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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER / SUPPLIER / CLIA IDENTIFICATION NUMBER 235074 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 09/29/2020 |
| NAME OF PROVIDER OF SUPPLIER MARLETTE COMM HOSP LTCU | | STREET ADDRESS, CITY, STATE, ZIP 2770 MAIN ST MARLETTE, MI 48453 | |
| For information on the nursing home's plan to correct this deficiency, please contact the nursing home or the state survey agency. | | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | | |
| F 0880 Level of harm - Minimal harm or potential for actual harm Residents Affected - Many | <p>Provide and implement an infection prevention and control program.</p> <p>**NOTE- TERMS IN BRACKETS HAVE BEEN EDITED TO PROTECT CONFIDENTIALITY**</p> <p>This Citation has 2 Deficient Practice Statements (DPS) DPS #1: Based on observation, interview and record review, the facility failed to confirm that the hand sanitizing product, that they were utilizing, had a label that identified the ingredients and product expiration date to ensure its effectiveness and provide for the safety for residents', staff and visitors' use, resulting in the potential for contamination and ineffectiveness against microorganisms that could spread illness to all residents, staff and visitors. Findings Include: During a tour of the facility on 9/23/20 at 12:46 PM with the Director of Nursing (DON) a hand sanitizer dispenser was observed outside of the hallway double doors to the facilities Long Term Care Unit (LTCU). Upon using it to sanitize this Surveyor's hands, the DON was asked, about their supply of Hand Sanitizer and she said, We don't have any problem. When it is empty Maintenance (technicians) fills a bucket from a drum (barrel) of hand sanitizer and refills our Sanitizers. Upon entry into the facilities hallway, staff including a nurse and Certified Nursing Assistant were observed using a Hand Sanitizer from a dispenser on the wall, when they were asked who filled their dispensers when empty, they said Maintenance filled it with a bucket of Hand Sanitizer. During an interview with Infection Control (IC) Nurse D, on 9/24/20 at 9:46 AM, she was asked about the facilities Hand sanitizing product and stated, They are filling from a bulk container. Housekeeping will keep an eye on Hand sanitizers while cleaning. Anyone can request for them to be filled. The IC Nurse was asked the name of the product and said she didn't know, but It is a recipe through the WHO (World Health Organization). It was a donation. The IC Nurse was asked who sent it and she stated, I can't find who sent it. When asked what the label on the product said it was comprised of, she said she didn't know if there was a label but the (Materials Manager/Director of Support Services J) would know. The IC Nurse was unable to confirm the Hand sanitizing product used in the Long Term Care facility was safe to use or effective against microorganisms including Covid-19. FDA (U.S. Food and Drug Administration), Hand Sanitizers/Covid-19, dated 8/31/2020 FDA plays a critical role in protecting the United States from emerging infectious diseases, such as the Coronavirus Disease 2019 (Covid-19) pandemic. FDA is committed to providing timely guidance to support continuity and response efforts to this pandemic . alcohol production firms can produce alcohol for making hand sanitizers provided they follow the conditions outlined in the FDA guidances for industry , the agency is maintaining a list of dangerous hand sanitizers, and recommends entities involved in distributing and selling hand sanitizers continuously check this list as it is being updated regularly .Firms that choose to temporarily produce hand sanitizers and the alcohol used in them should follow the formulas and processes outlined in FDA guidance for industry . FDA, Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (Covid-19), Guidance for Industry, March 2020, updated August 7, 2020, . To meet component quality requirements for hand sanitizer production, the alcohol manufactured as an API (active pharmaceutical ingredient) is not less than 94.9% [MEDICATION NAME] by volume . any water used to adjust the finished [MEDICATION NAME] content in the alcohol API is sterile . Alcohol ([MEDICATION NAME]) that is produced using fermentation and distillation processes typically used for consumable goods .may be considered for use in hand sanitizer, provided the alcohol meets the interim impurity levels . it is labeled with the [MEDICATION NAME] content . FDA, Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (Covid-19), Guidance for Industry, dated March 2020, Updated August 7, 2020, . Hand Hygiene is an important part of the response to Covid-19 If soap and water are not readily available the Centers for Disease Control and Prevention (CDC) recommends consumers use an alcohol-based hand sanitizer that contains at least 60 percent alcohol (also referred to as [MEDICATION NAME] or ethyl alcohol) . certain entities that are not currently regulated by FDA as drug manufacturers have requested guidance on the preparation and distribution of hand sanitizer products for the public's use . The hand sanitizer is manufactured using only the following ingredients in the preparation of the product, a. Select one of two options: alcohol ([MEDICATION NAME]) that is not less than 94.9% [MEDICATION NAME] by volume or United States pharmacopeia (USP grade) [MEDICATION NAME] alcohol . [MEDICATION NAME] ([MEDICATION NAME]) . (food grade) . Hydrogen peroxide . Sterile water . The finished hand sanitizer is manufactured according to the following formula consistent with World Health Organization (WHO) recommendations . Alcohol ([MEDICATION NAME]) . [MEDICATION NAME] . Hydrogen peroxide . Sterile distilled water or boiled cold water . The firm does not add other active or inactive ingredients . The firm packages the finished hand sanitizer product in packaging appropriate for liquid drug products that will seal sufficiently to prevent evaporation of the alcohol . Manual pump sprays that seal sufficiently to prevent evaporation are consistent with this policy . The hand sanitizer is labeled . An interview with the Director of Support Services J on 9/24/20 at 3:58 PM provided, As soon as Covid-19 hit we obtained bulk Hand sanitizer in a 50-gallon drum. Director J said if someone wanted the Hand sanitizer's refilled in the LTCU they would submit a work order or call and Maintenance would bring over a bucket with Hand sanitizer from the 50 gallon drum; Maintenance will pump from the 50 gallon drum to a smaller bucket, filling it in the storeroom. Director J was asked for the label on the product and said he didn't have one then stated, Our Emergency Services Manager K got the drum from a distillery. The Director J was asked if he had an invoice for the Hand sanitizer and stated, I don't have that on hand. Director J was asked how the facility would ensure the product was safe and able to perform Hand Sanitization as required to meet guidelines and regulations and stated, I am in agreement that we need that information. On 9/28/20 at 9:35 AM, an interview with the DON revealed, Thursday night (9/24/20) at 5:00 PM they were done. The DON said the Maintenance department had replaced the Hand sanitizing product in the facilities dispensers and filled them with the product designed for the dispensers. This Hand sanitizer was available from the storeroom in individual filled/sealed containers that fit into each Hand sanitizer dispenser. This was the product the facility used prior to receiving the 50-gallon drum of hand sanitizer. On 9/28/20 at 9:48 AM, during an interview with Emergency Services Manager K, he said he obtained the product from a distillery owned by someone that he knew. When asked when the product was obtained, he did not have the date, but he thought it was in the spring; he said he would have to contact the distillery. Manager K was asked for a copy of the label and invoice for the 50-gallon drum of hand sanitizer and he said he did not have either. He was asked how he could confirm what the drum contained and if it was safe and effective against infectious organisms including Covid-19 and said he would try to get a copy of the label. The name and phone number for the distillery was requested. A phone message was left for the distillery on 9/28/20 at 9:58 AM, with no return call prior to exit on 9/28/20 at 3:45 PM. A review of an email received from the DON and Director of Support Services J on 9/28/20 contained copies of 4 documents and stated, We are requesting additional information on the label they had provided, we will forward that upon receipt. A label for the product was not received before exit on 9/28/20 at 3:45 PM. The facility did not provide a label or documentation from the distillery that the following formulation and ingredients comprised the hand sanitizer in the 50-gallon drum. 1.WHO (World Health Organization, WHO Guidelines on Hand Hygiene in Health Care . dated 2009, WHO recommends the local production of the following formulations as an alternative when suitable commercial products are either unavailable or too costly . The choice of components for the WHO-recommended hand rub formulations takes into account cost constraints and microbicidal activity. The following two formulations are recommended for local production with a maximum of 50 liters (13.209 US</p> | | |
| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | | TITLE | (X6) DATE |

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| F 0880 Level of harm - Minimal harm or potential for actual harm Residents Affected - Many | <p>(continued... from page 1)</p> <p>gallons) per lot to ensure safety in production and storage . After mixing, the solution is immediately divided into smaller containers, e.g. 1000, 500, or 100 ml plastic bottles. The bottles should be kept in quarantine for 72 hours. This allows time for any spores present in the alcohol . to be eliminated . Labelling of the bottles: The bottles should be labeled in accordance with national guidelines. Labels should include the following: Name of institution, Date of production and batch number, Composition: [MEDICATION NAME] or [MEDICATION NAME] and hydrogen peroxide . and the following statements: WHO-recommended hand rub formulation; For external use only; Avoid contact with eyes; Keep out of reach of children; Use: apply a palmful of alcohol-based hand rub and cover all surfaces of the hands. Rub hands until dry. Flammable: keep away from flame and heat . 2. Neutral Grain Spirits, Safety Data Sheet, Revision date: 9/18/2015, . Product Form: Mixture . Synonyms: Alcohol, Beverage Alcohol, [MEDICATION NAME], NSG, Spirits, Vodka . Mixture: Ethyl alcohol, 92.3-94.6% (w/w); Water 5.4-7.7 % (w/w) . 3. ChemWorld.com, Worldwide Online Ordering and Consulting, undated . Product Identifier: Tradename: [MEDICATION NAME]; [MEDICATION NAME] . Substance, Component: [MEDICATION NAME] 50.0%-100.0%, Water <50.0% . 4. Maxill, Safety Data Sheet, Hydrogen Peroxide Topical Solution, dated 01 May, 2017, . Hydrogen Peroxide 3% . Mixture: Hydrogen peroxide 1-5% (w/w), Purified water 50-100% (w/w) On 9/28/20 at 1:37 PM, the Director of Support Services provided this information, The product was housed in a sterile drum, there was not an expiration date. Product was picked up by (facility) staff on April 17, 2020. Waiting on date of production. PO (purchase order) # is unavailable. When we requested a W9 to create a vendor and issue a PO number, the supplier stated he would donate the product. On 9/28/20 at 3:13 PM the Director of Support Services provided, Production date for our hand sanitizer was Saturday, March 28, 2020. A review of the facility policy titled, Hand Hygiene, dated effective: 7/3/2012, last revised 10/2/2017, last reviewed/approved: 9/30/19 and Expires: 9/29/20 provided, All employees will utilize Hand Hygiene procedures as stated below to reduce transmission of pathogenic microorganisms. Proper use of Hand Hygiene will decrease the number of Health Care Associated Infections (HAI's) in both the patient/residents population as well as in the Staff . Alcohol-based hand rub, (ABHR (Hand Sanitizer)) An alcohol-containing preparation designed for application to the hands for reducing the number of viable micro-organisms on the hands. In the United States, such preparations usually contain 60%-95% [MEDICATION NAME] or [MEDICATION NAME] (alcohol) . DPS #2: Based on observation, interview, and record review the facility failed to ensure Personal Protective Equipment was available for staff use to care for residents infected with the Covid-19 virus for 1 resident (Resident #1) of 3 residents reviewed for Covid-19 infection, resulting in Resident #1 testing positive for Covid-19 and staff, who were assigned to care for the resident, were told to shut the door and not enter until they were Fit tested for an N95 respirator, which could lead to unmet care needs for the resident and potential exposure of infectious illness for staff and residents. Findings Include: CDC (Centers for Disease Control and Prevention), Preparing for Covid-19 in Nursing Homes, June 25, 2020, . Given their congregate nature and resident population (e.g. older adults often with underlying chronic medical conditions), nursing home populations are at high risk of being affected by respiratory pathogens like Covid-19 . As demonstrated by the Covid-19 pandemic, a strong infection prevention and control (IPC) program is critical to protect both residents and healthcare personnel (HCP) . Educate residents, Healthcare Personnel and Visitors about Covid-19, Current precautions being taken in the facility, and actions they should take to protect themselves . Regularly review CDC's Infection Control Guidance for Healthcare Professionals bout Covid-19 . Reinforce adherence to standard IPC measures including hand hygiene and selection and correct use of personal protective equipment (PPE) . Facilities should have supplies of facemasks, respirators (if available and the facility has a respiratory protection program with trained, medically cleared, and fit-tested HCP) . Residents with known or suspected Covid-19 should be cared for using all recommended PPE, which includes use of an N95 or higher level respirator . Prior to entry into the facility, on 9/23/20 at 12:35 PM, a phone conversation with the Director of Nursing (DON), revealed the facility had recently transferred Resident #1 to another facility/Regional Hub after testing positive for the Covid-19 virus on 9/10/20. The DON said there had also been several employees that tested positive for Covid-19 from the beginning of August 2020 to September 15, 2020. During a tour of the facility on 9/23/20 at 12:50 PM, Droplet Precautions signs were observed posted at the beginning of each resident hallway (2 halls). The DON said the staff were to wear a mask (procedure/surgical) at all times in the facility. The DON was asked if staff had available N95 masks for use when caring for residents suspected or confirmed positive for Covid-19 and said, A few of the nurses have been fit tested and have N95 masks. The DON was asked if the Certified Nursing Assistants (CNA's) had been fit tested or had N95 masks to wear when caring for Covid-19 suspected or positive staff and said, No. A record review of the Face Sheet and Minimum Data Set (MDS) assessment for Resident #1 indicated the resident was admitted to the facility on [DATE] with Diagnoses: [REDACTED]. The MDS assessment dated [DATE] revealed the resident had severe memory impairment and needed 2-perons assistance with bed mobility, transfers, dressing, hygiene, bathing, and toileting. The resident was readmitted to the facility on [DATE]. A review of the medical record progress notes indicated the following: 9/10/20 at approximately 9:30 AM, Informed by the DON that the resident's Covid test results are in and are positive. Resident shows no signs and symptoms of infection . 9/10/20 at 9:45 AM, . plan for transfer to Regional Hub . would return to a private room for 14-day quarantine . 9/10/20 at 12:55 PM, . Transferred to Hub via ambulance . Notes written by Nurse B. An interview with Infection Control (IC) Nurse D on 9/24/20 at 9:46 AM, related to staff use of N95 respirators to care for Residents with Covid-19 infection stated, We have just started getting fitted for an N95. The IC Nurse was asked about the recent cases of Covid-19 positive staff and residents and said, We have talked about it and we don't know how they are being exposed. 9/24/20 at 3:58 PM, an interview with the Director of Support Services J related to availability of N95 masks for the Long-Term Care facility staff revealed the facility had 9 different brands of N95 masks. Director J said there was only a shortage of the small size in one brand, but there were 8 other brands/models to Fit test to also, If we don't have one, we can fit test them for the others. We have enough for everyone at this point. Director J said the facility continued to receive supplies of N95 masks and had approximately 7,000 on hand. A review of a list of Long Term Care facility staff Fit tested for an N95 mask and having one on hand for use to care for Covid-19 suspected or positive residents, indicated there were 4 nurses and the DON and one Physician's Assistant fit tested for an N95 mask. A review of the facility Schedule for September 2020 revealed the facility had 18 nurses plus the DON and MDS nurse on the schedule for September 2020. There were 26 CNA's, and 25 additional staff including CNA's, Unit Clerks, Activities staff and Restorative Aides. On 9/10/20 there were 3 nurses, 8 CNA's, 2 Unit clerk, 2 Activity Aides and 1 Restorative Aide working in the facility. One of the nurses was Fit tested and had an N95 mask. An interview with Nurse B and CNA M on 9/28/20 at 10:30 AM, revealed they were not provided an N95 mask to allow them to safely care for Resident #1 until after the resident tested positive for Covid-19. An interview with CNA O on 9/28/20 at 10:49 AM, I was given a hospital issue blue mask (procedure/surgical) mask. I was in the resident (#1's) room before she tested positive that day. I helped get her up. Then we found out later she was positive. After she tested positive I didn't go in there. Nobody was allowed in. An interview with Cardio-Pulmonary Manager L on 9/28/20 at 12:27 PM, We do the fit testing. If they call us, we do it. I don't have any issues with supplies. On 9/28/20 at 12:38 PM, an interview with Employee Health Nurse I revealed, I know we have Fit tested some people. It is a matter of getting them scheduled . A review of the facility policy titled, Covid-19 Prevention & Management- LTC, and dated effective 3/30/20; last reviewed and revised 9/3/2020, revealed, Purpose: Prevention of introduction of Covid-19 infection on the LTC Unit. To mitigate the transmission of Covid-19 infection on the LTC unit with early identification and isolation of those suspected or confirmed with Covid-19 infection . Managing resident Illness and Transfer: . If resident is suspected to have Covid-19 infection . Residents who develop symptoms . Residents will be placed into Transmission-Based Precautions . Staff should wear an N95 or higher-level respirator . when caring for these residents . Roommates of residents with Covid-19 should be considered exposed and potentially infected . 14 days after their last exposure . Staff should use all recommended Covid-19 PPE for the care of all residents on affected units . this includes both symptomatic and asymptomatic residents . Maintain Transmission-Based Precautions for all residents on the unit at least until there are no additional clinical cases for 14 days after implementation of all recommended interventions .</p> | | |

