STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
MARGARET M. O'NEILL BUILDING
410 FEDERAL STREET, SUITE 1
DOVER, DE 19901

VOICE: (302) 739-3620
TTY/TDD: (302) 739-3699
FAX: (302) 739-6704

MEMORANDUM

DATE: October 29, 2014

TO: The Honorable Mary Peterson, Director
Division of Long Term Care Residents Protection

FROM: Daniese McMullin-Powell, Chairperson
State Council for Persons with Disabilities

RE: 16 DE Reg. 282 [DLTCRP Proposed Rest (Family) Care Home Regulation]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/Division of Long Term Care Residents Protection's (DLTCRP's) proposal to completely revise its regulations covering rest (family) care homes. The proposed regulations were published as 18 DE Reg. 282 in the October 1, 2014 issue of the Register of Regulations. SCPD has the following observations.

First, in §3.1.2.1.1, consider the following amendment: "Violation of any of the provisions of these rules and regulations or 16 Del.C. Ch. 11." SCPD recognizes that the regulations address the Patient Bill of Rights in §8.0 and that §4.3 is expansively written. However, it may facilitate enforcement and DHSS defense of appeals under §3.1.2.3 if compliance with Chapter 11 is explicitly highlighted. For example, the regulations do not address failure to comply with mandatory reporting (16 Del.C. §1132) or criminal background check standards (16 Del.C. §1141).

Second, Section 4.4 could be improved. The following sentence could be added: "The level of care determination shall be made in consultation with the resident's personal primary care licensed independent practitioner, if any." Otherwise, the implication is that an agent of the placement agency (who may have marginal familiarity with the resident) may determine level of care based on a "1-stop" assessment lacking the long-term familiarity enjoyed by a PCP.

Third, in §4.7, consider substituting "admission to" for "placement in". Individuals may voluntarily solicit admission to a family care home. The term "placement in" suggests an involuntary or agency-directed admission. This section covers individuals whose admission is

not prompted by an agency.

Fourth, in §5.4.6.1, SCPD suspects the term "bcated" should be "located".

Fifth, Section 5.4.6.2 addresses the slope of any required ramp which generally tracks the historical ADA 1 foot rise in12 foot run standard. However, there are other "safety" aspects to ramps that could be included. See attachment downloaded from http://www.ada-compliance.com/ada-compliance/ada-ramp . The most obvious is the requirement of handrails, 36" width, and edge protection. Compare §5.9.1 (requiring handrails in stairways).

Sixth, Section 5.6 would categorically disallow use of a portable air conditioner. Individuals vary considerably in their tolerance for heat/cold. Disallowing a room air conditioner undermines "choice" among residents and ignores variations of temperature within a home which uses a central system. For example, an upstairs bedroom facing south or west will generally be hotter than a downstairs room facing east or north. Literally, §5.6 could be interpreted to mean that a resident could not complain if his/her room is 80 degrees in the summer. A room air conditioner simply provides some flexibility. Similar regulations [16 DE Admin Code 3320, §6.10)] do not ban even portable heating devices.

Seven, the regulations do not address stairglides, stairlifts and elevettes/elevators. The Division may wish to consider whether standards should be included.

Eighth, in §5.9.6 delete the apostrophe in "Camera's".

Nine, Section 5.10 could be improved by explicitly disallowing bunk beds. Compare 16 DE Admin Code 3320, §6.6.6. Otherwise, a provider could use bunk beds to circumvent other bedroom standards.

Tenth, Section 5.10.12 allows three (3) residents per bedroom. This is highly objectionable. It is not "normal" for three adults to share a bedroom. Compare 16 DE Admin Code 3310, §8.3 and 3230, §5.8.8. There is also some "tension" between this standard and §§4.9 and 8.12. Moreover, the definition of "family care home" refers to "a family living situation", not a dorm or institutional environment.

Eleventh, Section 5.11.3.2 has multiple plural pronouns (they; their) with a singular antecedent (resident). Consider the following substitute: "A resident may choose to provide an individual mattress to be used only by that resident."

Twelfth, Section 5.12 allows 1 toilet and 1 bathtub/shower for every eight (8) occupants. This is highly objectionable. Many of the residents will require assistance with bathing and toileting so "turnover" of the shower and toilet may be very slow. By analogy, the neighborhood home regulation requires 1 toilet and 1 bathtub/shower for every four (4) individuals. See 16 DE Admin Code 3310, §9.0. See also 16 DE Admin Code 3230, §5.9, and 16 DE Admin Code 3301, §5.9. Imagine three (3) residents (§2.0, definition of "family care home) with limited

capacities competing with five (5) family members (§2.0, definition of "occupant") for the bathroom every morning as they try to get ready for work or travel to a day program. Typically, the toilet will be in the same room as the shower/bathtub so no one will be able to use the toilet while someone is showering. This is an untenable arrangement.

Thirteenth, Section 5.15.6.4 allows the provider to complete laundry for residents. This standard should be embellished to ban commingling of laundry (including underwear) which can result in spread of disease, including C-Diff. See attached CDC Q&A documented published at http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html. Such embellishment would further the objectives of §7.1.5.3 and §8.14. Temperature and bleach standard could also be included. See 16 DE Admin Code 3201, §7.6 and 16 DE Admin Code 3301, § 5.12.6.

Fourteenth, Section 7.1.4 should be revised to refer to the "licensed independent practitioner" rather than simply "physician".

Fifteenth, Section 7.1.3 does not offer much flexibility if a resident wishes to keep his/her own medications. This is inconsistent with the definition of "family care provider" which adopts a standard of promoting maximum independence through individual choice. By analogy, the assisted living regulation [16 DE Admin Code 3225, §8.4] allows some residents to keep medications in a purse or facility-provided container.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations or recommendations on the proposed regulation.

cc: Mr. Brian Hartman, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

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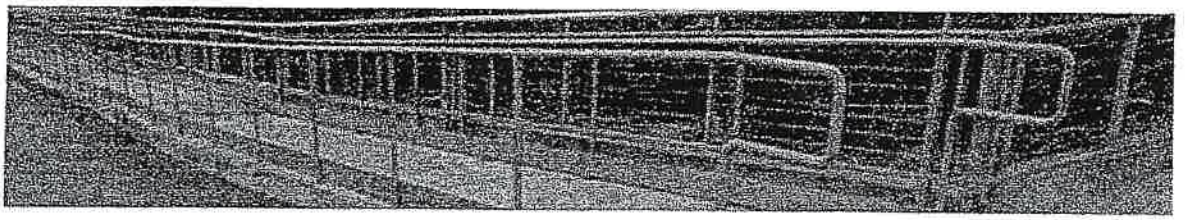
ADA Ramp

PRINT



ADA Ramp

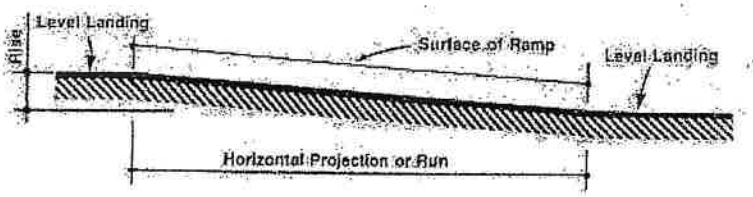
4.8 Ramps

4.8.1* General

Any part of an accessible route with a slope greater than 1:20 shall be considered a ramp and shall comply with 4.8.

4.8.2* Slope and Rise

The least possible slope shall be used for any ramp. The maximum slope of a ramp in new construction shall be 1:12. The maximum rise for any run shall be 30 in (760 mm). Curb ramps and ramps to be constructed on existing sites or in existing buildings or facilities may have slopes and rises as allowed in 4.1.6(3)(a) if space limitations prohibit the use of a 1:12 slope or less.



	Maximum Rise		Maximum Horizontal Projection	
Slope	in	mm	ft	in
1:12 to < 1:16	30	760	30	9
1:16 to < 1:20	30	760	40	12

4.8.3 Clear Width.

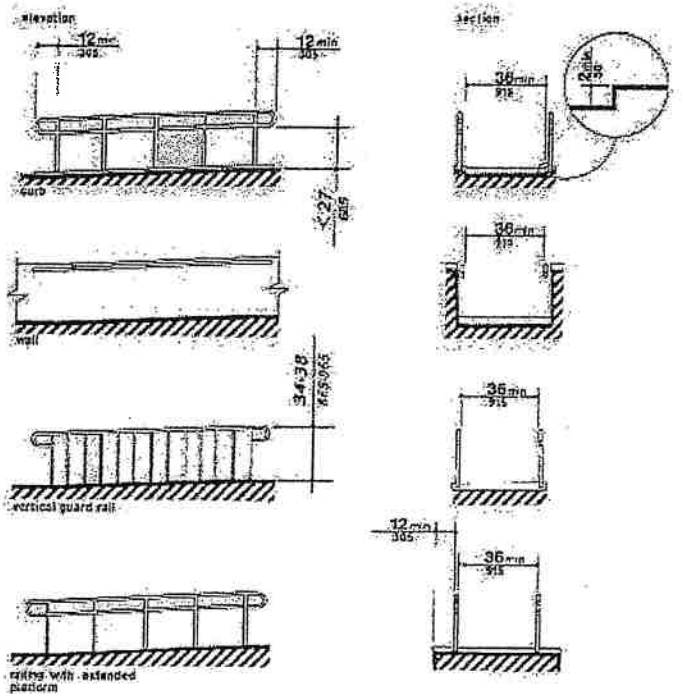
The minimum clear width of a ramp shall be 36 in (915 mm).

4.8.4* Landings
Ramps shall have level landings at bottom and top of each ramp and each ramp run. Landings shall have the following features:

(1) The landing shall be at least as wide as the ramp run leading to it.
(2) The landing length shall be a minimum of 60 in (1525 mm) clear.
(3) If ramps change direction at landings, the minimum landing size shall be 60 in by 60 in (1525 mm by 1525 mm).
(4) If a doorway is located at a landing, then the area in front of the doorway shall comply with 4.13.6.

4.8.5* Handrails
If a ramp run has a rise greater than 6 in (150 mm) or a horizontal projection greater than 72 in (1830 mm), then it shall have handrails on both sides. Handrails are not required on curb ramps or adjacent to seating in assembly areas. Handrails shall comply with 4.26 and shall have the following features:

(1) Handrails shall be provided along both sides of ramp segments. The inside handrail on switchback or dogleg ramps shall always be continuous.
(2) If handrails are not continuous, they shall extend at least 12 in (305 mm) beyond the top and bottom of the ramp segment and shall be parallel with the floor or ground surface.



(3) The clear space between the handrail and the wall shall be 1 - 1/2 in (38 mm).
(4) Gripping surfaces shall be continuous.
(5) Top of handrail gripping surfaces shall be mounted between 34 in and 38 in (865 mm and 965 mm) above ramp surfaces.
(6) Ends of handrails shall be either rounded or returned smoothly to floor, wall, or post.
(7) Handrails shall not rotate within their fittings.

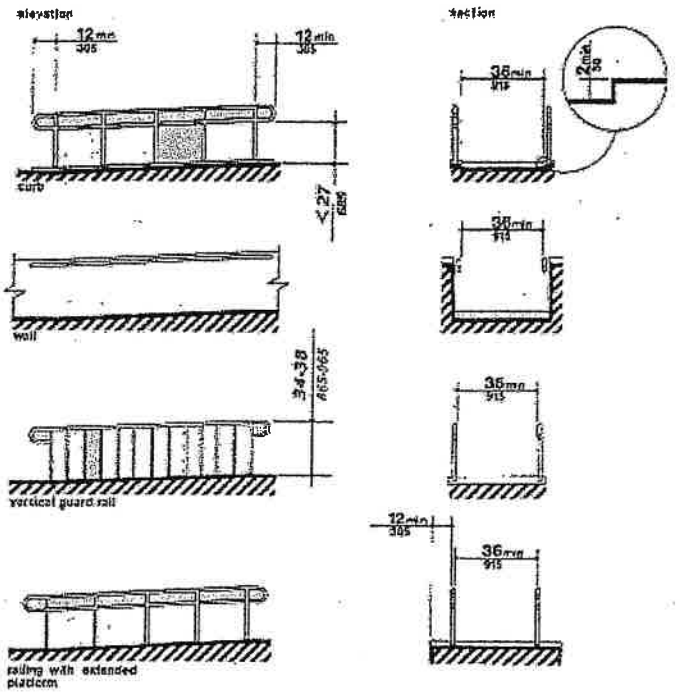
4.8.6 Cross Slope and Surfaces

The cross slope of ramp surfaces shall be no greater than 1:50. Ramp surfaces shall comply with 4.5.

4.8.7 Edge Protection

Ramps and landings with drop-offs shall have curbs, walls, railings, or projecting surfaces that prevent people from slipping off the ramp. Curbs shall be a minimum of 2 in (50 mm) high.

Examples of Edge Protection and Handrail Extensions



Examples of Edge Protection and Handrail Extensions.

Four types of edge protection and handrail design are shown. The first ramp (top) labeled "Curb" shows a handrail horizontal projection of 12 inches (305 mm) minimum at the top and bottom of the ramp. The horizontal projection begins at the point were the sloped ramp surface stops. Edge protection on both sides of the ramp is a raised surface at least 2 inches (50 mm) high. A minimum clear width of 36 inches (915 mm) is provided between handrails and the edge protection. A lower railing is shown parallel to the ramp mounted no higher than 27 inches (685 mm) above the ramp.

The second ramp (second from top) labeled "Wall" shows a railing mounted on a solid wall. The handrails on both sides have horizontal projections as above. A minimum of 36 inches (915 mm) is provided between handrails.

The third ramp (third from top) labeled "Vertical Guard Rail" has a series of vertical guard rails or pickets. The top of the handrail is shown as 34 - 38 inches (865 mm - 965 mm) above the ramp and landings (applies to all handrails on accessible ramps). A minimum of 36 inches (915 mm) is provided between handrails.

The fourth ramp (fourth from top) labeled "Railing with Extended Platform" shows a railing without edge protection on the ramp surface. The ramp surface extends a minimum of 12 inches (305 mm) to the side of the handrail. The handrail detail is the same as the first example with a bottom rail no more than 27 inches (305 mm) above the ramp and landings. A minimum of 36 inches (915 mm) is provided between handrails.

4.8.8 Outdoor Conditions

Outdoor ramps and their approaches shall be designed so that water will not accumulate on walking surfaces.

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Frequently Asked Questions about *Clostridium difficile* for Healthcare Providers

On this Page

What is *Clostridium difficile*?

Clostridium difficile is a spore-forming, Gram-positive anaerobic bacillus that produces two exotoxins: toxin A and toxin B. It is a common cause of antibiotic-associated diarrhea (AAD). It accounts for 15-25% of all episodes of AAD.

What diseases result from *Clostridium difficile* infection?

- pseudomembranous colitis (PMC)
- toxic megacolon
- perforations of the colon
- sepsis
- death (rarely)

What are the main clinical symptoms of *Clostridium difficile* infection?

Clinical symptoms include:

- watery diarrhea
- fever
- loss of appetite
- nausea
- abdominal pain/tendernes

Which patients are at increased risk for *Clostridium difficile* infection?

The risk for disease increases in patients with:

- antibiotic exposure
- proton pump inhibitors
- gastrointestinal surgery/manipulation
- long length of stay in healthcare settings
- a serious underlying illness
- immunocompromising conditions
- advanced age

What are the differences between *Clostridium difficile* colonization and *Clostridium difficile* infection?

Clostridium difficile colonization

- patient exhibits NO clinical symptoms
- patient tests positive for *Clostridium difficile* organism and/or its toxin
- more common than *Clostridium difficile* infection

Clostridium difficile infection

- patient exhibits clinical symptoms
- patient tests positive for the *Clostridium difficile* organism and/or its toxin

Which laboratory tests are commonly used to diagnose *Clostridium difficile* infection?

- Stool culture for *Clostridium difficile*: While this is the most sensitive test available, it is the one most often associated with false-positive results due to presence nontoxigenic *Clostridium difficile* strains. However, this can be overcome by testing isolates for toxin production (i.e. so called "toxigenic culture"). Nonetheless, stool cultures for *Clostridium difficile* are labor intensive, require an appropriate culture environment to grow anaerobic microorganisms, and have a relatively slow turn-around time (i.e. results available in 48-96 hours) making them overall less clinically useful. Results of toxigenic cultures do serve as a gold-standard against which other test modalities are compared in clinical trials of performance.
- Molecular tests: FDA-approved PCR assays, which test for the gene encoding toxin B, are highly sensitive and specific for the presence of a toxin-producing *Clostridium difficile* organism.
- Antigen detection for *Clostridium difficile*: These are rapid tests (<1 hr) that detect the presence of *Clostridium difficile* antigen by latex agglutination or immunochromatographic assays. Because results of antigen testing alone are non-specific,

antigen assays have been employed in combination with tests for toxin detection, PCR, or toxigenic culture in two-step testing algorithms.

- Toxin testing for *Clostridium difficile*:
  - Tissue culture cytotoxicity assay detects toxin B only. This assay requires technical expertise to perform, is costly, and requires 24-48 hr for a final result. It does provide specific and sensitive results for *Clostridium difficile* infection. While it served as a historical gold standard for diagnosing clinical significant disease caused by *Clostridium difficile*, it is recognized as less sensitive than PCR or toxigenic culture for detecting the organism in patients with diarrhea.
  - Enzyme immunoassay detects toxin A, toxin B, or both A and B. Due to concerns overtoxin A-negative, B-positive strains causing disease, most laboratories employ a toxin B-only or A and B assay. Because these are same-day assays that are relatively inexpensive and easy to perform, they are popular with clinical laboratories. However, there are increasing concerns about their relative insensitivity (less than tissue culture cytotoxicity and much less than PCR or toxigenic culture).
- *Clostridium difficile* toxin is very unstable. The toxin degrades at room temperature and may be undetectable within 2 hours after collection of a stool specimen. False-negative results occur when specimens are not promptly tested or kept refrigerated until testing can be done.

How is *Clostridium difficile* transmitted?

Clostridium difficile is shed in feces. Any surface, device, or material (e.g., commodes, bathing tubs, and electronic rectal thermometers) that becomes contaminated with feces may serve as a reservoir for the *Clostridium difficile* spores. *Clostridium difficile* spores are transferred to patients mainly via the hands of healthcare personnel who have touched a contaminated surface or item.

How is *Clostridium difficile* infection usually treated?

In about 20% of patients, *Clostridium difficile* infection will resolve within 2-3 days of discontinuing the antibiotic to which the patient was previously exposed. The infection can usually be treated with an appropriate course (about 10 days) of antibiotics, including metronidazole, vancomycin (administered orally), or recently approved fidaxomicin. After treatment, repeat *Clostridium difficile* testing is not recommended if the patients' symptoms have resolved, as patients may remain colonized.

How can *Clostridium difficile* infection be prevented in hospitals and other healthcare settings?

- Use antibiotics judiciously
- Use Contact Precautions: for patients with known or suspected *Clostridium difficile* infection:
  - Place these patients in private rooms. If private rooms are not available, these patients can be placed in rooms (cohorted) with other patients with *Clostridium difficile* infection.
  - Use gloves when entering patients' rooms and during patient care.
  - Perform Hand Hygiene after removing gloves.
    - Because alcohol does not kill *Clostridium difficile* spores, use of soap and water is more efficacious than alcohol-based hand rubs. However, early experimental data suggest that, even using soap and water, the removal of *C. difficile* spores is more challenging than the removal or inactivation of other common pathogens.

        - Preventing contamination of the hands via glove use remains the cornerstone for preventing *Clostridium difficile* transmission via the hands of healthcare workers; any theoretical benefit from instituting soap and water must be balanced against the potential for decreased compliance resulting from a more complex hand hygiene message.
        - If your institution experiences an outbreak, consider using only soap and water for hand hygiene when caring for patients with *Clostridium difficile* infection.
    - Use gowns when entering patients' rooms and during patient care.
    - Dedicate or perform cleaning of any shared medical equipment.
    - Continue these precautions until diarrhea ceases.
        - Because *Clostridium difficile*-infected patients continue to shed organism for a number of days following cessation of diarrhea, some institutions routinely continue isolation for either several days beyond symptom resolution or until discharge, depending upon the type of setting and average length of stay.
- Implement an environmental cleaning and disinfection strategy:
    - Ensure adequate cleaning and disinfection of environmental surfaces and reusable devices, especially items likely to be contaminated with feces and surfaces that are touched frequently.
    - Consider using an Environmental Protection Agency (EPA)-registered disinfectant with a sporicidal claim for environmental surface disinfection after cleaning in accordance with label instructions; generic sources of hypochlorite (e.g., household chlorine bleach) also may be appropriately diluted and used. (Note: Standard EPA-registered hospital disinfectants are not effective against *Clostridium difficile* spores .) Hypochlorite-based disinfectants may be most effective in preventing *Clostridium difficile* transmission in units with high endemic rates of *Clostridium difficile* infection.
    - Follow the manufacturer's instructions for disinfection of endoscopes and other devices.
- Recommended infection control practices in long term care and home health settings are similar to those practices taken in traditional health-care settings.

What can I use to clean and disinfect surfaces and devices to help control *Clostridium difficile*?

Surfaces should be kept clean, and body substance spills should be managed promptly as outlined in CDC's "Guidelines for Environmental Infection Control in Health-Care Facilities." [PDF 1.4 MB] (/hicpac/pdf/guidelines/eic_in_HCF_03.pdf) Routine cleaning should be performed prior to disinfection. EPA-registered disinfectants with a sporicidal claim have been used with success for environmental surface disinfection in those patient-care areas where surveillance and epidemiology indicate ongoing transmission of *Clostridium difficile*. **Note:** EPA-registered disinfectants are recommended for use in patient-care areas. When choosing a disinfectant, check product labels for inactivation claims, indications for use, and instructions.

How has *Clostridium difficile (C. difficile)* infections (CDI) changed?

Over the past several years nationwide, states have reported increased rates of *C. difficile* infection, noting more severe disease and an associated increase in mortality. *C. diff* infection remains a disease mostly associated with healthcare (at least 80%) Patients most at risk remain the elderly, especially those using antibiotics. Although the elderly are still most affected, more disease has been reported in traditionally 'low risk' persons such as healthy persons in the

community, and peripartum women. These changes may be largely due to the new emergence of the current epidemic strain of *C. difficile*, known by its names assigned by various typing schemes as restriction enzyme analysis type BI, North American Pulsed Field type 1 (NAP1), or PCR ribotype 027. BI/NAP1/027 has spread widely after first being found responsible for outbreaks in Pittsburgh (2000), Atlanta (2001-2), and Montreal (2003). This strain appears more virulent possibly due to its increased production of toxins A and B and its production of an additional toxin known as binary toxin, as well as other factors still under study. In addition to being more virulent, it is more resistant to a commonly-used class of antimicrobials known as the fluoroquinolones. Additional information about this strain and how it has changed the face of *C. diff* infection see Bench-to-bedside review: *Clostridium difficile* colitis [PDF - 198 KB] (/HAI/pdfs/cdiff/Gould_CritCare2008.pdf).

How is the epidemic strain detected?

Like other strains of *C. difficile*, BI/NAP1/027 can be detected in the stool of infected patients by using laboratory tests that are commonly available in most hospitals. However, none of the FDA-approved tests differentiate between the various strains of *C. difficile*. Fortunately, because the control measures for outbreaks of any strain of *C. difficile* are similar, identification of the specific strain is not imperative for controlling outbreaks.

Is treatment of BI/NAP1/027 different?

The usual treatment for *C. difficile* infection includes, if possible, stopping antibiotics being given for other purposes and/or treatment with metronidazole or vancomycin. In order to reduce selective pressure for vancomycin resistance in enterococci, current guidelines recommend the first-line use of metronidazole over vancomycin.

Recent reports suggest that BI/NAP1/027 may not respond as well to treatment with metronidazole despite the absence of laboratory evidence of metronidazole resistance. Evidence suggests that more severe disease should be treated with vancomycin, over metronidazole.

How does fluoroquinolone resistance affect management of BI/NAP1/027?

Increased fluoroquinolone resistance does not affect the management of infections caused by this strain. Fluoroquinolones have never been recommended for treatment of *C. difficile* infection and susceptibility testing is performed only as a part of an epidemiological investigation. However, resistance to fluoroquinolones may provide the new strain with an advantage over susceptible strains to spread within healthcare facilities where these antibiotics are commonly used.

What should healthcare facilities do in response to the emergence of the BI/NAP1/027?

Healthcare facilities should monitor the number of *C. difficile* infections and, especially if rates at the facility increase, the severity of disease and patient outcomes. If an increase in rates or severity is observed, healthcare facilities should reassess compliance with core recommended practices as outlined in the CDC Toolkit for Evaluation of Enviromental Cleaning [PDF - 1.05 MB] (/HAI/pdfs/toolkits/CDItoolkitwhite_clearance_edits.pdf). for known cases of *C. diff* infection including the following:

If compliance appears high to core recommendations, consideration should be made to implement supplemental recommendations as described in the toolkit.. If assistance is needed with these measures, additional help should be sought from local or state health departments and/or local infection control experts.

Where can I get more information?

The Centers for Disease Control and Prevention also has General Information about *Clostridium difficile.* (/hai/organisms/cdiff/Cdiff-patient.html#gen)

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National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Division of Healthcare Quality Promotion (DHQP)

Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329-4027, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC–INFO

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