ Amended/2 rules (FYR? \square) \square Rescinded/# rules (FYR? \square)			

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

Please review the next page.

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The rule(s):

□ a.	Require	a license,	permit,	or any	other	prior	authorization	to	engage	in	or
	operate a	line of bu	siness.								

- □ b. Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- ☑ c. Requires specific expenditures or the report of information as a condition of compliance.
- ☐ d. Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

The rules in this package establish requirements to include in, or exclude from, AAA¹-provider agreements (*i.e.*, contracts) that are paid, in whole or in part, with Title III-C Older Americans Act funds.

Rule 173-4-05 of the Administrative Code establishes requirements for AAA-provider agreements on nutrition projects. ODA proposes to amend this rule to achieve the following:

- Replace "consumer" with "consumers" in paragraph (A)(4)(c) of this rule.
- Delete "medical food or food for special dietary use" from paragraph (A)(10) of this rule.
- Indicate in paragraph (A)(10) of this rule that a diet order is not required for a therapeutic diet if the consumer chooses the therapeutic diet out of preference. This will correspond with the requirements in paragraph (A)(9) of this rule and 42 U.S.C. 3030g-21 to adjust meals to meet any special dietary needs of consumers, including meals adjusted for cultural considerations, and preferences, and medically-tailored meals.
- Prohibit a provider from paying for any supplement with Older Americans Act funds, unless the supplement is part of (vs. separate from) a meal with a therapeutic diet.

Rule 173-4-06 of the Administrative Code establishes diet-order requirements for AAA-provider agreements on nutrition projects. ODA proposes to amend this rule to achieve the following:

- Delete references to "food for special dietary use" and "medical food" from this rule.
- Allow the provider to provide a therapeutic diet to a consumer without a diet order if it is the consumer's preference to choose a therapeutic diet. See paragraph (B)(2)(a) of this rule and the corresponding change in paragraph (B)(2)(e) of this rule.

¹ "AAA" means "area agency on aging."

3. Please list the Ohio statutes that authorize the agency, board or commission to adopt the rule(s) and the statutes that amplify that authority.

R.C. §§ 121.07, 173.01, 173.02, and 173.392.

4. 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.

<u>42 U.S.C. 3025</u> says ODA is "primarily responsible" for Older Americans Act policy development in Ohio and 45 C.F.R. 1321.11 requires ODA to "develop policies governing all aspects of [Older Americans Act] programs."

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

These rules exist to implement the state laws ODA listed in its response to #2, which require ODA to establish the standards for AAA-provider agreements, and the federal law and federal regulation ODA listed in its response to #3, which require ODA to develop policies for all aspects of the Older Americans Act programs in Ohio.

6. 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)?

These rules exist to (1) comply with the state laws mentioned in ODA's response to #3, which require ODA to establish requirements for AAA-provider agreements, and (2) ensure necessary safeguards are in place to protect the health and safety of consumers receiving services paid with Older Americans Act funds.

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

To ensure compliance fostering the health and safety of consumers receiving services paid with Older Americans Act funds and compliance with monitoring (*i.e.*, auditing) requirements under 45 C.F.R. Part 75, Subpart F: (1) ODA regularly monitors AAAs for compliance with these rules and (2) AAAs regularly monitor providers for their compliance with AAA-provider agreements, the rules are judged as being successful when (1) ODA funds few violations in AAA-provider agreements and (2) AAAs find few violations against AAA-provider agreements.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. 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.

ODA's guide <u>Participating in ODA's Rule Development</u> and the <u>main rules webpage</u> on ODA's website encourage stakeholders and the general public to give input on improving ODA's rules and provide contact information for doing so. From each rule's effective date to the date of this BIA, ODA has received no input from stakeholders or the general public on any rule in this package via this method.

On May 24, 2023, the Common-Sense Initiative (CSI) emailed ODA and ODM to inform our departments that Meals on Wheels of Southwest Ohio and Northern Kentucky, a provider, and the Council on Aging of Southwest Ohio, an area agency on aging, jointly raised concerns about diet-order requirements in ODA's and ODM's rules with CSI.

CSI followed-up by scheduling a virtual meeting for ODA, ODM, CSI, the provider, and the AAA.

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

The concern in the May 24, 2023 email was that ODA's rule 173-4-06 of the Administrative Code and ODM's rule 5160-44-11 of the Administrative Code require diet orders for therapeutic diets/meals while the rules of neighboring states do not. The provider and AAA said that diet orders were difficult to obtain from physicians, which leads to delays in being able to provide consumers with therapeutic diets.

On April 17, 2023, ODA, ODM, CSI, the provider, and the AAA met to discuss the matter. ODA indicated that Indiana and Pennsylvania also require diet orders (see table below), but the provider insisted that if those states require diet orders, they do not enforce those requirements.

NEIGHBORING STATES' REQUIREMENTS			
IN's Older Americans Act Program	The FSSA Division of Aging Operations Manual requires a diet order from a physician that is dated, includes a diagnosis, and has an expiration date which may not be more than one year into the future. The Indiana FSSA confirmed this on April 10.2 Additionally, FSSA shared its list of therapeutic diets found in the operations manual, which did not include mechanically-altered meals (modified meals), but did include the following: 11. Carbohydrate Restricted Diet. 12. Low-Concentrated-Carbohydrate Diet. 13. Fat Restricted Diet. 14. Fiber-Restricted Diet. 15. High-Fiber Diet. 16. High-Calorie, High-Protein Diet. 17. Long-Chain-Triglyceride-Restricted or Medium-Chain-Triglyceride Diet. 18. Purine-Restricted Diet. 19. Tyramine-Controlled Diet. 20. Modified Mineral Diets, including a calcium-rich diet, iron-rich diet, potassium-modified diet, or sodium-restricted diet.		
IN's Aged & Disabled Medicaid Waiver Program	IN's approved Medicaid waiver application (10/14/2022) requires a physician's order for diet modifications. 455 IAC Article 2 does not cover the topic.		

² Stephanie Laskey, Senior Project Manager, Indiana Family and Social Services Administration: Division of Aging, email to Tom Simmons on April 10, 2023.

	NEIGHBORING STATES' REQUIREMENTS
KY's Older Americans Act Program	910 KAR 1:190 establishes the requirements for the Older Americans Act Nutrition Program in that state. The rule does not mention diet orders or therapeutic meals, but does mention mechanically-altered meals (modified meals) and does not require a diet order for those meals.
KY's Medicaid waiver programs	907 KAR 7:010 establishes the requirements for KY's Medicaid waiver programs. The rule does not mention therapeutic meals, diet orders, or modified meals.
MI's Older Americans Act Program	Michigan's Aging & Adult Services Agency established its operating standards in a manual rather than in rules. The meal planning portion of the manual considers mechanically-altered meals to be choices to be offered to consumers as part of person-centered planning. ³ The manual also repeats the language from the Older Americans Act that allows providers to adjust nutrition according to dietary needs and preferences. ⁴ The manual does not mention diet orders.
MI's MI Choice Program	MI's approved Medicaid waiver application (03/15/2022) mentions specialized and therapeutic diets, but does not mention diet orders.
PA's Older Americans Act Program	Aging Program Directive 15-03-02 regulates the Older Americans Act Nutrition Program in PA. The directive requires signed diet orders—literally <i>diet prescriptions</i> —for therapeutic diets, recommends nutrition counseling, and requires special monitoring. It includes a sample diet order. The directive does not consider a mechanically-altered meal to be a therapeutic diet.
PA's Medicaid Waiver Program	PA appears to operate the statewide Community HealthChoices program by giving an MCO authority over specific PA geographic regions and allowing each MCO to establish standards for that region (<i>e.g.</i> , in a provider manual).
WV's Older Americans Act Program	Neither the <u>Older Americans Act Policy Manual</u> nor the <u>Older Americans Act Nutrition Services Operations Manual</u> mentions diet orders or modified meals. The nutrition manual mentions <i>medical</i> meals, but says nothing about any special requirements for those meals. The Bureau of Senior Services confirmed that WV does not require diet orders for medical meals or therapeutic diets. ⁵
WV's Medicaid Waiver Program	<u>Title 76 of the WV Code of State Rules</u> does not mention therapeutic meals, diet orders, or modified meals. The Bureau of Senior Services confirmed that WV does not require diet orders for medical meals or therapeutic diets. ⁶

11. 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?

NA

12. 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?

R.C. §173.392 requires ODA to adopt rules to establish requirements for AAA-provider agreements. Additionally, the federal law and regulation ODA listed in its response to #3 require ODA to develop policies for all aspects of the Older Americans Act programs.

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

R.C. §173.392 authorizes only ODA to adopt rules to establish requirements for AAA-provider agreements.

⁴ Pg. 17.

³ Pg. 15.

⁵ Julie Craigo, West Virginia Bureau of Senior Services, email to Tom Simmons, April 13, 2023.

⁶ Ibid.

14. 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.

Before the proposed amendments take effect, ODA will send an email to subscribers of our rule-notification service to feature the rules. Through regular monitoring (*i.e.*, auditing) requirements under 45 C.F.R. Part 75, Subpart F: (1) ODA regularly monitors AAAs for compliance with these rules and (2) AAAs regularly monitor providers for their compliance with AAA-provider agreements.

Adverse Impact to Business

- 15. 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; and

Every nutrition provider/project with an AAA-provider agreement.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

The adverse impact of these rules is to ensure every AAA-provider agreement complies with the general requirements for AAA-provider agreements in rule 173-3-06 of the Administrative Code plus specific requirements for each service listed in individual rules of this package.

ODA's proposed amendments to these rules will reduce the adverse impact upon providers.

Providers establish the rate they are paid when they respond to a request for proposal (RFP) by submitting their bid to the AAA for how much they will charge per unit {i.e., per job (e.g., grocery shopping assistance), per item (e.g., a meal), or per a period of time (e.g., nutrition counseling)}. The amount an AAA pays a provider is an all-inclusive rate. It's intended to cover all costs incurred in providing the project or service, including administration, training, and reporting. Therefore, the provider's bid includes all costs anticipated in providing the project or service.

If the provider's bid wins, the provider is paid what it bid during the open and free competition for the AAA-provider agreement (*cf.*, 45 C.F.R. 75.329 and rules 173-3-04 and 173-3-05 of the Administrative Code).

16. Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. (Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors.)

Yes. Paragraph (A)(9) of rule 173-4-05 of the Administrative Code and 42 U.S.C. 3030g–21 currently require providers to adjust meals to meet any special dietary needs of consumers, including meals adjusted for cultural considerations, and preferences, and medically-tailored meals. ODA's proposal to amend rules 173-4-05 and 173-4-06 of the Administrative Code to allow provider to provide a therapeutic meal to a consumer who chooses that therapeutic meal by preference without obtaining a diet order from a licensed healthcare professional before doing so.

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

R.C. §173.392 requires ODA to develop rules establishing standards for AAA-provider agreements (*i.e.*, contracts and grants) and R.C. §173.01 requires ODA to represent the interests older Ohioans. Establishing standards for AAA-provider agreements in the rules of this package ensures the health and safety of the older Ohioans who are consumers of services through Older Americans Act programs, which fulfills both statutes.

There is no requirement for a provider to enter into an AAA-provider agreement in order to provide services in this state. An AAA-provider agreement is not a gateway to doing business in Ohio. Instead, a provider who wants to add the Older Americans Act programs to its lines of business may enter into an AAA-provider agreement in order for those Older Americans Act programs to pay the provider for the services it wants to provide to the consumers of those programs.

Additionally, providers voluntarily bid for AAA-provider agreements. A provider is only required to comply with an AAA-provider agreement if (1) the provider bids on providing the service to be paid with Older Americans Act funds, and (2) the provider's bid is a winning bid. Providers may provide the same service without entering into an AAA-provider agreement when paid by private pay, third-party insurers, or other government programs that do not use Older Americans Act funds.

Lastly, ODA's proposed amendments will reduce the regulatory burden on providers, as noted in ODA's response to question # 16.

Regulatory Flexibility

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

Because the primary purpose of these rules is to ensure the health and safety of consumers receiving services paid with Older Americans Act funds, these rules treat all providers the same, regardless of their size.

19. 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?

ODA is concerned primarily about protecting the health and safety of consumers receiving services paid with Older Americans Act funds through compliance with these rules. Whenever possible, ODA or AAAs will treat administrative violations that do not involve health and safety as opportunities for improvement through warning notices and solicitation of corrective action.

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

ODA and AAAs are available to help providers of all sizes with their questions. Any person may contact <u>Tom Simmons</u>, ODA's policy development manager, with questions about ODA's proposals for these rules.