

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-23

DATE: April 14, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes:** Delay in Effective Date for Revision of Appendix PP, State Operations Manual (SOM), Surveyor Guidance for Incontinence and Catheters

Letter Summary

- This memorandum establishes an effective date for new surveyor guidance for incontinence and catheters of June 27, 2005, to match the ASPEN release date.
- We are providing an advance copy of the final issuance to assist in training surveyors and notifying providers.

Discussion

The Centers for Medicare & Medicaid Services plans to issue the new surveyor guidance in Appendix PP for incontinence and catheters in the near future. Since this new guidance collapses current Tags F315 and F316 into one Tag, which will be F315, it necessitates a revision to ASPEN so that the ASPEN version of the regulatory text at F315 matches what is issued in Appendix PP. Because the next ASPEN update is scheduled for the week of June 21, 2005, we are scheduling the effective date of the change to Appendix PP to match the ASPEN release date. **Therefore, the effective date of the Appendix PP issuance will be June 27, 2005.**

We are attaching an advance copy of the final text of the new F315 to assist you in training your surveyors and notifying your providers about the new guidance. Note that the regulatory text that is currently at both F315 and F316 is now listed as regulatory text for the new F315, and that the content of the regulatory text is unchanged.

The new guidance contains Interpretive Guidelines, a new Investigative Protocol, and compliance and severity guidance. For questions on this memorandum, please contact Karen Schoeneman at (410) 786-6855 or e-mail at kschoeneman@cms.hhs.gov.

Effective Date: June 27, 2005

Training: The information contained in this announcement should be shared with all long term care survey staff, their managers and the state/RO training coordinators.

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management (G-5)

F315

§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) 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 urinary tract, 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.

OVERVIEW

Urinary incontinence is not normal. Although aging affects the urinary tract and increases the potential for urinary incontinence, urinary incontinence is not a normal part of aging. In the younger person, urinary incontinence may result from a single cause. In the older individual, urinary incontinence generally involves psychological, physiological, pharmacological and/or pathological factors or co-morbid conditions (e.g., later stages of dementia, diabetes, prostatectomy, medical conditions involving

dysfunction of the central nervous system, urinary tract infections, etc.). Because urinary incontinence is a symptom of a condition and may be reversible, it is important to understand the causes and to address incontinence to the extent possible. If the underlying condition is not reversible, it is important to treat or manage the incontinence to try to reduce complications.

Many older adults are incontinent of urine prior to admission to a nursing home. Urinary incontinence and related loss of independence are prominent reasons for a nursing home admission. Articles¹ and data currently available, including CMS data (e.g., MDS Active Resident Information Report (Item H1b) at www.cms.hhs.gov/states/mdsreports), indicate that more than 50% of the nursing home population experience some degree of urinary incontinence. Whether the resident is incontinent of urine on admission or develops incontinence after admission, the steps of assessment, monitoring, reviewing, and revising approaches to care (as needed) are essential to managing urinary incontinence and to restoring as much normal bladder function as possible.

Various conditions or situations may aggravate the severity of urinary incontinence in nursing home residents. In addition, urinary incontinence may be associated with changes in skin integrity, skin irritation or breakdown, urinary tract infections, falls and fractures, sleep disturbances, and psychosocial complications including social withdrawal, embarrassment, loss of dignity, feelings of isolation, and interference with participation in activities.

Various factors common to elderly individuals may increase the risk of infection including: underlying diseases (e.g., diabetes mellitus), medications that affect immune responses to infection (e.g., steroids and chemotherapy, history of multiple antibiotic usage), conditions that cause incontinence, and indwelling urinary catheters.

The urinary tract is a common source of bacteremia in nursing home residents. Urinary tract infection (UTI) is one of the most common infections occurring in nursing homes and is often related to an indwelling urinary catheter. Without a valid clinical rationale for an indwelling catheter, its use is not an acceptable approach to manage urinary incontinence. Although UTIs can result from the resident's own flora, they may also be the result of microorganisms transmitted by staff when handling the urinary catheter drainage system and/or providing incontinence care. Hand washing remains one of the most effective infection control tools available.

Resources

It is important for the facility to have in place systems/procedures to assure: assessments are timely and appropriate; interventions are defined, implemented, monitored, and revised as appropriate in accordance with current standards of practice; and changes in condition are recognized, evaluated, reported to the practitioner, and addressed. The medical director and the quality assessment and assurance committee may help the facility evaluate existing strategies for identifying and managing incontinence, catheter

use, and UTIs, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices to prevent, manage, and treat urinary incontinence, urinary catheterization, and UTI continues to evolve. Many recognized clinical resources on the prevention and management of urinary incontinence, infection, and urinary catheterization exist. Some of these resources include:

- The American Medical Directors Association (AMDA) at www.amda.com (Clinical Practice Guidelines: Clinical Practice Guidelines, 1996);
- The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives at www.medqic.org;
- The CMS Sharing Innovations in Quality website at www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp;
- Association for Professionals in Infection Control and Epidemiology (APIC) at www.apic.org;
- Centers for Disease Control at www.cdc.gov;
- The Annals of Long Term Care publications at www.mmhc.com;
- American Foundation for Urologic Disease, Inc. at www.afud.org; and
- The American Geriatrics Society at www.americangeriatrics.org.

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Resident Choice

In the course of developing and implementing care plan interventions for treatment and services related to achieving the highest practicable level of urinary continence, preventing and treating urinary tract infections, and avoiding the use of indwelling catheters without medical justification, it is important to involve the resident and/or her or his surrogate in care decisions and to consider whether the resident has an advance directive in place.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident's legal representative) must discuss the resident's condition, treatment options,

expected outcomes, and consequences of refusing treatment. The facility should address the resident's concerns and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights 483.10(b)(3) and (4) (F154 and F155).)

Advance Directive. A resident who is at the end of life or in terminal stages of an illness or who has multiple organ system failures may have written directions for his or her treatment goals (or a decision has been made by the resident's surrogate or representative, in accordance with State law).

Although a facility's care must reflect a resident's wishes as expressed in the Directive, in accordance with State law, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the Advance Directive. The presence of a "Do Not Resuscitate" (DNR) order does not indicate that the resident is declining appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

If the facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, and has implemented appropriate efforts to try to stabilize the resident's condition (or indicated why the condition cannot or should not be stabilized), and has provided care based on the assessed needs of the resident, then the development, continuation, or progression of urinary incontinence; the insertion and prolonged use of an indwelling urinary catheter; the development of infection or skin-related complications from urine or an indwelling catheter may be consistent with regulatory requirements.

URINARY INCONTINENCE

42 CFR 483.25 (d) (2) Urinary Incontinence requires that 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.

Urinary incontinence generally involves a number of transitory or chronic progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.

The first steps toward assuring that a resident receives appropriate treatment and services to restore as much bladder function as possible or to treat and manage the incontinence are to identify the resident already experiencing some level of incontinence or at risk of developing urinary incontinence and to complete an accurate, thorough assessment of factors that may predispose the resident to having urinary incontinence. This is followed by implementing appropriate, individualized interventions that address the incontinence, including the resident's capabilities and underlying factors that can be removed, modified, or stabilized, and by monitoring the effectiveness of the interventions and modifying them, as appropriate. The practitioner, may at his or her option, refer residents

to various practitioners who specialize in diagnosing and treating conditions that affect urinary function.

Assessment

Factors contributing to urinary incontinence sometimes may be resolved after a careful examination and review of history. In addition, for a resident who is incontinent of urine, determining the type of urinary incontinence can allow staff to provide more individualized programming or interventions to enhance the resident's quality of life and functional status. A resident should be evaluated at admission and whenever there is a change in cognition, physical ability, or urinary tract function. This evaluation is to include identification of individuals with reversible and irreversible (e.g., bladder tumors and spinal cord disease) causes of incontinence. If the resident has urinary incontinence that has already been investigated, documented, and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Documentation of assessment information may be found throughout the medical record, such as in an admission assessment, hospital records, history and physical, and the Resident Assessment Instrument (RAI). The location of RAI assessment information is identified on the Resident Assessment Protocol (RAP) summary form. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of urinary incontinence, including onset, duration and characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy) and previous treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;
- Voiding patterns (such as frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;
- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);²
- Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;
- Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);³
- Pelvic and rectal examination to identify physical features that may directly affect

- urinary incontinence, such as prolapsed uterus or bladder, prostate enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder, or bladder spasms;
- Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, pain with movement;
 - Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;
 - Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson's Disease or tumors that could affect the urinary tract or its function);
 - Identification of and/or potential of developing complications such as skin irritation or breakdown;
 - Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident's readiness for bladder rehabilitation programs; and
 - Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, availability of urinals, use of bed rails or restraints, or fear of falling).

Types of Urinary Incontinence. Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence.

- Urge Incontinence is characterized by abrupt urgency, frequency, and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson's Disease, multiple sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.
- Stress Incontinence is the loss of a small amount of urine with physical activity such as coughing, sneezing, laughing, walking stairs or lifting. Urine leakage

results from an increase in intra-abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.

- Mixed Incontinence is the combination of urge incontinence and stress incontinence. Many elderly persons (especially women) will experience symptoms of both urge and stress called mixed incontinence.
 - Overflow Incontinence occurs when the bladder is distended from urine retention. Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer, and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post void residual (PVR) volume (the amount of urine remaining in the bladder within 5 to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml. or less. A PVR of 150 to 200 may suggest a need for retesting to determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.
 - Functional Incontinence refers to incontinence that is secondary to factors other than inherently abnormal urinary tract function. It may be related to physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture), cognitive problems (e.g., confusion, dementia, unwillingness to toilet), various medications (e.g., anti-cholinergics, diuretics) or environmental impediments (e.g., excessive distance of the resident from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access). Refer to 42 CFR 483.15(e)(1) for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices).
- NOTE:** Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident's continence, may fail to solve the incontinence problem.
- Transient Incontinence refers to temporary or occasional incontinence that may be related to a variety of causes, for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction. The incontinence is transient because it is related to a potentially improvable or reversible cause.

Interventions

It is important that the facility follow the care process (accurate assessment, care planning, consistent implementation and monitoring of the care plan with evaluation of the effectiveness of the interventions, and revision, as appropriate). Recording and evaluating specific information (such as frequency and times of incontinence and toileting and response to specific interventions) is important for determining progress, changes, or decline.

A number of factors may contribute to the decline or lack of improvement in urinary continence, for example: underlying medical conditions, an inaccurate assessment of the resident's type of incontinence (or lack of knowledge about the resident's voiding patterns) may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the highest practicable level of functioning, may prevent or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc;
- Removing or improving environmental impediments that affect the resident's level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);
- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);
- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration); and
- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

Behavioral Programs. Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident's

behavior and/or environment. Critical aspects of a successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions.

NOTE: It is important for the comprehensive assessment to identify the essential skills the resident must possess to be successful with specific interventions being attempted. These skills include the resident's ability to: comprehend and follow through on education and instructions; identify urinary urge sensation; learn to inhibit or control the urge to void until reaching a toilet; contract the pelvic floor muscle (Kegel exercises) to lessen urgency and/or urinary leakage; and/or respond to prompts to void.⁴ Voiding records help detect urinary patterns or intervals between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident's cooperation and motivation in order for learning and practice to occur include the following:

- “Bladder Rehabilitation/Bladder Retraining” is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident's successful ability to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding, and positive reinforcement. This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly, or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his/her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks. Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining; and
- “Pelvic Floor Muscle Rehabilitation,” also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periurethral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

Programs that are dependent on staff involvement and assistance, as opposed to resident

function, include the following:

- “Prompted Voiding” is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding techniques have been shown to reduce urinary incontinence episodes up to 40% for elderly incontinent nursing home residents, regardless of their type of urinary incontinence or cognitive deficit—provided that they at least are able to say their name or reliably point to one of two objects.⁵ Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when the resident is continent and attempts to toilet. These methods require training, motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident’s cognition changes, the facility should consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing toileting program; and

- “Habit Training/Scheduled Voiding” is a behavioral technique that calls for scheduled toileting at regular intervals on a planned basis to match the resident’s voiding habits. Unlike bladder retraining, there is no systematic effort to encourage the resident to delay voiding and resist urges. Habit training includes timed voiding with the interval based on the resident’s usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

Intermittent Catheterization. Sterile insertion and removal of a catheter through the urethra every 3-6 hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in “Catheterization”.

Medication Therapy. Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. Therefore, it is important to weigh the risks and benefits before prescribing medications for continence management and to monitor for both effectiveness and side effects. As with all approaches attempting to improve control or management of incontinence, the

education and discussion with the resident (or the resident's surrogate) regarding the benefits and risks of pharmacologic therapies is important.

Pessary. A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use. If a pessary is to be used, it is important to develop a plan of care for ongoing management and for the prevention of and monitoring for complications.

Absorbent Products, Toileting Devices, and External Collection Devices. Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for moderate or heavy loss. Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit, and ease of use.

Advantages of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident's dignity and comfort.

NOTE: Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered.

The potential disadvantages of absorbent products are the impact on the resident's dignity, cost, the association with skin breakdown and irritation, and the amount of time needed to check and change them.⁶

It is important that residents using various toileting devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident's voiding pattern, accepted standards of practice, and the manufacturer's recommendations.

Skin-Related Complications

Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning.

One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes “soggy” texture.

The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis or skin erosion. Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly depressed area of skin.

One key to preventing skin breakdown is to keep the perineal skin clean and dry. Research has shown that a soap and water regimen alone may be less effective in preventing skin breakdown compared with moisture barriers and no-rinse incontinence cleansers.⁷ Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated. Moisturizers help preserve the moisture in the skin by either sealing in existing moisture or adding moisture to the skin. Moisturizers include creams, lotions or pastes. However, moisturizers should be used sparingly—if at all—on already macerated or excessively moist skin.

CATHETERIZATION

42 CFR 483.25 (d) (1) Urinary Incontinence requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident’s clinical condition demonstrates that catheterization was necessary. Some residents are admitted to the facility with indwelling catheters that were placed elsewhere (e.g., during a recent acute hospitalization). The facility is responsible for the assessment of the resident at risk for urinary catheterization and/or the ongoing assessment for the resident who currently has a catheter. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

Assessment

A resident may be admitted to the facility with or without an indwelling urinary catheter (urethral or suprapubic) and may be continent or incontinent of urine. Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter.

An admission evaluation of the resident’s medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord diseases. (See the assessment factors discussed under incontinence.) The assessment of continence/incontinence is based upon an interdisciplinary review. The comprehensive assessment should include underlying factors supporting the medical justification for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal.

The clinician's decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility's documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

Intermittent Catheterization

Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/atonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization until the bladder tone returns (e.g., up to approximately 7 days). A voiding trial and post void residual can help identify when bladder tone has returned.

Indwelling Catheter Use

The facility's documented assessment and staff approach to the resident should be based on evidence to support the use of an indwelling catheter. Appropriate indications for continuing use of an indwelling catheter beyond 14 days may include:⁸

- Urinary retention that cannot be treated or corrected medically or surgically, for which alternative therapy is not feasible, and which is characterized by:
 - Documented post void residual (PVR) volumes in a range over 200 milliliters (ml);
 - Inability to manage the retention/incontinence with intermittent catheterization; and
 - Persistent overflow incontinence, symptomatic infections, and/or renal dysfunction.
- Contamination of Stage III or IV pressure with urine which has impeded healing, despite appropriate personal care for the incontinence; and
- Terminal illness or severe impairment, which makes positioning or clothing changes uncomfortable, or which is associated with intractable pain.

Catheter-Related Complications

An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis. In addition, indwelling catheters are prone to blockage. Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones. In the absence of evidence indicating blockage, catheters need not be changed routinely as long as monitoring is adequate. Based on the resident's individualized assessment, the catheter may need to be changed more or less often than every 30 days.

Some residents with indwelling catheters experience persistent leakage around the catheter. Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. Because leakage around the catheter is frequently caused by bladder spasm, leakage should generally not be treated by using increasingly larger catheter sizes, unless medically justified. Current standards indicate that catheterization should be accomplished with the narrowest, softest tube that will serve the purpose of draining the bladder. Additional care practices related to catheterization include:

- Educating the resident or responsible party on the risks and benefits of catheter use;
- Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;
- Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;
- Monitoring for excessive post void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;
- Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter; and
- Securing the catheter to facilitate flow of urine.

Research has shown that catheterization is an important, potentially modifiable, risk factor for UTI. By the 30th day of catheterization, bacteriuria is nearly universal.⁹ The potential for complications can be reduced by:

- Identifying specific clinical indications for the use of an indwelling catheter;
- Assessing whether other treatments and services would appropriately address those conditions; and

- Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria, and leakage around the catheter.

URINARY TRACT INFECTIONS

Catheter-Related Bacteriuria and UTIs/Urosepsis

Most individuals with indwelling catheters for more than 7 days have bacteriuria. Bacteriuria alone in a catheterized individual should not be treated with antibiotics.

A long term indwelling catheter (>2 to 4 weeks) increases the chances of having a symptomatic UTI and urosepsis. The incidence of bacteremia is 40 times greater in individuals with a long term indwelling catheter than in those without one. For suspected UTIs in a catheterized individual, the literature recommends removing the current catheter and inserting a new one and obtaining a urine sample via the newly inserted catheter.¹⁰

Clinical Evidence That May Suggest UTI

Clinically, an acute deterioration in stable chronic symptoms may indicate an acute infection. Multiple co-existing findings such as fever with hematuria are more likely to be from a urinary source.

No one lab test alone proves that a UTI is present. For example, a positive urine culture will show bacteriuria but that alone is not enough to diagnose a symptomatic UTI. However, several test results in combination with clinical findings can help to identify UTIs such as the presence of pyuria (more than minimal white cells in the urine) on microscopic urinalysis, or a positive urine dipstick test for leukocyte esterase (indicating significant pyuria) or for nitrites (indicating the presence of Enterobacteriaceae). A negative leukocyte esterase or the absence of pyuria strongly suggests that a UTI is not present. A positive leukocyte esterase test alone does not prove that the individual has a UTI.¹¹

In someone with nonspecific symptoms such as a change in function or mental status, bacteriuria alone does not necessarily warrant antibiotic treatment. Additional evidence that could confirm a UTI may include hematuria, fever (which could include a variation from the individual's normal or usual temperature range), or evidence of pyuria (either by microscopic examination or by dipstick test). In the absence of fever, hematuria, pyuria, or local urinary tract symptoms, other potential causes of nonspecific general symptoms, such as fluid and electrolyte imbalance or adverse drug reactions, should be considered instead of, or in addition to, a UTI. Although sepsis, including urosepsis, can cause dizziness or falling, there is not clear evidence linking bacteriuria or a localized UTI to an increased fall risk.¹²

Indications to Treat a UTI

Because many residents have chronic bacteriuria, the research-based literature suggests treating only symptomatic UTIs. Symptomatic UTIs are based on the following criteria:¹³

- Residents without a catheter should have at least three of the following signs and symptoms:
 - Fever (increase in temperature of >2 degrees F (1.1 degrees C) or rectal temperature >99.5 degrees F (37.5 degrees C) or single measurement of temperature >100 degrees F (37.8 degrees C));¹⁴
 - New or increased burning pain on urination, frequency or urgency;
 - New flank or suprapubic pain or tenderness;
 - Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
 - Worsening of mental or functional status (e.g., confusion, decreased appetite, unexplained falls, incontinence of recent onset, lethargy, decreased activity).¹⁵
- Residents with a catheter should have at least two of the following signs and symptoms:
 - Fever or chills;
 - New flank pain or suprapubic pain or tenderness;
 - Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
 - Worsening of mental or functional status. Local findings such as obstruction, leakage, or mucosal trauma (hematuria) may also be present.¹⁶

Follow-Up of UTIs

The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not routinely necessary but may be useful in select situations. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (2 or more in 6 months) in a noncatheterized individual may warrant additional evaluation (such as a

determination of an abnormal post void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.

Recurrent symptomatic UTIs in a catheterized or noncatheterized individual should lead the facility to check whether perineal hygiene is performed consistently to remove fecal soiling in accordance with accepted practices. Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for perineal hygiene and catheter care, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic comorbid illnesses, cannot be modified readily, the facility should demonstrate that they:

- Employ standard infection control practices in managing catheters and associated drainage system;
- Strive to keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus);
- Take measures to maintain free urine flow through any indwelling catheter; and
- Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

ENDNOTES

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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 information 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 treatment 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 tract 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.

- o 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.

- o 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, maintain or prevent decline of 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 manage 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 catheter-related 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.