



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

OCT 16 2019

Robin P. Amicon
Vorys, Sater, Seymour and Pease LLP
52 East Gay Street
P.O. Box 1008
Columbus, Ohio 43216

Dear Ms. Amicon:

Thank you for your letter to the Environmental Protection Agency (EPA) dated August 20, 2019, asking for a regulatory interpretation about whether an Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF, also known as an ICF/ID or an ICF/IID) would meet the definition of a long-term care facility in § 266.500 of 40 CFR part 266 subpart P. Based upon the information that you provided in your letter, (see enclosure) combined with additional research that we conducted, we have concluded that an ICF does not meet the definition of long-term care facility and therefore is not a healthcare facility subject to 40 CFR part 266 subpart P.

Healthcare facilities that generate more than very small quantity generator (VSQG) amounts of hazardous waste are subject to part 266 subpart P.¹ A long-term care facility, which is a type of healthcare facility under subpart P, is defined in § 266.500 as:

A licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

¹ A very small quantity generator, as defined in 40 CFR 260.10, is a generator who generates less than or equal to the following amounts in a calendar month:

- (1) 100 kilograms (220 lbs) of non-acute hazardous waste; and
- (2) 1 kilogram (2.2 lbs) of acute hazardous waste listed in §261.31 or §261.33(e) of this chapter; and
- (3) 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in §261.31 or §261.33(e) of this chapter.

ICFs are regulated by the Centers for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services. The services provided by ICFs are defined in 42 CFR 440.150(a). As you noted in your letter, ICFs have some characteristics in common with long-term care facilities, such as being licensed and certified at the state-level, and providing institutional long-term care.² On the other hand, according to the Centers for Medicare and Medicaid Services (CMS), an “ICF/ID provides AT [active treatment], a continuous, aggressive, and consistent implementation of a program of specialized and generic training, treatment, and health or related services, directed toward helping the enrollee function with as much self-determination and independence as possible.”³ CMS notes that “[m]any ICF/ID residents work in the community, with supports, or participate in vocational or other activities outside of the residence, and engage in community interests of their choice.”⁴ Based on this information, along with the information that you provided in your letter (see enclosure), we have concluded that ICFs have more in common with group homes or assisted living facilities, which are not considered long-term care facilities, than to nursing facilities or skilled nursing facilities, which are considered long-term care facilities.

Because an ICF is not considered a long-term care facility, or other type of healthcare facility, as defined by 40 CFR 266.500, an ICF is not subject to 40 CFR Part 266 Subpart P. The wastes generated by residents at ICFs continue to be considered household wastes that are eligible for the household waste exclusion in 40 CFR 261.4(b)(1). That said, EPA strongly encourages environmentally sound disposal of pharmaceuticals by households. To that end, we strongly discourage the sewerage (e.g., flushing) of pharmaceuticals. Instead, we recommend the use of pharmaceutical take-back programs to protect both human health and the environment. Where take-back options are not available, we recommend that households mix their unused pharmaceuticals with an undesirable substance, such as used coffee grounds or kitty litter, before placing in the trash.

² <https://www.medicaid.gov/medicaid/tss/institutional/index.html>; accessed September 9, 2019.

³ <https://www.medicaid.gov/medicaid/tss/institutional/icfid/index.html>; accessed September 9, 2019.

⁴ *Ibid.*

Finally, we note that Ohio is authorized to implement the RCRA regulations in lieu of the federal government. Because Ohio is an authorized state that has not yet adopted Part 266 Subpart P, the final rule is not yet effective in Ohio.⁵ However, when Ohio adopts Part 266 Subpart P, they may be more stringent than the federal regulations. As a result, we advise you to keep in touch with your state as they go through the state adoption process.

If you need further assistance, please contact Kristin Fitzgerald at fitzgerald.kristin@epa.gov, or (703) 308-8286.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kathleen Salyer', with a stylized, cursive script.

Kathleen Salyer, Deputy Director
Office of Resource Conservation and
Recovery

Enclosure

⁵ The sewer prohibition in § 266.505 became effective in all states starting August 21, 2019, regardless of whether the state is authorized or has adopted Part 266 Subpart P.

Enclosure



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August 20, 2019

VIA EMAIL AND U.S. MAIL

Barnes Johnson, Director
Environmental Protection Agency
Office of Resource Conservation and Recovery
1200 Pennsylvania Ave., NW (5301P)
Washington DC 20460
Johnson.barnes@epa.gov

**Re: Applicability of New Standards for Hazardous Waste
Pharmaceuticals to ICFs**

Dear Director Johnson:

We have been in contact with the Ohio Environmental Protection Agency ("Ohio EPA") regarding whether an Intermediate Care Facility for Individuals with Intellectual Disabilities ("ICF") would meet the definition of a "long-term care facility" ("LTCF") at 40 C.F.R. § 266.500, and we write to seek your instruction on this matter.

As you know, under U.S. EPA's new management standards for hazardous waste pharmaceuticals (the "Standards"), LTCFs are no longer eligible for the household hazardous waste exclusion at 40 C.F.R. § 261.4(b)(1). However, the LTCF definition expressly excludes certain provider types (e.g., group homes) with which – as we describe in further detail below – ICFs share certain key attributes. That said, ICFs are also unique in several significant respects, such that we found it necessary to request specific guidance regarding the Standards' applicability to this provider type. Because the Standards originated at the federal level, Ohio EPA encouraged us to contact your agency.

Accordingly, to assist you in determining whether ICFs constitute LTCFs as defined at 40 C.F.R. § 266.500, we are providing this detailed explanation of what ICFs are, how they operate, and how pharmaceuticals are managed within their facilities.



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A. Overview of ICFs

1. ICFs provide active treatment that fosters independence and community involvement.

Historically speaking, ICFs are the product of a 1971 amendment to the Social Security Act, which – for the first time – made federal funding available to entities that serve individuals with intellectual disabilities. This amendment created an optional Medicaid benefit for items and services furnished in an ICF, provided that the facility (1) meets the requirements for a State license to provide services that are above the level of room and board; (2) has the primary purpose of furnishing health or rehabilitative services to individuals with an intellectual disability or related conditions; (3) meets certain conditions and procedural requirements for participation in the Medicaid program; and (4) provides “active treatment” to each beneficiary in its care.¹ For ICF clients, “active treatment” means that the client receives a continuous, individualized treatment program designed to (1) help him or her acquire the behaviors necessary to function with as much self-determination and independence as possible; and (2) prevent or slow regression or the loss of current optimal functional status.²

2. ICFs do not provide skilled nursing care and are staff primarily by unlicensed personnel.

Many ICF clients have multiple conditions for which they require support, including seizure disorders, behavioral issues, and/or visual or hearing impairments. However, these individuals do not require a “skilled nursing” level of care that would be provided in a nursing home setting. To the contrary, most ICFs are staffed primarily by unlicensed personnel trained to provide CPR, First Aid, crisis management, and/or assistance with activities of daily living (“ADLs”), and must transfer an individual to a facility if he or she requires complex medical treatment.

3. ICFs are licensed and certified at the State level.

Although ICFs are subject to federal standards for participation in the Medicaid program, primary authority for their regulation lies with the States. Each must be licensed and certified by State-level agencies (in Ohio, the Department of Developmental Disabilities and Department of Health, respectively), and each State has adopted its own eligibility criteria for the ICF benefit.³

¹ 42 C.F.R. § 440.150(a).

² 42 C.F.R. § 483.440(a).

³ For more information, please visit <https://www.medicaid.gov/medicaid/ltss/institutional/icfid/index.html>.



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State law also determines whether and to what extent unlicensed personnel may administer medications to ICF clients.⁴

4. The majority of ICFs are small, home-based settings.

Additionally, although ICFs are considered to be “institutions” under federal law,⁵ this designation applies to any establishment that furnishes “food, shelter, and some treatment or services to four or more persons unrelated to the proprietor.”⁶ Further, there has been “a major shift in thinking” in the field of developmental disabilities since the creation of the ICF Medicaid benefit, resulting in an emphasis on “people living in their own homes, controlling their own lives, and being an integral part of their home community.”⁷ Accordingly, most ICFs are now very small, home-like settings. Per applicable survey guidance, a “large” ICF is one with more than 16 beds.⁸ In Ohio, only 49 (a little over 10 percent) of the 424 ICFs licensed by the Department of Developmental Disabilities fall into this category, while 335 have eight beds or fewer. Going forward, the number of “large” ICF providers is likely to decrease even further, as Ohio law provides that “[t]he number of licensed beds in an [ICF] shall not exceed six unless the [Department of Developmental Disabilities] determines...that the [ICF] requires capacity greater than six to be financially viable, in which case the department may approve a capacity that is not greater than eight.”⁹

5. Medications are property of the individuals – not the ICFs.

Finally, all medications are property of the individual clients residing in the ICFs – not the ICFs. Medications are paid for by the individual’s health insurer or Medicaid like a typical household. Additionally, ICFs do not operate in-house pharmacies, but obtain and dispose of medications also as a typical household might (e.g., by mixing them with coffee grounds, returning to the pharmacy, or taking to a police department disposal receptacle).

Further, federal law permits substantial variation among ICFs with respect to their policies and procedures for handling medications. Each must have “an organized system for drug administration that identifies each drug up to the point of administration,” and must ensure

⁴ See 42 C.F.R. § 483.460(k)(3).

⁵ 42 U.S.C. § 1396d(d).

⁶ 42 C.F.R. § 435.1010 (emphasis added).

⁷ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/ICFIID.html>.

⁸ See State Operations Manual, Appendix J, section W369. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_j_interncare.pdf.

⁹ O.A.C. § 5123:2-3-08(C)(5).



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that all drugs are administered without error and in compliance with physician orders; however, ICF clients may self-administer their medications if they demonstrate competency to do so.¹⁰

B. The New Federal Standards

1. ICFs obtain and dispose of medications as a typical household.

Historically, long term care facilities and ICFs have fallen within the “household waste” exemption to the Resource Conservation and Recovery Act (“RCRA”), which excludes “any material...derived from households (including single and multiple residences)” from the definition of hazardous waste.”¹¹ As noted above, ICFs obtain and dispose of medications as any typical household might. In promulgating the new Standards, however, the U.S. EPA revised its policy on this point, stating that “LTCFs may no longer use the household hazardous waste exclusion.”¹²

2. ICFs are analogous to the provider types excluded under the Standards.

As defined at 40 C.F.R. § 266.500, the term “LTCF” means “a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility,” but expressly excludes “group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.” Discussing this definition in the Federal Register, the U.S. EPA explained that LTCFs generally do not qualify for the household hazardous waste exclusion because (1) as licensed health care facilities, LTCFs are “more similar to...hospital[s] than to...typical residence[s]”; and (2) LTCFs generate pharmaceutical wastes of substantially greater “quantity and breadth” than do typical residences.¹³

However, the U.S. EPA indicated that group homes remain eligible for the household waste exclusion because “they are typically very small (fewer than 10 beds),” and that the agency revised its original proposed definition to also exclude assisted living facilities (“ALFs”) because (1) the Drug Enforcement Agency (“DEA”) and Centers for Medicare & Medicaid Services (“CMS”) do not consider ALFs to be LTCFs; (2) primary regulatory oversight of ALFs resides with the States, with regulatory requirements and applicable definitions varying between them; and (3) ALFs differ from LTCFs in that (a) some ALFs do not provide medication management; and (b) many ALFs do not have on-site nursing or other medical staff.¹⁴

¹⁰ 42 C.F.R. § 483.460(k).

¹¹ 40 C.F.R. § 261.4(b)(1).

¹² See 84 F.R. 5816, 5853. Available at: <https://www.federalregister.gov/d/2019-01298/p-598>.

¹³ *Id.*

¹⁴ *Id.*



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Based on the above criteria, we believe that ICFs should be excluded from the definition of “long-term care facility” at 40 C.F.R. § 266.500. Like group homes, ICFs are typically very small and are truly intended to function as their clients’ homes. ICFs are designed, staffed, and equipped to support their clients’ day-to-day functions and to foster and support community involvement – not to provide complex medical care. Further, all medications are property of the individual clients – not the ICFs. And, to the extent ICFs administer medications, this function is carried out by unlicensed personnel. Like ALFs, ICFs are primarily regulated at the State level, and the regulatory requirements and definitions applicable to them may vary substantially from one State to another. In short, ICFs are not “more similar to...hospital[s] than to...typical residence[s],” but are more closely analogous to the provider types already excluded.

Accordingly, we respectfully request that the U.S. EPA clarify this issue. We appreciate your time and consideration of this matter. Please do not hesitate to contact me if you have questions or if there is any additional information you need.

Very truly yours,

A handwritten signature in dark ink that reads "Robin P. Amicon". The signature is written in a cursive, flowing style.

Robin P. Amicon

cc:

Kristin Fitzgerald, Environmental Protection Specialist, Office of Resource Conservation and Recovery, U.S. Environmental Protection Agency (via email only at fitzgerald.kristin@epa.gov)
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