



## §483.65 (F441) Infection Control

### Updated Guidance to Surveyors

December 3, 2009

Presenters

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Bob Huncosky, Nursing Home Program Specialist

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## Today's Agenda

- Regulation
- Interpretive Guidelines\*
- Investigative Protocol
- Determination of Compliance
- Deficiency Categorization
- Case Studies
- Off-Camera Q&A Session

On 11/30/09, CMS issued revisions to F441 through Transmittal 54

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## Training Objectives

- Demonstrate knowledge of the contents of the revised guidance to surveyors for F441
- Effectively & consistently survey nursing homes for compliance using the F441 interpretive guidance, investigative protocol and current standards of practice
- Appropriately categorize the scope and severity of noncompliance

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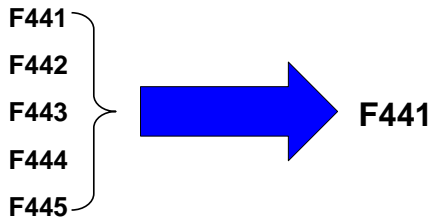
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## What's Different

Regulations **have not changed!**



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## What's Different

- Current guidance revised to create a **new** comprehensive investigative protocol to include:
  - Interpretive guidelines, Definitions, Overview, Investigative Protocol, Determination of Compliance, Deficiency Categorization
- Effective date **9/30/09**

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## What's Different?

- Before 9/30/09
- Appendix P
- Other Phase 2 Tasks
  - If concerns have been identified in the area of infection control, review policies & procedures including a focus on what preventive infection control practices the facility has in place

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## What's Different

- After 9/30/09
- Appendix PP - F441 Investigative Protocol
- Use
  - Use the F441 Investigative Protocol for every initial and recertification survey. In addition, use this protocol on revisit or abbreviated surveys (complaint investigations) when indicated.

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## What's Different

- After 9/30/09
- Appendix PP - F441 Investigative Protocol
- Procedures
  - The surveyor, throughout the survey, should conduct observations, interviews and record reviews outlined in the F441 Investigative Protocol. In addition, the surveyor(s) should also review the facility's IC policies, procedures, as well as documentation of staff training, and ...

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## F441- §483.65 Infection Control

The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

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## F441 - §483.65(a) Infection Control Program

- The facility must establish an infection control Program under which it –
  - 1) Investigates, controls, and prevents infections in the facility
  - 2) Decides what procedures, such as isolation, should be applied to an individual resident
  - 3) Maintains a record of incidents and corrective actions related to infections

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## Intent of Regulation

- Assure facility develops, implements, and maintains an Infection **Prevention** and Control Program in order to prevent, recognize, and control, to the extent possible, the onset and spread of infection within the facility.

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## Overview Interpretive Guidance

Infections are a **significant source of morbidity and mortality** for nursing home residents and account for up to half of all nursing home resident transfers to hospitals

**Infections occur an average of 2 to 4 times per year for each nursing home resident.**

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## Endemic Infections in NH Residents

- Most Frequently Occurring
- Other Commonly Occurring
- Urinary Tract
- Respiratory
  - Pneumonia or LRTI
  - Influenza
- Skin and Soft Tissue
  - Pressure Ulcers
- Viral Gastroenteritis caused by:
  - Rotavirus
  - Enteroviruses
  - Noroviruses
- Conjunctivities

SHEA/APIC Guideline - 2008

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## Critical Aspects of an Infection Prevention & Control Program

- Infection prevention and control
  - Is a continual process that starts at the time of a resident's admission and continues throughout his/her stay
  - Recognized infection prevention and control practices are followed and reflect current CDC Guidelines

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## Admission Screening Risk Factors for Infection

- ❖ Antibiotic use in past 30 days
- ❖ Current symptoms / diagnoses
- ❖ Cultures taken & results
- ❖ Immunization History
- ❖ Duration of use of indwelling catheter
- ❖ Presence of drug-resistant organisms
- ❖ Prior infections
- ❖ 2 step TB assessment

AMDA Clinical Practice Guideline  
Common Infections in the Long-Term Care Setting

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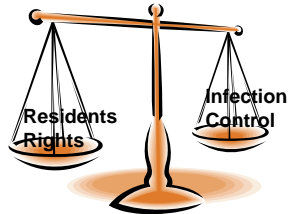
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## Considerations

- It may be difficult to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections



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## Components of an Infection Prevention & Control Program

- |                                   |                                  |
|-----------------------------------|----------------------------------|
| • Program Development & Oversight | • Documentation                  |
| • Infection Preventionist         | • Monitoring                     |
| • Policies & Procedures           | • Data Analysis                  |
| • Surveillance                    | • Communicable Disease Reporting |
|                                   | • Education                      |
|                                   | • Antibiotic Review              |

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## Program Development & Oversight

- Core focus of the program oversight is to:
  - Establish goals & priorities
  - Monitor implementation of the program
  - Respond to errors, problems, or other identified issues.

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## Personnel Responsible for Overall Program Oversight

- Facility program oversight should collaboratively include:
  - Administrator
  - Medical Director (or a designee)
  - DON
  - Other staff as appropriate (Infection Preventionist)

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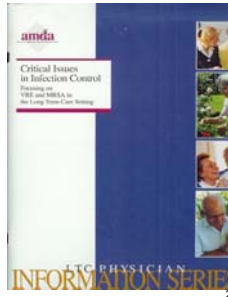
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## Medical Director Roles & Responsibilities in IC

- Advisory
  - Criteria for identifying infections
  - How to distinguish facility acquired from community-acquired
  - Appropriate surveillance activities
  - Data collection instruments
    - Antibiotic usage
    - Surveillance forms



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## Infection Preventionist

- **CMS**
- Coordinator of program and duties may include
  - Education/Training
  - Collecting & analyzing data to share w/ nursing staff & others
  - Consultation
- **SHEA / APIC Guideline**
- Directs infection control activities
- Implements, monitors & evaluates program

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## Polices and Procedures

- Serve as foundation of the program
- Periodically reviewed & revised to ensure consistent w/ current standards of practice and address facility concerns



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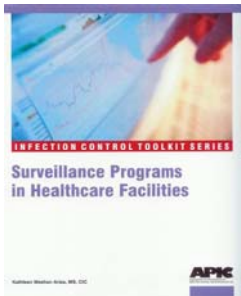
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## Surveillance



- Cornerstone of any infection control program.
  - **Based on surveillance definitions**
  - CDC
  - IDSA
  - McGeers
  - SHEA
  - WI Division of Public Health

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## Surveillance

The primary purpose of infection control surveillance is the collection of information for action.

Consensus conference on nosocomial infections in long-term care facilities. AJIC 1987;15:97-100

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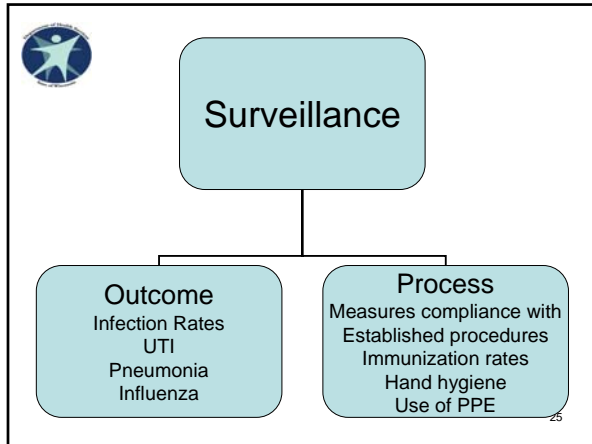
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## Documentation

- Reports must describe types of infections, healthcare acquired versus community acquired
- Identify trends and patterns
- Program defines how often and by what means data will be collected based on current standards of practice



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## Surveillance Data Documentation

Infections	December	January	February
<b>UTI</b>	<b>1.05</b> <b>3.25%</b>	<b>1.74</b> <b>5.04%</b>	<b>3.2</b> <b>9.92%</b>
<b>Respiratory</b>	<b>1.32</b> <b>4.13%</b>	<b>2.62</b> <b>8.13%</b>	<b>.58</b> <b>1.68%</b>

Rate versus Percentage

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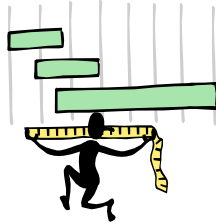
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## Monitoring

- Residents at risk for infection
- Residents with infections
- Outbreaks
- Implementation
- Effectiveness



IDSA Clinical Practice Guideline for Evaluation of Fever & Infection in Older Adult Residents of LTC Facilities, 2008

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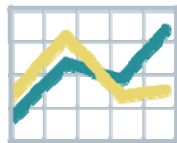
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## Data Analysis

- Compare current surveillance data to past to detect:
  - Unusual or unexpected outcomes
  - Trends
  - Effective practices
  - Performance issues



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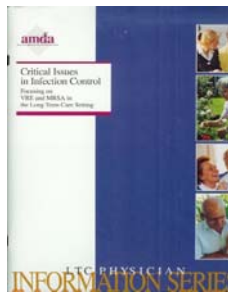
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## Medical Director Roles & Responsibilities in IC

- Review Infection Trends
- Help the facility
  - Analyze incidence & prevalence data & any patterns of infection
  - Identify patterns of infection
  - Review recent outbreaks
  - Identify follow-up action
  - Ensure compliance w/ managing & reporting outbreaks



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## Education

- Who – All staff, especially those providing direct resident care
- What
  - Basic hygiene, Hand hygiene, Respiratory Etiquette, Transmission of Infectious Diseases, Standard & Transmission Based Precautions, Federally required OSHA education, Policies & Procedures, Vaccines, etc
- When – Upon hire & regularly thereafter
- How – Inservices & Process surveillance

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## Communicable Disease Reporting

- DPH Disease Reporting Website located at <http://dhs.wisconsin.gov/communicable/diseasereporting/index.htm>
- DPH document "Reporting Requirements, Prevention & Control of Influenza & Other Respiratory Diseases in AL & LTC Facilities (including Novel Influenza H1N1) for the 2009 – 2010 influenza season." (8/21/09)
- DPH document "Recommendations for the Prevention & Control of Viral Gastroenteritis Outbreaks in WI Long-Term Care Facilities, Revised 10/20/09."

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## Antibiotic Review

- Widespread use associated with drug resistant organisms
- F329 - Determine if adequate indication for use
- Compare prescribed antibiotics with available susceptibility reports
- F425 – Medication Regimen Review



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## F441 – 483.65(b) Preventing Spread of Infection

- 1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident

**Remember – When appropriate, isolate the infection and not the resident!**

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## Standard Precautions

- Based upon the principle that all
  - Blood
  - Body fluids
  - Secretions
  - Excretions (except sweat)
  - Non-intact skin
  - Mucous membranes may contain transmissible infectious agents

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## Standard Precautions

- Used for care of **ALL** residents
- Not always possible to tell who is infected
- Resident signs / symptoms will determine what PPE is necessary
- Task being performed also will determine what PPE is necessary



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## Standard Precautions

- Includes:
  - Hand Hygiene
  - Proper use of PPE
    - Gloves
    - Gown
    - Mask, eye protection (goggles), face shield
  - Respiratory Hygiene / Cough Etiquette
- Includes:
  - Safe Injection Practices
  - Environmental Control
  - Laundry
  - Resident placement
    - Private room
    - Cohort
  - Appropriate waste disposal & management

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## Transmission Based Precautions

- Used in addition to Standard Precautions
- Three types:
  - Airborne
  - Contact
  - Droplet
- May need to use combination




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## Transmission-Based Precautions

- Used for residents who are;
  - Known to be infected
  - Suspected of being infected
  - Colonized with infectious agents or pathogens that require additional control measures to prevent transmission
- May need to be implemented while test results are pending based on signs/symptoms that may be indicative of infection
  - Temperature  $\geq$  with coughing
  - Abrupt onset of nausea, or vomiting, and/or diarrhea

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## Transmission-Based Precautions

- Should be maintained for only as long as necessary to prevent the spread of infection
- Use the least restrictive approach as possible to protect the resident and others
- Discontinuing Precautions
  - APIC Elimination Guide for MRSA in LTC
  - CDC Guideline for Management of MDROs in Health Care Settings, 2006
  - DPH Guidelines for Prevention & Control of AROs in Healthcare Settings, 2005

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## Safe Injection Practices

### RECOMMENDED INFECTION-CONTROL AND SAFE INJECTION PRACTICES TO PREVENT PATIENT-TO-PATIENT TRANSMISSION OF BLOODBORNE PATHOGENS

#### Diabetes Care Procedures & Techniques

- Prepare medications such as insulin in a centralized medication area; multiple dose insulin vials should be assigned to individual patients and labeled appropriately.
- Never reuse needles, syringes, or lancets.
- Restrict use of fingerstick capillary blood sampling devices to individual patients. Consider selecting single-use lancets that permanently retract upon puncture.
- Dispose of used fingerstick devices and lancets at the point of use in an approved sharps container.
- Environmental surfaces such as glucometers should be decontaminated regularly and anytime contamination with blood or body fluids occurs or is suspected.
- Glucometers should be assigned to individual patients. If a glucometer that has been used for one patient must be reused for another patient, the device must be cleaned and disinfected.



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## F441 – 483.65(b) Preventing Spread of Infection

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.



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## F441- §483.65(b) Preventing Spread of Infection

- 3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

**Hand Hygiene is the single most effective means of preventing the spread of infection**



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## Hand Hygiene (ABHR)

Alcohol-Based Hand Rub (ABHR) may be utilized in situations where hand washing with soap and water is not specifically required

Alcohol concentration must be 60-90%

Not recommended before eating or after using the restroom. Must wash hands!

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## Hand Hygiene

If Alcohol Based Hand Rub (ABHR) is one of the forms of hand hygiene utilized by the facility, staff must know the situations when hand washing with soap and water is specifically required:

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## F441 - §483.65(c) Linens

- Personnel must handle, store, process and transport linens as to prevent the spread of infections



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## Recognizing Outbreaks

- Based on current recommendations & standards of practice – CDC, WI DPH
- An outbreak is typically one of the following:
  - One case of an infection that is highly communicable.
    - Tuberculosis, Influenza,
  - Trends that are 10 percent higher than the historical rate of infection for the facility that may reflect an outbreak or seasonal variation and therefore warrant further investigation.
  - Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.

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## Medical Director Roles & Responsibilities in IC

- Possible Outbreaks
  - Help
    - Analyze & manage outbreaks internally & address with LPHD
    - Determine presence of outbreak
  - Advise on measures to prevent spread
  - Review surveillance efforts
  - Recommend policy revisions after outbreak is over



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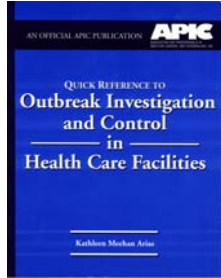
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## Outbreak Preparedness

- **Prior** to any outbreak
- Determine usual rates of infection based on facility surveillance data
- In collaboration with medical director, develop policies and procedures to address an outbreak



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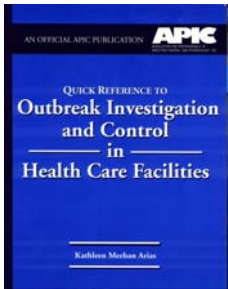
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## Outbreak Preparedness



- Educate staff re: their role in prevention and control
  - Employee Health
  - Handwashing
  - Implementing Precautions
  - Resident & Staff Line Lists
  - Specimen collection
  - Monitor resident health
  - LPHD notification

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## Outbreak Control

- Priority is to prevent, control and prevent further transmission.
- **Prevent one persons infection from becoming another persons infection!**

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## Gastrointestinal Outbreaks LTCFs 1/1/06 – 6/30/09

Year	Residents	Staff	Hosp	Deaths
2006	1458	608	42	3
2007	1316	434	33	3
2008	2925	1189	68	18
YTD 09	2799	1545	81	12
Totals	8498	3776	224	36

DPH NFBO Data

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## Investigative Protocol Objectives

- The facility has an Infection Prevention and Control Program that prevents, investigates and controls infections in the facility
- The facility has a program that collects and analyzes data regarding infections acquired in the facility
- Staff practices are consistent with current infection control principles
- Staff with communicable diseases are prohibited from direct contact with resident

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## Investigative Protocol Procedures

- Observations
  - Staff - Various disciplines to include, nursing, dietary and housekeeping
  - Residents – Signs / symptoms of potential infections
  - Visitors
  - Cleaning & Disinfection practices

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## Investigative Protocol Procedures

- Interviews
  - Resident, family or responsible party regarding receipt of infection control education and information
  - Direct care staff
  - Pharmacist, Physicians as needed
  - Personnel responsible for coordination and program oversight (Administrator, DON, Medical Director, Infection Preventionist)

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## Investigative Protocol Procedures

- Resident Record Review
  - Evaluation of risk factors for infection, presence of infection and identification of the infection and potential causes and contributing factors
  - Plan of care identifies interventions
  - Community acquired versus facility acquired

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## Investigative Protocol Procedures

- Facility Record Reviews
  - Record of incidents of infection and related corrective action
  - Policies and procedures
  - Surveillance documentation
  - Employee records

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### Criteria for Compliance with F441

**The facility is in compliance if staff:**

- Demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection;
- Demonstrates practices and processes consistent with infection prevention and prevention of cross-contamination;

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### Criteria for Compliance with F441

**The facility is in compliance if staff:**

- Demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;
- Uses procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents;

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### Criteria for Compliance with F441

**The facility is in compliance if staff:**

- Demonstrates appropriate hand hygiene practices, after each direct resident contact; and
- Demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.

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# Deficiency Categorization

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## DEFICIENCY CATEGORIZATION (Part IV, Appendix P) Severity Determination Key Components

SCOPE	ISOLATED	PATTERN	WIDESPREAD
SEVERITY/HARM			
(4) Immediate jeopardy to resident health or safety	J	K	L
(3) Actual harm that is not immediate jeopardy	G	H	I
(2) No actual harm with potential for more than minimal harm that is not immediate jeopardy	D	E	F
(1) No actual harm with potential for no more than minimal harm	A	B	C

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### Factor 1 Determining Actual or Potential Harm

**Actual or potential harm/negative outcomes for F441 may include the onset or spread of infections in the facility**

*Did the deficient practice lead to or contribute to **the onset or spread of infection** or did it only lead to the potential for the onset or spread of infection?*

*What is the harm that occurred or could have occurred?*

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Factor 2

### Determining Degree of Harm

**How serious is the harm that occurred or could have occurred?**

*Did the harm cause or could it potentially have caused **serious injury, impairment, or death**?*

*Did the harm **compromise** or could it potentially have compromised a resident's **functioning or well being**?*

*Did the harm or potential harm cause only **discomfort** to a resident or residents?*

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Factor 3

### Immediacy for harm

**Is/was immediate correction required to prevent resident harm?**

*At the point in time that the deficient practice occurred, was immediate intervention required to prevent serious harm from occurring? Is immediate intervention required now?*

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### Level 4 Immediate Jeopardy

**A situation that caused or is likely to cause serious injury, serious harm, impairment or death to a resident. Immediate corrective action is/was needed to prevent a serious outcome from occurring.**

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**Level 4**  
**Example #1**

The facility failed to clean the spring-loaded lancet devices or glucometers before or after use and reused the same equipment on subsequent residents who required blood sugar monitoring without cleaning between use.

*Rationale:* Readily exposes multiple residents in the facility who required blood sugar testing to the spread of blood borne infections.

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**Level 4**  
**Example #2**

The facility failed to restrict a staff member with a documented open, draining and MRSA-infected skin lesion from working with residents without adequately covering the area.

*Rationale:* May readily result in the transmission of MRSA to one or more residents under that staff person's care.

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**Level 4**  
**Example #3**

The facility failed to investigate, document surveillance of and try to contain an outbreak of gastrointestinal illness among residents.

*Rationale:* This caused, or is very likely to cause, additional residents becoming ill with diarrheal illnesses, which, especially in the elderly, can lead to serious complications such as dehydration and death.

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### Level 3

Actual Harm that is *not* Immediate Jeopardy

The deficient practice has caused a negative outcome that has resulted in physical or psychosocial compromise or decline, or prevented the resident from attaining or maintaining his/her highest practicable level of well-being.

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### Level 3 Example #1

The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics. As a result, two residents got antibiotic-related colitis and sustained significant weight loss.

*Rationale: Residents sustained harm that has compromised their well being.*

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### Level 3 Example #2

The facility did not institute internal surveillance for hand washing or the appropriate use of masks during an influenza outbreak. Staff were observed not washing hands between residents or not using respiratory precautions. As a result, additional residents developed influenza.

*Rationale: Breakdown in a component of the facility's infection control system has led to harm to other residents but is not immediate jeopardy because implementation of all other parts of the facility's infection control program mitigates against the possibility that serious harm is likely to occur in the immediate future.*

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### Level 2

No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

- Noncompliance that results in no more than minimal discomfort to a resident, and/or
- Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being.

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### Level 2 Example #1

A 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 and wash or sanitize her hands between residents.

*Rationale: Has the potential to spread infection but not immediate or serious.*

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### Level 2 Example #2

The facility did not implement a surveillance program including the investigation of infections or attempt to distinguish facility-acquired infections from community-acquired infections. The facility has not had an outbreak of infections.

*Rationale: No evidence that the deficient practice has caused harm or is likely to cause serious harm in the immediate future.*

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## Level 2 Example #3

As part of its infection prevention and control program, the facility identified issues related to staff infection control practices. The facility did not follow up to identify the cause and did not institute measures to correct the problems.

*Rationale: No evidence that this has led to harm or that serious harm is likely to result in the immediate future.*

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## Level 1 No Actual Harm with Potential for Minimal Harm

Severity Level 1 does not apply. A deficient practice at F441, at a minimum, creates a potential for harm that could compromise a resident.

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## Practice Example 1

Resident #2 has a diagnosis of MRSA (Methicillin Resistant Staph Aureus).

A nurse placed dressing supplies on a table without a barrier in Resident #2's room. During this dressing change the nurse obtained a scissors from her pocket with her contaminated hands, used it and then placed it back in her pocket. When the nurse completed the dressing change, she did not remove her contaminated gloves or wash or sanitize her hands prior to exiting the room, potentially infecting other sources outside the room. The nurse took the unused supplies out of the room and placed them in a clean environment in the medication room.

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## Practice example 2

- \* The facility did not ensure that residents who were not ill and had no symptoms were not exposed to other residents who were presenting with indicators of acute gastrointestinal infection. Ill and non-ill residents were allowed to intermingle at meals and activities.
- \* The facility did not monitor the incidence of staff illness in all pertinent departments. The facility did not have a system to ensure that staff, who were or had been ill with symptoms of norovirus, were no longer contagious prior to returning to work

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## Practice example 2 (con't)

- \* The facility did not implement their established procedures for tracking residents with signs and symptoms of infection. Information was not consistently provided to the designated infection control person in order to determine if infections were occurring on the same unit, what the infectious organism was and whether more aggressive infection control measures needed to be implemented. The facility was unable to track and trend illness.
- \*The facility did not immediately implement procedures to manage the resident environment following the outbreak and to limit the incidence of further contamination. The facility did not increase the frequency of routine cleaning of resident rooms and common areas with a bleach solution as recommended by the CDC guidelines. The facility did not ensure that all departments, including laundry services, were utilizing standard and contact precautions to prevent transmission of infection.

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## Practice example 3

The facility identified an outbreak of gastrointestinal illness. Although the facility kept residents with symptoms in their rooms and separate from those who were not ill, the facility did not inform public health of the gastrointestinal illness outbreak until six days after the outbreak. The facility had a daily line listing of residents and staff who were ill but this list did not include wellness dates, symptoms and date of onset of illness in all cases. Staff members who came down with signs and symptoms of gastrointestinal illness were told to stay home 24 hours after symptoms subsided and not told to remain out of the facility for 48 hours after their symptoms subsided per guidelines.

The facility continued to admit new residents to the facility and did not inform them of the outbreak in the facility. Three of the newly admitted residents developed signs and symptoms of gastrointestinal illness after they were admitted to the facility.

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### Practice example 4

The facility was notified of the antibiotic-resistant organism called ESBL (Extended-spectrum beta-lactamase) on 07/23/08, which was detected in Resident #1's urine. The facility did not initiate the required CDC (Centers for Disease Control and Prevention) guidelines for contact precautions until 08/03/08.

Nurse's notes revealed that Resident #1 was incontinent of bladder multiple times per day. MDS completed on 07/09/08, noted that Resident #1 required extensive assist of 2 or more people for toileting, transfers, and bed mobility. In addition, Resident #1 was incontinent of bowel 2-3 times per week.

... the infection control nurse, stated that the facility did not initiate contact precautions prior to 08/03/08 because the facility had no prior knowledge of this type of antibiotic-resistant organism and was unfamiliar with the CDC requirements for contact precautions. She stated that standard precautions were used from 7/23 until 8/3/08.

No other residents became infected.

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### Practice example 5

On 10/8/08 at 12:10 p.m. RN-Z entered resident #26's room to perform an accucheck. RN-Z drew blood from the resident's finger and brought the glucometer up to the droplet of blood. After completing the test and without cleansing the machine, RN-Z repeated the above steps for resident #27. When the accucheck had been completed for that resident, and without cleansing the glucometer machine, RN-Z placed the machine back on the top of the medication cart, wheeled the medication cart into the medication room and placed the glucometer back into the medication cart drawer and locked the cart. RN-Z verified to the surveyor that the facility utilized one glucometer for all the residents on that unit who required accuchecks.

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