

Determination of Compliance



F315



Urinary Incontinence (UI)



Determination of Compliance

(Task 6, Appendix P)



Synopsis of regulation (F315)

Three aspects:

- 1) A resident who does not have an indwelling urinary catheter does not have one inserted unless the resident's clinical condition demonstrates that it was necessary
- 2) The facility provides appropriate treatment and services to prevent urinary tract infections (UTI's)
- 3) The facility attempts to assist the resident to restore as much normal bladder function as possible



Criteria for Compliance

For a resident who was admitted with an indwelling catheter or who had one placed after admission, the facility is in compliance if staff:



- Recognize and assess factors affecting urinary function and identify the medical justification
- Define and implement interventions to minimize complications/remove if indicated
- Monitor and evaluate interventions
- Revise approaches as appropriate
- If not, cite F315



Criteria for Compliance



For a resident who is incontinent of urine, the facility is in compliance if staff:

- Recognize and assess factors affecting risk of symptomatic UTI's and impaired urinary function
- Define and implement interventions to address correctable underlying causes and minimize symptomatic UTI's
- Monitor and evaluate preventive and treatment interventions
- Revise approaches as appropriate
- If not, cite F315



Criteria for Compliance



For a resident who has/had symptomatic UTI, the facility is in compliance if staff:

- Recognize and assess factors affecting risk of symptomatic urinary tract infections (UTI's) and impaired urinary function
- Define and implement interventions to minimize symptomatic UTI's and address correctable underlying causes
- Monitor and evaluate preventive and treatment interventions
- Revise approaches as appropriate
- If not, cite F315



Criteria for Noncompliance

After completing the Investigative Protocol, surveyors will analyze the data to determine if noncompliance with the regulation exists.





F315 Noncompliance

- Noncompliance for F315 **may** include (but is not limited to) one or more of the following examples:
 - 1) Failure to provide care and treatment to prevent incontinence and/or improve urinary continence and restore as much normal bladder function as possible





F315 Noncompliance

- 2) Failure to provide medical justification for the use of a catheter or provide services for a resident with a urinary catheter
- 3) Failure to assess, prevent (to the extent possible) and treat a symptomatic UTI as indicated by clinical condition, physician treatment plan and the resident's choice





F315 Noncompliance

- 4) Failure to accurately or consistently assess a resident's continence status on admission and as indicated thereafter
- 5) Failure to identify and address risk factors for developing UI
- 6) Failure to implement interventions (such as bladder rehabilitative programs) to try to improve, maintain or prevent decline of UI, consistent with the resident's assessed need and current standards of practice





F315 Noncompliance

- 7) Failure to provide clinical justification for developing urinary incontinence or for the failure of existing urinary incontinence to improve
- 8) Failure to identify and manage symptomatic UTI's, or explain adequately why they could or should not do so
- 9) Failure to implement approaches to manage an indwelling urinary catheter based upon standards of practice, including infection control procedures





F315 Noncompliance

- 10) Failure to identify and apply relevant policies and procedures to manage urinary incontinence, urinary catheters and/or UTI's
- 11) Failure to notify the MD of the resident's condition or changes in the resident's continence status or development of symptoms that may represent a symptomatic UTI (in contrast to asymptomatic bacteriuria)





Other Tags for Consideration During Deficiency Determination

Review possible concerns with other related outcome, process or structure requirements

F157 - Notification of Changes

- Staff notify MD, resident and/or resident's representative of significant continence changes, catheter usage, or the development, treatment and/or change in symptomatic UTI





Additional Tags to Consider

F241 – Dignity

- Resident receives continence care and/or catheter care in a timely manner that respects his/her dignity
- Staff help residents who cannot request assistance
- Staff minimize feelings of embarrassment, humiliation and/or isolation related to impaired continence





Additional Tags to Consider

F272 - Comprehensive Assessments

- Comprehensively assess resident's continence status and resident-specific risk factors

F279 - Comprehensive Care Plans

- Specific interventions including preventive measures
- Measurable objectives, timetables





Additional Tags to Consider

F280 - Comprehensive Care Plan Revision

- Care plan reviewed and revised as necessary

F281 - Services Provided Meet Professional Standards

- Urinary incontinence, catheter care and/or symptomatic UTI's services/care meet accepted professional standards





Additional Tags to Consider

F309 - Quality of Care

- Identify and implement appropriate measures to address any pain related to the use of an indwelling urinary catheter and services in accordance with the comprehensive assessment and plan of care

F312 - Quality of Care

- Identify and implement appropriate measures to provide good personal hygiene for the resident who cannot perform relevant activities of daily living





Additional Tags to Consider

F353 - Sufficient Staff

- Qualified staff in sufficient numbers to provide necessary care

F385 - Physician Supervision

- MD evaluates and addresses medical issues related to preventing or managing urinary incontinence, catheter usage, and symptomatic UTI's

F444 - Infection Control: Hand Washing

- Handwashing after providing incontinence care, and before and after providing catheter care





Additional Tags to Consider

F498 - Proficiency of Nurse Aides

- Nursing assistants correctly deliver continence and catheter care

F501 - Medical Director

- Assist in development of policies and procedures based on current standards of practice
- Interacts, if requested by the facility, with the MD supervising the care of the resident related to management of urinary incontinence, catheter or infection issues



Deficiency Categorization

(Part V, Appendix P)



If Non-Compliance is determined, surveyors will determine appropriate Scope & Severity Levels.



Scope

- Isolated
- Pattern
- Widespread





Severity Levels

- **Level 1** no actual harm with potential for minimal harm
- **Level 2** no actual harm with potential for more than minimal harm that is not immediate jeopardy
- **Level 3** actual harm that is not immediate jeopardy
- **Level 4** immediate jeopardy to resident health or safety (IJ)





Scope / Severity Grid

**S
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Y**

Immediate jeopardy to resident health or safety	J	K	L
Actual harm that is not immediate	G	H	I
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D	E	F
No actual harm with potential for minimal harm	A	B	C
SCOPE	Isolated	Pattern	Widespread

Key Elements Determining Severity

- ✓ Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care
- ✓ Degree of harm (actual or potential)
- ✓ The immediacy of correction required



Presence of Harm: potential for, or negative outcomes



- Development, recurrence, persistence, or increasing frequency of urinary incontinence, which is not the result of underlying clinical conditions
- Complications such as urosepsis or urethral injury related to the presence of an indwelling urinary catheter that is not clinically justified



Presence of Harm:
potential for, or negative
outcomes



- Significant changes in psychosocial functioning, such as isolation, withdrawal, or embarrassment, related to un-assessed or unmanaged urinary incontinence and/or a decline in continence, and/or the use of a urinary catheter without a clinically valid medical justification
- Complications such as skin breakdown related to the failure to manage urinary incontinence



Degree of Harm:
(actual or potential)



- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort
- If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident



Immediacy of Correction
Required

- Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents



- The survey team will evaluate the harm or potential for harm based upon the following levels of severity for tag F315



Severity Level 4 Considerations:
Immediate Jeopardy (IJ) to Resident Health or Safety

IJ is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to allow/cause/result in serious injury, harm, impairment, or death to a resident
- Requires immediate correction



Examples of possible negative outcomes at Level 4 *may* include:

- **Complications resulting from utilization of urinary appliance(s) without medical justification**
- **Extensive failure in multiple areas of incontinence care and/or catheter management**

Note: If IJ has been ruled out based upon the evidence, then evaluate actual harm that is not immediate jeopardy exists at severity Level 3.



Severity Level 3 Considerations:
Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being



Severity Level 3 Considerations

Examples of avoidable negative outcomes may include, but are not limited to:

- The development of a symptomatic UTI
- The failure to identify, assess and manage urinary retention
- The failure to provide appropriate catheter care



Severity Level 3 Considerations

- Medically unjustified use of an indwelling catheter with complications
- Decline or failure to improve continence status
- Complications due to urinary incontinence
- **NOTE: If Severity Level 3 (actual harm that is not immediately jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists**



Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not IJ

Level 2 indicates **noncompliance** that results in a resident outcome of *no more than minimal discomfort* and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.



Severity Level 2 Considerations

Examples of potentially avoidable negative outcomes may include, but are not limited to:

- Medically unjustified use of an indwelling catheter
- Complications associated with inadequate care and services for an indwelling catheter
- Potential for decline or complications



Severity Level 1 Considerations:

No Actual Harm with potential for minimal harm

The failure of the facility to provide appropriate care and services to improve continence, manage indwelling catheters, and minimize negative outcome places residents at risk for more than minimal harm

Therefore, Severity Level 1 does not apply for this regulatory requirement





Scope / Severity Grid

S E V E R I T Y	4	Immediate jeopardy to resident health or safety	J	K	L
	3	Actual harm that is not immediate	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 minimal harm	A	B	C
		SCOPE	Isolated	Pattern	Widespread



Scope / Severity Grid

S E V E R I T Y	4	Immediate jeopardy to resident health or safety	J	K	L
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	1	No actual harm with potential for minimal harm	A	B	C
SCOPE		Isolated	Pattern	Widespread	



Web Site References



CMS S&C memo 05-23

<http://www.cms.hhs.gov/medicaid/survey-cert/sc0523.pdf>

Appendix P (Survey Protocol for LTC)

http://www.cms.hhs.gov/manuals/107_som/som107ap_p_ltc.pdf

Appendix PP (Regulations and Interpretive Guidelines)

http://www.cms.hhs.gov/manuals/107_som/som107ap_pp_guidelines_ltc.pdf



Thank you!


