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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.

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]

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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.

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

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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/CertificationandComplianc/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_intermcare.pdf.
9 O.A.C. § 5123:2-3-08(C)(5).

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]

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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*.

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,

Robin P. Amicon

cc:

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