Lunch & Learn Series

Enhanced Enforcement Penalties

for Infection Control Citations

W. H. Heaton

Sources Used in Developing This Session:

- **F880** – Infection Prevention and Control Regulations and Guidelines
- **QSO 20-31** – COVID-19 Survey Activities, Enhanced Enforcement for Infection Control Deficiencies.
- **QSO 20-29** – COVID-19 Reporting Requirements.
- **COVID-19** Infection Control Focused Survey for Nursing Homes.
- **CMS-20054** – Infection Control Critical Element Pathways.
- **SOM Chapter 7, §7500** – Directed Plan of Correction.

- The following handouts are included as a part of this lunch & learn training session: Use at your discretion.
  - **Handout #1** – Participant Session Outline.
  - **Handout #2** – F880: Infection Prevention & Control Regulations.
  - **Handout #3** – QSO Memo #20-31 and QSO Memo #20-29.
  - **Handout #4** – CMS-20054 – Infection Prevention and Control CE Pathway.
  - **Handout #5** – SOM Chapter 7, §7500 – Directed Plan of Correction.
  - **Handout #6** – F880 Root Cause Analysis Worksheets.

- **OPTIONAL**: Provide participants with a copy of **Handout #1** – Participant Session Outline.

Session Objectives

Upon completing this session, you should be able to:

- Discuss the **two factors** that drive the **penalties** that will be assessed for infection control citations;
- Discuss the **criteria used** and the **penalties assessed** for infection control noncompliance at:
  - ✓ **Levels D and E;**
  - ✓ **Level F;**
  - ✓ **Levels G, H, or I; and**
  - ✓ **Levels J, K, or L.**
- Discuss the **additional** COVID-19 Survey Activities CMS will be **conducting**;
- Discuss the **expanded** Survey Activities and **how** CMS will **prioritize** expanded survey activities; and
- Discuss the **purpose** and **use** of the **handouts** included in this lunch and learn session.

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- Each of these objectives are discussed during the training session.

Background

1. As the COVID-19 pandemic rages on and long-term care residents are at enhanced risk, infection control procedures and practices in nursing facilities are **back** under the **microscope**.
2. As part of its **renewed** emphasis on **proper** infection control in nursing facilities, CMS issued **QSO 20-31-NH** Memo on June 1, 2020 **detailing** the **enhanced** enforcement penalties that facilities will **now** face for deficiency **citations** related to **F880-Infection Prevention and Control** requirements.
3. CMS will **impose remedies** for any deficiency associated with infection control requirements at scope and severity level **D and above**. The **harshness** of the remedy will be based on **two** factors:
   a. The facility's **current** and **past** compliance history relative to Infection Control Deficiencies; and
   b. The scope and severity of the citation, escalating from levels **D & E**, to **Level F**, to Harm (**G, H, I**), to Immediate Jeopardy (**J, K, L**).

- **OPTIONAL**: Provide participants with **Handout #2** – F880 Regulations, **Handout #3** – QSO Memo **#20-31,** QSO Memo **#20-29, and Handout #4 – CMS-20054** Infection Prevention and Control CE Pathway.

- With the pressure the public and Congress is placing on CMS, it is **likely** this type of enhanced and focused survey process will be the **new norm** for **all** different types of survey activities (e.g., abuse, resident rights, staffing, competency, etc.).

- **In view of Paragraph #3 a, and b**, it is **critical** that facilities review their facility's current and past two (2) year's **F880** compliance history to be prepared for their next survey.

- **Current** Infection Control Survey Tags Include: **F441**, **F880, F881, F883 (SQC Tag), F884, and F885. However**, the **focus** of these **enhanced** enforcement penalties **apply** to **F880**.

- An "**Associated"** infection control requirement most likely includes **F945** – Infection Control Training **IF** the failure to provide Infection Control Training contributed to, or caused, the citation.

Enforcement Remedies

IF the facility had NO infection control citations in the last year or on its last standard survey, AND the facility is CITED for infection control noncompliance on its NEXT survey at a--

Scope and Severity Level of D or E

The Enhanced Enforcement Penalties will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis).

Scope and Severity Level of F

The Enhanced Enforcement Penalties will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND**
- ✓ **A Discretionary DPNA for new admissions.**
- ✓ The facility will have **45-days** to demonstrate **compliance** with infection control deficiencies.

- **NOTE**: These Scope and Severity **levels** indicate **"No actual harm with potential for more than minimal harm but NOT Immediate Jeopardy."**
- A "Directed Plan of Correction" **(DPoC)** is a **Category 1** enforcement action. (Refer to **§7500** – Directed Plan of Correction.) **See Handout #5**
- A **DPoC** is a plan that the State or the CMS Regional Office, or temporary manager, develops to **require** a facility to **take** action within **specified** time frames.
- This **DPoC** enforcement remedy **requires** the facility's use of a **Root Cause Analysis** as part of the facility's **corrective** action process. (This involves your QAPI/QAA Committee. Upon **revisit**, CMS will ask for the QA Plan to determine the earliest date of compliance.)
- If there is **NO** evidence of the quality assurance being implemented, the **earliest** correction date will be the **date** of the **revisit**.
- A **Root Cause Analysis** is a process designed to **identify** root causes of an event that resulted in an **undesired** outcome and **develop** corrective actions.
- The **purpose** of the Root Cause Analysis is to find out **what** happened, **why** it happened, and determine **what changes** need to be made to correct the issue.
- **NOTE**: A *Root Cause Analysis and Worksheets* are provided in **Handout #6**. It will be **reviewed** at the **end** of this session.

Enforcement Remedies

IF the facility has been cited ONCE for infection control (IC) noncompliance in the last year or on its last standard survey, AND the facility is CITED for IC noncompliance on its NEXT survey at a--

Scope and Severity Level of D or E	**The Enhanced Enforcement Penalty will be:** ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND** ✓ **A Discretionary DPNA for new admissions; AND** ✓ **A $5,000** per instance CMP. ✓ The facility will have **45-days** to demonstrate **compliance** with infection control deficiencies.
Scope and Severity Level of F	**The Enhanced Enforcement Penalties will be:** ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND** ✓ **A Discretionary DPNA for new admissions; AND** ✓ **A $10,000** per instance CMP. ✓ The facility will have **45-days** to demonstrate **compliance** with infection control deficiencies.

- **NOTE**: These Scope and Severity **levels** indicate **"No actual harm with potential for more than minimal harm but NOT Immediate Jeopardy."**
- CMPs of **$10,000** or more will **automatically** result in the **loss** of your Nurse Aide Training Program (NATP) for two (2) years.

Enforcement Remedies

IF the facility has been cited TWO or MORE times in the last two years or TWICE since the second to last standard survey for infection control (IC) noncompliance, AND the facility is CITED for IC noncompliance on its NEXT survey at a--

Scope and Severity Level of D or E	**The Enhanced Enforcement Penalty will be:** ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND** ✓ **A Discretionary DPNA for new admissions; AND** ✓ **A $15,000** per instance CMP (or per day CMP as long as the total amount **exceeds** $15,000). ✓ The facility will have **30-days** to demonstrate **compliance** with infection control deficiencies.
Scope and Severity Level of F	**The Enhanced Enforcement Penalties will be:** ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND** ✓ **A Discretionary DPNA for new admissions; AND** ✓ **A $20,000** per instance CMP (or **per day** CMP as long as the total amount **exceeds** $20,000). ✓ The facility will have **30-days** to demonstrate **compliance** with infection control deficiencies.

- **NOTE**: These Scope and Severity **levels** indicate **"No actual harm with potential for more than minimal harm but NOT Immediate Jeopardy."**
- **Notice** the **higher** the penalty levels, the **LESS days** you have to **demonstrate** compliance.
- **REMEMBER**, CMPs of **$10,000** or more will **automatically** result in the **loss** of your Nurse Aide Training Program (NATP) for two (2) years.

Enforcement Remedies

IF the facility is cited for infection control noncompliance on the NEXT survey at Levels G, H, or I, REGARDLESS of past history--

The Enhanced Enforcement Penalty will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND**
- ✓ **A Discretionary DPNA for new admissions; AND**
- ✓ **Enforcement imposed by CMS location** per current policy, but **CMP imposed** at the **highest** amount option within the appropriate **(non-immediate jeopardy)** range in the CMP analytic tool.
- ✓ The facility will have **30-days** to demonstrate **compliance** with infection control deficiencies.

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- **NOTE**: These Scope and Severity **levels** indicate **"Actual Harm that is NOT Immediate Jeopardy."**
- CMPs and other remedies **will** be imposed based on the **current** enforcement remedies as outlined in **Chapter 7** of the SOM, **§7500** through **§7701**.
- Another **Key Element** that **should** be reviewed by the facility is any **past** participation in an **IDR** or **Independent IDR** for infection control citations. What was the outcome and, if successful, have those been **removed** from **ASPEN** or Nursing Home Compare. (**Note**: If **not** removed, it **could** result in additional enforcement remedies being imposed.)

Enforcement Remedies

IF the facility is cited for infection control noncompliance on the NEXT survey at Levels J, K, or L, REGARDLESS of past history--

The Enhanced Enforcement Penalty will be:

- ✓ **Mandatory Termination OR Imposition of a Temporary Manager; AND**
- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND**
- ✓ **A Discretionary DPNA for new admissions; AND**
- ✓ **Enforcement imposed by CMS location** per current policy, but **CMP imposed** at the **highest** amount option within the appropriate **(immediate jeopardy)** range in the CMP analytic tool.
- ✓ The facility will have **15-days** to demonstrate **compliance** with infection control deficiencies.

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- **NOTE**: These Scope and Severity **levels** indicate **"Immediate Jeopardy to Resident Health or Safety."**
- **Notice** that the **Mandatory Termination OR Imposition of a Temporary Manager** has been **ADDED** to these levels.
- **CMPs** and **other** remedies **will** be imposed based on the **current** enforcement remedies as outlined in **Chapter 7** of the SOM, **§7500** through **§7701**.
- **Notice** that the time frame for **demonstrating compliance** has been **reduced** from 30-days to **15-days**.
- Another **Key Element** that **should** be reviewed by the facility is any **past** participation in an **IDR** or **Independent IDR** for infection control citations. What was the outcome and, if successful, have those been **removed** from **ASPEN** or Nursing Home Compare. (**Note**: If **not** removed, it **could** result in additional enforcement remedies being imposed.)

Enforcement Action for F884 and F885

1. **QSO** Letter **20-29 requires** nursing homes to **report** COVID-19 facility data to **CDC** and to **residents**, their **representatives**, and **families** of residents in nursing homes on a **weekly** basis.
2. **Failure** to report data can **result** in an **enforcement** action.
3. **F884 – COVID-19 Reporting to CDC**.
   a. **F884** is conducted **OFFSITE** by **CMS** using the **weekly** data reported to CDC.
   b. **Facilities identified** as **not** reporting data timely **will** receive a deficiency citation at an **F Level** and a one-day CMP of **$1,000**. CMP amounts are **increased** by **$500** for each week data is not submitted.
4. **F885 – Facility Reporting COVID-19 Information to Residents, Representatives, and Families**:
   a. **F885** is conducted **ONSITE during** the Focused Survey Process.
   b. **If** the surveyor finds **noncompliance**, a citation **will** be entered on the 2567 and **enforcement** actions will be **implemented** in accordance with QSO

- **Only** CMS can **cite** a facility at **F884**. It is considered a **FEDERAL** Survey.
- Failure to timely report COVID-19 data (every **Sunday**), will result in an **"F" level** citation with a **$1,000 CMP**. Reports are provided to CMS every **Monday** morning.
- Citations are **automatically** generated and sent to the facility's **CASPER** (ePOC) file.
- **CMPs** are issued for **one-day for the failure to report that week**. For **each subsequent** week the facility fails to submit the required report, the noncompliance will result in an **additional** one-day CMP imposed at an amount **increased** by $**500**.
- **Example**: **$1,000 for Week 1**; **$1,500 for Week 2**; and so forth. If you **file** for Week 3, but **fail** to report on **Week 4**, the **CMP** would be **$2,000** for **Week 4**. (See **Handout #3** – QSO Memo **20-29**, page 5).
- **F885** review is conducted **onsite** during the focused infection control survey. Failure to report findings to residents, families, and representatives, **can** result in enforcement actions.
- **CMS** and **CDC** have indicated there have been issues with the **F884** data submission. Citations have been **erroneously** issued and CMS is working to correct those. Be sure you are reviewing your **CASPER** (ePOC) file often and challenge unsubstantiated citation through your Independent IDR process.

COVID-19 Survey Activities

1. **In addition** to completing the **Focused Infection Control** surveys of nursing homes, CMS is also **requiring** State Survey Agencies to **implement** the **following** COVID-19 survey activities:
2. **Perform on-site** surveys (**within three to five days of identification**) of **any** nursing home with **three (3) or more new** COVID-19 **suspected** and **confirmed** cases since the **last NHSN COVID-19 report**; **OR**
3. **One (1) confirmed** resident case in a facility that was **previously COVID-Free**.
4. **Starting October 1, 2020**, perform **annual** *Focused Infection Control Survey* of **20%** of nursing homes **based** on State discretion **OR** additional data that **identifies facility** and **community risks**.

- Data contained in **Paragraphs 2 and 3** are **extracted** from **NEWLY** added Columns (**BE and BF**) on the NHSN reporting data sheet and is used to **identify** facilities that **will** receive an **on-site** *COVID-19 Focused Survey* **within** three (3) to five (5) days of the released data. (See also **Handout #3**, QSO Memo **20-31**, page 3.)
- **NHSN** data must be reported to CDC **every** Sunday evening. That data is **released** to CMS **every** Monday morning. It is posted to the public website eleven (11) days later.
- **CMS** provides the State Survey Agency with a **listing** of those facilities meeting the **criteria** in Paragraphs #2 and #3 every Monday morning.
- State Survey Agencies are **required** to **complete** the **on-site visit** within **three** to **five** days of receiving the **notification** from CMS.
- Infection control **citations** issued during **this** survey process have the **same** enhanced enforcement penalties applied.

COVID-19 NHSN Report

(Corporate)

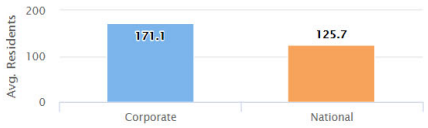
IntelliLogix

REPORT DATE: 07/31/2020

Company Information	Report Information
Company: Test Company	Week Ending: 07/19/2020 CMS Data Release Date: 07/30/2020 Triggered: Value greater than National Average Average: Average number of cases per facility

7,639	5,147	0	1	11	7
# All Beds	# Occupied Beds	# Facs Missing Data	# Facs Failed QA	# Facs w/ 3 or More Cases Reported	# Facs w/ Initial Confirmed Cases Reported

Confirmed COVID-19 Cases Per 1,000 Residents



COVID-19 Deaths Per 1,000 Residents

Deaths as a Percentage of Confirmed COVID-19 Cases

Resident

Number | Average

COVID-19	Weekly			Total	
	4 Week Trend	Corporate	National	Corporate	National
Admissions		14	3,796	126	63,726
Confirmed		124	9,430	833	152,281
Suspected		13	5,337	146	96,648
Confirmed & Suspected		137	14,767	979	248,929
Deaths		29	1,647	177	40,273

Staff/Personnel

Number | Average

COVID-19	Weekly			Total	
	4 Week Trend	Corporate	National	Corporate	National
Confirmed		93	9,750	635	111,711
Suspected		17	6,916	263	100,641
Confirmed & Suspected		110	16,666	898	212,352
Deaths		0	34	3	767

Resident & Staff Total

Number | Average

COVID-19	Weekly			Total	
	4 Week Trend	Corporate	National	Corporate	National
Confirmed		217	19,180	1,468	263,992
Suspected		30	12,253	409	197,289
Confirmed & Suspected		247	31,433	1,877	31,433
Deaths		29	1,681	180	41,040

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Expanded Survey Activities

1. Finally, to **transition** States to more **routine** oversight and survey activities, once a state has entered **Phase 3** of the Nursing Homes Re-opening guidance **or earlier**, at the state's discretion, States are authorized to **expand** beyond the current survey prioritization (Immediate Jeopardy, Focused Infection Control, and Initial Certification surveys) to perform:
   a. **Complaint** investigation that are **triaged** as Non-Immediate Jeopardy – High **(G, H, and I)**;
   b. **Revisit surveys** of **any** facility with **removed IJ** (but still out of compliance);
   c. **Special Focus Facility** and Special Focus Facility **Candidate Recertification Surveys**; **and**
   d. **Recertification** surveys that are **greater** than **15 months**.

- See **Handout #3** – QSO Memo **20-31**, page 3.
- See also **Handout #3** – QSO Memo **20-29** for the *COVID-19 Focused Survey for Nursing Homes* and **Handout #4** for current *Infection Prevention and Control Critical Element Pathway* (CMS-20054).

Expanded Survey Activities

2. When **determining** the **order** in which to schedule more routine surveys, States are instructed to **prioritize** providers **based** on those with a **history** of **noncompliance**, or **allegations** of **noncompliance**, with the following requirements:

   a. Abuse or Neglect **(F600 – F610)**.
   b. Infection Control **(F880 – F885)**.
   c. Violations of Transfer or Discharge Requirements **(F552, F623; F655; F657; F660)** **(Waivers may apply)**;
   d. Insufficient Staffing or Competency **(F725; F726)** **(Waivers may apply)**; **OR**
   e. Other Quality of Care Issues (e.g., falls **[F689]**; Pressure Ulcers **[F686]**; etc.)

- **NOTE**: **Paragraph 2e** only lists two Quality of Care Tags. **However**, there are of **17** Quality of Care Tags **(F684 – F700).**
- See **Handout #3** – QSO Memo **20-31**, page 3.
- See also **Handout #3** – QSO Memo **20-29** for the *COVID-19 Focused Survey for Nursing Homes* and **Handout #4** for current *Infection Prevention and Control Critical Element Pathway* (CMS-20054).

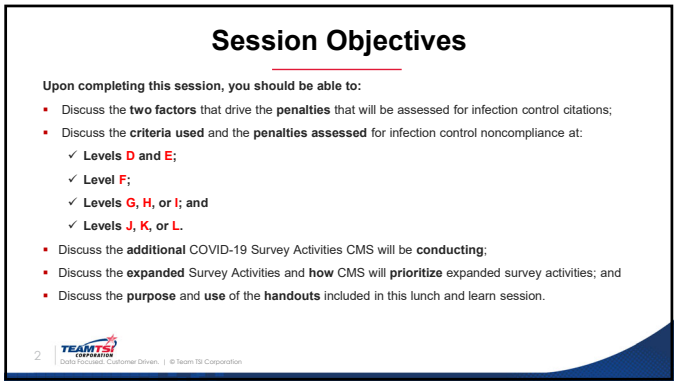
Review of Handouts

Question and Answer Session

- **Encourage** participants to **ask questions** to ensure they understand the importance of the **enhanced enforcement actions** that CMS will impose for infection control citations and the impact it could have on the facility.
- It is **critical** that **all** staff members be **aware** of the focused infection control survey process and the **importance** of working together to ensure the facility remains in compliance with infection control regulatory requirements.

Handout #1 - Participant Session Outline

1



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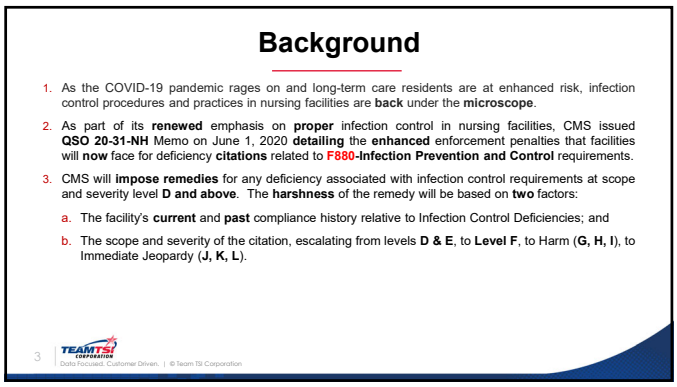

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Enforcement Remedies

IF the facility had NO infection control citations in the last year or on its last standard survey, AND the facility is CITED for infection control noncompliance on its NEXT survey at a--

Scope and Severity Level of D or E

The Enhanced Enforcement Penalties will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis).

Scope and Severity Level of F

The Enhanced Enforcement Penalties will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND**
- ✓ **A Discretionary DPNA for new admissions.**
- ✓ The facility will have **45-days** to demonstrate **compliance** with infection control deficiencies.

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Enforcement Remedies

IF the facility has been cited ONCE for infection control (IC) noncompliance in the last year or on its last standard survey, AND the facility is CITED for IC noncompliance on its NEXT survey at a--

Scope and Severity Level of D or E

The Enhanced Enforcement Penalty will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND**
- ✓ **A Discretionary DPNA for new admissions; AND**
- ✓ **A $5,000** per instance CMP.
- ✓ The facility will have **45-days** to demonstrate **compliance** with infection control deficiencies.

Scope and Severity Level of F

The Enhanced Enforcement Penalties will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND**
- ✓ **A Discretionary DPNA for new admissions; AND**
- ✓ **A $10,000** per instance CMP.
- ✓ The facility will have **45-days** to demonstrate **compliance** with infection control deficiencies.

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IF the facility has been cited TWO or MORE times in the last two years or TWICE since the second to last standard survey for infection control (IC) noncompliance, AND the facility is CITED for IC noncompliance on its NEXT survey at a--

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The Enhanced Enforcement Penalty will be:

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- ✓ **A $15,000** per instance CMP (or per day CMP as long as the total amount **exceeds** $15,000).
- ✓ The facility will have **30-days** to demonstrate **compliance** with infection control deficiencies.

Scope and Severity Level of F

The Enhanced Enforcement Penalties will be:

- ✓ **A Directed Plan of Correction** (including the use of a Root Cause Analysis); **AND**
- ✓ **A Discretionary DPNA for new admissions; AND**
- ✓ **A $20,000** per instance CMP (or **per day** CMP as long as the total amount **exceeds** $20,000).
- ✓ The facility will have **30-days** to demonstrate **compliance** with infection control deficiencies.

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Enforcement Remedies

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Enforcement Remedies

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Enforcement Action for F884 and F885

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COVID-19 Survey Activities

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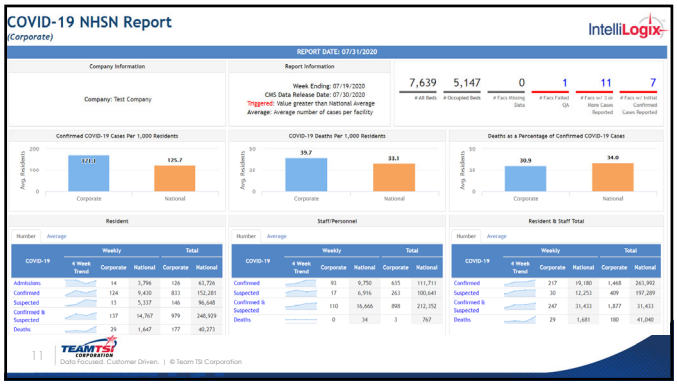

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Expanded Survey Activities

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Expanded Survey Activities

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   c. Violations of Transfer or Discharge Requirements **(F552, F623; F655; F657; F660) (Waivers may apply)**;
   d. Insufficient Staffing or Competency **(F725; F726) (Waivers may apply)**; **OR**
   e. Other Quality of Care Issues (e.g., falls **[F689]**; Pressure Ulcers **[F686]**; etc.)

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Question and Answer Session

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Handout #2

F880 - Infection Prevention & Control

Old Tag Number: F441

§483.80 Infection Control

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

§483.80(a) Infection prevention and control program.

The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

§483.80(a)(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards;

§483.80(a)(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;

(ii) When and to whom possible incidents of communicable disease or infections should be reported;

(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;

(iv) When and how isolation should be used for a resident; including but not limited to:

(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and

(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.

(v)The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and

(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.

(vii) 483.80(a)(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

(viii) 483.80(e) Linens.

Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

§483.80(f) Annual review.

The facility will conduct an annual review of its IPCP and update their program, as necessary.

INTENT 483.80(a),(e),(f)

The intent of this regulation is to ensure that the facility:

- Develops and implements an ongoing infection prevention and control program (IPCP) to prevent, recognize, and control the onset and spread of infection to the extent possible and reviews and updates the IPCP annually and as necessary. This would include revision of the IPCP as national standards change;
- Establishes facility-wide systems for the prevention, identification, investigation and control of infections of residents, staff, and visitors. It must include an ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility and procedures for reporting possible incidents of communicable disease or infections; **NOTE**: For purposes of this guidance, "staff" includes employees, consultants, contractors, volunteers, caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions.
- Develops and implements written policies and procedures for infection control that, at a minimum:
  - Explain how standard precautions and when transmission-based precautions should be utilized, including but not limited to the type and duration of precautions for particular infections or organisms involved and that the precautions should be the least restrictive possible for the resident given the circumstances and the resident's ability to follow the precautions;
  - Prohibit staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and
  - Require staff follow hand hygiene practices consistent with accepted standards of practice.
- Requires staff handle, store, process, and transport all linens and laundry in accordance with accepted national standards in order to produce hygienically clean laundry and prevent the spread of infection to the extent possible.

DEFINITIONS

"Airborne precautions": actions taken to prevent or minimize the transmission of infectious agents/organisms that remain infectious over long distances when suspended in the air. These infectious particles can remain suspended in the air for prolonged periods of time and can be carried on normal air currents in a room or beyond, to adjacent spaces or areas receiving exhaust air.[40]

"Alcohol-based handrub (ABHR)": a 60-95 percent ethanol or isopropyl alcohol- containing preparation base designed for application to the hands to reduce the number of viable microorganisms.

"Cleaning": removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and is normally accomplished manually or mechanically using water with detergents or enzymatic products.

"Cohorting": the practice of grouping residents infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible residents (cohorting residents).[40] During outbreaks, healthcare staff may be assigned to a specific cohort of residents to further limit opportunities for transmission (cohorting staff). The terms "cohort or cohorting" is standardized language used in the practice of infection prevention and control; the use of this terminology is not intended to offend residents or staff.

"Colonization": the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression. [40]

"Communicable disease" (also known as [a.k.a.] "contagious disease"): an infection transmissible (e.g., from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (e.g., contaminated object).

"Community-acquired infections" (a.k.a. "present on admission")**:** infections that are present or incubating at the time of admission and which generally develop within 72 hours of admission.

"Contact precautions": measures that are intended to prevent transmission of infectious agents which are spread by direct or indirect contact with the resident or the resident's environment.[40]

"Contaminated laundry": laundry which has been soiled with blood/body fluids or other potentially infectious materials or may contain sharps.

"Decontamination": the use of physical or chemical means to remove, inactivate, or destroy pathogenic organisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

"Disinfectant": usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. [41]

"Disinfection": thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores). [41]

40 Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., & the Healthcare Infection Control Practices Advisory Committee. (2007). *2007 Guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Accessed on June 9, 2017 from https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

"Disinfection": thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores). [41]

"Droplet precautions": actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.

"Hand hygiene": a general term that applies to hand washing, antiseptic hand wash, and alcohol-based hand rub.[42]

"Hand washing": the vigorous, brief rubbing together of all surfaces of hands with plain (i.e., nonantimicrobial) soap and water, followed by rinsing under a stream of water.[43]

"Healthcare-associated infection (HAI)": an infection that residents acquire, that is associated with a medical or surgical intervention (e.g., podiatry, wound care debridement) within a nursing home and was not present or incubating at the time of admission.

"Hygienically clean": being free of pathogens in sufficient numbers to cause human illness.[44]

"Infection": the establishment of an infective agent in or on a suitable host, producing clinical signs and symptoms (e.g., fever, redness, heat, purulent exudates, etc.).

"Infection preventionist": term used for the person(s) designated by the facility to be responsible for the infection prevention and control program. **NOTE:** Designation of a specific individual, detailed training, qualifications, and hourly requirements for an infection preventionist are not required until implementation of Phase 3.

"Personal protective equipment (PPE)": protective items or garments worn to protect the body or clothing from hazards that can cause injury and to protect residents from cross-transmission.

"(Regulated) Medical waste": liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling (e.g., blood-soaked bandages); contaminated sharps.[45]

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41 Centers for Disease Control and Prevention. (2008). Guideline for disinfection and sterilization in healthcare facilities, 2008. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

42 Centers for Disease Control and Prevention. (2002, October 25). Guideline for hand hygiene in health-care settings: Recommendations of The Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR; 51(No.RR-16). Accessed on June 9, 2017 from http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

43 Centers for Disease Control and Prevention (2009, July 20). OPRP – General information on hand hygiene.
Accessed on June 9, 2017 from https://www.cdc.gov/nceh/vsp/cruiselines/hand_hygiene_general.htm. 44 Association for the Advancement of Medical Instrumentation (AAMI). (2009). ANSI/AAMI ST65:2008/(R)2013. Processing of reusable surgical textiles for use in health care facilities, 2008. Arlington, VA.

NOTE: Authorities having jurisdiction may have more stringent regulations than OSHA.

"Standard Precautions": infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. Standard precautions is based on the principle that all blood, body fluids, secretions, excretions except sweat, regardless of whether they contain visible blood, non-intact skin, and mucous membranes may contain transmissible infectious agents. Furthermore, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents. Standard precautions include but are not limited to hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; safe injection practices, and respiratory hygiene/cough etiquette. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wear gloves for direct contact, properly clean and disinfect or sterilize reusable equipment before use on another patient).[40]

"Transmission-based precautions" (a.k.a. "Isolation Precautions"): actions (precautions) implemented, in addition to standard precautions, that are based upon the means of transmission (airborne, contact, and droplet) in order to prevent or control infections. **NOTE**: Although the regulatory language refers to "isolation," the nomenclature widely accepted and used in this guidance will refer to "transmission-based precautions" instead of "isolation".

NOTE: References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

GUIDANCE §483.80(a),(e),(f)

INFECTION PREVENTION AND CONTROL PROGRAM

Healthcare-associated infections (HAIs) can cause significant pain and discomfort for residents in nursing homes and can have significant adverse consequences. The facility must establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. This program must include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, and visitors. The IPCP must follow national standards and guidelines.

45 Occupational Safety and Health Administration. Title 29 Part 1910.1030. Bloodborne pathogens. Accessed on June 9, 2017 from http://www.ecfr.gov/cgi-bin/text-idx?SID=4e5245f66094d270bc2bd93105f6a92d&mc=true&node=se29.6.1910_11030&rgn=div8

For purposes of this guidance, we would expect facilities to tailor the emphasis of their IPCP for visitors. We expect facilities to work to prevent transmission of infection to the resident from the visitor using reasonable precautions and national standards.[40] For example, passive screening through the use of signs at the entrances to alert visitors with signs and symptoms of communicable diseases not to enter the facility.[40] If a facility has a visitor exception protocol (e.g., end-of-life care), this would need to be determined by the facility. In this case, if a symptomatic visitor/family member must enter the facility, the visitor must still follow the facility's policies for prevention of transmission (e.g., following respiratory hygiene/cough etiquette procedures).

The Infection Prevention and Control Program must include the following parts:

- A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases that:
  - Covers all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement;
  - Is based on the individual facility assessment;
  - Follows accepted national standards;
- Written standards, policies and procedures in accordance with §483.80(a)(2);
- A system for recording incidents identified under the IPCP and corrective actions taken by the facility; and
- An antibiotic stewardship program (ASP) (F881).

FACILITY ASSESSMENT

Pursuant to §483.70(e) (F838), the facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include a facility-based and community-based risk assessment, utilizing an all-hazards approach. See §483.70(e) (F838) for guidance on the facility assessment. The results of the facility assessment must be used, in part, to establish and update the IPCP, its policies and/or protocols to include a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for residents, staff, and visitors.

NOTE: A community-based risk assessment should include review for risk of infections (e.g., multidrug-resistant organisms- MDROs) and communicable diseases such as tuberculosis and influenza. Appropriate resident tuberculosis screening should be performed based on state requirements.

NOTE: While not required for compliance, a sample tool of an infection control risk assessment is available for adaptation.[46]

INFECTION CONTROL POLICIES AND PROCEDURES

The facility must develop and implement written policies and procedures for the provision of infection prevention and control. The facility administration and medical director should ensure that current standards of practice based on recognized guidelines are incorporated in the resident care policies and procedures. These IPCP policies and procedures must include, at a minimum:

- As necessary, and at least annually, review and revision of the IPCP based upon the facility assessment (according to 483.70(e)) which includes any facility and community risk;
- An ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;
- When and to whom possible incidents of communicable disease or infections should be reported within the facility;
- Which communicable diseases are reportable to local/state public health authorities;
- How to use standard precautions and how and when to use transmission-based precautions (i.e., contact precautions, droplet precautions, airborne isolation precautions). The areas described below are part of standard and transmission-based precautions[40] which are further described under their respective sections. For example:
    - Hand hygiene (HH) (e.g., hand washing and/or ABHR): consistent with accepted standards of practice such as the use of ABHR instead of soap and water in all clinical situations except when hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected Clostridium (C.) difficile or norovirus infection during an outbreak, or if infection rates of C. difficile infection (CDI) are high; in these circumstances, soap and water should be used;[47] **NOTE:** According to the CDC, strict adherence to glove use is the most effective means of preventing hand contamination with C. difficile spores as spores are not killed by ABHR and may be difficult to remove even with thorough hand washing. For further information on appropriate hand hygiene practices see the following CDC website: http://www.cdc.gov/handhygiene/providers/index.html
- The selection and use of PPE (e.g., indications, donning/doffing procedures) and the clinical conditions for which specific PPE should be used (e.g., CDI, influenza);
- Addressing the provision of facemasks for residents with new respiratory symptoms;
- Addressing resident room assignment (e.g. single/private room/cohorted) as appropriate and/or available, based on a case by case analysis of the presence of risk factors for increased likelihood of transmission (e.g., uncontained drainage, stool incontinence);[40]
- The process to manage a resident on transmission-based precautions when a single/ private room is not available;

46 Association for Professionals in Infection Control and Epidemiology. IC risk assessment tool form and IC risk assessment analysis. Accessed on June 9, 2017 from

47 Dubberke, E.R., & Gerding, D.N. (2011). Rationale for hand hygiene recommendations after caring for a patient with Clostridium difficile infection. In A compendium of strategies to prevent healthcare-associated infections in acute care hospitals: A fall 2011 update. Accessed on June 9, 2017 from https://www.shea-online.org/images/patients/CDI-hand-hygiene-Update.pdf

- Limiting the movement of a resident with a highly infectious disease (e.g., norovirus, CDI) who is on transmission-based precautions with active symptoms (e.g., resident has diarrhea, vomiting, draining wounds, or other uncontained excretions or secretions) while outside of his/her room for medically necessary purposes only;[40] and
- Respiratory Hygiene/Cough Etiquette[40]: Implementing policies and procedures would include providing resources and instructions for performing HH in or near lobby areas or entrances; provide conveniently-located dispensers of ABHR and supplies for hand washing where sinks are available. During times of increased prevalence of respiratory infections in the community, facilities must have facemasks available and should offer facemasks to coughing or sneezing visitors and other symptomatic persons (e.g., family who accompany ill residents upon entry to the facility). Symptomatic (e.g., coughing) visitors should wear a facemask or maintain at least a three foot separation from others in common areas (e.g., admitting office). In addition, the facility should consider posting signs in the facility with instructions to family/ visitors with symptoms of respiratory infection to cover their mouth/nose when coughing or sneezing; use and dispose of tissues; perform hand hygiene after contact with respiratory secretions; and to take appropriate precautions if they are having symptoms of respiratory infection or other communicable diseases.

- Resident Care Activities:
  - The use and care of urinary catheters, which must include a written rationale for the use, consistent with evidence-based guidelines (e.g., acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures) (Refer to §483.25(e)(2)(i)(ii)&(iii) Incontinence, F690, for further information.);
  - Wound care, fecal/urinary incontinence care, and skin care. Since the IPCP must be based on the facility assessment, the presence of certain resident conditions would require that the facility have policies and procedures related to other specific services such as mechanical ventilation, infusion therapy, and/or dialysis either onsite or at an offsite dialysis facility;
  - Performing fingersticks and point-of-care testing (e.g., assisted blood glucose monitoring) to the extent identified as a resident need based on the facility assessment;
  - Preparation, administration, and care for medications administered by injection or peripheral and central venous catheters, if performed by the facility; and
  - Use and care of peripheral and central venous catheters, if performed by the facility.

- Environmental cleaning/disinfection:
  - Routine cleaning and disinfection of high-touch surfaces in common areas, resident rooms, and at the time of discharge; and

    NOTE: Privacy curtains in the resident's room should be changed when visibly dirty by laundering or cleaning with an Environmental Protection Agency (EPA)-registered disinfectant per manufacturer's instructions.
  - Cleaning/disinfection of resident care equipment including equipment shared among residents (e.g., blood pressure cuffs, rehabilitation therapy equipment, blood glucose meters, etc.).

- Written occupational health policies that address:
  - Reporting of staff illnesses and following work restrictions per nationally recognized standards and guidelines;[48]
  - Prohibiting contact with residents or their food when staff have potentially communicable diseases or infected skin lesions;
  - Assessing risks for tuberculosis (TB) based on regional/community data and screening staff to the extent permitted under applicable federal guidelines [49] and state law;
  - Monitoring and evaluating for clusters or outbreaks of illness among staff;
  - Implementing an exposure control plan in order to address potential hazards posed by blood and body fluids, from dialysis, glucose monitoring or any other point of care testing; and
  - Education and competency assessment: facilities must ensure staff follow the IPCP's standards, policies and procedures. Therefore, staff must be informed and competent. Knowledge and skills pertaining to the IPCP's standards, policies and procedures are needed by all staff in order to follow proper infection control practices (e.g., hand hygiene and appropriate use of personal protective equipment) while other needs are specific to particular roles, responsibilities, and situations (e.g., injection safety and point of care testing). Furthermore, residents and their representatives should receive education on the facility's IPCP as it relates to them (e.g., hand hygiene, cough etiquette) and to the degree possible/consistent with the resident's capacity. For example, residents should be advised of the IPCP's standards, policies and procedures regarding hand hygiene before eating and after using the restroom.

SURVEILLANCE

The facility must establish a system for surveillance based upon national standards of practice and the facility assessment, including the resident population and the services and care provided. The facility must establish routine, ongoing, and systematic collection, analysis, interpretation, and dissemination of surveillance data to identify infections (i.e., HAI and community-acquired), infection risks, communicable disease outbreaks, and to maintain or improve resident health status. As part of the system of surveillance, identification and prevention, the facility should determine how it will track the extent to which staff are following the facility's IPCP policies and procedures, and facilities would want to particularly address any areas that are related to a corrective action.

48 Bolyard, E.A., Tablan, O.C., Williams, W.W., Pearson, M.L., Shapiro, C.N., Deitchman, S.D., & The Healthcare Infection Control Practices Advisory Committee. (1998). Guideline for infection control in health care personnel, 1998. American Journal of Infection Control 26, 289-354. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/InfectControl98.pdf

49 Jensen, P.A., Lambert, L.A., Iademarco, M.F., & Ridzon, R. (CDC's Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention). (2005, December 30). Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings, 2005. MMWR; 54 (No.RR-17). Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm

The facility's surveillance system must include a data collection tool and the use of nationally-recognized surveillance criteria such as but not limited to CDC's National Healthcare Safety Network (NHSN) Long Term Care Criteria to define infections or updated McGeer criteria[50]. Furthermore, the facility must know when and to whom to report communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks (e.g., list of communicable diseases which are reportable to local/state public health authorities). The facility must document follow-up activity in response to important surveillance findings (e.g., outbreaks).

In addition, the facility must establish and implement a system, including who to notify (e.g. infection preventionist), for early detection and management of a potentially infectious, symptomatic resident at the time of admission. This includes the identification and use of appropriate transmission-based precautions.[40] This is important to incorporate into the resident's baseline care plan that must be developed within 48 hours of admission and include the minimum healthcare information necessary to properly care for a resident, including physician orders (e.g., medication orders). See §483.21, Comprehensive Person-Centered Care Planning for further information.

Furthermore, the facility must have a process for communicating information at the time of transfer (e.g., CDC, state, or other standardized inter-facility infection transfer form) when a resident has an infection or is colonized.[51] When a resident is transferred, the information provided to the receiving provider must include special instructions or precautions for ongoing care and other necessary information including a discharge summary. When a resident is discharged, the discharge summary must include the resident's disease diagnoses and health conditions, course of illness/treatment or therapy, medications, and pertinent lab, radiology, consultation results, and instructions or precautions for ongoing care. See §483.21(c)(2), Discharge Summary (F661) and §483.15(c)(2)(iii), Transfer and Discharge (F622) for further information on these requirements.

Additionally, as part of the overall IPCP for surveillance, the facility shall establish process and outcome surveillance.

Process Surveillance

Process surveillance is the review of practices by staff directly related to resident care.[52] The purpose is to identify whether staff implement and comply with the facility's IPCP policies and procedures. Some areas that facilities may want to consider for process surveillance are the following:

- *Hand hygiene;*
- *Appropriate use of personal protective equipment (e.g., gowns, gloves, facemask);*
- *Injection safety;*

50 Stone, N.D., Ashraf, M.S., Calder, J., Crnich, C. J., Crossley, K., Drinka, P.J., …Bradley, S.F. (2012). Surveillance definitions of infections in long-term care facilities: Revisiting the McGeer criteria. Infect Control Hosp Epidemiology. 33(10), 965-977.

51 Siegel, J.D., Rhinehart, E., Jackson, M., and Chiarello, L. (2006). Management of multidrug-resistant organisms in healthcare settings, 2006. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/mdro/mdroguideline2006.pdf

- Point-of-care testing (e.g., during assisted blood glucose monitoring);
- Implementation of infection control practices for resident care such as but not limited to urinary catheter care, wound care, injection/IV care, fecal/urinary incontinence care, skin care, respiratory care, dialysis care, and other invasive treatments;

- Managing a bloodborne pathogen exposure.

  NOTE: This may not lend itself to monitoring and feedback;

- Cleaning and disinfection products and procedures for environmental surfaces and equipment;
- Appropriate use of transmission-based precautions; and
- Handling, storing, processing, and transporting linens so as to prevent the spread of infection.

Outcome Surveillance

Another component of a system of identification is outcome surveillance. For example, this addresses the criteria that staff would use to identify and report evidence of a suspected or confirmed HAI or communicable disease. This process consists of collecting/documenting data on individual resident cases and comparing the collected data to standard written definitions (criteria) of infections.

NOTE: Refer to the CDC/SHEA Position Statement: Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria[50] or NHSN at https://www.cdc.gov/nhsn/ for examples of nationally accepted surveillance definitions.

The following are some sources of data that can be utilized in outcome surveillance for infections, antibiotic use and susceptibility: Monitoring a resident(s) with fever or other signs or symptoms suspicious for infection;

- Laboratory cultures or other diagnostic test results consistent with potential infections to detect clusters, trends, or susceptibility patterns;
- Antibiotic orders;
- Medication regimen review reports;
- Documentation from the clinical record of residents with suspicion of an infection such as physician orders/progress notes; and/or
- Transfer/discharge summaries for new or readmitted residents for infections.[52]

52 Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J.... Stevenson, K. (2008). SHEA/APIC Guideline: infection prevention and control in the long-term care facility. *Infect Control Hosp Epidemiology. 29*(9), 785-814.

SYSTEM OF SURVEILLANCE: DATA ANALYSIS, DOCUMENTATION AND REPORTING

The facility's policies and procedures for a system of surveillance must include data to properly identify communicable diseases or infections before they spread. Therefore, the policies and procedures would include identifying:

- Data to be collected, including how often and the type of data to be documented, including:
  - The infection site (i.e., type of infection), pathogen (if available), signs and symptoms, and resident location, including summary and analysis of the number of residents
    (and staff, if applicable) who developed infections;
  - Observations of staff including the identification of ineffective practices (e.g., not practicing hand hygiene and/or using PPE when indicated as well as practices that do not follow the facility's IPCP policies and procedures), if any; and
  - The identification of unusual or unexpected outcomes (e.g. foodborne outbreak), infection trends and patterns.
- How the data will be used and shared with appropriate individuals (e.g., staff, medical director, director of nursing, quality assessment and assurance committee- QAA), when applicable, to ensure that staff minimize spread of the infection or disease (e.g., require revision of staff education and competency assessment).

The facility must identify how reports will be provided to staff and/or prescribing practitioners in order to revise interventions/approaches and/or re-evaluate medical interventions related to the infection rates and outcomes.

RECOGNIZING, CONTAINING AND REPORTING COMMUNICABLE DISEASE OUTBREAKS

The facility must know how to recognize and contain infectious disease outbreaks. An outbreak is the occurrence of more cases than expected in a given area or among a specific group of people over a particular period of time.[53] If a condition is rare or has serious health implications, an outbreak may involve only one case. While a single case of a rare infectious condition or one that has serious health implications may or may not constitute an outbreak, facilities should not wait for the definition of an outbreak to act. For example, one case of laboratory confirmed influenza in a resident should alert the facility to begin an outbreak investigation.[54] If an outbreak is identified, the facility must:

- Take the appropriate steps to diagnose and manage cases, implement appropriate precautions, and prevent further transmission of the disease as well as documentation of follow-up activity in response; and
- Comply with state and local public health authority requirements for identification, reporting, and containing communicable diseases and outbreaks.

53 Centers for Disease Control and Prevention. (2015, January 21). Epidemiology glossary. Accessed on June 9, 2017 from http://www.cdc.gov/reproductivehealth/data_stats/glossary.html#O

54 Schweon, S., Burdsall D., Hanchett, M., Hilley, S., Greene, D., Kenneley, I., Marx, J., Rosenbaum, P. (2013). Infection preventionist's guide to long-term care. Washington DC: APIC.

NOTE: Some states have specific regulations regarding responding to and reporting outbreaks that must be included in the IPCP.

PREVENTION AND CONTROL OF TRANSMISSION OF INFECTION

Infectious organisms (e.g., bacteria, viruses, or parasites) may be transmitted by direct contact (e.g., skin-to-skin) or indirect contact (e.g., inanimate objects). Healthcare staff and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms.

Direct Contact Transmission (Person-to-Person) occurs when microorganisms such as methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), carbapenem-resistant Enterobacteriaceae (CRE), influenza, or mites from a scabies-infected resident are transferred from an infected or colonized person to another person. In nursing homes, resident-to-resident direct contact transmission may occur in common areas of the facility such as the recreation room, rehabilitation area, and/or dining room.

Indirect Contact Transmission: involves the transfer of an infectious agent through a contaminated inanimate object or person.

The following are examples of opportunities for indirect contact transmission:

- Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and C. difficile); and
- Contamination of high touch environmental surfaces (e.g., bedside table, bed rails, toilets, sinks, and handrails), contributes to transmission of pathogens including C. difficile and norovirus.

Certain pathogens may contaminate and survive on equipment and environmental surfaces for long periods of time. Examples include, but are not limited to:

- C. difficile spores can live on inanimate surfaces for up to 5 months;[55]
- The hepatitis B virus can last up to a week on inanimate surfaces;[56] and
- The influenza virus can survive on fomites (e.g., any inanimate object or substance capable of carrying infectious organisms and transferring them from one individual to another) for up to 8 hours.[57]

Mechanisms to prevent and control transmission of infectious organisms through direct and indirect contact include standard and transmission-based precautions and are described in their subsequent sections.

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55 Kim, K.H., Fekety, R., Batts, D.H.,Brown, D., Cudmore , M., Silva, J. Jr., & Waters, D. (1981, January 1). Isolation of Clostridium difficile from the environment and contacts of residents with antibiotic-associated colitis. Journal of Infectious Disease. 143(1), 42-50.

56 Centers for Disease Control and Prevention (CDC). Hepatitis B FAQs for health professionals. Accessed on June 9, 2017 from http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm

57 Centers for Disease Control and Prevention (CDC). (2007, February 15). Preventing seasonal flu. Accessed on June 9, 2017 from https://www.cdc.gov/flu/protect/vaccine/index.htm

STANDARD PRECAUTIONS

Standard precautions represent the infection prevention measures that apply to all resident care, regardless of suspected or confirmed infection status of the resident, in any setting where healthcare is being delivered. These evidence-based practices are designed to protect healthcare staff and residents by preventing the spread of infections among residents and ensuring staff do not carry infectious pathogens on their hands or via equipment during resident care. As mentioned in the definitions section, standard precautions include hand hygiene, use of PPE (e.g., gloves, gowns, facemasks), respiratory hygiene and cough etiquette, safe injection practices, and safe handling of equipment or items that are likely contaminated with infectious body fluids, as well as cleaning and disinfecting or sterilizing of potentially contaminated equipment.[40]

In order to perform hand hygiene appropriately, soap, water, ABHR, and a sink should be readily accessible in appropriate locations including but not limited to resident care areas, and food and medication preparation areas. Staff must perform hand hygiene (even if gloves are used):

- Before and after contact with the resident;
- Before performing an aseptic task;
- After contact with blood, body fluids, visibly contaminated surfaces or after contact with objects in the resident's room;
- After removing personal protective equipment (e.g., gloves, gown, facemask);
- After using the restroom; and
- Before meals.

If residents need assistance with hand hygiene, staff should assist with washing hands after toileting, before meals, and use of ABHR or soap and water at other times when indicated.

The use of PPE during resident care is determined by the nature of staff interaction and the extent of anticipated blood, body fluid, or pathogen exposure to include contamination of environmental surfaces. Furthermore, appropriate use of PPE includes but is not limited to the following:

- Gloves worn before and removed after contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves changed and hand hygiene performed before moving from a contaminated-body site to a clean-body site during resident care;
- Gown worn for direct resident contact if the resident has uncontained secretions or excretions or with contaminated or potentially contaminated items;
- Appropriate mouth, nose, and eye protection (e.g., facemasks, face shield) is worn for procedures that are likely to generate splashes or sprays of blood or body fluids;
- PPE appropriately discarded after resident care prior to leaving room followed by hand hygiene; and
- Supplies necessary for adherence to proper PPE use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (i.e., nursing units, therapy rooms) although, equipment supply carts should not be brought into the resident's room.

The facility must prevent infections through indirect contact transmission. This requires the decontamination (i.e., cleaning and/or disinfecting an object to render it safe for handling) of resident equipment, medical devices, and the environment. Alternatively, the facility may also consider using single-use disposable devices or designating reusable equipment for only an individual resident. **NOTE**: Refer to the CDC website for information on environmental cleaning - https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

The facility must identify the decontamination method based upon the risk of infection to the resident coming into contact with equipment or medical devices. Equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g., wear gloves for handling soiled equipment and properly clean and disinfect or sterilize reusable equipment before use on another resident).[40]

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical, and noncritical.[58] This includes:

- Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) enter sterile tissue or the vascular system. These items or equipment must be sterile when used, based on one of several accepted sterilization procedures. Most of the items in this category should be purchased as sterile or be sterilized;
- Semi-critical items (e.g., dental, podiatry equipment, electric razors) contact mucous membranes or non-intact skin. Such items require meticulous cleaning followed by high-level disinfection treatment using a Food and Drug Administration (FDA)- approved high-level chemical disinfectant, or they may be sterilized. High-level disinfection is traditionally defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. Refer to the specific disinfectant label claim to determine effectiveness; and
- Non-critical items are those that come in contact with intact skin but not mucous membranes. Noncritical items are divided into noncritical resident care items (e.g., blood pressure cuffs, stethoscopes, wheelchairs, therapy equipment) and noncritical environmental surfaces (e.g., bed rails, bedside tables). They require low level disinfection by cleaning periodically and after visible soiling, following manufacturer's instructions with an EPA-registered disinfectant, detergent or germicide that is approved for health care settings. All applicable label instructions on EPA-registered disinfectant products must be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use and disposal).

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Single-use devices must be discarded after use and are never used for more than one resident. Nursing homes may purchase reprocessed single-use devices when these devices are reprocessed by an entity or a third party reprocessor that is registered with the FDA. The

58 Sehulster, L.M., Chinn, R.Y., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., … Cleveland, J. (2003, June 6). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR; 52(*No. RR-10). Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

nursing home must have documentation from the third party reprocessor that indicates that it has been cleared by the FDA to reprocess the specific device in question.

NOTE: Refer to the CDC website for information on disinfection and sterilization – https://www.cdc.gov/infectioncontrol/guidelines/Disinfection/index.html

TRANSMISSION-BASED PRECAUTIONS

Transmission-based precautions must be used when a resident develops signs and symptoms of a transmissible infection, arrives at a nursing home with symptoms of an infection (pending laboratory confirmation), or has a laboratory confirmed infection and is at risk of transmitting the infection to other residents. For example, a resident with influenza and signs of infection should wear a facemask (e.g., surgical or procedure facemask) when leaving his/her room for medically-necessary care (i.e., droplet precautions for the duration of the illness). The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation. However, since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, transmission-based precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.[40, 51]

Facility policies must identify the type (i.e., contact, droplet, airborne) and duration of the transmission-based precautions required, depending upon the infectious agent or organism involved. Furthermore, transmission-based precautions should be the least restrictive possible for the resident based on his/her clinical situation and used for the least amount of time. When used appropriately, transmission-based precautions is not to be considered involuntary seclusion. However, once the resident is no longer a risk for transmitting the infection (e.g., duration of the illness and/or can contain secretions), removing transmission-based precautions is required in order to avoid unnecessary involuntary seclusion. For example, a resident with vancomycin-resistant enterococci (VRE) who is colonized based on a urine culture, but is continent and cognizant, should be instructed regarding or as necessary, assisted with performing hand hygiene before leaving his/her room, but is not placed on transmission-based precautions.

Facility staff should take measures to reduce or minimize any potential psychosocial negative effects of isolation for whom transmission-based precautions are being used. Boredom, anger, withdrawal or depression are just some of the mood changes that could occur. The facility must pro-actively ensure that individualized needs (e.g., activities) are met.

Implementation of Transmission-Based Precautions

When implementing transmission-based precautions, consideration should be given to the following:[40]

- The identification of resident risk factors that increase the likelihood of transmission, (such as uncontained secretions or excretions, non-compliance, cognition deficits, incontinence, etc.);
- The provision of a private room as available/appropriate;
- Cohorting residents with the same pathogen; and
- Sharing a room with a roommate with limited risk factors (e.g., without indwelling or invasive devices, without open wounds, and not immunocompromised) as appropriate.

When a resident is placed on transmission-based precautions, the staff should implement the following:

- Clearly identify the type of precautions and the appropriate PPE to be used;
- Place signage in a conspicuous place outside the resident's room such as the door or on the wall next to the doorway identifying the CDC category of transmission-based precautions (e.g. contact, droplet, or airborne), instructions for use of PPE, and/or instructions to see the nurse before entering. Ensure that signage also complies with residents' rights to confidentiality and privacy;
- Make PPE readily available near the entrance to the resident's room;
- Don appropriate PPE upon entry into the environment (e.g., room or cubicle) of resident on transmission-based precautions (e.g., contact precautions); [40]
- Use disposable or dedicated noncritical resident-care equipment (e.g., blood pressure cuff, bedside commode). If noncritical equipment is shared between residents, it will be cleaned and disinfected following manufacturer's instructions with an EPA-registered disinfectant after use; [40]
- Clean and disinfect objects and environmental surfaces that are touched frequently (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) with an EPA-registered disinfectant for healthcare use at least daily and when visibly soiled; [40] and
- Provide education to residents (to the degree possible/consistent with the resident's capacity) and their representatives or visitors on the use of transmission-based precautions.

NOTE: Refer to CDC guidelines for current recommendations on standard and transmission-based precautions. http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

Contact Precautions

Contact precautions are intended to prevent transmission of infections that are spread by direct (e.g., person-to-person) or indirect contact with the resident or environment, and require the use of appropriatePPE, including a gown and gloves upon entering (i.e., before making contact with the resident or resident's environment) the room or cubicle. Prior to leaving the resident's room or cubicle, the PPE is removed and hand hygiene isperformed.

Droplet Precautions

The use of droplet precautions applies when respiratory droplets contain viruses or bacteria particles which may be spread to another susceptible individual. Respiratory viruses can enter thebody via the nasal mucosa, conjunctivae and less frequently the mouth.[59] Examples of droplet-borne organisms that may cause infections include, but are not limited to Mycoplasma pneumoniae, influenza, and other respiratory viruses.

59 Hall, C.B., Douglas, Jr., R.G., Schnabal, K.C., and Geiman, J.M. (1981, September). Infectivity of respiratory syncytial virus by various routes of inoculation. *Infection and Immunity. 33*(3), 779-783.

Respiratory droplets are generated when an infected person coughs, sneezes, talks, or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation.[40] The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.[40] In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances.

Facemasks are to be used upon entry (i.e., within three feet of a resident) into a resident's room or cubicle with respiratory droplet precautions.[40] If substantial spraying of respiratory secretions is anticipated, gloves and gown as well as goggles (or face shield in place of goggles) should be worn.[40] The preference for a resident on droplet precautions would be to place the resident in a private room.[40] If a private room is not available, the resident could be cohorted with a resident with the same infectious agent, or share a room with a roommate with limited risk factors.[40] Spatial separation of at least 3 feet and drawing the curtain between resident beds is especially important for residents in multi-bed rooms with infections transmitted by the droplet route.[40]

Airborne Precautions

Airborne transmission occurs when pathogens are so small that they can be easily dispersed in the air, and because of this, there is a risk of transmitting the disease through inhalation. These small particles containing infectious agents may be dispersed over long distances by air currents and may be inhaled by individuals who have not had face-to-face contact with (or been in the same room with) the infectious individual. Staff caring for residents on airborne precautions should wear a fit-tested N95 or higher level respirator that is donned prior to room entry.[40]

NOTE: According to the CDC, preventing the spread of pathogens that are transmitted by the airborne route requires the use of special air handling and ventilation systems such as an airborne infection isolation room (AIIR) to contain and then safely remove the infectious agent.[40] Residents with infections requiring an AIIR must be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed. In cases when AIIR is required, such as for a resident with TB, it is important for the facility to have a plan (e.g., public health notification and exposure workup) in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer to an acute care setting.[40]

MEDICAL DEVICE SAFETY

Medical devices may be used for administration of medications, point-of-care testing, or for other medical uses.

Point-of-Care Testing

Point-of-care testing is diagnostic testing that is performed at or near the site of resident care. This may be accomplished through use of portable, handheld instruments such as blood glucose meters or prothrombin time meters. This testing may involve obtaining a blood specimen from the resident using a fingerstick device. The guidance regarding fingerstick devices and blood glucose meters is applicable to other point-of-care devices where a blood specimen is obtained (e.g., prothrombin time meters).

Fingerstick Devices

CDC recommends the use of single-use, auto-disabling fingerstick devices in settings where assisted blood glucose monitoring is performed. This practice prevents inadvertent reuse of fingerstick devices for more than one person. Additionally, the use of single-use, auto-disabling fingerstick devices protects healthcare staff from needlestick injuries. If reusable fingerstick devices are used for assisted monitoring of blood glucose, then they **must never be used for more than one resident**. Although the package instructions for some fingerstick devices may indicate or imply the potential for multiple resident use, CMS guidance, based upon nationally recognized standards of practice from the CDC and FDA, prohibits the use of fingerstick devices for more than one resident.

NOTE: If fingerstick devices are used on more than one resident, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. Furthermore, the state survey agency (SA) must notify the appropriate state public health authority of the deficient practice.

NOTE: For information on fingerstick safety, please refer to:

- https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html
- https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

Blood Glucose Meters

Blood glucose meters, can become contaminated with blood and, if used for multiple residents, must be cleaned and disinfected after each use according to manufacturer's instructions for multi-patient use. Additionally, staff must **not** carry blood glucose meters in pockets.
The FDA has released guidance for manufacturers regarding appropriate products and procedures for cleaning and disinfection of blood glucose meters. This guidance can be found at the FDA's website:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm
An excerpt from this guidance reads:

> "The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B virus. Outbreak episodes have been largely due to transmission of Hepatitis B and C viruses. However, of the two, Hepatitis B virus is the most difficult to kill. Please note that 70% ethanol solutions are not effective against viral bloodborne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device." A list of Environmental Protection Agency (EPA) registered disinfectants can be found at the following website: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.

Furthermore, "healthcare personnel should consult the manufacturers of blood glucose meters in use at their facilities to determine what products, meeting the criteria specified by the FDA, are compatible with their meter prior to using any EPA-registered disinfectant for disinfection

purposes. If manufacturers are unable to provide this information then the meter should not be used for multiple patients."[60]

Blood glucose meters dedicated for single-resident use should be stored in a manner that will protect against inadvertent use of the device for additional residents and also cross-contamination via contact with other meters or equipment.

NOTE: If the facility failed to clean and disinfect, per device manufacturer's instructions, and blood glucose meters are used for more than one resident, surveyors must cite this tag and utilize the guidelines in Appendix Q as it may constitute immediate jeopardy.

For more information on point-of-care testing, refer to CDC's website at: https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

Safe Medication Administration

All injectable medications must be prepared and administered in accordance with safe injection practices, including but not limited to the following:

- Injections are prepared using aseptic technique in a clean area, free from potential sources of contamination (e.g., blood, body fluids, contaminated equipment);
- Needles and syringes are used for only one resident (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).
  NOTE: If it is identified that needles or syringes are used for more than one resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;

- Medication containers are entered with a new needle and a new syringe, even when obtaining additional doses for the same resident. If noncompliance is found, further investigation is warranted.
  NOTE: If the medication container is used for more than one resident, a new needle and/or syringe was not used with each access, and the container was then used for another resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;

- Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one resident;

- Medication administration tubing and connectors are used for only one resident.

  NOTE: Surveyors must cite at this tag if noncompliance is identified and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state

60 Centers for Disease Control and Prevention. (2016). Frequently asked questions (FAQs) regarding assisted blood glucose monitoring and insulin administration. Accessed on June 9, 2017 from https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

public health authority of the deficient practice; and

- Multi-dose vials to be used for more than one resident are kept in a centralized medication area (e.g., medication room or cart) and do not enter the immediate resident treatment area (e.g., resident room). If multi-dose vials enter the immediate resident treatment area, they should be discarded immediately after use.
  NOTE: For more information on multi-dose vials, please refer to:
  https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use, using a new needle for each injection. **Insulin pens are designed to be used multiple times by a single resident only and must never be shared.** Facility staff must follow manufacturer's instructions for administration. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one resident, even when the needle is changed. The FDA makes the following recommendations to prevent transmission of bloodborne infections in residents who require insulin pens:

- Insulin pens containing multiple doses of insulin are meant for single-resident use only, and must never be used for more than one person, even when the needle is changed;
- Insulin pens must be clearly labeled with the resident's name and other identifiers to verify that the correct pen is used on the correct resident; and
- Facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.

NOTE: Sharing insulin pens, or similar devices, between residents is similar to reusing needles or syringes for more than one resident. If noncompliance is found, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the finding.

For more information on insulin pens, please refer to:
https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProvid ers/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm

Accessing Vascular Devices

Vascular access devices, especially central venous catheters (CVC), increase the risk for local and systemic infections as well as additional complications such as septic thrombophlebitis. Intravascular access devices such as implanted ports may be accessed multiple times per day, for hemodynamic measurements or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to CVCs for only the primary purpose may help reduce the risk of infection. The following CDC guidelines are provided as a reference for current standards of practice for the care of CVCs:

- http://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/central-venous-catheters.html
- http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Central-Venous-Catheter-STH-Protocol.pdf

- http://www.cdc.gov/dialysis/PDFs/collaborative/Catheter-Exit-Site-Care-Observations.pdf
- http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

SYSTEM OF RECORDING IPCP INCIDENTS

A facility must develop and implement a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility based on the investigation of the incidents. A facility-identified incident (e.g., HAI) may include the spread of disease due to errors in infection prevention and control. The facility's system should include defining, identifying, analyzing, and reporting incidents related to failures in infection control practices to the director of nursing, medical director, and the QAA committee. These may include but are not limited to the following:

- Identification of methods by which the facility would obtain information on incidents from residents, family, and direct care/direct access staff;
- A description of how the facility addresses and investigates the incident(s);
- Measures to be implemented for the prevention of incidents or potential incidents as they relate to infection prevention and control;
- Development and implementation of corrective actions;
- Monitoring for the effectiveness of its implemented changes; and
- Methods for feedback to appropriate individuals involved in the failed practices.

LINENS

Laundry Services

The facility must develop and follow practices on handling, storing, processing, and transporting laundry. The facility must monitor to ensure that the laundry practices are implemented, any deviations from practices must be identified, and corrective actions are put in place.

Laundry includes resident's personal clothing, linens, (i.e., sheets, blankets, pillows), towels, washcloths, and items from departments such as nursing, dietary, rehabilitative services, beauty shops, and environmental services. Laundry services may be provided onsite or the facility may have a written agreement in place for offsite laundry services. Regardless of the location where the laundry is processed, the facility must ensure that all laundry is handled, stored, processed and transported in a safe and sanitary method.

Handling Laundry

The facility staff should handle all used laundry as potentially contaminated and use standard precautions (i.e., gloves). Alternatively, if not all used linens are handled as potentially contaminated, staff would provide separation with special identification of bags and containers for contaminated linens with labels, color coding, or other alternative means of separation of the laundry for appropriate handling and processing. The facility should use the following practices:

- Contaminated laundry is bagged or contained at the point of collection (i.e., location where it was used); [58]
- Leak-resistant containers or bags are used for linens or textiles contaminated with blood or body substances;[58]
- Sorting and rinsing of contaminated laundry at the point of use, hallways, or other open resident care spaces is prohibited; and [58]

- Staff should handle soiled textiles/linens with minimum agitation to avoid the contamination of air, surfaces, and persons. [58]

Transport of Laundry

The facility practices must include how staff will handle and transport the laundry with appropriate measures to prevent cross-contamination. This includes but is not limited to the following:

- Contaminated linen and laundry bags are not held close to the body or squeezed when transporting;[45]
- No special precautions (i.e., double bagging) or categorizing for linen originating in transmission-based precaution rooms is necessary;[58]
- Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag;[45]
- Contaminated linen carts must be cleaned and disinfected whenever visibly soiled and according to a schedule developed by the facility;[41]
- Separate carts must be used for transporting clean and contaminated linen. If this is not possible, the contaminated linen cart should be thoroughly cleaned and disinfected per facility protocol before being used to move clean linens; and [58]
- Clean linens must be transported by methods that ensure cleanliness and protect from dust and soil during intra or inter-facility loading, transport, and unloading. [58]

Linen Storage

Facility practices must address linen storage, and should include but are not limited to:

- Covers are not needed on contaminated textile hampers in resident care areas (unless state licensing rules require them); and [58]
- Clean linen must always be kept separate from contaminated linen. The use of separate rooms, closets, or other designated spaces with a closing door provides the most secure methods for reducing the risk of accidental contamination.[61]

Processing Laundry Including the Use of Laundry Equipment and Detergents in the Facility

The facility must have a process to clean laundry. Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. Advances in laundry equipment technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted. Washing/drying processes includes the use of manufacturer's instructions for use (IFU) for laundry additives and equipment maintenance. The facility staff must prevent contamination of laundry in processing areas. The facility has laundry practices that includes but are not limited to the following:

- Availability and use of hand hygiene products, as well as appropriate PPE (i.e., gloves and gowns) while sorting and handling contaminated linens; [58]
- The receiving area for contaminated textiles is clearly separated from clean laundry areas. Workflow should prevent cross-contamination; [58]

61 Healthcare Laundry Accreditation Council. (2015). Checklist: Accreditation standards 2016 edition. Accessed on June 9, 2017 from http://media.wix.com/ugd/076879_24e999ab2b484cac8c3c30ee9af77cc0.pdf

- If using fans in laundry processing areas, prevent cross-contamination of clean linens from air blowing from soiled processing areas (i.e., the ventilation should not flow from soiled processing areas to clean laundry areas); [58]
- Laundry equipment (e.g., washing machines, dryers) is used and maintained according to the manufacturer's IFU to prevent microbial contamination of the system; [58]
- Damp laundry is not left in machines overnight; [58]
- Laundry detergents, rinse aids or other additives are used according to the manufacturer's IFU's; [58]

  NOTE: Facilities should communicate information regarding allergies that may impact how an individual resident's laundry is processed.

- Ozone cleaning systems are acceptable for processing laundry;
- If laundry chutes are used, they are designed and maintained so as to minimize dispersion of aerosols from contaminated laundry (e.g., no loose items in the chute and bags are closed before tossing into the chute); [58] and
- The facility should be using the fabric manufacturer's recommended laundry cycles, water temperatures and chemical detergent products:
  - Recommendations for laundry processed in hot water temperatures is 160ºF (71ºC) for 25 minutes;[58] and
  - For laundry that is not hot water compatible, low temperature washing at 71 to 77 ºF (22-25 ºC) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.[58]

  NOTE: The facility is not required to monitor water temperatures during laundry processing cycles, unless specified by state rules. A chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach. The facility should refer to the manufacturer's recommendations for the use of the detergent and items being laundered.

Offsite Professional Laundry Services

If linen is sent off-site to a professional laundry, the facility has practices that address how the service will be provided, including how linen is processed and handled to prevent contamination from dust and dirt during loading and transport. The facility should assure that this laundry service meets healthcare industry laundry standards.

Mattresses and Pillows

Standard permeable mattresses and pillows can become contaminated with body substances duringresident care if the integrity of the covers of these items is compromised. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. **NOTE**: Bed and bath linens must be maintained in good condition (Refer to §483.10(i) Safe environment, F584, for further information).

The facility must have practices that address the methods for cleaning and disinfecting items that are to be used for another resident after an individual resident's use such as but not limited to the following:[58]

- Mattress covers with tears or holes are replaced;
- Moisture resistant mattress covers are cleaned and disinfected between use for different residents with an EPA-approved germicidal detergent to help prevent the spread of infections;
- Fabric mattress covers are laundered between use for different residents;
- Pillow covers and washable pillows are laundered in a hot water laundry cycle between use for different residents or when they become contaminated with body substances; and
- Mattresses are discarded if bodily fluids have penetrated into the mattress fabric.

ANNUAL REVIEW OF IPCP

The facility's IPCP and its standards, policies and procedures must be reviewed at least annually to ensure effectiveness and that they are in accordance with current standards of practice for preventing and controlling infections; the IPCP must be updated as necessary. In addition, the facility population and characteristics may change over time, and the facility assessment may identify components of the IPCP that must be changed accordingly.

INVESTIGATIVE SUMMARY

Surveyors would use the Infection Control Facility Task to determine compliance with the infection control part of the survey. One surveyor should coordinate the review of the facility's overall infection prevention and control program **(**IPCP), however, each member of the survey team should assess for compliance throughout the entire survey when observing his/her assigned areas and tasks. The IPCP must be facility-wide and include all departments and contracted services. The surveyor should corroborate any concerns observed through interviews and record and/or document review.

Observations

Specific observations for the provision of infection prevention and control practices such as following standard precautions (e.g., hand hygiene and the appropriate use of PPE) should be made by all team members throughout the survey. Observe care of a resident on transmission-based precautions, if any, to determine if implemented appropriately based on precaution type (i.e., contact, droplet, airborne). If concerns are identified, expand the sample to include more residents with transmission-based precautions.

Observe laundry services throughout the survey (e.g., resident and laundry rooms) to determine whether staff handle, store, and transport linens appropriately.

Interviews

Surveyors should interview appropriate facility staff regarding the IPCP. In addition, any potential concerns should be followed up with interviews and record reviews as needed.

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F880, the surveyor's investigation will generally show that the facility failed to do **any one** or more of the following:

- Establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent development and transmission of disease and infection;
- The IPCP must be reviewed at least annually and updated as necessary;
- Implement a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement, based on the facility assessment (see §483.70(e)) and follows accepted national standards;
- Develop and implement written IPCP standards, policies, and procedures that are current and based on national standards. These must include:
  - When and to whom possible incidents of communicable diseases should be reported;
  - Developing and implementing a system of surveillance to identify infections or communicable diseases;
  - How to use standard precautions (to include appropriate hand hygiene) and how and when to use transmission-based precautions (i.e., "isolation precautions"); and/or
  - Prohibiting staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.
- Assure that staff handle, store, process and transport laundry to prevent the spread of infection; and/or
- Maintain a system for recording identified incidents, and taking appropriate corrective actions.

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- The facility failed to follow standard precautions during the performance of routine testing of blood glucose. The facility reused fingerstick devices for more than one resident. This practice of reusing fingerstick devices for more than one resident created an immediate jeopardy to resident health by potentially exposing residents who required blood glucose testing to the spread of bloodborne infections in the facility.
- The facility failed to investigate, document surveillance of, and implement preventative measures to address an outbreak of gastrointestinal illness among residents in one unit of the facility. As a result, several residents in an adjoining unit became seriously ill with diarrheal illnesses resulting in dehydration.
- Facility staff failed to handle soiled linens using safe and sanitary techniques. A resident was observed to have an acute onset of vomiting and diarrhea resulting in soiled clothing and linens. The nursing staff removed the soiled/contaminated clothing and linens, rinsed them out in the bathroom sink, and placed the wet/soiled linen onto the floor. The bathroom was shared with a roommate who utilized the sink for oral hygiene purposes and stored his/her toothbrush and glass on the sink. The roommate, subsequently developed vomiting and diarrhea, with the development of severe dehydration, resulting in hospitalization.

An Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- The facility failed to identify and prevent the spread of infestation when a case of scabies (i.e., a highly contagious skin condition caused by the itch mite Sarcoptes scabiei) was not diagnosed or adequately treated, and the resident was not placed on transmission-based precautions. Resident A was admitted with an undiagnosed, reddened, itchy pin-point rash which spread, became infected, and disrupted the resident's sleep. A month later, multiple residents developed a red, pin-point rash with severe itching, which was not present prior to resident A being admitted. The facility failed to identify through assessment and therefore, implement control measures to prevent the transmission of scabies among multiple residents in the facility, causing the residents physical harm. In addition to the physical harm, the residents experienced psychosocial harm due to anxiety and loss of sleep from severe itching and lack of timely diagnosis.
- The facility failed to ensure that linens were handled and processed in a manner to prevent the spread of pediculosis (i.e., head lice) after a resident (resident A) in a semi private room was diagnosed with pediculosis. Staff were aware of the presence of pediculosis, but did not handle the resident's linens or clothing appropriately, removing bed linens and placing them on the roommate's chairs and other furnishings. The resident's roommate (resident B) became infested with pediculosis. The resident's roommate was non-verbal and unable to express that he had intense itching and began to scratch himself.

An Example of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy includes but is not limited to:

- The facility failed to ensure that its staff demonstrates proper use of gloves with hand hygiene between residents to prevent the spread of infections. The nurse administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The nurse did not remove the used gloves nor perform hand hygiene between the two residents.
- The facility failed to implement appropriate measures for the transport of contaminated linens. As a result, the potential exists for transmission of organisms from contaminated uniforms to residents during the delivery of care. A nursing assistant was observed removing bed linens contaminated with urine and fecal material without the use of gloves, and carrying the contaminated linens against his/her uniform down the hall to the laundry bin. The nursing assistant proceeded to assist the resident's roommate with transferring to his/her chair, and his/her uniform made contact with the resident's skin and clothing.
- The facility failed to ensure that a staff member implemented appropriate processes related to handling and storing wound care supplies. As a result, the potential existed for transmission of organisms between residents who received dressing changes. A staff member who was providing wound care, was observed to place dressing supplies on one resident's bedding and after completing the dressing change, placed the supplies, which are used for other residents, in the unit's dressing cart.

An Example of Severity Level 1 Non-Compliance: No actual harm with potential for minimal harm includes but is not limited to:

- The facility failed to ensure that the IPCP program was reviewed annually. The survey was conducted and it was determined that the facility last reviewed the IPCP at 14 months instead of annually (i.e., 12 months). There were no infection control findings outside of annual review and documentation.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

For staff competency concerns, refer to the following F tags:

- F725 or 726, §483.35(a),(c) for Nursing Services;
- F741, §483.40 for any Behavioral Health staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;
- F801, §483.60(a) for Food and Nutrition staff; and
- F839, §483.70(f), Administration for any other staff not referenced above.

If the surveyor has concerns about 1) the overuse of transmission-based ("isolation") precautions, 2) the inappropriate transferring of rooms unnecessarily; or 3) the inappropriate use of PPE such as gloves when used unnecessarily, where residents indicate they are "untouchable," dirty or unclean, review under §483.10(a)(1), F550, Resident Rights (Dignity) or §483.24, F675, Quality of Life.

For concerns related to possible involuntary seclusion, refer to §483.12 (a)(1), F603.

Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to bloodborne pathogens (refer to 483.45, F755, Pharmacy Services for further information on reconciliation concerns).

For concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns, refer to 483.75(g)(2)(ii), F867, QAA Activities.

For concerns related to the medical director's role in responsibility for care, refer to §483.70(h), F841, Medical Director.

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-31-All

DATE: **June 1, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: COVID-19 Survey Activities, CARES Act Funding, Enhanced Enforcement for Infection Control deficiencies, and Quality Improvement Activities in Nursing Homes

Memorandum Summary

- ***CMS is committed*** *to taking critical steps to protect vulnerable Americans to ensure America's health care facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).*
- ***CMS has implemented*** *a new COVID-19 reporting requirement for nursing homes and is partnering with CDC's robust federal disease surveillance system to quickly identify problem areas and inform future infection control actions.*
- ***Following the March 6, 2020 survey prioritization,*** *CMS has relied on State Survey Agencies to perform Focused Infection Control surveys of nursing homes across the country. We are now initiating a performance-based funding requirement tied to the Coronavirus Aid, Relief and Economic Security (CARES) Act supplemental grants for State Survey Agencies. Further, we are providing guidance for the limited resumption of routine survey activities.*
- ***CMS is also enhancing the penalties for noncompliance*** *with infection control to provide greater accountability and consequence for failures to meet these basic requirements. This action follows the agency's prior focus on equipping facilities with the tools they needed to ensure compliance, including 12 nursing home guidance documents, technical assistance webinars, weekly calls with nursing homes, and many other outreach efforts. The enhanced enforcement actions are more significant for nursing homes with a history of past infection control deficiencies, or that cause actual harm to residents or Immediate Jeopardy.*
- ***Quality Improvement Organizations*** *have been strategically refocused to assist nursing homes in combating COVID-19 through such efforts as education and training, creating action plans based on infection control problem areas and recommending steps to establish a strong infection control and surveillance program.*

Background

The coronavirus presents a unique challenge for nursing homes. Therefore, CMS is using every tool at our disposal to protect our nation's most vulnerable citizens and aid the facilities that care for them. Since the pandemic began, CMS, in coordination with the Centers for Disease Control and Prevention (CDC), has provided ongoing technical guidance and assistance to all Medicare and Medicaid certified providers and suppliers, including nursing homes. Nursing homes have been ground zero for COVID-19. As the data from our required COVID-19 reporting from nursing homes indicates, additional immediate action is necessary to safeguard the health and safety of residents.

Further, to complement our technical assistance efforts, States and CMS have completed Focused Infection Control surveys in approximately 53% of the nation's nursing homes. We are calling on States to ensure that all Medicare and Medicaid certified nursing homes receive this onsite, targeted review and access to the new CARES Act funding will be tied to a state's progress on completing these surveys.

Guidance

Focused Infection Control Nursing Home Surveys and CARES Act Supplemental Funding

Currently, States receive over $397 million to perform oversight surveys and certification of Medicare and Medicaid certified providers and suppliers.

On March 4, 2020, CMS called for States to focus surveys on infection control and on March 23, 2020 provided a streamlined tool to facilitate these efforts. There is currently wide variation in the number of Focused Infection Control surveys of nursing homes performed by States, between 11%-100% (with a national average of approximately 54.1%). Based on the COVID-19 nursing home data being reported to the CDC, CMS believes further direction is needed to prioritize completion of focused infection control surveys in nursing homes.

Therefore, States that have not completed 100% of their focused infection control nursing home surveys by July 31, 2020 will be required to submit a corrective action plan to their CMS location outlining the strategy for completion of these surveys within 30 days. If, after the 30-day period, States have still not achieved surveys in 100% of their nursing homes, their CARES Act FY2021 allocation may be reduced by up to10%. Subsequent 30-day extensions could result in an additional reductions up to 5%. These funds would then be redistributed to those States that completed 100% of their focused infection control surveys by July 31.

Access to FY 2020 CARES Act allocations will be based on the following:

- All States may request FY 2020 CARES Act supplemental funding, up to their FY 2020 proportional allocation cap.
- States that have completed 100% of their nursing home focused infection control surveys will be able to request their entire FY 2020-FY2023 CARES ACT funding allocation (at their discretion) and can also apply for redistributed funding from States that failed to meet performance goals.

COVID-19 Survey Activities

In addition to completing the Focused Infection Control surveys of nursing homes, CMS is also requiring States to implement the following COVID-19 survey activities:

1. Perform on-site surveys (*within 30 days of this memo)* of nursing homes with previous COVID-19 outbreaks, defined as:
    - Cumulative confirmed cases/bed capacity at 10% or greater; **or**
    - Cumulative confirmed plus suspected cases/bed capacity at 20% or greater; **or**
    - Ten or more deaths reported due to COVID-19.
2. Perform on-site surveys (*within three to five days of identification*) of any nursing home with 3 or more new COVID-19 suspected and confirmed cases in the since the last National Healthcare Safety Network (NHSN) COVID-19 report, **or** 1 confirmed resident case in a facility that was previously COVID-free. State Survey Agencies are encouraged to communicate with their State Healthcare Associated Infection coordinators prior to initiating these surveys.
3. Starting in FY 2021, perform annual Focused Infection Control surveys of 20 percent of nursing homes based on State discretion or additional data that identifies facility and community risks.

States that fail to perform these survey activities timely and completely could forfeit up to 5% of their CARES Act Allocation, annually.

Additional COVID Activities

CARES Act funds may also be used for State-specific interventions (such as Strike Teams, enhanced surveillance, or monitoring of nursing homes). In addition, in August 2020, State Survey Agency priorities may also be informed by recommendations from the *Coronavirus Commission for Safety and Quality in Nursing Homes*.

Expanded Survey Activities

Finally, to transition States to more routine oversight and survey activities, once a state has entered Phase 3 of the Nursing Homes Re-opening guidance (https://www.cms.gov/files/document/nursing-home-reopening-recommendations-state-and-local-officials.pdf), or earlier, at the state's discretion, States are authorized to expand beyond the current survey prioritization (Immediate Jeopardy, Focused Infection Control, and Initial Certification surveys) to perform (**for all provider and supplier types**):

- Complaint investigations that are triaged as Non-Immediate Jeopardy-High
- Revisit surveys of any facility with removed Immediate Jeopardy (but still out of compliance),
- Special Focus Facility and Special Focus Facility Candidate recertification surveys, and
- Nursing home and Intermediate Care Facility for individuals with Intellectual Disability (ICF/IID) recertification surveys that are greater than 15 months.

When determining the order in which to schedule more routine surveys, States should prioritize providers based on those with a history of noncompliance, or allegations of noncompliance, with the below items:

- Abuse or neglect;
- Infection control;
- Violations of transfer or discharge requirements;
- Insufficient staffing or competency; or
- Other quality of care issues (e.g., falls, pressure ulcers, etc.).

Accrediting organizations may resume normal survey activities based on state reopening criteria. Any variations from the approved reaccreditation survey process must receive CMS-approval prior to implementation

Enhanced Enforcement for Infection Control Deficiencies

While CMS infection control deficiencies have been an ongoing compliance concern, the COVID-19 pandemic highlights the imperative that nursing home staff adhere to these fundamental health and safety protocols. Due to the heightened threat to resident health and safety for even low-level, isolated infection control citations (such as proper hand-washing and use of personal protective equipment (PPE), CMS is expanding enforcement to improve accountability and sustained compliance with these crucial practices. In addition to enhanced enforcement, CMS is also providing Directed Plans of Correction, including use of Root Cause Analysis, to facilitate lasting systemic changes within facilities to drive sustained compliance.

Therefore, substantial non-compliance (D or above) with any deficiency associated with Infection Control requirements will lead to the following enforcement remedies:

- Non-compliance for an Infection Control deficiency when none have been cited in the last year (or on the last standard survey):
    - Nursing homes cited for current non-compliance that is not widespread (Level D & E) - *Directed Plan of Correction*
    - Nursing homes cited for current non-compliance with infection control requirements that is widespread (Level F) - *Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **45**-days to demonstrate compliance with Infection Control deficiencies.*

- Non-compliance for Infection Control Deficiencies cited once in the last year (or last standard survey):
    - Nursing Homes cited for current non-compliance with infection control requirements that is not widespread (Level D & E) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **45**-days to demonstrate compliance with Infection Control deficiencies, Per Instance Civil Monetary Penalty (CMP) up to $5000 (at State/CMS discretion)*
    - Nursing Homes cited for current non-compliance with infection control requirements that is widespread (Level F) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **45**-days to*

demonstrate compliance with Infection Control deficiencies, $10,000 Per Instance CMP

- Non-compliance that has been cited for Infection Control Deficiencies twice or more in the last two years (or twice since second to last standard survey)
    - Nursing homes cited for current non-compliance with Infection Control requirements that is not widespread (Level D & E) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions, **30**-days to demonstrate compliance with Infection Control deficiencies, $15,000 Per Instance CMP (or per day CMP may be imposed, as long as the total amount exceeds $15,000)*
    - Nursing homes cited for current non-compliance with Infection Control requirements that is widespread (Level F) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions, **30**-days to demonstrate compliance with Infection Control deficiencies, $20,000 Per Instance CMP (or per day CMP may be imposed, as long as the total amount exceeds $20,000)*

- Nursing Homes cited for current non-compliance with Infection Control Deficiencies at the Harm Level (Level G, H, I), regardless of past history -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **30** days to demonstrate compliance with Infection Control deficiencies.* Enforcement imposed by CMS Location per current policy, but CMP imposed at highest amount option within the appropriate (non-Immediate Jeopardy) range in the CMP analytic tool.

- Nursing Homes cited for current non-compliance with Infection Control Deficiencies at the Immediate Jeopardy Level (Level J, K, L) regardless of past history –In addition to the mandatory remedies of Temporary Manager or Termination, *imposition of Directed Plan of Correction, Discretionary Denial of Payment for New Admissions, **15**-days to demonstrate compliance with Infection Control deficiencies.* Enforcement imposed by CMS Location per current policy, but CMP imposed at highest amount option within the appropriate (IJ) range in the CMP analytic tool.

Quality Improvement Organization Support

While we have taken these important actions at a regulatory level, we have also strategically refocused the approach of the Quality Improvement Organizations (QIO) to assist in combating COVID-19 within these facilities.

In November 2019, CMS took a major step toward improving quality for Medicare beneficiaries in nursing homes as well as rural and underserved communities by awarding contracts to 12 experienced, community-based organizations to serve as QIOs and focus on areas of immediate need as well as urgent healthcare priorities. With varying degrees of intensity, QIOs provide education and training to every nursing home in the country. All nursing homes across the country can take advantage of weekly National Infection Control Training that focuses on all aspects of infection control, prevention and management to help nursing homes prevent the transmission of COVID-19 in facilities and keep residents safe. Additionally, as part of their ongoing work, the

QIOs provide more direct assistance to around 6000 small, rural nursing homes and those serving vulnerable populations in areas where access to care is limited with helping them understand and comply with CMS and CDC reporting requirements, sharing best practices related to infection control, testing and patient transfers.

Lastly, the QIOs are being deployed to provide technical assistance to nursing homes, which includes a targeted focus on approximately 3,000 low performing nursing homes who have a history of infection control challenges. Further, States may request QIO technical assistance specifically targeted to nursing homes that have experienced an outbreak. These requests should be sent to Anita Monteiro, Acting Director of the iQuality Improvement and Innovation Group at CMS: anita.monteiro@cms.hhs.gov. The QIOs help nursing homes identify what their greatest areas of infection control problems are, then create an action plan, and implement specific steps to establish a strong infection control and surveillance program in the nursing home. For instance, they train staff on proper use of personal protective equipment (PPE), cohorting residents appropriately and transferring residents safely. They monitor compliance with infection control standards and practices in the nursing home.

Nursing homes can locate the QIO responsible for their state here: http://www.qioprogram.org/locate-your-qio.

Contact

Questions about this memorandum should be addressed to DNH_Enforcement@cms.hhs.gov.

Effective Date

Effective immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately. This guidance will cease to be in effect when the Secretary determines there is no longer a Public Health Emergency due to COVID-19. At that time, CMS will send public notice that this guidance has ceased to be effective via its website.

/s/
David R. Wright

cc: Survey and Operations Group Management

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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-29-NH

DATE: **May 6, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On May 8, 2020, CMS will publish an interim final rule with comment period.
- **COVID-19 Reporting Requirements**: CMS is requiring nursing homes to report COVID-19 facility data to the Centers for Disease Control and Prevention (CDC) and to residents, their representatives, and families of residents in facilities.
- **Enforcement:** Failure to report in accordance with 42 CFR §483.80(g) can result in an enforcement action.
- **Updated Survey Tools:** CMS has updated the COVID-19 Focused Survey for Nursing Homes, Entrance Conference Worksheet, COVID-19 Focused Survey Protocol, and Summary of the COVID-19 Focused Survey for Nursing Homes to reflect COVID-19 reporting requirements.
- **COVID-19 Tags**: F884 and F885.
- **Transparency:** CMS will begin posting data from the CDC National Healthcare Safety Network (NHSN) for viewing by facilities, stakeholders, or the general public. The COVID-19 public use file will be available on https://data.cms.gov/.

Background

On April 19, 2020, CMS released memo QSO-20-26, "Upcoming Requirements for Notification of Confirmed COVID-19 (or COVID-19 Persons under Investigation) Among Residents and Staff in Nursing Homes," summarizing new facility reporting requirements that would soon be released through rulemaking.

On May 8, 2020, CMS will publish an interim final rule with comment period, titled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of

Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program". The unpublished rule is available for public inspection at the Federal Register website (Agency Docket: CMS-5531-IFC and Regulation ID Number (RIN): 0938-AU32).

Prior to the COVID-19 PHE and this interim final rule, regulations at 42 CFR §483.80(a)(2)(ii), already required LTC facilities (i.e., skilled nursing facilities and/or nursing facilities) to have written standards, policies and procedures regarding infection control, to include when and to whom possible incidents of communicable disease or infections should be reported, such as to local/state health authorities. In an effort to support surveillance of COVID-19 cases and increase transparency for residents, their representatives, and families, we have added to the infection control requirements provisions to establish reporting for confirmed or suspected COVID-19 cases at new §483.80(g), as follows:

§ 483.80 Infection control.

(g) *COVID-19 Reporting*. The facility must—

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to--

(i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;
(ii) Total deaths and COVID-19 deaths among residents and staff;
(iii) Personal protective equipment and hand hygiene supplies in the facility;
(iv) Ventilator capacity and supplies in the facility;
(v) Resident beds and census;
(vi) Access to COVID-19 testing while the resident is in the facility;
(vii) Staffing shortages; and
(viii) Other information specified by the Secretary.

(2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—

(i) Not include personally identifiable information;
(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and
(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

We understand that state and local health departments may currently require nursing homes to report certain COVID-19 related information to them. A key difference between the state/local reporting and this new national reporting requirement is that reporting to state/local health departments allows them to understand the status of their local environment and intervene (e.g., direct staffing and supplies), whereas this national requirement provides standardized information to assist with national surveillance on the status of COVID-19 in all nursing homes. State and local health departments are also able to submit the required data on behalf of a nursing homes, although this does not relieve facilities of their accountability to report in accordance with the regulation.

Reporting COVID-19 Information to CDC's NHSN

The NHSN Long-Term Care Facility COVID-19 Module is available. Facilities should immediately gain access to the NHSN system and visit the home page for important information, including how to register: https://www.cdc.gov/nhsn/. The following provides an overview of the registration process:

Step 1 – Prepare your computer to interact with NHSN

You may need to change your email and internet security settings to receive communications from NHSN during the enrollment process

Step 2A – Register Facility with NHSN

The person who will serve as the NHSN Facility Administrator must access and read the NHSN Facility/Group Administrator Rules of Behavior from https://nhsn.cdc.gov/RegistrationForm/index

Step 2B – Register with SAMS (Security Access Management System)

After CDC receives your completed registration, you will receive an ***Invitation to Register with SAMS*** via email

Step 3 – Complete NHSN Enrollment

On the SAMS homepage, click the link to the NHSN labeled **NHSN Enrollment** and Complete Facility Contact Information

Step 4 – Electronically Accept the NHSN Agreement to Participate and Consent

After successfully completing enrollment, the NHSN Facility Administrator and Component Primary Contact (may be the same person) will receive an NHSN email with instructions on how to electronically accept the *NHSN Agreement to Participate and Consent*.

Please note: It is critical for facilities to ensure their CMS Certification Number (CCN) is entered correctly into the NHSN system, so CMS can confirm the facility has met the reporting requirement.

For NHSN questions, please email: NHSN@cdc.gov and add "LTCF" in the subject header.

Facilities must submit their first set of data by 11:59 p.m. Sunday, May 17, 2020. To be compliant with the new requirement, facilities must submit the data through the NHSN reporting system at least once every seven days. Facilities may choose to submit multiple times a week. CMS is not prescribing which day of the week the data must be submitted, although reporting should remain consistent with data being submitted on the same day(s) each week. The collection period should also remain consistent (e.g., Monday through Sunday). Each Monday,

CMS will review the data submitted to assess if each facility submitted data at least once in the previous seven days. The data pulled each Monday will also be used to update the data that is publicly reported.

Updates to the COVID-19 Focused Survey for Nursing Homes

CMS has updated the "COVID-19 Focused Survey for Nursing Homes," "Entrance Conference Worksheet," "COVID-19 Focused Survey Protocol," and "Summary of the COVID-19 Focused Survey for Nursing Homes" to include an updated assessment of the new requirements for facilities to report to the NHSN and to residents, their representatives, and their families. These updated forms are posted to the Survey Resources folder in the COVID-19 Focused Survey sub-folder on the CMS Nursing Homes website. Surveyors should begin using these revised documents immediately, and facilities should also begin using the revised "COVID-19 Focused Survey for Nursing Homes" to perform their self-assessment. The documents include the following new deficiency tags for citing noncompliance with the new requirements:

F884: COVID-19 Reporting to CDC as required at §483.80(g)(1)-(2)

Review for F884 will be conducted offsite by CMS Federal surveyors (state surveyors should not cite this F-tag). Following an initial reporting grace period granted to facilities, CMS will receive the CDC NHSN COVID-19 reported data and review for timely and complete reporting of all data elements. Facilities identified as not reporting will receive a deficiency citation at F884 on the CMS-2567 with a scope and severity level at an F (no actual harm with a potential for more than minimal harm that is not an Immediate Jeopardy [IJ] and that is widespread; this is a systemic failure with the potential to affect a large portion or all of the residents or employees), and be subject to an enforcement remedy imposed as described below.

F885: COVID-19 Reporting to Residents, their Representatives, and Families as required at §483.80(g)(3)(i)-(iii)

Review for F885 is included in the "COVID-19 Focused Survey Protocol" and will occur onsite by State and/or Federal surveyors. If the survey finds noncompliance with this requirement, a deficiency citation at this tag will be recorded on the CMS-2567 and enforcement actions will follow the memo QSO-20-20-All. We note that there are a variety of ways that facilities can meet this requirement, such as informing families and representatives through email listservs, website postings, paper notification, and/or recorded telephone messages. We do not expect facilities to make individual telephone calls to each resident's family or responsible party to inform them that a resident in the facility has laboratory-confirmed COVID-19. However, we expect facilities to take reasonable efforts to make it easy for residents, their representatives, and families to obtain the information facilities are required to provide.

In addition, when the State Survey Agency is planning to conduct these surveys, the COVID-19 Focused Survey should be coded in the Automated Survey Process Environment (ASPEN) under "Survey Type" as U=COVID-19. If the survey is taking place with an IJ complaint investigation, the survey should be coded in ASPEN under "Survey Type" as A=complaint and U=COVID-19. This will help ensure consistent, accurate reporting.

Enforcement for F884

A determination that a facility failed to comply with the requirement to report COVID-19 related information to the CDC pursuant to §483.80(g)(1)-(2) (tag F884) will result in an enforcement action. These regulations require a minimum of weekly reporting, and noncompliance with this requirement will receive a deficiency citation and result in a civil money penalty (CMP) imposition.

CMS will provide facilities with an initial two-week grace period to begin reporting cases in the NHSN system (which ends at 11:59 p.m. on May 24, 2020). Facilities that fail to begin reporting after the third week (by 11:59 p.m. on May 31st) will receive a warning letter reminding them to begin reporting the required information to CDC. For facilities that have not started reporting in the NHSN system by 11:59 p.m. on June 7th, ending the fourth week of reporting, CMS will impose a per day (PD) CMP of $1,000 for one day for the failure to report that week. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional one-day PD CMP imposed at an amount increased by $500. For example, if a facility fails to report in week four (following the two week grace period and receipt of the warning letter), it will be imposed a $1,000 one-day PD CMP for that week. If it fails to report again in week five, the noncompliance will lead to the imposition of another one-day PD CMP in the amount of $1,500 for that failure to report (for a CMP total of $2,500). In this example, if the facility complies with the reporting requirements and submits the required report in week six, but then subsequently fails to report as required in week seven, a one-day PD CMP amount of $2,000 will be imposed (which is $500 more than the last imposed PD CMP amount) for a total of $4,500 imposed CMPs.

For enforcement-related questions, please email: DNH_Enforcement@cms.hhs.gov

Posting Facility-Level COVID-19 Data

Reporting COVID-19 data supports CMS's responsibility to protect and ensure the health and safety of residents and is necessary to ensure the appropriate tracking, response, and mitigation of the spread and impact of COVID-19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID-19 infections in their area. We believe that this action strengthens CMS's response to the COVID-19 pandemic, and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents. CMS anticipates publicly posting CDC's NHSN data (including facility names, number of COVID-19 suspected and confirmed cases, deaths, and other data as determined appropriate) weekly on https://data.cms.gov/ by the end of May.

Contact: For questions or concerns regarding this memo, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Branch training coordinators immediately.

/s/
David R. Wright

Attachments:
COVID-19 Focused Survey for Nursing Homes
Long-term Care Facility Notification Frequently Asked Questions

cc: Survey & Operations Group (SOG) Management

COVID-19 Focused Survey for Nursing Homes

Infection Control

This survey tool must be used to investigate compliance at F880, F884 (CMS Federal surveyors only), F885, and E0024. Surveyors must determine whether the facility is implementing proper infection prevention and control practices to prevent the development and transmission of COVID-19 and other communicable diseases and infections. Entry and screening procedures as well as resident care guidance has varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey. Refer to QSO memos released at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to- States-and-Regions.

This survey tool provides a focused review of the critical elements associated with the transmission of COVID-19, will help surveyors to prioritize survey activities while onsite, and identify those survey activities which can be accomplished offsite. These efficiencies will decrease the potential for transmission of COVID-19, as well as lessen disruptions to the facility and minimize exposure of the surveyor. Surveyors should be mindful to ensure their activities do not interfere with the active treatment or prevention of transmission of COVID-19.

If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: "Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] **COVID-19**."

If surveyors see concerns related to compliance with other requirements, they should investigate them in accordance with the existing guidance in Appendix PP of the State Operations Manual and related survey instructions. Surveyors may also need to consider investigating concerns related to Emergency Preparedness in accordance with the guidance in Appendix Z of the State Operations Manual (e.g., for emergency staffing).

For the purpose of this survey tool, "staff" includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) must be facility-wide and include all departments and contracted services.

Critical Element #8 is only for consideration by CMS Federal Survey staff. Information to determine the facility's compliance at F884 is only reported to each of the 10 CMS locations.

Surveyor(s) reviews for:

- The overall effectiveness of the Infection Prevention and Control Program (IPCP) including IPCP policies and procedures;
- Standard and Transmission-Based Precautions;
- Quality of resident care practices, including those with COVID-19 (laboratory-positive case), if applicable;
- The surveillance plan;

- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff;
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19; and
- How the facility informs residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility.

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1. Standard and Transmission-Based Precautions (TBPs)

CMS is aware that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of PPE (e.g., due to supplier(s) shortage which may be a regional or national issue), the facility should contact their health department or healthcare coalition for assistance (https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx), follow national and/or local guidelines for optimizing their current supply or identify the next best option to care for residents. Among other practices, optimizing their current supply may mean prioritizing use of gowns based on risk of exposure to infectious organisms, blood or body fluids, splashes or sprays, high contact procedures, or aerosol generating procedures (AGPs), as well as possibly extending use of PPE (follow national and/or local guidelines). Current CDC guidance for healthcare professionals is located at: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html and healthcare facilities is located at: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html. Guidance on strategies for optimizing PPE supply is located at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions:

☐ Are staff performing the following appropriately:

- Respiratory hygiene/cough etiquette,
- Environmental cleaning and disinfection, and
- Reprocessing of reusable resident medical equipment (e.g., cleaning and disinfection of glucometers per device and disinfectant manufacturer's instructions for use)?

Hand Hygiene:

☐ Are staff performing hand hygiene when indicated?

☐ If alcohol-based hand rub (ABHR) is available, is it readily accessible and preferentially used by staff for hand hygiene?

☐ If there are shortages of ABHR, are staff performing hand hygiene using soap and water instead?

☐ Are staff washing hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids)?

☐ Do staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;
- After contact with blood, body fluids, or visibly contaminated surfaces;
- After contact with objects and surfaces in the resident's environment;
- After removing personal protective equipment (e.g., gloves, gown, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care)?

☐ When being assisted by staff, is resident hand hygiene performed after toileting and before meals?

☐ Interview appropriate staff to determine if hand hygiene supplies (e.g., ABHR, soap, paper towels) are readily available and who they contact for replacement supplies.

Personal Protective Equipment (PPE):

☐ Determine if staff appropriately use PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
- Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care; and
- An isolation gown is worn for direct resident contact if the resident has uncontained secretions or excretions.

☐ Is PPE appropriately removed and discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national/local recommendations), followed by hand hygiene?

☐ If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?

☐ Interview appropriate staff to determine if PPE is available, accessible and used by staff.

- Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what procedures is the facility taking to address this issue?
- Do staff know how to obtain PPE supplies before providing care?
- Do they know who to contact for replacement supplies?

Transmission-Based Precautions (Note: PPE use is based on availability and latest CDC guidance. See note on Pages 1-2):

☐ Determine if appropriate Transmission-Based Precautions are implemented:

- For a resident on Contact Precautions: staff don gloves and isolation gown before contact with the resident and/or his/her environment;
- For a resident on Droplet Precautions: staff don a facemask within six feet of a resident;
- For a resident on Airborne Precautions: staff don an N95 or higher level respirator prior to room entry of a resident;
- For a resident with an undiagnosed respiratory infection: staff follow Standard, Contact, and Droplet Precautions (i.e., facemask, gloves, isolation gown) with eye protection when caring for a resident unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis);
- For a resident with known or suspected COVID-19: staff wear gloves, isolation gown, eye protection and an N95 or higher-levelrespirator if available. A facemask is an acceptable alternative if a respirator is not available. Additionally, if there are COVID-19 cases in the facility or sustained community transmission, staff implement universal use of facemasks while in the facility (based on availability). When COVID-19 is identified in the facility, staff wear all recommended PPE (i.e., gloves, gown, eye protection and respirator or facemask) for the care of all residents on the unit (or facility-wide based on the location of affected residents), regardless of symptoms (based on availability).
    - Some procedures performed on residents with known or suspected COVID-19 could generate infectious aerosols (i.e., aerosol- generating procedures (AGPs)). In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously. If performed, the following should occur:
        - Staff in the room should wear an N95 or higher-level respirator, eye protection, gloves, and an isolation gown.
        - The number of staff present during the procedure should be limited to only those essential for resident care and procedure support.
        - AGPs should ideally take place in an airborne infection isolation room (AIIR). If an AIIR is not available and the procedure is medically necessary, then it should take place in a private room with the door closed.
        - Clean and disinfect the room surfaces promptly and with appropriate disinfectant. Use disinfectants on List N of the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-COV-2 or other national recommendations;
- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant for healthcare setting prior to use on another resident;
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare setting (effective against the organism identified if known) at least daily and when visibly soiled; and
- Is signage on the use of specific PPE (for staff) posted in appropriate locations in the facility (e.g., outside of a resident's room, wing, or facility-wide)?

☐ Interview appropriate staff to determine if they are aware of processes/protocols for Transmission-Based Precautions and how staff is monitored for compliance.

☐ If concerns are identified, expand the sample to include more residents on Transmission-Based Precautions.

1. Did staff implement appropriate Standard (e.g., hand hygiene, appropriate use of PPE, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment) and Transmission-Based Precautions (if applicable)? ☐ Yes ☐ **No F880**

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2. Resident Care

☐ If there is sustained community transmission or case(s) of COVID-19 in the facility, is the facility restricting residents (to the extent possible) to their rooms except for medically necessary purposes? If there is a case in the facility, and residents have to leave their room, are they wearing a facemask, performing hand hygiene, limiting their movement in the facility, and performing social distancing (efforts are made to keep them at least 6 feet away from others). If PPE shortage is an issue, facemasks should be limited to residents diagnosed with or having signs/symptoms of respiratory illness or COVID-19.

☐ Has the facility cancelled group outings, group activities, and communal dining?

☐ Has the facility isolated residents with known or suspected COVID-19 in a private room (if available), or taken other actions based on national (e.g., CDC), state, or local public health authority recommendations?

☐ For the resident who develops severe symptoms of illness and requires transfer to a hospital for a higher level of care, did the facility alert emergency medical services and the receiving facility of the resident's diagnosis (suspected or confirmed COVID-19) and precautions to be taken by transferring and receiving staff as well as place a facemask on the resident during transfer (as supply allows)?

☐ For residents who need to leave the facility for care (e.g. dialysis, etc.), did the facility notify the transportation and receiving health care team of the resident's suspected or confirmed COVID-19 status?

☐ Does the facility have residents who must leave the facility regularly for medically necessary purposes (e.g., residents receiving hemodialysis and chemotherapy) wear a facemask (if available) whenever they leave their room, including for procedures outside of the facility?

2. Did staff provide appropriate resident care? ☐ Yes ☐ **No F880**

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3. IPCP Standards, Policies and Procedures

☐ Did the facility establish a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?

☐ Does the facility's policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?

☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

3. Does the facility have a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19? ☐ Yes ☐ **No F880**

4. Infection Surveillance

☐ How many residents and staff in the facility have fever, respiratory signs/symptoms, or other signs/symptoms related to COVID-19?

☐ How many residents and staff have been diagnosed with COVID-19 and when was the first case confirmed?

☐ How many residents and staff have been tested for COVID-19? What is the protocol for determining when residents and staff should be tested?

☐ Has the facility established/implemented a surveillance plan, based on a facility assessment, for identifying (i.e., screening), tracking, monitoring and/or reporting of fever (at a minimum, temperature is taken per shift), respiratory illness, and/or other signs/symptoms of COVID-19 and immediately isolate anyone who is symptomatic?

☐ Does the plan include early detection, management of a potentially infectious, symptomatic resident that may require laboratory testing and/or Transmission-Based Precautions/PPE (the plan may include tracking this information in an infectious disease log)?

☐ Does the facility have a process for communicating the diagnosis, treatment, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals?

☐ Can appropriate staff (e.g., nursing and unit managers) identify/describe the communication protocol with local/state public health officials?

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

4. Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No F880**

5. Visitor Entry

☐ Review for compliance of:

- Screening processes and criteria (i.e., screening questions and assessment of illness);
- Restriction criteria; and

- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors ofnew procedures/restrictions.

☐ For those permitted entry, are they instructed to frequently perform hand hygiene; limit their interactions with others in the facility and surfaces touched; restrict their visit to the resident's room or other location designated by the facility; and offered PPE (e.g., facemask) as supply allows? What is the facility's process for communicating this information?

☐ For those permitted entry, are they advised to monitor for signs and symptoms of COVID-19 and appropriate actions to take if signs and/or symptoms occur?

5. Did the facility perform appropriate screening, restriction, and education of visitors? ☐ Yes ☐ **No F880**

6. Education, Monitoring, and Screening of Staff

☐ Is there evidence the facility has provided education to staff on COVID-19 (e.g., symptoms, how it is transmitted, screening criteria, work exclusions)?

☐ How does the facility convey updates on COVID-19 to all staff?

☐ Is the facility screening all staff at the beginning of their shift for fever and signs/symptoms of illness? Is the facility actively taking their temperature and documenting absence of illness (or signs/symptoms of COVID-19 as more information becomes available)?

☐ If staff develop symptoms at work (as stated above), does the facility:

- Place them in a facemask and have them return home;
- Inform the facility's infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and
- Follow current guidance about returning to work (e.g., local health department, CDC: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html).

6. Did the facility provide appropriate education, monitoring, and screening of staff? ☐ Yes ☐ **No F880**

7. Reporting to Residents, Representatives, and Families

Identify the mechanism(s) the facility is using to inform residents, their representatives, and families (e.g., newsletter, email, website, recorded voice message)

☐ Did the facility inform all residents, their representatives, and families by 5 PM the next calendar day following the occurrence of a single confirmed COVID-19 infection or of three or more residents or staff with new onset of respiratory symptoms that occurred within 72 hours of each other?

☐ Did the information include mitigating actions taken by the facility to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered (e.g., restrictions to visitation or group activities)?

☐ Did the information include personally identifiable information?

☐ Is the facility providing cumulative updates to residents, their representatives, and families at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: each time a confirmed COVID-19 infection is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other?

☐ Interview a resident and a resident representative or family member to determine whether they are receiving timely notifications.

7. Did the facility inform residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility along with mitigating actions in a timely manner? ☐ Yes ☐ **No F885**

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8. Reporting to the Centers for Disease Control and Prevention (CDC) – Performed Offsite by CMS. For consideration by CMS Federal Surveyors only.

☐ Review CDC data files provided to CMS to determine if the facility is reporting at least once a week.

☐ Review data files to determine if all data elements required in the National Healthcare Safety Network (NHSN) COVID-19 Module are completed.

8. Did the facility report at least once a week to CDC on all of the data elements required in the NHSN COVID-19 Module?
☐ Yes ☐ **No F884**

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9. Emergency Preparedness – Staffing in Emergencies

☐ Policy development: Does the facility have a policy and procedure for ensuring staffing to meet the needs of the residents when needed during an emergency, such as COVID-19 outbreak?

☐ Policy implementation: In an emergency, did the facility implement its planned strategy for ensuring staffing to meet the needs of the residents? (N/A if an emergency staff was not needed).

9. Did the facility develop and implement policies and procedures for staffing strategies during an emergency?
☐ Yes ☐ **No E0024** ☐ N/A

Long-term Care (LTC) Facility Requirements for Notification of Confirmed and Suspected Coronavirus Disease 2019 (COVID-19) Cases Among Residents and Staff: Frequently Asked Questions (FAQs)

May 6, 2020

The purpose of this FAQ is to provide additional information on the updated reporting requirements for LTC facilities at 42 CFR §483.80(g), which will be published on May 8, 2020, in an interim final rule with comment period. The unpublished rule is available for public inspection at the Federal Register website. The new reporting requirements specify that facilities must report COVID-19 data to the Centers for Disease Control and Prevention (CDC), and to all residents, their representatives, and families.

Note: The terms "nursing home" and "long-term care facility" are used interchangeably in this document, and both refer to a facility that is certified to provide Medicare skilled nursing facility (SNF) services, and/or Medicaid nursing facility (NF) services.

Reporting to CDC's National Healthcare Safety Network (NHSN)

1. **Q: What actions are the Centers for Medicare & Medicaid Services (CMS) taking by revising the Requirements for Participation for LTC facilities?**

   A: CMS is requiring facilities to report COVID-19 facility data on residents and staff to CDC and to residents, their representatives, and families of residents in facilities. CMS has updated the COVID-19 Focused Survey for Nursing Homes, Entrance Conference Worksheet, COVID-19 Focused Survey Protocol, and Summary of the COVID-19 Focused Survey for Nursing Homes to reflect these COVID-19 reporting requirements and created two new deficiency tags (F884 and F885). Facilities must submit data through CDC NHSN Long-Term Care Facility COVID-19 Module at least once a week. CMS will begin posting aggregated data from CDC NHSN to https://data.cms.gov/ by the end of May for viewing by LTC facilities, stakeholders, and the general public.

2. **Q: How will CMS and CDC use this information?**

   A: CDC will use information collected through the new NHSN Long-Term Care Facility COVID-19 Module to strengthen COVID-19 surveillance locally and nationally. Nursing home reporting to CDC is a critical component of national COVID-19 surveillance efforts and is consistent with White House guidelines, Opening Up America Again. CMS will use the information to ensure nursing homes are following all requirements for participation, specifically those focused on infection control. CMS may also use the information to determine survey prioritization.

   Facility-level data collected through NHSN as part of the Long-Term Care Facility COVID-19 Module will also be available to a broader set of federal, state, and local agencies. Specifically, COVID-19 data at the state, county, territory, and facility level submitted to

NHSN will continue to be used for public health emergency response activities by CDC's emergency COVID-19 response, by the U.S. Department of Health and Human Services' (HHS') COVID-19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response (ASPR) as part of the National Response Coordination Center at the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force.[1]

3. **Q: If states are already collecting COVID-19 information from nursing homes, why is CMS requiring it to be reported to CDC?**

   A: The new reporting tool complements existing, state level reporting efforts. Due to variation in state and local reporting requirements for COVID-19, NHSN's Long-Term Care Facility Module aims to provide a standardized, national lens on the experience of long-term care facilities to support and inform the public health response at the local, state, and federal levels.

   The NHSN Module is not intended as a replacement for state and local public health reporting requirements, and nursing homes are required to continue to report COVID-19 data to state and local health departments in accordance with state and local requirements via existing mechanisms. In some public health jurisdictions, the data that nursing homes report to the new module may supplement the data that they already report to state and local public health authorities. NHSN uses existing functionality (NHSN's Group Function) to make COVID-19 data immediately accessible to state and local health departments for surveillance and public health response decisions. State and local health departments are also able to submit the required data on behalf of nursing homes, although this does not relieve facilities of their accountability to report in accordance with the regulation.

4. **Q. Will CDC offer technical assistance/user support to facilities to help them begin reporting data?**

   A: Yes, CDC will offer users training and technical support through a variety of mechanisms, including the following:
   - Detailed instructions and copies of the reporting forms, which will be posted on the NHSN Long-Term Care Facility COVID-19 Module webpage
   - Web-based trainings, which will be recorded and similarly posted to the NHSN Long-Term Care Facility webpage
   - Live office hours, which will offer participants an opportunity to ask detailed questions and receive answers from CDC subject matter experts
   - E-mail updates on new functions or resources available through NHSN
   - Response to questions submitted to: NHSN@cdc.gov

[1] Members of the White House Coronavirus Task Force are listed here:
https://www.whitehouse.gov/briefings-statements/vice-president-pence-secretary-azar-add-key-administration-officials-coronavirus-task-force-2/
https://www.whitehouse.gov/briefings-statements/statement-press-secretary-regarding-presidents-coronavirus-task-force/

5. **Q: Can state health departments report COVID-19 data to NHSN on a nursing home's behalf?**

   A: Yes. Each nursing home must first enroll in NHSN to submit its data. Once enrolled, state and local health departments may submit data on behalf of a nursing home. Additionally, data can be batched and submitted as a single file for multiple facilities. We note this does not relieve facilities of their accountability to report in accordance with the regulation. CDC and CMS will work with state health departments and other partners to enable batch data reporting by state health departments or other entities (such as state hospital associations, corporate headquarters and IT vendors). CDC and CMS will work with state health departments and other partners to communicate and help them utilize this option.

6. **Q: How will nursing homes know their data was received?**

   A: Nursing homes will be able to view their data in the NHSN application upon data submission. NHSN's analysis and reporting features allows nursing homes to quickly verify that their data have been received.

7. **Q: Will CMS cite facilities for noncompliance at F884 and penalize any nursing home with a case of COVID-19 reported to CDC's NHSN?**

   A: The presence of COVID-19 in a nursing home does not automatically mean that noncompliance exists. CMS will not use the data to penalize nursing homes for the presence of COVID-19. Until further notice, surveys will continue to be conducted in accordance with CMS memorandum QSO-20-20-All, which includes surveying for Immediate Jeopardy allegations and Focused Infection Control surveys. CMS has updated the COVID-19 Focused Survey for Nursing Homes with processes related to the new reporting requirements. Surveyors will only cite noncompliance with federal requirements for infection control and prevention based on their investigations, and not based on the COVID-19 information reported through the NHSN system.

   We note, however, that facilities will be cited and subject to enforcement action for not submitting complete data through the NHSN system in accordance with the new reporting requirements.

   CMS will provide facilities with an initial two-week grace period to begin reporting cases in the NHSN system (which ends at 11:59 p.m. on May 24, 2020). Facilities that fail to begin reporting after the third week (by 11:59 p.m. on May 31st) will receive a warning letter reminding them to begin reporting the required information to CDC. For facilities that have not started reporting in the NHSN system by 11:59 p.m. on June 7th, ending the fourth week of reporting, CMS will impose a per day (PD) civil money penalty (CMP) of $1,000 for one day for the failure to report that week. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional one-day PD CMP imposed at an amount increased by $500. For example, if a facility fails to report in week four (following the two week grace period and receipt of the warning letter), it will be

imposed a $1,000 one-day PD CMP for that week. If it fails to report again in week five, the noncompliance will lead to the imposition of another one-day PD CMP in the amount of $1,500 for that failure to report (for a CMP total of $2,500 in PD CMPs). In this example, if the facility complies with the reporting requirements and submits the required report in week six, but then subsequently fails to report as required in week seven, a one-day PD CMP amount of $2,000 will be imposed (which is $500 more than the last imposed PD CMP amount) for a total of $4,500 imposed CMPs.

8. **Q. What if a facility under-reports COVID-19 data to CDC's NHSN?**

   A: CMS expects facilities to submit complete and accurate information through the NHSN system. We understand identifying cases of COVID-19 in a nursing home can be challenging. However, accurate data is critical to directing public health action and ensuring critical resources and assistance are available to facilities that need them. If, upon further investigation, CMS identifies that a facility did not submit complete and accurate information, the facility would not be in compliance with the new reporting requirements and would be subject to enforcement actions.

9. **Q: How long will reporting to CDC's NHSN system and to residents, resident representatives, and families continue to be required?**

   A: These requirements go into effect with the publication of the interim final rule. CMS will inform the public and all stakeholders of any changes in the reporting requirements. Until any changes are announced, these requirements remain in effect.

10. **Q: Are facilities required to report data that predates the effective date of the interim final rule?**

    A: No, there is no requirement in the rule to collect older data. The NHSN system has capability for retrospective reporting from January 2020 onward, consistent with CDC's mission-critical work, but CMS will not take enforcement action if a nursing home is unable to accurately report information from that time. However, we encourage facilities to report older data as it will help with CDC's ongoing surveillance and response efforts to assess burden of COVID-19 in nursing homes, and support a comprehensive national surveillance of the pandemic.

11. **Q. Must a facility report deaths of residents which occur in hospitals to the NHSN's LTCF COVID-19 Module?**

    A: Yes, the LTCF COVID-19 Module does include reporting of deaths in another location. This is clarified in the COVID-19 module instructions that facilities will use when reporting on resident impact and facility capacity.

12. Q: Must the facility notify all residents, representatives, and families, or just those affected?

A: Facilities must notify all residents in the facility, their representatives, and families, not just those who are suspected or confirmed cases of COVID-19. Notification must include data when a confirmed COVID-19 case is identified or when three or more residents or staff have new onset of respiratory symptoms that occur within 72 hours of each other in the facility. Cumulative updates must be provided when other confirmed cases or clusters of three or more residents or staff with respiratory symptoms occur within 72 hours of each other, and at least weekly. We note that there are a variety of ways that facilities can meet this requirement, such as informing families and representatives through email listservs, website postings, and/or recorded telephone messages. We do not expect facilities to make individual telephone calls to each resident's family or responsible party to inform them that a resident in the facility has laboratory-confirmed COVID-19. However, we expect facilities to make all reasonable efforts to properly inform residents, their representatives, and families of the information facilities are required to provide.

13. Q: What information is required to be reported to residents, their representatives, and families? Will this information include new cases as well as total cases?

A: Cumulative, confirmed COVID-19 cases as well as clusters of three or more residents or staff with respiratory symptoms within 72 hours must be reported. The facility is not required to identify new versus total cases.

14. Q: Can you clarify what symptoms CMS is referring to in the requirement to report if three or more residents or staff have respiratory symptoms within 72 hours of each other?

A: Respiratory symptoms consistent with COVID-19 are shortness of breath, difficulty breathing, new or change in cough, sore throat, or new loss of taste or smell. To a lesser extent, symptoms have included new sputum production, rhinorrhea, or hemoptysis. For more information on updated symptoms, please view CDC's webpages: Symptoms of Coronavirus and Preparing for COVID-19: Long-term Care Facilities, Nursing Homes.

15. Q: Must the facility report any suspected case of COVID-19 of a resident or staff member to residents, their representatives, and families?

A: No. The regulation does not require facilities to report to residents, their representatives, and families every suspected case of COVID-19 in residents and staff of the facility. However, it does require facilities to report suspected cases when three or more occur within 72 hours of each other.

16. Q: For dedicated COVID-19 facilities and those with COVID-19 units, must they inform residents, their representatives, and families each time a new resident with confirmed COVID-19 is admitted or staff member tests positive? Similarly, what is the time frame for notifying residents, their representatives, and families for subsequent COVID-19 activity?

A: Yes. The facility must provide any cumulative updates for residents, their representatives, and families. Updates must occur at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: a confirmed infection of COVID-19 is identified (including new admissions), or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

17. **Q: Who are considered "staff" for purposes of reporting confirmed cases or clusters of respiratory symptoms to residents, their representatives, and families?**
A: "Staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents in the facility, including nurse aides that have not yet completed a nurse aide training, competency, and evaluation program (NATCEP) but are providing services to residents.

18. **Q: When informing residents, their representatives, and families of suspected and confirmed COVID-19 cases in the facility, does the facility have to specify whether individual cases are residents or staff?**
A: No. CMS does not require this.

19. **Q: Do facilities need to inform anyone who walks through their doors (e.g., a hospice or other healthcare provider) of the same numbers of suspected and confirmed COVID-19 cases that they are sharing with residents, their representatives, and families?**
A: No. Facilities are not required to provide the same COVID-19 information reported to residents, their representatives, and families. However, facilities would share with the visiting healthcare provider, if the resident receiving care is suspected of, or has laboratory-confirmed COVID-19. Any precautions the provider should take while in the facility (e.g., specific personal protective equipment) will be communicated to that provider by the facility as part of their standard practices under the infection prevention and control program requirement.

20. **Q: What if a facility has never had a suspected or confirmed COVID-19 case? Is the facility required to inform all residents, their representatives, and families?**
A: No. CMS does not require this, however, we encourage facilities to transparently communicate regularly with residents, their representatives, and families about the status of the facility.

21. **Q: What if a facility has three or more residents or staff with new onset of respiratory symptoms but not within 72 hours of each other? Does the facility still need to report this to all residents, their representatives, and families?**
A: No. CMS does not require this.

22. Q: Does the reporting requirement at 42 CFR §483.80(g)(3)(i)-(iii) (F885) fulfill the requirement at §483.10(g)(14)(i)(B), Notification of Changes (F580)?

A: No. The new reporting requirement at §483.80(g)(3)(i)-(iii) (F885) requires facilities to notify residents, their representatives, and families of cumulative numbers of confirmed COVID-19 cases and clusters of three or more residents or staff with respiratory symptoms within 72 hours of each other. By way of comparison, §483.10(g)(14)(i)(B) requires nursing homes to notify the resident, the resident's physician and as applicable, the resident's representative(s) of an individual resident's change in condition (F580) if he/she is suspected or confirmed to have COVID-19.

Handout #4

Infection Prevention, Control & Immunizations

Infection Control: *This facility task must be used to investigate compliance at F880, F881, and F883. For the purpose of this task, "staff" includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) program must be facility-wide and include all departments and contracted services. If a specific care area concern is identified, it should be evaluated under the specific care area, such as for pressure ulcers, respiratory care, catheter care, and medication pass observations which include central lines, peripheral IVs, and oral/IM/respiratory medications.*

Coordination:

☐ One surveyor coordinates the facility task to review for:

- The overall Infection Prevention and Control Program (IPCP);
- The annual review of the IPCP policies and practices;
- The review of the surveillance and antibiotic stewardship programs; and
- Tracking influenza/pneumococcal immunization of residents.

☐ Team assignments must be made to include the review of:

- Laundry services;
- A resident on transmission-based precautions, if any;
- Five sampled residents for influenza/pneumococcal immunizations; and
- Other care-specific observations if concerns are identified.

☐ Every surveyor assesses IPCP compliance throughout the survey and communicates any concerns to the team.

Hand Hygiene:

☐ Staff implement standard precautions (e.g., hand hygiene and the appropriate use of personal protective equipment (PPE)).

☐ Appropriate hand hygiene practices are followed.

☐ Alcohol-based hand rub (ABHR) is readily accessible and placed in appropriate locations. These may include:

- Entrances to resident rooms;
- At the bedside (as appropriate for resident population);
- In individual pocket-sized containers by healthcare personnel;
- Staff work stations; and
- Other convenient locations.

☐ Staff wash hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected C. difficile infection (CDI) or norovirus during an outbreak, or if endemic rates of CDI are high. ABHR is not appropriate to use under these circumstances.

☐ Staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;

- After contact with blood, body fluids, or visibly contaminated surfaces or other objects and surfaces in the resident's environment;
- After removing personal protective equipment (e.g., gloves, gown, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care).

☐ When being assisted by staff, resident hand hygiene is performed after toileting and before meals.

☐ Interview appropriate staff to determine if hand hygiene supplies are readily available and who they contact for replacement supplies.

☐ Soap, water, and a sink are readily accessible in appropriate locations including, but not limited to, resident care areas, food and medication preparation areas.

1. Did staff implement appropriate hand hygiene? ☐ Yes ☐ **No F880**

Personal Protective Equipment (PPE):

☐ Determine if staff appropriately use and discard PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
- Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care;
- A gown is worn for direct resident contact if the resident has uncontained secretions or excretions;
- A facemask is worn if contact (i.e., within 3 feet) with a resident with new acute cough or symptoms of a respiratory infection (e.g., influenza-like illness);
- Appropriate mouth, nose, and eye protection (e.g., facemasks, face shield) is worn for performing aerosol-generating and/or procedures that are likely to generate splashes or sprays of blood or body fluids;
- PPE is appropriately discarded after resident care, prior to leaving room, followed by hand hygiene; and
- Supplies necessary for adherence to proper PPE use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (i.e., nursing units, therapy rooms).

☐ Interview appropriate staff to determine if PPE supplies are readily available and who they contact for replacement supplies.

2. Did staff implement appropriate use of PPE? ☐ Yes ☐ **No F880**

Transmission-Based Precautions:

☐ Determine if appropriate transmission-based precautions are implemented, including but not limited to:

- PPE use by staff (i.e., don gloves and gowns before contact with the resident and/or his/her environment while on contact precautions; don facemask within three feet of a resident on droplet precautions; don a fit-tested N95 or higher level respirator prior to room entry of a resident on airborne precautions;

- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant prior to use on another resident;
- The least restrictive TBP possible under the circumstances;
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare use at least daily and when visibly soiled.

☐ Interview appropriate staff to determine if they are aware of processes/protocols for transmission-based precautions and how staff is monitored for compliance.

☐ If concerns are identified, expand the sample to include more residents with transmission-based precautions.

3. Did the staff implement appropriate transmission-based precautions? ☐ Yes ☐ **No F880** ☐ NA

Laundry Services:

☐ Determine whether staff handle, store, and transport linens appropriately including, but not limited to:

- Using standard precautions (i.e., gloves) and minimal agitation for contaminated linen;
- Holding contaminated linen and laundry bags away from his/her clothing/body during transport;
- Bagging/containing contaminated linen where collected, and sorted/rinsed only in the contaminated laundry area (double bagging of linen is only recommended if outside of the bag is visibly contaminated or is observed to be wet on the outside of the bag);
- Transporting contaminated and clean linens in separate carts; if this is not possible, the contaminated linen cart should be thoroughly cleaned and disinfected per facility protocol before being used to move clean linens. Clean linens are transported by methods that ensure cleanliness, e.g., protect from dust and soil;
- Ensuring mattresses, pillows, bedding, and linens are maintained in good condition and are clean (Refer to F584); and
- If a laundry chute is in use, laundry bags are closed with no loose items.

☐ Laundry Rooms – Determine whether staff:

- Maintain/use washing machines/dryers according to the manufacturer's instructions for use;
- If concerns, request evidence of maintenance log/record; and
- Use detergents, rinse aids/additives, and follow laundering directions according to the manufacturer's instructions for use.

4. Did the facility store, handle, transport, and process linens properly? ☐ Yes ☐ **No F880**

Infection Prevention, Control & Immunizations

Policy and Procedure:

☐ The facility established a facility-wide IPCP including written IPCP standards, policies, and procedures that are current and based on national standards.

☐ The policies and procedures are reviewed at least annually.

☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

5. Did the facility develop and implement an overall IPCP including policies and procedures that are reviewed annually?
☐ Yes ☐ **No F880**

Infection Surveillance:

☐ The facility has established/implemented a surveillance plan, based on a facility assessment, for identifying, tracking, monitoring and/or reporting of infections.

☐ The plan includes early detection, management of a potentially infectious, symptomatic resident and the implementation of appropriate transmission-based precautions.

☐ The plan uses evidence-based surveillance criteria (e.g., CDC NHSN Long-Term Care or revised McGeer Criteria) to define infections and the use of a data collection tool.

☐ The plan includes ongoing analysis of surveillance data and review of data and documentation of follow-up activity in response.

☐ The facility has a process for communicating the diagnosis, antibiotic use, if any, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals.

☐ The facility has a current list of reportable communicable diseases.

☐ Staff can identify to whom and when communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks must be reported.

☐ Prohibiting employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

6. Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No F880**

Antibiotic Stewardship Program:

☐ Determine whether the facility has an antibiotic stewardship program that includes:

- Written antibiotic use protocols on antibiotic prescribing, including the documentation of the indication, dosage, and duration of use of antibiotics;
- Protocols to review clinical signs and symptoms and laboratory reports to determine if the antibiotic is indicated or if adjustments to therapy should be made and identify what infection assessment tools or management algorithms are used for one or more infections (e.g., SBAR tool for urinary tract infection (UTI) assessment, Loeb minimum criteria for initiation of antibiotics);
- A process for a periodic review of antibiotic use by prescribing practitioners: for example, review of laboratory and medication orders, progress notes and medication administration records to determine whether or not an infection or communicable disease has been documented and whether an appropriate antibiotic has been prescribed for the recommended length of time. Determine whether the antibiotic use monitoring system is reviewed when the resident is new to the facility, when a prior resident returns or is transferred from a hospital or other facility, during each monthly drug regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic drug regimen review as requested by the QAA committee;
- Protocols to optimize the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotic;
- A system for the provision of feedback reports on antibiotic use, antibiotic resistance patterns based on laboratory data, and prescribing practices for the prescribing practitioner.

7. Did the facility conduct ongoing review for antibiotic stewardship? ☐ Yes ☐ **No F881**

Influenza and Pneumococcal Immunizations:

☐ Select five residents in the sample to review for the provision of influenza/pneumococcal immunizations.

☐ Document the names of residents selected for review.

☐ Give precedence in selection to those residents whom the survey team has selected as sampled residents.

☐ Review the records of the five residents sampled for documentation of:

- Screening and eligibility to receive the vaccine;
- The provision of education related to the influenza or pneumococcal immunizations (such as the benefits and potential side effects)*;*
- The administration of pneumococcal and influenza vaccine, in accordance with national recommendations. Facilities must follow the CDC and ACIP recommendations for vaccines; and
- Allowing a resident or representative to refuse either the influenza and/or pneumococcal vaccine. If not provided, documentation as to why the vaccine was not provided.

☐ For surveys occurring during influenza season, unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program, especially during the early weeks of the influenza season. Ask the facility to demonstrate that:

- The vaccine has been ordered and the facility received a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available; and
- Plans are developed on how and when the vaccines are to be administered.

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☐ As necessary, determine if the facility developed influenza and pneumococcal vaccine policies and procedures, including the identification and tracking/monitoring of all facility residents' vaccination status.

8. Did the facility provide influenza and/or pneumococcal immunizations as required or appropriate? ☐ Yes ☐ **No F883**

7500 - Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7500.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These procedures implement the regulatory requirements in 42 CFR 488.424 for imposing a directed plan of correction. A directed plan of correction is one of the category 1 remedies the State or regional office can select when it finds a facility out of compliance with Federal requirements.

7500.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The purpose of the directed plan of correction is to achieve correction and continued compliance with Federal requirements. A directed plan of correction is a plan that the State or the regional office, or the temporary manager (with State or regional office approval), develops to require a facility to take action within specified time frames.

Achieving compliance is ultimately the facility's responsibility, whether or not a directed plan of correction is followed. If the facility fails to achieve substantial compliance after complying with the directed plan of correction, the State or regional office may impose another remedy until the facility achieves substantial compliance or is terminated from the Medicare or Medicaid programs.

7500.3 - Elements of a Directed Plan of Correction

A directed plan of correction should address all of the elements required for a facility-developed plan of correction. (See §7304)

7500.4 - Causes
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Use of a directed plan of correction should be dependent upon causes identified by the State, regional office, or temporary manager. For example, a directed plan of correction may be appropriate when a facility's heating system fails. The directed plan of correction would specify that the heating system must be repaired or replaced within a specific time frame. If the cause of the noncompliance was a specific structural problem, the facility could be directed to implement identified structural repairs such as a new roof, or renovations such as replacement of rusted sinks in common bathrooms.

7500.5 - Notice of Imposition of Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A directed plan of correction may be imposed 15 calendar days after the facility receives notice in non-immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations. The date the directed plan of correction is imposed does not mean that all corrections must be completed by that date.