SELF SURVEY MODULE
§483.25(d) Urinary Incontinence

TAG F315

REGULATION: F315 §483.25(d) Urinary Incontinence

Based on the resident's comprehensive assessment, the facility must ensure that --

§483.25(d) (1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

§483.25(d) (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

INTENT: (F315) 42 CFR 483.25 (d) (1) and (2) Urinary Incontinence and Catheters

The intent of this requirement is to ensure that:

- Each resident who is incontinent of urine is identified, assessed and provided appropriate treatment and services to achieve or maintain as much normal urinary function as possible;
- An indwelling catheter is not used unless there is valid medical justification;
- An indwelling catheter for which continuing use is not medically justified is discontinued as soon as clinically warranted;
- Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the catheter; and
- A resident, with or without a catheter, receives the appropriate care and services to prevent infections to the extent possible.

DEFINITIONS

Definitions are provided to clarify clinical terms related to evaluation and treatment of urinary incontinence and catheter use.

- "Bacteremia" is the presence of bacteria in the bloodstream.
- "Bacteriuria" is defined as the presence of bacteria in the urine.
- "Urinary Incontinence" is the involuntary loss or leakage of urine. There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:
  - "Functional Incontinence" refers to loss of urine that occurs in residents whose urinary tract function is sufficiently intact that they should be able to maintain continence, but who cannot remain continent because of external factors (e.g., inability to utilize the toilet facilities in time);
  - "Mixed Incontinence" is the combination of stress incontinence and urge incontinence;
  - "Overflow Incontinence" is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended;
  - "Stress Incontinence" (outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.;

- "Transient Incontinence" refers to temporary episodes of urinary incontinence that are reversible once the cause(s) of the episode(s) is (are) identified and treated; and
- "Urge Incontinence" (overactive bladder) is associated with detrusor muscle overactivity (excessive contraction of the smooth muscle in the wall of the urinary bladder resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full).

• "Urinary Retention" is the inability to completely empty the urinary bladder by micturition.

• "Urinary Tract Infection" (UTI) is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinarytract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

• "Urosepsis" refers to the systemic inflammatory response to infection (sepsis) that appears to originate from a urinary tract source. It may present with symptoms such as fever, hypotension, reduced urine output, or acute change in mental status.

INVESTIGATIVE PROTOCOL
URINARY CONTINENCE AND CATHETERS

Objectives

• To determine whether the initial insertion or continued use of an indwelling catheter is based upon clinical indication for use of a urinary catheter;

• To determine the adequacy of interventions to prevent, improve and/or manage urinary incontinence; and

• To determine whether appropriate treatment and services have been provided to prevent and/or treat UTIs.

Use

Use this protocol for a sampled resident with an indwelling urinary catheter or for a resident with urinary incontinence.

Procedures

Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. Staff are expected to assess and provide appropriate care from the day of admission, for residents with urinary incontinence or a condition that may contribute to incontinence or the presence of an indwelling urinary catheter (including newly admitted residents). Corroborate observations by interview and record review.

NOTE: Criteria established in this protocol provide general guidelines and best practices which should be considered when making a determination of compliance, and is not an exhaustive list of mandatory elements.

1. Observation

Observe whether staff consistently implemented care plan interventions across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan or from current standards of practice, as well as potential negative outcomes.

Observe whether staff make appropriate resident accommodations consistent with the assessment, such as placing the call bell within reach and responding to the call bell, in relation to meeting toileting needs; maintaining a clear pathway and ready access to toilet facilities; providing (where indicated) elevated toilet seats, grab bars, adequate lighting, and assistance needed to use devices such as urinals, bedpans and commodes.
Observe whether assistance has been provided to try to prevent incontinence episodes, such as whether prompting, transfer, and/or stand-by assist to ambulate were provided as required for toileting.

For a resident who is on a program to restore continence or is on a prompted void or scheduled toileting program, note:

- The frequency of breakthrough or transient incontinence;
- How staff respond to the incontinence episodes; and
- Whether care is provided in accord with standards of practice (including infection control practices) and with respect for the resident's dignity.

For a resident who has been determined by clinical assessment to be unable to participate in a program to restore continence or in a scheduled toileting program and who requires care due to incontinence of urine, observe:

Whether the resident is on a scheduled check and change program; and
Whether staff check and change in a timely fashion.

For a resident who has experienced an incontinent episode, observe:

The condition of the pads/sheets/clothing (a delay in providing continence care may be indicated by brown rings/circles, saturated linens/clothing, odors, etc.);
The resident's physical condition (such as skin integrity, maceration, erythema, erosion);
The resident's psychosocial outcomes (such as embarrassment or expressions of humiliation, resignation, about being incontinent);

- Whether staff implemented appropriate hygiene measures (e.g., cleansing, rinsing, drying and applying protective moisture barriers or barrier films as indicated) to try to prevent skin breakdown from prolonged exposure of the skin to urine; and

Whether the staff response to incontinence episodes and the provision of care are consistent with standards of practice (including infection control practices) and with respect for the resident's dignity.

For a resident with an indwelling catheter, observe the delivery of care to evaluate:

- Whether staff use appropriate infection control practices regarding hand washing, catheter care, tubing, and the collection bag;
- Whether staff recognize and assess potential evidence of symptomatic UTI or other related changes in urine condition (such as onset of bloody urine, cloudiness, or oliguria, if present);
- How staff manage and assess urinary leakage from the point of catheter insertion to the bag, if present;
- If the resident has catheter-related pain, how staff assess and manage the pain; and
- What interventions (such as anchoring the catheter, avoiding excessive tugging on the catheter during transfer and care delivery) are being used to prevent inadvertent catheter removal or tissue injury from dislodging the catheter.

For a resident experiencing incontinence and who has an indwelling or intermittent catheter, observe whether the resident is provided and encouraged to take enough fluids to meet the

resident's hydration needs, as reflected in various measures of hydration status (approximately 30ml/kg/day or as indicated based on the resident's clinical condition). For issues regarding hydration, see Guidance at 42 CFR 483.25(j), F327.

2. Interviews

Interview the resident, family or responsible party to the degree possible to identify:

• Their involvement in care plan development including defining the approaches and goals, and whether interventions reflect preferences and choices;

• Their awareness of the existing continence program and how to use devices or equipment;

• If timely assistance is provided as needed for toileting needs, hydration and personal hygiene and if continence care and/or catheter care is provided according to the care plan;

• If the resident comprehends and applies information and instructions to help improve or maintain continence (where cognition permits);

• Presence of urinary tract-related pain, including causes and management;

• If interventions were refused, whether consequences and/or other alternative approaches were presented and discussed; and

• Awareness of any current UTI, history of UTIs, or perineal skin problems.

If the resident has a skin problem that may be related to incontinence, or staff are not following the resident's care plan and continence/catheter care program, interview the nursing assistants to determine if they:

Are aware of, and understand, the interventions specific to this resident (such as the bladder or bowel restorative/management programs);

Have been trained and know how to handle catheters, tubing and drainage bags and other devices used during the provision of care; and

Know what, when, and to whom to report changes in status regarding bowel and bladder function, hydration status, urine characteristics, and complaints of urinary-related symptoms.

3. Record Review

Assessment and Evaluation. Review the RAI, the history and physical, and other nformation such as physician orders, progress notes, nurses' notes, pharmacist reports, lab reports and any flow sheets or forms the facility uses to document the resident's voiding history, including the assessment of the resident's overall condition, risk factors and information about the resident's continence status, rationale for using a catheter, environmental factors related to continence programs, and the resident's responses to catheter/continence services. Request staff assistance, if the information is not readily available.

Determine if the facility assessment is consistent with or corroborated by documentation within the record and comprehensively reflects the status of the resident for:

• Patterns of incontinent episodes, daily voiding patterns or prior routines;

• Fluid intake and hydration status;

• Risks or conditions that may affect urinary continence;

• Use of medications that may affect continence and impaired continence that could reflect adverse drug reactions;

• Type of incontinence (stress, urge, overflow, mixed, functional, or transient incontinence) and contributing factors;

• Environmental factors that might facilitate or impede the ability to maintain bladder continence, such as access to the toilet, call bell, type of clothing and/or continence products, ambulation devices (walkers, canes), use of restraints, side rails;
• Type and frequency of physical assistance necessary to facilitate toileting;
• Clinical rationale for use of an indwelling catheter;
• Alternatives to extended use of an indwelling catheter (if possible); and
• Evaluation of factors possibly contributing to chronically recurring or persistent UTIs.

Care Plan.

If the care plan refers to a specific facility treatment protocol that contains details of the reatment regimen, the protocol must be available to the direct care staff, so that they may be familiar with it and use it. The care plan should clarify any significant deviations from such a protocol for a specific resident. If care plan interventions that address aspects of continence and skin care related to incontinence are integrated within the overall care plan, the interventions do not need to be repeated in a separate continence care plan.

Review the care plan to determine if the plan is based upon the goals, needs and strengths specific to the resident and reflects the comprehensive assessment. Determine if the plan:
• Identifies quantifiable, measurable objectives with time frames to be able to assess whether the objectives have been met;

• Identifies interventions specific enough to guide the provision of services and treatment (e.g., toilet within an hour prior to each meal and within 30 minutes after meals, or check for episodes of incontinence within 30 minutes after each meal or specific times based upon the assessment of voiding patterns);
• Is based upon resident choices and preferences;
• Promotes maintenance of resident dignity;
• Addresses potential psychosocial complications of incontinence or catheterization such as social withdrawal, embarrassment, humiliation, isolation, resignation;
• Includes a component to inform the resident and representative about the risks and benefits of catheter use, on continence management approaches, medications selected, etc.;
• Addresses measures to promote sufficient fluid intake, including alternatives such as food substitutes that have a high liquid content, if there is reduced fluid intake;
• Defines interventions to prevent skin breakdown from prolonged exposure to urine and stool;
• Identifies and addresses the potential impact on continence of medication and urinary ract stimulants or irritants (e.g., caffeine) in foods and beverages;
• Identifies approaches to minimize risk of infection (personal hygiene measures and catheter/tubing/bag care); and
• Defines environmental approaches and devices needed to promote independence in toileting, to maintain continence, and to maximize independent functioning.
For the resident who is not on a scheduled toileting program or a program to restore normal bladder function to the extent possible, determine if the care plan provides specific approaches for a check and change program.
For the resident who is on a scheduled toileting or restorative program (e.g., retraining, habit training, scheduled voiding, prompted voiding, toileting devices), determine whether the care plan:

• Identifies the type of urinary incontinence and bases the program on the resident's voiding/elimination patterns; and
• Has been developed by considering the resident's medical/health condition, cognitive and functional ability to participate in a relevant continence program, and needed assistance.

For the resident with a catheter, determine whether the care plan:
• Defines the catheter, tubing and bag care, including indications, according to facility protocol, for changing the catheter, tubing or bag;
• Provides for assessment and removal of the indwelling catheter when no longer needed; and
• Establishes interventions to minimize catheter-related injury, pain, encrustation, excessive urethral tension, accidental removal, or obstruction of urine outflow.

Care Plan Revision.

Determine if the resident's condition and effectiveness of the care plan interventions have been monitored and care plan revisions were made (or justifications for continuing the existing plan) based upon the following:
• The outcome and/or effects of goals and interventions;
• A decline or lack of improvement in continence status;
• Complications associated with catheter usage;
• Resident failure to comply with a continence program and alternative approaches that were offered to try to maintain or improve continence, including counseling regarding the potential consequences of not following the program;
• Change in condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems;
• Input by the resident and/or the responsible person; and
• An evaluation of the resident's level of participation in, and response to, the continence program.

4. Interviews with Health Care Practitioners and Professionals

If inconsistencies in care or potential negative outcomes have been identified, or care is not in accord with standards of practice, interview the nurse responsible for coordinating or overseeing the resident's care. Determine:
• How the staff monitor implementation of the care plan, changes in continence, skin condition, and the status of UTIs;
• If the resident resists toileting, how staff have been taught to respond;
• Types of interventions that have been attempted to promote continence (i.e., special clothing, devices, types and frequency of assistance, change in toileting schedule, environmental modifications);
• If the resident is not on a restorative program, how it was determined that the resident could not benefit from interventions such as a scheduled toileting program;
• For the resident on a program of toileting, whether the nursing staff can identify the programming applicable to the resident, and:
  - The type of incontinence;
  - The interventions to address that specific type;
  - How it is determined that the schedule and program is effective (i.e., how continence is maintained or if there has been a decline or improvement in continence, how the program is revised to address the changes); and

- Whether the resident has any physical or cognitive limitations that influence potential improvement of his/her continence;

• For residents with urinary catheters, whether the nursing staff:

- Can provide appropriate justification for the use of the catheter;
- Can identify previous attempts made (and the results of the attempts) to remove a catheter; and
- Can identify a history of UTIs (if present), and interventions to try to prevent recurrence.

If the interventions defined or care provided do not appear to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. Depending on the issue, ask about:

• How it was determined that the chosen interventions were appropriate;
• Risks identified for which there were no interventions;
• Changes in condition that may justify additional or different interventions; or how they validated the effectiveness of current interventions; and
• How they monitor the approaches to continence programs (e.g., policies/procedures, staffing requirements, how staff identify problems, assess the toileting pattern of the resident, develop and implement continence-related action plans, how staff monitor and evaluate resident's responses, etc.).

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F315)

The urinary incontinence requirement has three aspects. The first aspect requires that 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. The second aspect requires the facility to provide appropriate treatment and services to prevent urinary tract infections; and the third is that the facility attempt to assist the resident to restore as much normal bladder function as possible.

Criteria for Compliance

• Compliance with 42 CFR 483.25(d)(1) and (2), F315, Urinary Incontinence

- For a resident who was admitted with an indwelling urinary catheter or who had one placed after admission, the facility is in compliance with this requirement, if staff have:
  - Recognized and assessed factors affecting the resident's urinary function and identified the medical justification for the use of an indwelling urinary catheter;
  - Defined and implemented pertinent interventions to try to minimize complications from an indwelling urinary catheter, and to remove it if clinically indicated, consistent with resident conditions, goals, and recognized standards of practice;
  - Monitored and evaluated the resident's response to interventions;

  and
  - Revised the approaches as appropriate.

If not, the use of an indwelling urinary catheter is not medically justified, and/or the ongoing treatment and services for catheter care were not provided consistent with the resident's needs. Cite F315.

- For a resident who is incontinent of urine, the facility is in compliance with this requirement if they:
  - Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
  - Defined and implemented interventions to address correctable underlying causes of urinary incontinence and to try to minimize the occurrence of symptomatic urinary tract infections in accordance with resident needs, goals, and recognized standards of practice;
  - Monitored and evaluated the resident's response to preventive efforts and treatment interventions; and
  - Revised the approaches as appropriate.

If not, the facility is not in compliance with the requirement to assist the resident to maintain or improve the continence status, and/or prevent the decline of the condition of urinary incontinence for the resident. Cite F315.

- For a resident who has or has had a symptomatic urinary tract infection, the facility is in compliance with this requirement if they have:
  - Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
  - Defined and implemented interventions to try to minimize the occurrence of symptomatic urinary tract infections and to address correctable underlying causes, in accordance with resident needs, goals, and recognized standards of practice;
  - Monitored and evaluated the resident's responses to preventive efforts and treatment interventions; and
  - Revised the approaches as appropriate.

If not, the development of a symptomatic urinary tract infection, and/or decline of the resident with one, was not consistent with the identified needs of the resident. Cite F315.

Noncompliance for F315

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F315 may include (but is not limited to) one or more of the following, including failure to:

- Provide care and treatment to prevent incontinence and/or improve urinary continence and restore as much normal bladder function as possible;
- Provide medical justification for the use of a catheter or provide services for a resident with a urinary catheter;
- Assess, prevent (to the extent possible) and treat a symptomatic urinary tract infection (as indicated by the resident's choices, clinical condition and physician treatment plan);
- Accurately or consistently assess a resident's continence status on admission and as indicated thereafter;
- Identify and address risk factors for developing urinary incontinence; • Implement interventions (such as bladder rehabilitative programs) to try to improve bladder function

or prevent urinary incontinence, consistent with the resident's assessed need and current standards of practice;
• Provide clinical justification for developing urinary incontinence or for the failure of existing urinary incontinence to improve;
• Identify and manage symptomatic urinary tract infections, or explain adequately why they could or should not do so;
• Implement approaches to manage an indwelling urinary catheter based upon standards of practice, including infection control procedures;
• Identify and apply relevant policies and procedures to manage urinary incontinence, urinary catheters and/or urinary tract infections;
• Notify the physician 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).

Potential Tags for Additional Investigation
During the investigation of 42 CFR 483.25(d)(1) and (2), the surveyor may have identified concerns related to outcome, process and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process and/or structure requirements that should be considered:

• 42 CFR 483.10(b)(11), F157, Notification of Changes
  - Determine if staff notified the physician of significant changes in the resident's continence, catheter usage, or the development, treatment and/or change in symptomatic UTIs; or notified the resident or resident's representative (where one exists) of significant changes as noted above.

• 42 CFR 483.15(a), F241, Dignity
  - Determine if staff provide continence care and/or catheter care to the resident in a manner that respects his/her dignity, strives to meet needs in a timely manner, monitors and helps the resident who cannot request assistance, and strives to minimize feelings of embarrassment, humiliation and/or isolation related to impaired continence.

• 42 CFR 483.20(b)(1), F272, Comprehensive Assessments
  - Determine if the facility comprehensively assessed the resident's continence status and resident-specific risk factors (including potential causes), and assessed for the use of continence-related devices, including an indwelling catheter.

• 42 CFR 483.20(k), F279, Comprehensive Care Plans
  - Determine if the facility developed a care plan (1) that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and with current standards of practice and (2) that includes measurable objectives, approximate timetables, specific interventions and/or services needed to prevent or address incontinence, provide catheter care; and to prevent UTIs to the extent possible.

• 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
  - Determine if the care plan was reviewed and revised periodically, as necessary, related to preventing, managing, or improving incontinence, managing an indwelling urinary

catheter, possible discontinuation of an indwelling catheter, and attempted prevention and management of UTIs.

• 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards

- Determine if services and care were provided for urinary incontinence, catheter care and/or symptomatic UTIs in accordance with accepted professional standards.

• 42 CFR 483.25, F309, Quality of Care

- Determine if staff identified and implemented appropriate measures to address any pain related to the use of an indwelling urinary catheter or skin complications such as maceration, and to provide the necessary care and services in accordance with the comprehensive assessment plan of care.

• 42 CFR 483.25 (a)(3) F312, Quality of Care

- Determine if staff identified and implemented appropriate measures to provide good personal hygiene for the resident who cannot perform relevant activities of daily living, and who has been assessed as unable to achieve and/or restore normal bladder function.

• 42 CFR 483.40(a), F385, Physician Supervision

- Determine if the physician has evaluated and addressed, as indicated, medical issues related to preventing or managing urinary incontinence, catheter usage, and symptomatic UTIs.

• 42 CFR 483.65(b)(3), F444, Infection Control: Hand Washing

- Determine if staff wash their hands after providing incontinence care, and before and after providing catheter care.

• 42 CFR 483.75(f), F498, Proficiency of Nurse Aides

- Determine if nurse aides correctly deliver continence and catheter care, including practices to try to minimize skin breakdown, UTIs, catheter-related injuries, and dislodgement.

• 42 CFR 483.30(a), F353, Sufficient Staff

- Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services on a 24-hour basis, based upon the comprehensive assessment and care plan, to prevent, manage and/or improve urinary incontinence where possible.

• 42 CFR 483.75(i)(2), F501, Medical Director

- Determine whether the medical director, in collaboration with the facility and based on current standards of practice, has developed policies and procedures for the prevention and management of urinary incontinence, for catheter care, and for the identification and management of symptomatic urinary tract infections; and whether the medical director interacts, if requested by the facility, with the physician supervising the care of the resident related to the management of urinary incontinence, catheter or infection issues.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F315 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F315 may include, but is not limited to:
   - 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;
   - Significant changes in psychosocial functioning, such as isolation, withdrawal, or embarrassment, related to the presence of 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; and
   - Complications such as skin breakdown that are related to the failure to manage urinary incontinence;

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:
   - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
   - If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident; and

3. The 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 must evaluate the harm or potential for harm based upon the following levels of severity for tag F315. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity.

(Follow the guidance in Appendix Q, Immediate Jeopardy.)

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

Immediate Jeopardy 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; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of possible negative outcomes as a result of the facility's deficient practices may include:

- **Complications resulting from utilization of urinary appliance(s) without medical justification:** As a result of incorrect or unwarranted (i.e., not medically indicated) utilization of a urinary catheter, pessary, etc., the resident experiences injury or trauma (e.g., urethral tear) that requires surgical intervention or repair.
- **Extensive failure in multiple areas of incontinence care and/or catheter management:** As a result of the facility's noncompliance in multiple areas of continence care or catheter management, the resident developed urosepsis with complications leading to prolonged decline or death.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether 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.

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

- **The development of a symptomatic UTI:** As a result of the facility's noncompliance, the resident developed a symptomatic UTI, without long term complications, associated with the use of an indwelling catheter for which there was no medical justification.
- **The failure to identify, assess and mange urinary retention:** As a result of the facility's noncompliance, the resident had persistent overflow incontinence and/or developed recurrent symptomatic UTIs.
- **The failure to provide appropriate catheter care:** As a result of the facility's noncompliance, the catheter was improperly managed, resulting in catheterrelated pain, bleeding, urethral tears or urethral erosion.
- **Medically unjustified use of an indwelling catheter with complications:** As a result of the facility's noncompliance, a resident who was admitted with a urinary catheter had the catheter remain for an extended period of time without a valid medical justification for its continued use, or a urinary catheter was inserted after the resident was in the facility and used for an extended time without medical justification, during which the resident experienced significant complications such as recurrent symptomatic UTIs.
- **Decline or failure to improve continence status:** As a result of the facility's failure to assess and/or re-assess the resident's continence status, utilize sufficient staffing to implement continence programs and provide other related services based on the resident's assessed needs, and/or to evaluate the possible adverse effects of medications on continence status, the resident failed to maintain or improve continence status.
- **Complications due to urinary incontinence:** As a result of the facility's failure to provide care and services to a resident who is incontinent of urine, in accordance with resident need and accepted standards of practice, the resident developed skin maceration and/or erosion or declined to attend or participate in social situations (withdrawal) due to embarrassment or humiliation related to unmanaged urinary incontinence.

NOTE: If Severity Level 3 (actual harm that is not immediate 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 Immediate Jeopardy

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.

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

- **Medically unjustified use of an indwelling catheter:** As a result of the facility's noncompliance, the resident has the potential for experiencing complications, such as symptomatic UTIs, bladder stones, pain, etc.
- **Complications associated with inadequate care and services for an indwelling catheter:** As a result of the facility's noncompliance, the resident has developed potentially preventable non-life-threatening problems related to the catheter, such as leaking of urine due to blockage of urine outflow, with or without skin maceration and/or dermatitis.
- **Potential for decline or complications:** As a result of the facility's failure to consistently implement a scheduled voiding program defined in accordance with the assessed needs, the resident experiences repeated episodes of incontinence but has not demonstrated a decline or developed complications.

Severity Level 1: No actual harm with potential for minimal harm

The failures 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.