



Date: August 17, 2023
TO: FTCA Deemed Health Centers
FROM: Associate Administrator, Bureau of Primary Health Care

SUBJECT: Determination of Coverage for Community-Based Prescription and Distribution of Naloxone to Individuals Who Are Not Health Center Patients

Background

Section 224(g)-(n) of the Public Health Service (PHS) Act, 42 U.S.C. § 233(g)-(n), provides eligibility for certain liability protections, including medical malpractice liability coverage under the Federal Tort Claims Act (FTCA), for the performance of medical, dental, surgical, and related functions within the scope of employment for qualified individuals, as further described in federal regulations at 42 CFR part 6 and other Health Center FTCA Program policy issuances. Similar statutory liability protections apply under section 224(q) of the PHS Act, as further described in other Health Center FTCA Program policy issuances, to the provision of qualifying health services on behalf of a health center by volunteer health professionals for whom a health center deeming sponsorship application has been approved under section 224(q).

On October 26, 2017, the Acting Secretary of Health and Human Services determined that, because of the continued consequences of the opioid crisis affecting our nation, an opioid public health emergency exists nationwide. On July 7, 2023 this determination was renewed. See <https://aspr.hhs.gov/legal/PHE/Pages/Opioid-7July2023.aspx>. With regard to the opioid public health emergency, HRSA recognizes that, according to the CDC, “The number of overdose deaths involving opioids, including [prescription opioids](#), [heroin](#), and synthetic opioids (like [fentanyl](#)), in 2021 was 10 times the number in 1999. Overdoses involving opioids killed more than 80,000 people in 2021, and nearly 88% of those deaths involved synthetic opioids.” See [CDC Opioid Data](#). With the right tools such as Naloxone, individuals can act to prevent overdose deaths. Anyone can carry naloxone, give it to someone experiencing an overdose, and potentially save a life. Naloxone will not harm someone if they are overdosing on drugs other than opioids, so it is always best to use it if you think someone is overdosing. Naloxone is easy to use and light to carry. There are two forms of naloxone that anyone can use without medical training or authorization. Carrying naloxone is no different than carrying an epinephrine auto-injector (commonly known by the brand name EpiPen) for someone with allergies. It simply provides an extra layer of protection for those at a higher risk for overdose. (For more information, see [Lifesaving Naloxone \(cdc.gov\)](#)).

Determination of Coverage

This sets forth my determination, in accordance with 42 U.S.C. § 233(g)(1)(B) and (C), and under regulations set forth in 42 C.F.R. § 6.6, that health centers that have been deemed as Public Health Service employees for purposes of liability protections and any officer, governing board member,

employee, qualified contractor, or volunteer health professional of such an entity (“eligible individuals”), should have liability protections under section 224 of the PHS Act for the provision of health services within the health center’s scope of project to individuals who are not patients of the health center in circumstances described below.

Health centers and eligible individuals that prescribe and dispense naloxone as a service within the health center’s Health Center Program scope of project to individuals who are not patients of the health center at a health center service site or at offsite locations within the community served by the health center and where the health center is providing care (including at offsite programs or events carried out by the health center), whether in-person or through telehealth, benefit patients of these entities and general populations that could be served by these entities through community-wide opioid overdose intervention efforts within the communities served by such entities, and therefore are eligible for liability protections for the provision of such services under section 42 U.S.C. § 233(g)-(n) and (q). All such activities must be conducted on behalf of the health center. Health services provided under a contractual arrangement between a health center or a health center provider and a third party are ineligible for coverage. Additionally, activities undertaken by the health center for the sole benefit of employees, family, or other associates of an entity, company, or corporation that are not made available to all members of the community are not eligible for coverage. The health center should maintain a record of each encounter to the extent practicable, including the service(s) provided, the location where services were administered, the name of the provider(s) administering the services, and the date and time the services were administered. Where possible, the record should also identify the individual who receives the health service.

Services provided by health center providers must continue to comply with applicable Health Center and Health Center FTCA Program requirements (including applicable scope of project) and applicable state and federal law. If you have any questions, please contact the Health Center Program Support Phone: 1-877-464-4772, Option 1 8:00 a.m. to 5:30 p.m. ET, Monday through Friday (except Federal holidays) or use the [BPHC Contact Form](#).

This determination will expire one year from its date of issuance, unless renewed.

Sincerely,

/James Macrae/

James Macrae
Associate Administrator