

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Midwest Division of Survey and Certification
Chicago Regional Office
233 North Michigan Avenue, Suite 600
Chicago, IL 60601-5519



OCT 25 2013

October 24, 2013

Theodore E. Wymyslo, MD, Director
Ohio Department of Health
246 High Street
Columbus, Ohio 43215

Dear Dr. Wymyslo:

You and John L. Martin, Director of the Ohio Department of Developmental Disabilities (DODD), sought the Centers for Medicare & Medicaid Services (CMS) approval for Ohio to implement a pilot project that combined the federal certification survey and the state licensure review process for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs). We carefully reviewed the proposal and consulted with CMS Central Office.

The introduction of the proposal asserts that a combined certification survey and licensure review process in Ohio would result in a process more efficient for the State Agencies and the ICF/IID providers and yield improved results. While we were able to identify the possibility for significant benefit to the DODD and for the Ohio ICF/IID provider community, we were not able to identify any benefits for the Ohio State Survey Agency (ODH) or CMS's survey process. In fact, as our comments below will discuss, we see the possibility within this proposal for increased responsibility and workload for ODH and the risk that ODH will be non-compliant with the 1864 Agreement with the Secretary.

Section 1864 of the Social Security Act provides for "...an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized for [the Secretary] for the purpose of determining whether..." providers and suppliers qualify for certification in the Medicare program. The current Section 1864 Agreement between the Secretary of Health and Human Services and the State of Ohio was signed by then-Director of Health David L. Jackson. Ohio Revised Code §3721.022 designates the Ohio Department of Health as the single Medicare State Survey Agency.

The 1864 Agreement does not preclude a State Survey Agency (SA) from entering into a written contract with another agency to assist them in the completion of their survey activities. However, this must be done under a written arrangement with the responsibilities of each party clearly identified. The written arrangement must be approved by the CMS Regional Office prior to implementation. The SA must retain all responsibility for all activities performed under this arrangement and in no case may the SA delegate any certification responsibilities to include compliance determinations and all certification/recertification/termination actions. The Medicare/Medicaid survey program is complex and highly technical. In addition to being a qualified health professional, surveyors in the Medicare/Medicaid survey program must be determined qualified to conduct Medicare/Medicaid

surveys. All surveyors performing survey activity as a part of any arrangement must have successfully completed the appropriate CMS Basic Surveyor training course and follow all survey protocols as prescribed by CMS.

The Ohio proposal does not discuss or include a written arrangement between ODH and DODD. The proposal does not clearly stipulate and delineate the manner in which all certification responsibilities will be retained within the SA. Statements within the proposal are worrisome in this regard such as, "...regardless of which surveyor/reviewer observes or identifies an area of non-compliance, the team will rely on that surveyor/reviewer's experience, expertise and appropriate follow-up to issue the citation." (Task 3 and 4 of the proposal)

The proposal does not provide for the appropriate training of any surveyors utilized under such an arrangement. The proposal suggests that all surveyors (DODD and ODH) be trained on a new survey process in lieu of national CMS Basic ICF/IID training which is required by CMS for all surveyors of ICFs/IID and cannot be waived.

The second paragraph of the proposal states that licensure surveys and certification surveys in Ohio are two distinctly different surveys that often result in contradictory findings due to variations between State laws and federal regulations. While we appreciate the fact that this may create a conundrum for the provider, we fail to see how the simple merging of the two processes, without any changes to those laws and regulations, could result in any different outcome.

The proposal states that separate surveys affect the delivery of services to Medicaid recipients in that the typical routine of facility operations is interrupted for two to five working days while surveyors are on site. However, it appears that currently (except for the very largest facilities) DODD reviewers are only on site one day every one to three years. This proposal does not reduce the number of days that the SA surveyors will be onsite *every year*. Therefore, it would appear that the reduction in disruption to the providers as a result of this proposal would be negligible.

The proposal states that combining the efforts of the two agencies would "lead to some reduction in the number of surveyors for DODD and some reduction in the number of days and perhaps surveyors for ODH." We see no indication in this proposal to support that assumption. The "Scheduling" section of the proposal indicates that DODD staff will assign reviewers to conduct the licensure survey alongside the ODH surveyors and that all DODD staff will attend the first day of the review with the option to extend if necessary. Since the DODD reviewers are currently only spending one day in most facilities we do not understand how this reduces the number of their reviewers or the number of days they will spend on site. The SA surveyors will have to continue to be onsite the same number of days as they are currently in order to complete all the required survey tasks. It does not appear from the proposal that the DODD reviewers will be providing any assistance to the SA surveyors in observations, record review and interviews since they will only be in the facility one day and are concentrating on licensure requirements. Additionally, references in the Task 2 section of this proposal indicate that DODD reviewers will not go onsite with the survey team in years when the licensure review is not due. We fail to see how this proposal can reduce either survey days or numbers of surveyors for ODH.

It is also important to reiterate that costs for licensure and certification survey activities **may not be blended**. These are separate and distinct costs with different funding sources. While it is not prohibitive for SA surveyors to conduct licensure activity during the survey process those activities must be separately documented and separately funded. And, the intensity of the current ICF/IID certification survey process all but prohibits licensure activity.

Of particular concern in this proposal are references to sharing of the survey schedule with DODD up to six weeks prior to the survey date. This was repeated in the proposal three times as if for emphasis. With extremely limited exception, this is prohibited. This would *only* be acceptable in those limited circumstances where DODD was operating under a written arrangement with ODH to perform certification survey activities and a clear fire wall was in place to ensure that DODD staff under arrangement with ODH, had no association with the sections of DODD providing operation/consultation of the facilities being surveyed. We assume that DODD *operates* all State ICF/IID facilities in Ohio. Therefore, they could not enter into any arrangement with ODH to perform certification surveys at any State facility and they could not be privy to those survey schedules.

Under the Preparation Tasks section of the proposal, one task was, “Develop teleworking policy for HCF5s conducting surveys.” Perhaps we do not understand this task but the terms “teleworking” and “surveys” are mutually exclusive.

While we can see the advantage of having the DODD complaint information available as additional information that may assist in directing the survey process, **it cannot replace the activities required as part of the onsite survey process.** Investigation of incidents by the surveyors involves not only reviewing the reporting of the incident but the safeguards put into place, changes to policy based upon lessons learned and interviews with person(s) involved. This must all be done onsite.

The proposal was also not clear in the discussion in Tasks 3 and 4 as to how the joint team can conduct a pre-exit conference if the DODD reviewers are not staying onsite after the first day of the survey.

With regard to the specific Expected Efficiencies listed on page seven of the proposal, we respond as follows:

1. We do not understand, and this proposal does not support, how combining two separate and distinct processes will result in clearer expectations of compliance for the providers. How would combining the processes clarify the distinct processes?
2. Same response as above.
3. We have already commented that we do not agree that this proposal will reduce either time or days for ODH surveyors in ICFs/IID.
4. The proposal erroneously asserts that an expected efficiency would be only one regulatory visit per year unless there are complaints. ODH most likely will be in the facility at least twice per year with follow-up visits and perhaps more.
5. As we stated previously, the addition of pre-survey information such as LOC assessments (which may be very old) and the information contained in the DODD complaint system might augment the survey process but cannot replace the onsite activities required by the survey protocols.
6. We do not agree that the time that will be spent by ODH surveyors at the ICFs/IID will be reduced.
7. Same response as 5 above.

The proposal references a single communication to the provider with the certification and licensure report. While these findings may go out under the same cover, they must be clearly identified separately. There is no discussion in the proposal as to how this “single” document would be developed.

A continuing concern in reviewing the proposal was the relationship that DODD has with the operation of ICFs/IID in the State of Ohio in general. The proposal did not discuss this nor did it discuss any measures that might be taken by DODD to avoid any real or perceived conflicts of interest.

In summary, based upon the information submitted, and in consultation with CMS Central Office, we were unable to identify any positive benefit to the ODH survey operation through application of this proposal and accordingly cannot support the proposal.

If you have any questions regarding this response, please contact Elizabeth Honiotes, Manager, Survey Branch Two, via email at Elizabeth.Honiotes@cms.hhs.gov or via phone at (312) 353-1588; or me, at Nadine.Renbarger@cms.hhs.gov or at (312) 886-0783.

Sincerely,

A handwritten signature in black ink that reads "Nadine Renbarger". The script is cursive and fluid, with the first name and last name clearly distinguishable.

Nadine Renbarger
Associate Regional Administrator