

DATE: 10/11/2019 12:31 PM Empowering Elders. Strengthening Communities.

Mike DeWine, Governor Ursel J. McElroy, Director

PUBLIC-COMMENT PERIOD NURSING HOME QUALITY INITIATIVE

August 21, 2019

ODA reviewed Chapter 173-60 of the Administrative Code and now proposes to amend that chapter's rules.

Please feel free to review ODA's proposed amendments to the rules and the business impact analysis (BIA) to those rules. Please also feel free to offer recommendations for improving the rules and BIA. Submit recommendations to rules@age.ohio.gov no later than Wednesday, September 4, 2019 at 11:59PM.

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Business Impact Analysis

Agency, Board, or Commission Name	: OHIO DEPT. OF AGING
Rule Contact Name and Contact Info	rmation: Tom Simmons <u>rules@age.ohio.gov</u>
NURSING HOME QUALITY INITIA These rules (1) establish the requirements for become	oming an ODA-approved quality-improvement project, (2) establish the ement projects, and (3) require the publication of quality-improvement
Rule Number(s): Chapter 173-60 (173-60-01,	173-60-02, 173-60-03, 173-60-04)
Date of Submission for CSI Review: A	ugust 21, 2019
Public Comment Period End Date: Sep	otember 4, 2019 at 11:59PM.
Rule Type/Number of Rules:	
☑ New/2 rules	\square No Change/ 0 rules (FYR? \boxtimes)
✓ Amended/# rules (FYR? ✓)	☑ Rescinded/2 rules (FYR? ☑)

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.

The rule(s):

\Box a	Require	a license,	permit,	or any	other	prior	authorization	to	engage	in	or
	operate a	line of bu	isiness.								

- □ 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.

ODA proposes to make no substantive changes to this chapter (*i.e.*, the NHQI rules). Instead, ODA proposes to improve the NHQI rules with the following non-substantive changes:

- Add "Nursing home quality initiative:" to the beginning each rule's title because analysis shows most "hits" to links for rules published on ODA's website are from internet searches and adding the name of the program to each rule will help the public to find these rules when conducting such searches.
- Rename the <u>website</u> referenced in 173-60-01, 173-60-03, and 173-60-04 as the "Nursing Home Quality Initiative" website, which aligns the website's name with the name of the initiative in R.C. §173.60.
- Delete the date of July 1, 2013 from 173-60-01 since it is no longer necessary.
- Delete "ODA's" and "of quality improvement projects" from the title of 173-60-02.
- Replace in 173-60-03 "propose that ODA approve its project sending a description of the project to the email inbox that ODA provides on the...website" with "apply for ODA approval of its project by completing the application found by following the 'submit your proposal here' link on the...website."
- Insert the URL https://aging.ohio.gov/nursinghomequalityimprovement after the first occurrence of "website" in 173-60-03.
- Delete (A)(2) from 173-60-03 because R.C. §121.75 allows ODA to incorporate the online application by reference if the online application requests information, but does not create a principle of law not found in the rule. This also involves deleting a reference to (A)(2) in (A)(3) [which became (A)(2) after the deletion of (A)(2).
- Replace "email" with "application" in 173-60-03(A)(3) [which became (A)(2) after the deletion of (A)(2)].
- Replace the mistaken use of "will" with "shall" in 173-60-03.
- Replace "each quality improvement project that it has approved" in 173-60-04 with "each approved quality improvement project."

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- Replace "to demonstrate compliance" in 173-60-04 with "to demonstrate the nursing home's compliance with section 3721.072 of the Revised Code."
- Replace "criteria" with "requirements" in 173-60-01, 173-60-02, and 173-60-03.
- Define "ODA" and "ODH" and use both acronyms throughout this chapter instead of the "Ohio Department of Aging" and the "Ohio Department of Health."
- Delete unnecessary use of "that" throughout this chapter.

Because the amendments to 173-60-03 and 173-60-04 comprise approximately 50% of the text, ODA proposes to file these rules as proposed new rules instead of proposed amended rules to comply with §4.3.1 of the Legislative Service Commission's *Rule Drafting Manual.*

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

R.C. §§ 173.01, 173.02, and 173.60.

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.

NHQI rules exist to comply with the state laws mentioned in ODA's response to #2. Although, no federal rules require NHQI, compliance with NHQI satisfies requirements for federal rules. For more information, please review ODA's response to #15 (last paragraph).

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

The rules exist to comply with the state laws mentioned in ODA's response to #2.

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 are vital to the success of the Nursing Home Quality Initiative. They accomplish the following:

- The rules establish the requirements for becoming an ODA-approved quality-improvement project.
- The rules establish the approval and rescission process for quality-improvement projects.
- The rules require the publication of quality-improvement projects on the Nursing Home Quality Initiative website.
- 7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

ODA considers these rules to be successful when sponsoring entities propose new projects to ODA and when nursing homes participate in those projects.

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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.

On July 30, 2019, ODA emailed the following stakeholders to request their input on improving this chapter of rules:

- Chris Murray of the Ohio Academy of Senior Health Sciences, Inc.
- Mandy Smith of the Ohio Health Care Association.
- Stephanie DeWees and Anne Shelley of LeadingAge Ohio.
- Shelly Szarek-Skodny of the Ohio Person-Centered Care Coalition.
- Jayson Rogers of the Ohio Dept. of Health.
- 10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

In its August 15, 2019 email response to those comments, ODA said that it recently added a new portal to the NHQI webpage through which sponsoring entities may more easily submit proposed quality-improvement projects. ODA proposes to amend 173-60-03 accordingly. Although the comments are on the NHQI program instead of the NHQI rules, ODA does want to assure stakeholders that ODA also wants to see more approved quality-improvement projects and has actively encouraged sponsoring entities to submit proposals for quality-improvement projects to ODA for approval.

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?

Although scientific data was not used to develop the NHQI rules, science is the basis for many NHQI projects (e.g., Clostridium difficile quality initiative).

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?

Although R.C. §3721.072 does not allow nursing homes to choose an alternative to NHQI, the program itself allows nursing homes to choose from a list of quality-improvement projects.

13. 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.

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ODA considers rules for a quality-improvement program, such as NHQI, to be performance-based. The process is dictated by the improvement project each nursing home chooses to complete.

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

R.C. §173.60 authorizes only ODA to develop rules to implement the NHQI and no other state agency has adopted rules to duplicate ODA's NHQI rules.

15. 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 new rules take effect, ODA will post them on ODA's website. ODA will also send an email to subscribers of our rule-notification service to feature the rule.

ODH monitors nursing homes for compliance.

Adverse Impact to Business

16. 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

Sponsoring Entities: Entities proposing for ODA to approve projects for NHQI are subject to 173-60-03.

Nursing Homes: Although the NHQI program affects nursing homes, ODA's NHQI rules do not regulate nursing homes. Instead, it is R.C. §3721.072 and 3701-17-06 that require every Ohio nursing home to to participate in an ODA-approved quality-improvement project at least once every two years.

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

Sponsoring Entities: Administrative time/duties:

- The adverse impact is the cost of submitting a proposal to ODA through the "submit your proposal here" feature
 on the NHQI website.
- If an entity voluntarily proposes to sponsor a quality-improvement that would require the entity to offer training, technical assistance, monitoring, etc. to participating nursing homes, the adverse impact on the sponsoring entity would be the training, technical assistance, monitoring, etc. that the sponsoring entity proposed to offer through the quality-improvement project.

Nursing Homes:

 Although not required by ODA's NHQI rules, sponsoring entities of some quality-improvement projects may charge nursing homes fees for to participate in their projects. Participation in a quality-improvement project may involve training staff, covering the duties of staff while they
participate in training, revising staff policies, reporting data to the sponsoring entity of the quality-improvement
project, and submitting a certificate of completion from the sponsoring entity to ODH.¹

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.

Sponsoring Entities: Entities voluntarily propose to sponsor quality-improvement projects. If they do, the project they sponsor, if approved, may require them to offer training, technical assistance, monitoring, *etc.* to participating nursing homes. 173-60-03 requires the sponsoring entity the minor adverse impact of the administrative expense of submitting a proposal to ODA through the new "submit your proposal here" feature on the NHQI website.

Nursing Homes:

- Fees vary from project to project. Some projects are free.² Others are free for members of associations.³ Others charge fees. For example, one project charges \$395 for on-site training of a person as a coach and \$175 to train each additional person as a coach, plus \$35 per trainee for a training packet.⁴ Another project charges \$3,750 per person trained as a coach.⁵
- Administrative requirements also vary from project to project depending on the degree of change required in a
 given nursing home to achieve a project's goals. A higher-quality nursing home may require less administration
 to reach new quality-improvement goals and, therefore, incur lower costs in reaching those goals.

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

Sponsoring Entities: Sponsoring entities voluntary decide to submit proposed quality-improvement projects to ODA for approval for NHQI. ODA does not prohibit sponsoring entities from charging fees for participating in their projects. Thus, sponsoring entities may recoup any expenses they incur for administering projects.

Nursing Homes: Improving the conditions for consumers in nursing homes (or any other long-term care setting) is one of ODA's primary missions. The NHQI rules facilitate this mission by establishing the requirements for becoming an ODA-approved quality-improvement project and establishing the process for approving proposed quality-improvement projects

These rules do not directly regulate nursing homes. Nevertheless, when nursing homes participate in quality-improvement projects, they see a return on their investment—whether the investment was in administration or administration plus fees. Participating in some quality improvement projects⁶ may increase occupancy rates and reduce operating margins and are, therefore, not adverse. Participating in some quality-improvement projects ⁷ may also satisfy continuing-education requirements for nursing home administrators.

In <u>3701-17-06</u>, ODH deems that a nursing home participating in a NHQI project can count as meeting federal QAPI requirements in <u>42 C.F.R. 483.75</u>. Therefore, participation in NHQI, which R.C. §<u>173.60</u> created in 2013, also brings a nursing home into compliance with 42 C.F.R. 483.75, which the Centers for Medicare and Medicaid Services adopted in 2016.

¹ To document compliance with 3701-17-06.

² For example, <u>Creating a Culture of Person-Centered Dementia Care</u>, EDEN ALTERNATIVE & STATE LONG-TERM CARE OMBUDSMAN OF OHIO.

³ For example, Hospital Readmission Reduction 2018-2020, COMPREHENSIVE POST-ACUTE NETWORK (CPAN).

⁴ <u>Dementia Live</u>, AGE-u-cate Training Institute (ATI). ATI also offers <u>grants</u> to Ohio nursing homes.

⁵ Care Transitions Intervention, University of Colorado (Denver): Care Transitions Program.

⁶ For example, *Fast Facts: The Quality Award Program*, American Health Care Association, Jul 2018.

⁷ For example, <u>Creating a Culture of Person-Directed Dementia Care</u>, EDEN ALTERNATIVE & STATE LONG-TERM CARE OMBUDSMAN OF OHIO.

Regulatory Flexibility

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

Because the purposes of these rules are to establish the requirements for becoming an ODA-approved quality-improvement project and to establish the process for approving proposed quality-improvement projects, ODA treats entities who propose projects the same, regardless of their size; and treats nursing homes 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?

Because the purposes of these rules are to establish the requirements for becoming an ODA-approved quality-improvement project and to establish the process for approving proposed quality-improvement projects, ODA will treat administrative violations that do not involve health and safety as opportunities for improvement.

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

ODA and its designees are available to help sponsoring entities and nursing homes of all sizes with their NHQI questions. Additionally, R.C. §5165.771 requires ODA to provide nursing homes selected for the CMS Special Focus Facility Program with technical assistance if the nursing homes are facing termination as Medicaid providers. Any person may contact Tom-Simmons, ODA's policy development manager, with questions about the rules.

Additionally, ODA maintains an <u>online rules library</u> to help sponsoring entities and nursing homes find rules regulating them. Providers may access the online library 24 hours per day, 365 days per year.

173-60-01 <u>Nursing home quality initiative:</u> <u>Introduction</u> <u>introduction</u> and <u>definition</u>.

- (A) Introduction: Beginning on July 1, 2013, division Division (B) of section 3721.072 of the Revised Code requires every nursing home to participate in a quality improvement project at least once every two years. Pursuant to section 173.60 of the Revised Code, the Ohio department of aging (ODA) ODA has adopted Chapter 173-60 of the Administrative Code this chapter to establish the criteria requirements for becoming an ODA-approved quality improvement project, the approval and rescission process for quality improvement projects, and the publication of quality improvement projects on the "Ohio Long-Term Care Nursing Home Quality Initiative" website (https://aging.ohio.gov/nursinghomequalityimprovement).
- (B) Definition for Chapter 173 60 of the Administrative Code: "nursing home" has the same meaning as in section 3721.01 of the Revised Code.
- (B) Definitions for this chapter:

"Nursing home" has the same meaning as in section 3721.01 of the Revised Code.

"ODA" means the department of aging.

"ODH" means the department of health.

173-60-02

Nursing home quality incentive: Quality improvement projects: criteria requirements for ODA approval.

To be included in ODA's list of approved receive ODA approval, a quality improvement projects, the project shall meet the following eriteria requirements:

- (A) The project shall improve the quality of a nursing home.
- (B) The project shall have elements that include a plan, action aimed at improving quality, evaluation of the action, and new action resulting from the evaluation.

173-60-03

Nursing home quality initiative: Quality improvement projects: approval and rescission processes for quality improvement projects.

(A) Approval:

- (1) An entity that sponsors a quality improvement project may propose that ODA approve apply for ODA's approval of its project by sending a description of the project to the email inbox that ODA provides on completing the application found by following the "submit your proposal here" link on the "Ohio Long-Term Care Nursing Home Quality Initiative" website (https://aging.ohio.gov/nursinghomequalityimprovement).
- (2) In the description, the sponsoring entity shall include the following information:
 - (a) The project's name.
 - (b) The project's focus and expected quality improvement.
 - (c) The project's dates of availability for nursing homes.
 - (d) The contact information for the project's sponsoring entity.
 - (e) The expected activities the nursing home would undertake as part of the quality improvement project.
 - (f) The quality improvements that the sponsoring entity predicts nursing homes would experience if they participate in its project.
 - (g) The evidence that a participating nursing home would provide to the Ohio department of health to demonstrate participation.
- (3)(2) ODA shall deny a proposed project if the email application in paragraph (A)(1) of this rule does not contain all the information required under paragraph (A)(2) of this rule submit a complete application.
- (4)(3) ODA, in consultation with the state long-term care ombudsman, shall review a proposed project, then decide whether to approve or deny the project.
- (B) Rescission: If a quality-improvement project no longer meets the <u>criteria</u> requirements in rule 173-60-02 of the Administrative Code, ODA <u>will shall</u> remove it from the "Ohio Long-Term Care Nursing Home Quality Initiative" website.

173-60-04

Nursing home quality initiative: Quality improvement projects: online publication of approved quality improvement projects.

On the "Ohio Long-Term Care Nursing Home Quality Initiative" website, ODA shall list the following:

- (A) Each approved quality improvement project that it has approved.
- (B) A description of the evidence that participating nursing homes shall produce for the Ohio department of health ODH surveyors to demonstrate the nursing home's compliance with section 3721.072 of the Revised Code.