

# **Federal Requirements & Regulatory Provisions Relevant to Dementia Care & The Use Of Antipsychotic Drugs**

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## **Federal Law**

The Omnibus Budget Reconciliation Act of 1987 contains the Nursing Home Reform Law, legislation enacted to improve nursing home quality.<sup>1</sup> The Reform Law requires skilled nursing facilities receiving federal funding for Medicare and/or Medicaid to conform to specific standards of care, including the requirement that nursing staff help residents attain or maintain the highest practicable physical, mental, and psychosocial well-being of each individual resident. The emphasis on patient-centered care was intended to reduce widespread problems in long term care facilities, like abuse and neglect, and improve quality of life. Unfortunately, many of the reforms have not been fully implemented. The widespread inappropriate use of antipsychotics in nursing homes across the country is, in many ways, emblematic of weaknesses in implementation of the Reform Law, such as in its standards regarding freedom from unnecessary drugging; freedom from chemical restraints; and rights to be informed about, participate in and refuse treatment.

## **Federal Regulation & Oversight**

The Centers for Medicare and Medicaid Services (CMS) has recently begun a campaign to address problems of antipsychotic drugging in nursing homes. The campaign was launched in March 2012 and it includes education and outreach to providers and consumers as well as strengthening oversight and provider accountability for providing appropriate, resident-centered dementia care. CMS's first goal is to decrease the use of antipsychotics in nursing homes nationwide by 15% in 2012.<sup>2</sup> Following is an overview of federal (CMS) efforts to improve nursing home quality and accountability that relate (or are relevant to) the campaign to decrease inappropriate use of antipsychotic drugs in nursing homes.

## **Transparency**

"Nursing Home Compare,"<sup>3</sup> part of the medicare.gov website, contains information about every Medicaid and Medicare-certified nursing home in the United States. The public can view information about individual facilities such as the facility's staffing levels (self-reported, as of October 2012), measures that indicate a facility's qualities in certain categories (also self-reported), the dates and results of recent inspections, and the level and frequency of penalties against a specific facility. The public can also compare these statistics against statewide and national averages.

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<sup>1</sup> Nursing Home Reform Law, 42 U.S.C. §§1395i-3(a)-(h), 1396r(a)-(h) (Medicare and Medicaid, respectively) (December 1987). The Reform Law's text is available at: <http://law.justia.com/cfr/title42/42-3.0.1.5.22.html#42:3..15.22.2>.

<sup>2</sup> Goals for 2013 and beyond are expected but have not been announced as of October 2012.

<sup>3</sup> Nursing Home Compare website available at: <http://www.medicare.gov/NursingHomeCompare/search.aspx?bhcp=1>.

As of July 2012, CMS has added two important new categories of quality measures information for nursing homes on the Nursing Home Compare website related to antipsychotic drugging. The public can view (1) the percent of short-stay residents who newly received an antipsychotic medication and (2) the percent of long-stay residents who received an antipsychotic medication. As with other categories in Nursing Home Compare, the public can compare these statistics for nursing homes they select with state and national averages.

### **Provider Training**

CMS is developing a series of training videos for nursing facilities called “Hand in Hand,” emphasizing person-centered care and prevention of abuse. The videos are expected to be distributed to nursing homes and state oversight agencies nationwide in the fall 2012. If they are made available to the public LTCCC will post a link to them on our page dedicated to dementia care and antipsychotic drug use:

<http://www.nursinghome411.org/?articleid=10042>.

### **Surveyor Training**

CMS is developing a training program for surveyors on antipsychotic drugging and dementia care. The program will be mandatory for all surveyors. As of September 2012 the program is still in the development phase. LTCCC will post further information and a link at <http://www.nursinghome411.org/?articleid=10042> if the training is made available to the public.

### **Guidance: Enforcement of Minimum Standards**

CMS provides nursing home surveyors (inspectors) with a system to help them identify relevant criteria for evaluating whether a nursing home is meeting quality of care, quality of life, safety and other standards. Based on the law and regulations, this system is comprised of “F-Tags” (data tags used to identify specific federal nursing home regulations) and guidance to help surveyors understand the regulatory requirements and how to evaluate for compliance with them.

F-Tags are cited in the Statements of Deficiencies (SODs, also known as Form 2567) that are the written record of a surveyor’s findings of a facility’s failure to comply with one or more standard. The SODs for every nursing home are now posted on Nursing Home Compare (as noted above, under “Transparency”). Following is an overview of the F-Tags that are – or may be – relevant when antipsychotic drugs are administered inappropriately. Each F-Tag description includes its specific citation in the Code of Federal Regulations (CFR), followed by the relevant text from the code and a description of how the F-Tag is relevant in the context of antipsychotic drug use.

## The Principal F-Tags Related to Antipsychotic Drug Use: F-329 & F-222<sup>4</sup>

### F -329 – Free from Unnecessary Drugs - 42 CFR 483.25(l)(2)(i, ii)<sup>5</sup>

- (2)(i): Residents who haven't used antipsychotics are not given them unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed/documented in the clinical record, and
- (2)(ii): Residents who use antipsychotics receive gradual dose reductions, and behavioral interventions (unless clinically contradicted) in an effort to discontinue these drugs.

F-329 is perhaps the most important F-Tag for inappropriate antipsychotic drugging. The first purpose of F-329 related to antipsychotic drug use is to prevent nursing home staff from giving a resident an unnecessary antipsychotic drug. Despite the FDA's black box warning of the potentially fatal side effects of antipsychotics for people suffering from dementia, these powerful drugs are too often used as a means of sedating elderly nursing home residents with dementia, as a substitute for appropriate care.<sup>6</sup> This is contrary to the Nursing Home Reform Law's requirement of promoting patient-centered care that enables each individual to maintain his or her highest practicable physical, emotional and social well-being. It is often evidenced by a failure to try non-pharmacological approaches to dementia care, such as when a resident becomes agitated and is subdued with an antipsychotic drug without first trying other, non-drugging options.

The second purpose of this F-Tag relating to antipsychotics is to ensure that facilities take steps to wean residents off of antipsychotics drugs whenever the drugs are given. This goal is accomplished through either the implementation of behavioral interventions (unless diagnoses do not call for such interventions) or through recorded and monitored gradual dose reductions (GDR) (or, most likely, a combination of the two). A facility's systematic failure to implement GDRs could be an example of staff relying on antipsychotics as a primary treatment mechanism, rather than attempting to discontinue the use of the drugs.

### F-222 – Right to be free from chemical restraints - 42 CFR 483.13(a)

- Resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat medical symptoms.

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<sup>4</sup> For the CMS guidance for all of the F-Tags, see "State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities" (Hereinafter "CMS Guidance"). Available at: [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf).

<sup>5</sup> The following guidance and discussion on F-329 are limited to those provisions relating to antipsychotic drugging specifically. For more information on F-329, including its provisions related to unnecessary drugging generally, criteria for compliance and criteria for noncompliance, please see the Appendix.

<sup>6</sup> *The Boston Globe*, "A Rampant Prescription, A Hidden Peril" (April 29, 2012). Available at: <http://www.canhr.org/newsroom/canhrnewsarchive/2012/BostonGlobe20120429.html>.

A facility may be in violation of F-222 if an antipsychotic is administered and not required to treat medical symptoms. While in practice this most often is done to make care of behaviors associated with dementia easier for the caregivers, it is important to note that the prohibition exists whether or not the antipsychotic is given for convenience or disciplinary purposes. Conversely, even if the antipsychotic is required to treat a particular medical symptom, pursuant to F-222, the drug should not be administered for convenience or disciplinary purposes. F-222 is deliberately broad in this sense. Facilities sometimes rely on antipsychotic drugs as a means of treating residents deemed to be difficult or uncooperative. For example, if a resident is behaving in a manner that the facility determines is difficult to treat, a staff member could claim that the resident is exhibiting a “behavioral problem” and administer an antipsychotic drug to sedate the resident. This treatment may be easier for the staff member but it is not necessarily therapeutic for the resident; masking behavioral symptoms of dementia is not an appropriate substitute for care that responds to a resident’s needs.<sup>7</sup> F-222 is relevant when antipsychotics are used as a convenient or disciplinary means of treatment for a resident, or if the treatment is not needed to treat the resident’s medical condition.

### **Additional F-Tags Relevant When Antipsychotic Drugs Are Used Inappropriately**

#### **F-154 – Right to be Fully Informed - 42 CFR 483.10(b)(3) and 483.10(d)(2)**

- (b)(3): *The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including, but not limited to, his or her medical condition.*
- (d)(2): *The resident has the right to be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident’s well-being.*

In the context of antipsychotic drug use, the second provision noted above is particularly relevant. A resident is fully informed when he or she receives information about the benefits and reasonable risks of treatment, potential changes to his or her medical condition, and information about reasonably available alternatives. A citation under F-154 may be appropriate when a resident, or his or her representative, is not informed of the potential mental and/or physical side effects and corresponding health risks associated with antipsychotic drugs, reasonable and available non-pharmacological alternatives to antipsychotic drugging, or any other changes in treatment or care that may affect that resident’s well being.

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<sup>7</sup> California Advocates for Nursing Home Reform, “No Surprises: Chemical Restraints Sedate and Subdue the Elderly with Dementia” (January 3, 2012). Available at: <http://www.canhr.org/stop-drugging/archives/839>.

**F-155 – Right to Refuse Treatment or [participation in experimental] Research - 42 CFR 483.10(b)(2)(4)**

- *The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section.*

A resident's right to refuse treatment encompasses that resident's right to refuse specific types of treatment, like the use of antipsychotic drugs. Even if antipsychotics are clinically appropriate in certain circumstances, the resident has the right to reject their use. This F-Tag is relevant if a resident has been denied the right to refuse treatment with an antipsychotic medication.

**F-223 – Right to be Free From Abuse - 42 CFR 483.13(b)**

- *The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.*

F-223 is relevant when a resident is given drugs as a form of punishment or discipline. It also may be relevant when the drugs result in a resident suffering from certain side effects of antipsychotic drugging such as (but not limited to) depression, difficulty in thinking and concentrating, and deficiencies in cognition and reward motivation.<sup>8</sup> When antipsychotic drugs are given to a resident, the presence of these side effects may constitute a form of mental abuse.

**F-240 – Facility Promotes/Enhances Quality of Life - 42 CFR 483.15**

- *A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.*

An antipsychotic drug's capacity to diminish a resident's quality of life is well documented. Given the mental side effects of these powerful drugs, in addition to numerous potential physical side effects including weight gain, tremors and persistent muscle spasms (among others), the use of antipsychotics has significant potential to be detrimental to a resident's

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<sup>8</sup> For more information on these side effects, see Journal of Clinical Pharmacology, "Antipsychotic-associated Mental Side Effects and their Relationship to Dopamine D2 Receptor Occupancy in Striatal Subdivisions" (August 2011). Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21694619> and International Clinical Psychopharmacology, "Prevalence and Extent of Distress of Adverse Effects of Antipsychotics Among Callers to a United Kingdom National Mental Health Helpline" (May 2001). Available at: [http://journals.lww.com/intclinpsychopharm/Abstract/2001/05000/Prevalence\\_and\\_ext\\_of\\_distress\\_of\\_adverse.4.aspx](http://journals.lww.com/intclinpsychopharm/Abstract/2001/05000/Prevalence_and_ext_of_distress_of_adverse.4.aspx).



physical and mental well-being.<sup>9</sup> F-240 is relevant when a resident's quality of life is diminished because of the effects of antipsychotic drugs.

#### **F-241 – Dignity - 42 CFR 483.15(a)**

- *Facility must promote care for residents in a manner that maintains or enhances each resident's dignity and respect in full recognition of his/her individuality.*

F-241 is relevant when antipsychotics are used inappropriately since, as the previous descriptions of F-Tags indicate, inappropriate use is typically indicative of non-resident centered care and a failure to provide care that enhances or maintains a resident's dignity. If a nursing home failed to incorporate the resident's input and individual needs in his or her care planning, and failed to incorporate that, as much as possible, into non-pharmacological approaches to dementia related behaviors, citation under F-241 may be merited.

#### **F-248 – Activity Program Meets Individual Needs - 42 CFR 483.15(f)(1)**

- *The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.*

F-248 emphasizes the importance of patient-appropriate activities as a component of good care. Activities should be tailored to meet the physical, mental, and psychosocial needs of each resident, including those with dementia. F-248 is relevant when the facility is not providing activities that engage and are appropriate for its residents, particularly in an antipsychotic drugging context when drugs have been used in place of non-pharmacological approaches to good dementia care.

#### **F-250 – Medically Related Social Services - 42 CFR 483.15(g)**

- *The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.*

The guidance for F-250 requires "that facilities *aggressively identify* the need for medically-related social services, and pursue the provision of these services."<sup>10</sup> The guidelines also enumerate numerous examples of services that may be employed, as appropriate, for

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<sup>9</sup> In addition to the discussions on the side effects of antipsychotics in the articles cited in the previous footnote, see the following for a good overview of mental health medications, including antipsychotics, and their potential side effects and government warnings: National Institute of Mental Health, "Mental Health Medications" (February 9, 2012). Available at: <http://www.nimh.nih.gov/health/publications/mental-health-medications/complete-index.shtml>.

<sup>10</sup> CMS Guidance at p. 107(emphasis added).



meeting this requirement. In the context of antipsychotic drug use, following are several relevant examples:

- Providing alternatives to drug therapy or restraints by understanding and communicating to staff why residents act as they do, what they are attempting to communicate, and what needs the staff must meet....  
- - -
- Through the assessment and care planning process, identifying and seeking ways to support residents' individual needs....  
- - -
- Finding options that most meet the physical and emotional needs of each resident....  
- - -
- Assisting staff to inform residents and those they designate about the resident's health status and health care choices and their ramifications.....<sup>11</sup>

The guidance also provides important information on relevant factors that may be having a negative effect on physical, emotional or psychosocial well being, such as "[n]eed for a home-like environment, control, dignity, privacy...", and some of the conditions that facilities should be responding to with social services (by their staff or referral to an outside source), including:

- Lack of an effective family/support system;
- Behavioral symptoms;
- If a resident with dementia strikes out at another resident, the facility should evaluate the resident's behavior. For example, a resident may be re-enacting an activity he or she used to perform at the same time everyday. If that resident senses that another is in the way of his re-enactment, the resident may strike out at the resident impeding his or her progress. The facility is responsible for the safety of any potential resident victims while it assesses the circumstances of the resident's behavior);
- Presence of a chronic disabling medical or psychological condition (e.g., multiple sclerosis, chronic obstructive pulmonary disease, Alzheimer's disease, schizophrenia); [and]  
- - -
- A physical or chemical restraint.<sup>12</sup>

**F-272 – Resident Assessment - 42 CFR 483.20 and 42 CFR 483.20(b)(1)**

- *483.20: The facility must conduct initially and periodically a comprehensive, accurate, standardized reproducible assessment of each resident's functional capacity.*

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<sup>11</sup> *Id.* at p. 108.

<sup>12</sup> *Id.* at p. 109.

- *483.20(b)(1): A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:*
  - *Identification and demographic information.*
  - *Customary routine.*
  - *Cognitive patterns.*
  - *Communication.*
  - *Vision.*
  - *Mood and behavior patterns.*
  - *Psychosocial well-being.*
  - *Physical functioning and structural problems.*
  - *Continence.*
  - *Disease diagnoses and health conditions.*
  - *Dental and nutritional status.*
  - *Skin condition.*
  - *Activity pursuit.*
  - *Medications.*
  - *Special treatments and procedures.*
  - *Discharge potential.*
  - *Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.*
  - *Documentation of participation in assessment.*

A facility is expected to primarily rely on direct observation and communication with the resident in order to assess his or her functional capacity when completing a resident's RAI. According to the CMD Guidance, "In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts...."<sup>13</sup> Many of the issues listed above, including customary routine, psychosocial well-being, cognitive patterns, and mood and behavior patterns, are relevant in the context of antipsychotic drugging. For example, a resident suffering from dementia may behave in an uncooperative or disruptive manner because his or her routine was disrupted; it is the surveyor's responsibility to check to see if an assessment of the situation has been recorded and has taken the resident's individual needs into consideration. In short, it is the job of the surveyor to make sure that residents' assessments have been performed in a way that is both appropriate and complete. A citation under F-272 may be indicated when the record indicates that a resident's needs have been incompletely or incorrectly assessed.

#### **F-279 – Development of Comprehensive Care Plans – 42 CFR 483.20(k)(1)(i, ii)**

- *42 CFR 483.20(d): A facility must... use the results of the assessment to develop, review, and revise the resident's comprehensive care plan*
- *42 CFR 483.20(k)(1)(i, ii): The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a*

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<sup>13</sup> *Id.* at 119.

*resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following:*

- *The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under 42 CFR 483.25; and*
- *Any services that would otherwise be required under 42 CFR 483.25 but are not provided due to the resident's exercise of rights under 42 CFR 483.10, including the right to refuse treatment under 42 CFR 483.10(b)(4).*

The development of a comprehensive care plan is an important component of a facility's mandate to provide good and appropriate care that is tailored to the needs and desires of each resident. In the context of antipsychotic drugging, the specific provisions of requiring a description of services "to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being" and documentation of resident's right to refuse treatment are particularly relevant in determining whether F-279 should be cited.<sup>14</sup>

#### **F-280 – Develop.Prepare.Review of Comp Care Plan – 42 CFR 483.10(d)(3) and 42 CFR 483.20(k)(2)**

- *42 CFR 483.10(d)(3): The resident has the right to – unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.*
- *42 CFR 483.20(k)(2): A comprehensive care plan must be:*
  - *Developed within 7 days after the completion of the comprehensive assessment;*
  - *Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and*
  - *Periodically reviewed and revised by a team of qualified persons after each assessment.*

CMS defines "participate in planning care and treatment" as meaning that the resident is afforded the opportunity to select from alternative treatments, in both the initial decisions about treatment options and when revisions are made throughout the course of the resident's care, and that the attending physician, among other qualified staff members, must be a part of the interdisciplinary team that prepares the care plan.<sup>15</sup> CMS's guidance instructs surveyors to investigate how the facility and its staff involved residents, families and representatives in care planning meetings, including whether or not (and, if so, how) they reached out to them, made the meetings accessible and made the process

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<sup>14</sup> *Id.* at 136.

<sup>15</sup> *Id.* at 138.

understandable. Without the opportunity to participate in the planning or developmental stages of a care plan, the resident or his or her representative may not know that alternative methods of treatment might be viable options; conversely, without appropriate personnel comprising the interdisciplinary team, alternative treatment options may never be properly considered during the initial planning stage or developed throughout the course of a treatment plan. F-280 may be an appropriate citation if a resident or his or her representative is not given the chance to select from alternative, non-pharmacological alternatives to antipsychotic drugging, both in the initial decisions about care and treatment as well as in periodic revisions to these decisions, or if certain personnel are not a part of the interdisciplinary team involved in a resident's care planning.

#### **F-281 – Services Meet Professional Standards of Quality – 42 CFR 483.20(k)(3)(i)**

- *The services provided or arranged by the facility must meet professional standards of quality.*

CMS defines “professional standards of quality” as relating to services that are provided according to accepted standards of clinical practice.<sup>16</sup> At least half of the residents in nursing facilities have Alzheimer's Disease or another form of dementia.<sup>17</sup> Thus, good and appropriate dementia care is an integral part of meeting these standards. Given also the FDA's black box warning of the potential for increased mortality when antipsychotic drugs are given to individuals suffering from dementia, as well as the links between antipsychotics and a decline in cognition and other serious problems, the off label use of antipsychotics should, minimally, trigger an inquiry into whether professional standards of care are being provided.<sup>18,19</sup> Additionally, it is important to remember that F-281 may be relevant when other F-tags related to antipsychotic drugs are cited. For example, if a facility's staff gave a resident a drug unnecessarily (F-329) or violated a resident's right to be free from chemical restraints (F-222), the facility may have failed to meet a professional standard of quality in the provision of services, in violation of F-281.

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<sup>16</sup> *Id.* at 141.

<sup>17</sup>For more information on prevalence of Alzheimer's Disease in nursing homes see the Alzheimer's Association website at [http://www.alz.org/join\\_the\\_cause\\_special\\_care\\_units.asp](http://www.alz.org/join_the_cause_special_care_units.asp).

<sup>18</sup> For more information on the risks of mortality to dementia sufferers posed by antipsychotic drugs, see Dorsey, ER, Rabbani, A, Gallagher, SA, Conti, RM, and Alexander, GC, “Impact of FDA Black Box Advisory on Antipsychotic Medication.” The American Medical Association. January 11, 2010. Available at: <http://www.rwjf.org/content/rwjf/en/research-publications/find-rwjf-research/2010/01/impact-of-fda-black-box-advisory-on-antipsychotic-medication-use.html>.

<sup>19</sup> For more information on dementia care, see Coggins, Mark D., PharmD, CGP, FASCP, “Dementia-related Behavior Management,” *AgingWell*, Vol. 5, No.1, P. 32. (January/February 2012). Available online at: <http://www.agingwellmag.com/archive/012312p32.shtml>.

**F-282 – Care Provided by Qualified Persons in Accordance with Plan of Care – 42 CFR 483.20(k)(3)(ii)**

- *The services provided or arranged by the facility must be provided by qualified persons in accordance with each resident's written plan of care.*

The implementation of an individual resident's care plan is a crucial aspect of appropriate, resident-centered care. Unfortunately, some facilities fail to adhere to the federal standards when carrying out a care plan: a July 2012 report issued by the Office of the Inspector General found, in a review of 375 records from 640 nursing homes, that these Medicare and Medicaid-funded facilities failed to meet federal requirements in care plan implementation 17.9% of the time.<sup>20</sup> F-282 is relevant if a resident is given an antipsychotic drug and the use of antipsychotics is not indicated in that resident's care plan, as this may indicate that the care provided is inconsistent with the appropriate implementation of the resident's written care plan (and is inappropriate for the resident).

**F-309 – Necessary Care for Highest Practicable Well Being - 42 CFR 483.25**

- *Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well being, in accordance with the comprehensive assessment and plan of care.*

A resident's ability to attain and maintain his or her highest practicable physical, mental, or psychosocial well-being is a focal point of the patient-centered approach required by the Nursing Home Reform Law. F-309 is relevant when antipsychotics are used and the use has a negative effect on the resident's ability to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

**F-310 – Activities of Daily Living ("ADL") do not Decline Unless [the decline is] Unavoidable - 42 CFR 483.25(a)(1)(i – v)**

- *Based on the comprehensive assessment of a resident, the facility must ensure that a resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to:*
  - *Bathe, dress and groom;*
  - *Transfer and ambulate;*
  - *Toilet;*

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<sup>20</sup> "Office of the Inspector General: Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs." July 2012. Available at: <http://oig.hhs.gov/oei/reports/oei-07-08-00151.pdf>. Importantly, the OIG's assessment also found that "99 percent of records did not contain evidence that Federal requirements for care plans... were met... [and] 18 percent of records that listed care plan interventions for antipsychotic drug use did not contain evidence that those interventions... actually occurred."

- *Eat; and*
- *Use speech, language, or other functional communication systems.*

A resident's abilities in terms of ADLs and other functionality are likely to be adversely affected by antipsychotic drugs. This is especially true for elderly residents with dementia who, as noted earlier, are at serious risk of harm from antipsychotics. For many, a decline in ADLs due to antipsychotic drugging could be avoided if nursing home staff employed non-pharmacological methods of treatment. F-310 is applicable in the antipsychotic drugging context if a resident's ADLs diminish due to antipsychotic treatment and if the diminution was avoidable through selection of different, non-pharmacological treatment, use of a lower dose or different drug or by employing GDR (gradual dose reduction).

#### **F-319 – Mental/Psychosocial Treatment - 42 CFR 483.25(f)(1)**

- *Based on the comprehensive assessment of a resident, the facility must ensure that a resident who displays mental or psychosocial adjustment difficulty receives appropriate treatment and services to correct the assessed problem.*

F-319 may be relevant when a resident displays mental or psychosocial adjustment difficulties and is administered antipsychotics inappropriately. As noted in the earlier discussion for F-329, an antipsychotic must be clinically appropriate for the resident and not used for convenience or disciplinary purposes, for instance as a means to address a resident's mental or psychosocial adjustment difficulties in a manner that is most convenient for medical and/or care staff, rather than what is appropriate for the resident.

#### **F-320 – No Development of Mental Problems - 42 CFR 483.25(f)(2)**

- *A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.*

The development of mental health problems, such as depressed or withdrawn behavior, could be present in a resident who is given antipsychotic drugs and may even be exacerbated by the use antipsychotics.<sup>21</sup> Thus, F-320 may be relevant when a resident is treated with antipsychotics when they are not clinically indicated and when the resident's mental and/or psychosocial well-being deteriorates.

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<sup>21</sup> International Clinical Psychopharmacology, "Prevalence and Extent of Distress of Adverse Effects of Antipsychotics Among Callers to a United Kingdom National Mental Health Helpline" (May 2001). Available at: [http://journals.lww.com/intclinpsychopharm/Abstract/2001/05000/Prevalence\\_and\\_extent\\_of\\_distress\\_of\\_adverse.4.aspx](http://journals.lww.com/intclinpsychopharm/Abstract/2001/05000/Prevalence_and_extent_of_distress_of_adverse.4.aspx).



**F-353 – Sufficient Nursing Staff on 24-hour Basis - 42 CFR 483.30(a)(1)**

- *The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans.*

As noted in *The Boston Globe's* national report on antipsychotic drugging, "There is a clear link between the rate of antipsychotic use in a nursing home and its staffing level."<sup>22</sup> Because of the inverse relationship between low staff levels and high antipsychotic use, F-353 is relevant when antipsychotic drugs are used inappropriately in a nursing home, especially when there are indications that inappropriate use affects multiple residents. A pattern of inappropriate use should trigger an assessment of whether or not there is sufficient staffing to provide appropriate care, including meeting the standard of care for dementia and dementia related behavioral symptoms.

**F-385 – Residents' Care Supervised by Physician - 42 CFR 483.40(a)(1, 2)**

- *The facility must ensure that the medical care of each resident is supervised by a physician, and another physician supervises the medical care of residents when their attending physician is unavailable.*

F-385 relates to an important distinction between supervision of a resident's care, which must be provided by a physician, and the carrying out of certain tasks, some of which must be carried out by a physician and some of which may be carried out by designated staff or others with appropriate training and/or licensure. F-385 is relevant when there are indications that a resident has been given antipsychotic drugs inappropriately or if there are patterns of extensive off-label use of antipsychotics or extensive reliance on PRNs (*pro re nata*) which allow nursing home staff to give a resident drugs on an "as needed" basis, at their own discretion. Any of these situations should trigger an inquiry into whether the physician(s) supervised their residents' care in a meaningful way when these drugs were used, as the law requires.<sup>23</sup>

**F-428 – Drug Regimen Reviewed Monthly - 42 CFR 483.60(c)(1)**

- *The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.*

The purpose of F-428 is to improve oversight and accountability in drug prescribing practices in nursing facilities. The pharmacist is charged with identifying potential medication-related problems such as: use of a medication without adequate indication for

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<sup>22</sup> The Boston Globe, "Nursing Home Residents with Dementia Often Given Antipsychotics Despite Health Warnings" (April 29, 2012). Available at: [http://www.boston.com/lifestyle/health/articles/2012/04/29/nursing\\_home\\_residents\\_with\\_dementia\\_often\\_given\\_antipsychotics\\_despite\\_health\\_warnings/?page=3](http://www.boston.com/lifestyle/health/articles/2012/04/29/nursing_home_residents_with_dementia_often_given_antipsychotics_despite_health_warnings/?page=3).

<sup>23</sup> For a discussion of roles and tasks that physicians may delegate in LTC settings see Wilson, Kathleen M., PhD, "Physicians May Delegate Tasks, Not Supervision," *Caring For the Ages*, Vol. 9, No. 11 (November 2008). Available at [www.CaringfortheAges.com](http://www.CaringfortheAges.com).



its use, use of a medication without identifiable evidence that safer alternatives (including more clinically appropriate medications) have been considered and use of an appropriate medication that is not reaching treatment goals.<sup>24</sup> According to the guidance,

It may be necessary for the pharmacist to conduct the MRR [Medication Regimen Review] more frequently, for example weekly, depending on the resident's condition and the risks for adverse consequences related to current medications.

Generally, MRRs are conducted in the facility because important information about indications for use, potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the resident.<sup>25</sup>

Given the critical safeguards that an independent pharmacist's review provides, cases where inappropriate use of antipsychotics have been identified should trigger a review of whether these requirements were met.

#### **F-490 – Facility administered effectively – 42 CFR 483.75**

- *A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.*

Inappropriate antipsychotic drug use is often associated with systemic problems in a facility, such as insufficient staffing and a lack of knowledge and/or use of non-pharmacological treatment options for dementia care. F-490 is relevant if antipsychotics are administered inappropriately, particularly when there are indications that inappropriate use occurs often or systematically in a nursing home.

#### **F-498 – Proficiency of Nurse Aides – 42 CFR 483.75(f)**

- *The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.*

Facilities are required to ensure that nurse aides have the knowledge and ability necessary to meet the various needs of their residents. The Interpretive Guidelines for F-498 note the

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<sup>24</sup> For more examples and further information on F-428 see presentation by Maher, Robert L. Jr., Pharm.D, BCPS, CGP, *F-Tag 428 Medication Regimen Review Drug Use Problems in Long Term Care Residents and Key Elements to Performing a Drug Regimen Review* (October 2007). Available at <http://www.slideserve.com/lavina/f-tag-428-medication-regimen-review-drug-use-problems-in-long-term-care-residents-and-key-elements-to-performing-a-dru>.

<sup>25</sup> CMS Guidance at p. 540.

need for competency in a range of skills, including two areas particularly relevant to the use of antipsychotics: the ability to provide sufficient and appropriate care to (1) meet residents' mental health and social service needs and (2) uphold residents' rights.<sup>26</sup> The effects of antipsychotic drugs upon the mental health of a given resident, as well as that resident's right to a dignified existence (among other rights), are clearly articulated throughout the regulations and the guidance for the other F-tags. Additionally, appropriate dementia care is an important part of nursing home care in general, given that about one of every two nursing home residents suffers from dementia.<sup>27</sup> F-498 is relevant when antipsychotic drugs are administered, particularly for off-label indications, and observation, interviews and/or a review of the records indicate that nurse aide staff have not been providing services that demonstrate these important competencies.

**F-501 – Responsibilities of Medical Director – 42 CFR 483.75(i)(1, 2)(i, ii)**

- *The facility must designate a physician to serve as medical director.*
- *The medical director is responsible for:*
  - *Implementation of resident care policies*
  - *The coordination of medical care in the facility*

The medical director has an important role in ensuring that a nursing home's residents have access to appropriate care that reflects current standards of practice. The CMS Guidance for this F-tag has a section that specifically addresses the intent of this requirement, including: providing "clinical guidance and oversight regarding the implementation of resident care policies," collaborating "with the facility leadership, staff, and other practitioners and consultants to help develop, implement and evaluate resident care policies and procedures that reflect current standards of practice," and helping the facility identify and address clinical concerns and issues affecting "resident care, medical care or quality of life...."<sup>28</sup> F-501 is relevant when antipsychotic drugs are administered to residents and there are indications that the facility's medical director has not provided appropriate clinical guidance and oversight in the care of the residents.

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<sup>26</sup> CMS Guidance at p. 622.

<sup>27</sup> Estimations of the prevalence of dementia in nursing homes vary; our review of the literature indicated a rate of approximately 50% or higher. See, for example, the American Society of Consultant Pharmacists' web article, "Antipsychotic Medication Use in Nursing Facility Residents," available at <https://www.ascp.com/articles/antipsychotic-medication-use-nursing-facility-residents>.

<sup>28</sup> CMS Guidance at p. 624.

## Appendix: Further Guidance & Information Relating to F-329

### F-Tag 329: Free From Unnecessary Drugging

Following are excerpts from the extensive guidance provided by CMS for F-Tag 329, 42 CFR 483.25(l).<sup>29</sup> We are providing additional information on F-329 here because it is generally considered central when there is an issue of unnecessary or inappropriate use of antipsychotic drugs. This appendix includes both general provisions and those specifically relating to antipsychotic drug use (which was the focus of the summary of this F-Tag at the beginning of the report), followed by the intent of this regulation, gradual dose reduction considerations relating to antipsychotics, and criteria for compliance and noncompliance.

The complete guidance is over 80 pages long and includes important **Definitions**, such as “adverse consequence” and “medication regimen review”;<sup>30</sup> an **Overview** of the issue, including a discussion on the pervasiveness of unnecessary antipsychotic drugging and examples of non-pharmacological interventions;<sup>31</sup> a section dedicated to the requirements pertaining to **Medication Management**;<sup>32</sup> and a table of various **Medications and Issues/Concerns**.<sup>33</sup>

We urge readers to give special consideration to the last paragraph of the appendix, **Antipsychotic Medications without Gradual Dose Reduction and Behavioral Interventions unless Clinically Contraindicated**, which we believe provides an excellent and succinct account of typical indicators when a facility is failing to meet minimum standards.

**Note:** The guidance for F-329 is currently (October 2012) undergoing review and update by CMS. Please visit our website page dedicated to antipsychotic drugging, <http://www.nursinghome411.org/?articleid=10042>, for future updates to this report.

### Federal Code

**1. Unnecessary drugs—(1)General.** *Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:*

- (i) In excessive dose (including duplicate therapy); or*
- (ii) For excessive duration; or*
- (iii) Without adequate monitoring; or*
- (iv) Without adequate indications for its use; or*
- (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or*
- (vi) Any combinations of the reasons above.*

**(2) Antipsychotic Drugs.** *Based on a comprehensive assessment of a resident, the facility must ensure that:*

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<sup>29</sup>CMS Guidance, pp. 344-427.

<sup>30</sup> *Id.* at p. 346.

<sup>31</sup> *Id.* at p. 349.

<sup>32</sup> *Id.* at p. 353.

<sup>33</sup> *Id.* at 371.

- (i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and*
- (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.*

### **Intent**

The intent of this requirement is that each resident's entire drug/medication regimen be managed and monitored to achieve the following goals:

- The medication regimen helps promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;
- Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);
- Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
- Clinically significant adverse consequences are minimized; and
- The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.<sup>34</sup>

### **Gradual dose reduction: Considerations Specific to Antipsychotics**

- Within the first year in which a resident is admitted on an antipsychotic medication or after the facility has initiated an antipsychotic medication, the facility must attempt a GDR [Gradual Dose Reduction] in two separate quarters (at least a month between attempts) unless clinically contraindicated.
  - After the first year, a GDR must be attempted annually, unless clinically contraindicated.
- For any individual who is receiving an antipsychotic medication to treat behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:
  - The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and
  - The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or increase distressed behavior.
- For any individual who is receiving an antipsychotic medication to treat a psychiatric disorder other than behavioral symptoms related to dementia, the GDR may be considered contraindicated if:
  - The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; or

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<sup>34</sup> *Id.* at p. 345.

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.<sup>35</sup>

#### **Criteria for compliance**

- Assessed the resident to ascertain, to the extent possible, the causes of the condition or symptoms requiring treatment, including recognizing, evaluating, and determining whether the condition or symptoms may have reflected an adverse medication consequence;
- Based on the assessment, determined that medication therapy was indicated and identified the therapeutic goals for the medication;
- Utilized only those medications in appropriate doses for the appropriate duration, which are clinically necessary to treat the resident's assessed condition(s)'
- Implemented a gradual dose reduction and behavioral interventions for each resident receiving antipsychotic medications unless clinically contraindicated;
- Monitored the resident for progress towards the therapeutic goal(s) and for the emergence or presence of adverse consequences, as indicated by the resident's condition and the medication(s); and
- Adjusted or discontinued the dose of a medication in response to adverse consequences, unless clinically contraindicated.<sup>36</sup>

#### **Criteria for noncompliance**

- Inadequate indications for use – Include, but not limited to, examples below:
  - Failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using medication(s) for a specific resident.
  - Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed as opposed to other reactions.
  - Failure to provide a clear rationale for continuing a medication that may be causing an adverse consequence.
  - Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause or environmental or psychosocial stressor.
  - Initiation of medication presenting clinically significant risks without considering relative risks and benefits or potentially lower risks medications.
  - Concomitant use of two or more medications in the same pharmacological class without a clinically pertinent explanation.
- Inadequate monitoring – Include, but not limited to, examples below:

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<sup>35</sup> *Id.* at p. 366.

<sup>36</sup> *Id.* at p. 418.

- Failure to monitor the responses to or effects of a medication and failure to respond when monitoring indicates a lack of progress toward the therapeutic goal or the emergence of an adverse consequence
- Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines
- Failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences
- Excessive dosage – Include, but not limited to, examples below:
  - Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale.
  - Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication.
  - Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.
- Excessive Duration – Include, but not limited to, examples below:
  - Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facility-established stop order policies, or clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification.
  - Continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit.
- Adverse Consequences – Include, but not limited to, examples below:
  - Failure to act upon a report of the risk for or presence of clinically significant adverse consequence(s).
  - Failure to respond to actual or potentially clinically significant adverse consequences related to the use of warfarin when the PT/INR exceeds the target goal.
- Antipsychotic Medications without Gradual Dose Reduction and Behavioral Interventions unless Clinically Contraindicated – Include, but not limited to examples below:
  - Failure to attempt GDR in the absence of identified and documented clinical contraindications.
  - Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
  - Failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.<sup>37</sup>

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<sup>37</sup> *Id.* at pp. 419-421.