

Antimicrobial Stewardship in Long-Term Care Facilities Kick-Off Summit  
September 14, 2018

# Regulatory Issues and LTCF Survey Implications

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# DISCLOSURE / CONTACT INFO

## Disclosure

### Jen

- Remedi SeniorCare
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### Bill

- Remedi SeniorCare
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## Institute for Safe Medication Practices

A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

“Welcome to the ISMP ***Long-Term Care Advise-ERR***, a medication safety newsletter designed specifically to meet the needs of administrators, nursing directors, and nurses who transcribe medication orders, administer medications, monitor the effects of medications on residents, and/or supervise those who carry out these important tasks.”

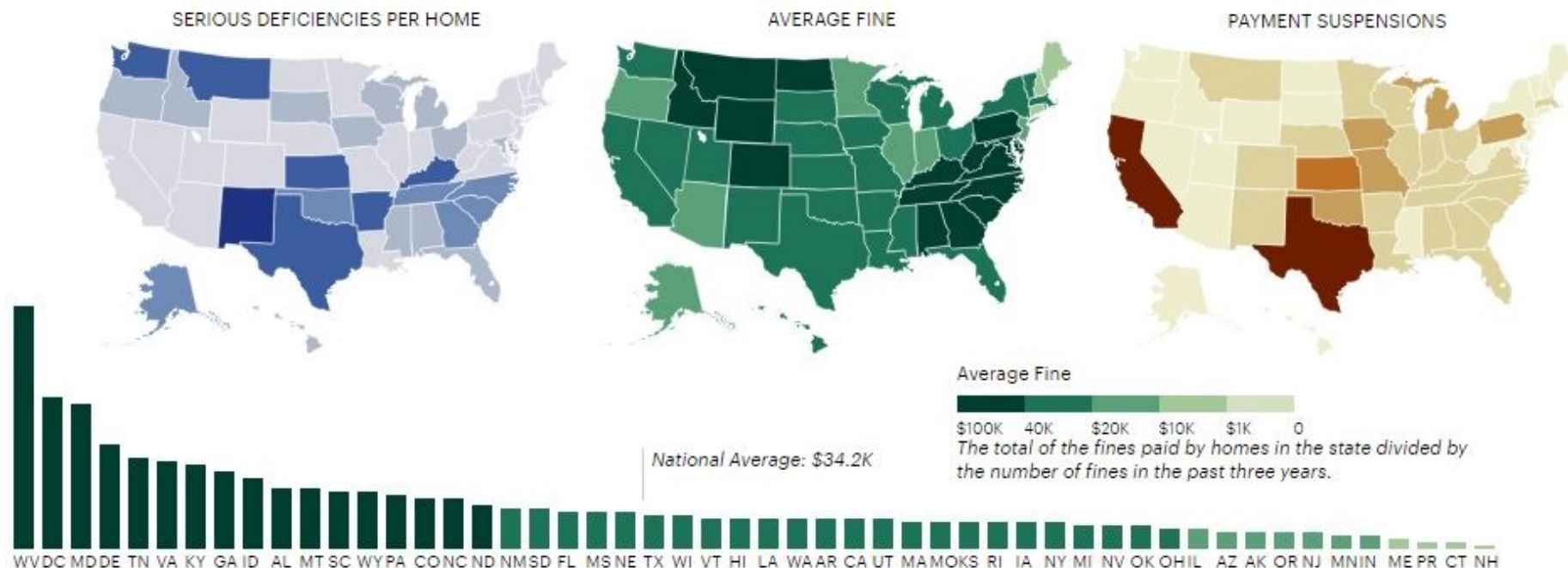
<http://www.ismp.org/Newsletters/longtermcare/default.aspx>

# OBJECTIVES

- 1) Describe current federal regulatory requirements regarding antibiotic stewardship.
  - 2) Discuss trends and patterns involving deficiencies related to antibiotic stewardship.
  - 3) Describe two interventions which will improve compliance with antibiotic stewardship requirements.
- Note: Federal (CMS) regulations apply only to nursing homes, not assisted living facilities

# THE FEDERAL SURVEY PROCESS

## Inconsistent Penalties Across the Country



Source: ProPublica (updated June, 2018)  
<https://projects.propublica.org/nursing-homes/>

# ANTIBIOTIC STEWARDSHIP

**F881**

***§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)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.***

# OPEN TO INTERPRETATION

## Intent<sup>1</sup>

- 1. Appropriate prescribing*
- 2. Risk reduction*
  - 1. Adverse events*
  - 2. Resistance*
- 3. Ongoing monitoring*



<sup>1</sup>*Guidance to surveyors F 881*



Does F 881 require that facilities incorporate CDC's core elements of antibiotic stewardship into their use protocols and monitoring system?



# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

*The facility **must develop** an antibiotic stewardship program which includes the development of **protocols** and a **system to monitor antibiotic use**. This development **should include** leadership support and accountability via the participation of the medical director, consulting pharmacist, nursing and administrative leadership, and individual with designated responsibility for the infection control program if different*

– *Guidance to Surveyors F 881*

# USE OF INTERPRETIVE GUIDANCE BY SURVEYORS FOR LONG TERM CARE FACILITIES

Words like **should** or may create **permissive standards**, vs. words like shall and must that indicate requirements. ... **permissive duties are not requirements** ... surveyors must base all cited deficiencies on a violation of statutory and/or regulatory requirements, rather than sections of the interpretive guidelines. The deficiency citation must be written to explain how the entity fails to comply with the regulatory requirements, not how the facility fails to comply with the guidelines for the interpretation of those requirements

*-CMS memorandum S&C-08-10*

# USE PROTOCOLS

*Up to 75 percent of antibiotics prescribed in nursing homes are prescribed incorrectly. The most common prescribing problems in nursing homes are using an antibiotic when not needed, choosing the wrong antibiotic, and using the correct antibiotic but for the wrong dose or duration.*

- Center for Disease Control and Prevention

# USE PROTOCOLS

- Evidenced based
  - Standardized tool /criteria
    - No specific mandate
  - Infection v. colonization
- Implementation
  - Content of orders
  - Impact of EHR
  - Response to deviation
- Communication
  - Clinical
  - Laboratory
  - Resident / surrogate



# SYSTEM TO MONITOR

## ➤ Data

- Real time v. anecdotal
- Pharmacy
- Laboratory
- Infection control practitioner

## ➤ Process / Outcomes

- No mandate

## ➤ Analysis

## ➤ Feedback

- QAPI
- Prescribers
- Residents / surrogates

# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

## Dispensing pharmacist

- F 755 Pharmacy services
- F 757 Unnecessary drugs

## Consultant pharmacist

- F 756 Drug regimen review

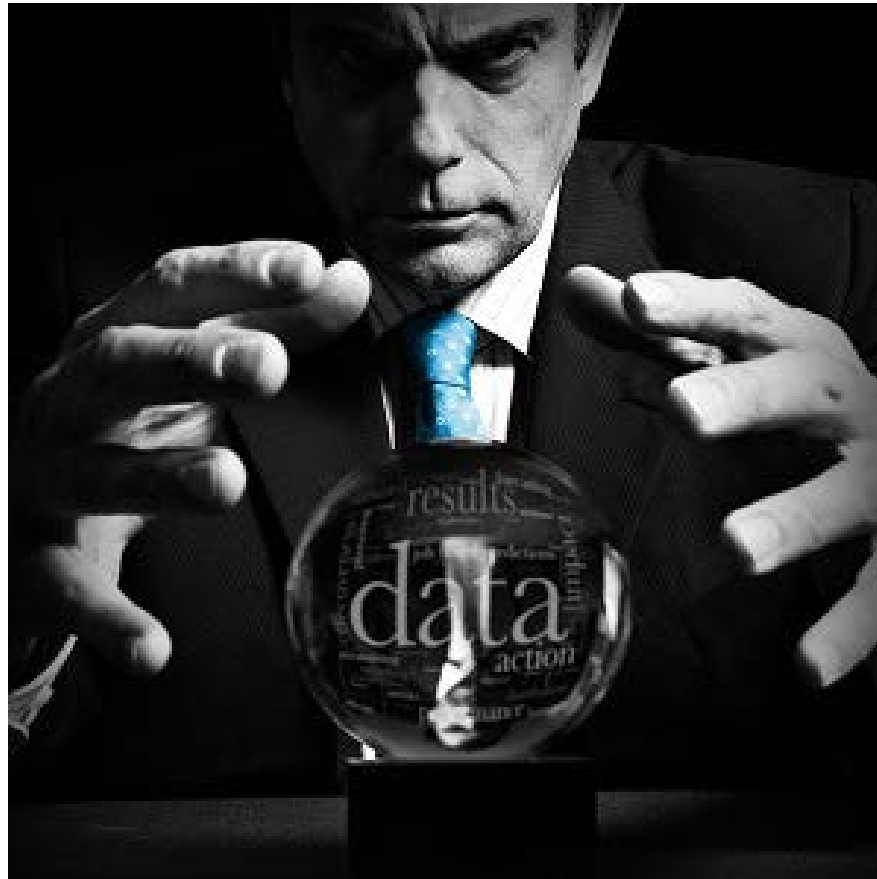
### ***The Antibiotic Stewardship Program in Relation to Pharmacy Services***

*The assessment, monitoring, and communication of antibiotic use shall occur by a licensed pharmacist in accordance with §483.45(c), F756, Drug Regimen Review <sup>1</sup>*

- F 757 Unnecessary drugs

<sup>1</sup>Guidance to surveyors F 881

# DEFICIENCY CITATIONS



# DATA SOURCES



## 1) Data portal

<https://data.medicare.gov/>

## 2) Aggregate health deficiencies cited in federally certified nursing homes

<https://data.medicare.gov/Nursing-Home-Compare/Health-Deficiencies/npft-b6wt>

## 3) Redacted deficiencies for specific nursing homes

<https://www.medicare.gov/nursinghomecompare/search.html>

## 4) Unredacted deficiencies for specific nursing homes

<https://projects.propublica.org/nursing-homes/>

➤ **Accessed: August 28, 2018**

**Caution:** Delay in posting survey results / look back period/redaction



# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

## Survey Dates

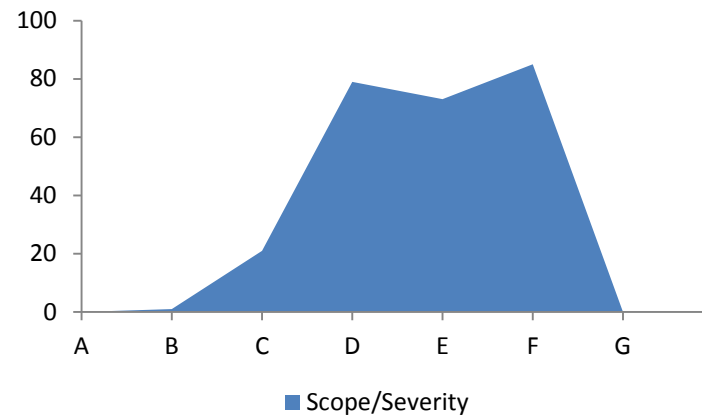
November 28, 2017 → July 31, 2018

### National

Total = 259\*

Nothing > F

Majority = F



# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

S/S = C

## Failure to implement program

*Interview conducted on 05/03/18 at 1:57 P.M. with Nurse #26 revealed the facility had no documentation of the antibiotic stewardship program nor any infection control log for the months of January, February, and March. She stated **the infection control program was undocumented for three months because the employee responsible for collecting the data no longer worked for the facility.***

# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

S/S= F

## Failure to implement program

*Review of the facility's infection control log revealed no evidence the facility implemented an Antibiotic Stewardship Program. On **05/09/18** at 10:45 A.M. interview with Registered Nurse (RN) #12 verified the facility had **not implemented an antibiotic stewardship program to date.***



# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

## Policy

*The facility failed to ensure residents receiving antibiotic therapy were properly **assessed**, **evaluated** and **educated** before the initiation of the antibiotic therapy. The Director of Nursing (DON) confirmed the facility was not appropriately evaluating antibiotics given to residents. The DON verified the facility was not following up and assessing residents who were receiving antibiotics according to their policy. Review of the policy revealed the use of the antibiotics will be monitored in all residents with appropriate lab work. **Antibiotics orders will be reviewed for appropriateness** and clarification with the physicians as needed. If and when antibiotics were prescribed over the phone, **the physician will assess the resident within 72 hours.***

# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

## Failure to establish program

*“In an interview on 04/19/18 at 11:40 a.m. the RDO said they did not currently have an antibiotic stewardship program up and running ... In an interview on 04/19/18 at 12:20 p.m., the Administrator said she was not aware that the facility had not started the antibiotic stewardship program”*

*“Interview on 5/18/18 with the DON revealed the facility has not instituted antibiotic stewardship program. She stated the consultant pharmacy brought her a policy and procedure and the corporate nurse brought a better policy. DON stated she is not instituted the policy yet because she is acting as interim DON and will leave as soon”*

*“On 5/23/18 at 3:00 PM, Administrative Nurse D stated he/she managed the infection control program and verified the logs were not complete. Administrative Nurse D stated there were multiple urinary tract infections, including several on one hallway, and he/she verified the facility had no antibiotic stewardship program in place.”*

# F 881: INFECTION PREVENTION / CONTROL

## ABT STEWARDSHIP

### Failure to follow protocols

*The facility failed to accurately implement the protocols using the Surveillance Data Collection Form established by the facility, to ensure residents reviewed for infections with antibiotics were screened correctly. The form did not include the check marks to indicate if the criteria was met for the use of the antibiotic.*

*According to the Centers for Disease Control and Prevention (CDC), there are identified core elements/actions a nursing home **should** ensure to prevent antibiotic resistance. The nursing home should:*

- 1. Educate their providers on the potential harm of antibiotics.*
- 2. Document the met criterias for the use of the antibiotic and making this information accessible (e.g., verifying indication and planned duration is documented on transfer paperwork) helps ensure that antibiotics can be modified as needed based on additional laboratory and clinical data and/or discontinued in a timely manner to reduce unnecessary antibiotic exposure and improve resident outcomes*

# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

Does F 881 require that facilities incorporate CDC's core elements of antibiotic stewardship into their use protocols and monitoring system?

# F 881: INFECTION PREVENTION / CONTROL

## ABT STEWARDSHIP

### Failure to assess for continued use

*The DON acknowledged the resident's course for the use of the antibiotic had not been assessed or monitored. The DON verified the facility lacked documented evidence of a rationale for the continued administration of the antibiotic from 02/02/18 to 05/22/18.*

*The Physician's Assistant (PA) acknowledged the resident had been on the antibiotic since 02/02/18. The PA indicated the infection was colonized as the resident had been on the antibiotic for an extended period of time. The PA indicated the resident was supposed to see a pulmonologist. The PA indicated the pulmonologist would have made recommendations regarding the continued administration of the antibiotic. The PA indicated there was a lack of documented evidence a rationale for the continued use of the antibiotic.*



# YOU ARE NOW THE SURVEYOR: SCOPE/SEVERITY ?



**Immediate Jeopardy** - “A situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.”

- Appendix Q

# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

## Failure to communicate laboratory results

4/21: UA findings positive for a urinary tract infection. [indication for UA not specified] → MD call → Cipro bid x 5 days (1<sup>st</sup> dose administer 4/23)

4/23: C&S resistant to Cipro → no MD notification → Cipro administered x 5 days

*“The ADON said the facility was still in the process of developing an antibiotic stewardship program and did not have a policy and procedure to provide.”*

# F 881: INFECTION PREVENTION / CONTROL

## ABT STEWARDSHIP

Standardized tool /criteria for diagnosis

Timely administration

Communication

Antibiotic time out

Black box warning

*Because the risk of these serious side effects generally outweighs the benefits for patients with acute bacterial sinusitis, acute exacerbation of chronic bronchitis and **uncomplicated urinary tract infections**, the FDA has determined that fluoroquinolones should be reserved for use in patients with these conditions who have no alternative treatment options.*



# F 881: INFECTION PREVENTION / CONTROL ABT STEWARDSHIP

## Bottom Line

- Develop a program (Streamline)
- Follow the program
- Do the basics



**§483.10(C) PLANNING AND IMPLEMENTING CARE.**

**THE RESIDENT HAS THE RIGHT TO BE INFORMED OF, AND PARTICIPATE IN, HIS OR HER TREATMENT, INCLUDING:**

**§483.10(C)(1) THE RIGHT TO BE FULLY INFORMED IN LANGUAGE THAT HE OR SHE CAN UNDERSTAND OF HIS OR HER TOTAL HEALTH STATUS, INCLUDING BUT NOT LIMITED TO, HIS OR HER MEDICAL CONDITION.**

**§483.10(C)(4) THE RIGHT TO BE INFORMED, IN ADVANCE, OF THE CARE TO BE FURNISHED AND THE TYPE OF CARE GIVER OR PROFESSIONAL THAT WILL FURNISH CARE.**

**§483.10(C)(5) THE RIGHT TO BE INFORMED IN ADVANCE, BY THE PHYSICIAN OR OTHER PRACTITIONER OR PROFESSIONAL, OF THE RISKS AND BENEFITS OF PROPOSED CARE, OF TREATMENT AND TREATMENT ALTERNATIVES OR TREATMENT OPTIONS AND TO CHOOSE THE ALTERNATIVE OR OPTION HE OR SHE PREFERS.**

# F 552: IMPLEMENTING / PLANNING CARE

## What is your process?

- Risks/Benefits/Alternatives – How much is enough?
- Black box warnings?
- Which staff member?
- Documentation?
- Signed consent?
- Unavailability of surrogate?
- QAPI → data



Thank  
You

