Examining Inappropriate Use of Antipsychotic Drugs
Part One:
How Seven States Cite Antipsychotic Drug Deficiencies

The misuse of antipsychotic drug is a pervasive problem in American nursing facilities. Misuse causes physical and psychological harm and death to residents and costs many hundreds of millions of dollars annually,[1] both for the drugs themselves and in efforts to reverse the poor resident outcomes that are the common consequence of their misuse. *Examining Inappropriate Use of Antipsychotic Drugs*, a Report in three Parts, looks at antipsychotic drug use in skilled nursing facilities (SNFs) and nursing facilities (NFs) from two perspectives. First, it analyzes all of the approximately 300 antipsychotic drug deficiencies that were cited in seven states in calendar years 2010 and 2011 (Part One). Second, it reports the perspectives of more than 400 state Surveyors on the survey process, in general, and the citing of antipsychotic drug deficiencies, in particular, based on a detailed Questionnaire sent to Surveyors in ten states (Part Two). Third, it presents the recommendations for specific and important ways to improve the citing of antipsychotic drug deficiencies, and consequently, to improve the health, safety, welfare, and rights of nursing home Residents throughout the United States (Part Three).

I. Background

The misuse of antipsychotic drugs in nursing facilities is not a new issue. Decades ago, the Senate Special Committee on Aging first expressed concerns about the misuse of these powerful drugs in nursing facilities.

In July 1991, the Senate Special Committee on Aging held a Workshop on "Reducing the Use of Chemical Restraints in Nursing Homes" that identified problems in antipsychotic drug use in nursing homes.[2] Several months later, in February 1992, in the preamble to proposed regulations (which were never made final) that would have given residents new protections from chemical restraints, the Health Care Financing Administration (HCFA) (predecessor agency to the Centers for Medicare & Medicaid Services, CMS) described the long-standing and "significant public health problem in many, but not all of this nation's long-term care facilities."[3] The problem described by HCFA in 1992 was, even then, recognized for at least 15 years:

> For many years, there have been allegations of misuse of psychoactive drugs in these facilities. In 1975, the Special Committee on Aging of the U.S. Senate held hearings on this public health problem and made reference to "chemical straight jackets" in nursing homes. In 1980, the House Select Committee on Aging held hearings on the same subject. They entitled their report, "Drug Abuse in Nursing Homes." Most recently, articles that deal with the subject have appeared in a number of medical journals. These

[1] Office of Inspector General, Department of Health and Human Services, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, page ii, OEI-07-08-00150 (May 2011), http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf (reporting that for the six-month period between January 1 and June 30, 2007, claims for atypical antipsychotic drugs for nursing home residents amounted to $309 million).

[2] Senate Special Committee on Aging, *Reducing the Use of Chemical Restraints in Nursing Homes*" (Workshop, July 22, 1991), http://aging.senate.gov/publications/7221991.pdf.

[3] 57 Federal Register 4516, 4519 (Feb. 5, 1992), 1992 West Law 17302 (F.R.).

papers generally question the extent of the use of psychopharmacologic drugs in nursing homes and question whether adequate monitoring of the use of these drugs exists.[4]

Attention to the misuse of antipsychotic drugs, particularly the newer atypical antipsychotic drugs, was most recently brought to public attention by journalist Lucette Lagnado. Writing in *The Wall Street Journal* in December 2007, she reported that atypical antipsychotic drugs are used off-label in nursing facilities as a substitute for adequate staffing and to quiet residents. The 2007 article, "Prescription Abuse Seen In U.S. Nursing Homes; Powerful Antipsychotics Used to Subdue Elderly; Huge Medicaid Expense," described multiple reasons for the off-label use of antipsychotic drugs in nursing homes, including the 1987 Nursing Home Reform Law's limits on the use of physical restraints, off-label marketing of antipsychotic drugs by drug companies, and insufficient staffing in nursing facilities. Lagnado reported that the Medicaid program spent more on antipsychotic drugs than on any other class of drugs.[5]

Concerned by Lagnado's report, Senator Charles Grassley (R, IA) asked the Department of Health and Human Services's Office of Inspector General (OIG) to investigate the use of antipsychotic drugs by nursing facilities. The Inspector General's report *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* described rampant misuse of antipsychotic drugs by nursing facilities. OIG reported, "In total 95 percent (nearly 1.4 million) of Medicare claims for atypical antipsychotic drugs were for elderly nursing home residents diagnosed with off-label conditions and/or the condition specified in the boxed warning."[6]

On March 29, 2012, CMS launched a new *Initiative to Improve Behavioral Health and Reduce the Use of Antipsychotic Medications in Nursing Home Residents*.[7] The *Initiative*, renamed *Partnership to Improve Dementia Care in Nursing Homes* on May 30, includes enhanced training for facilities and Surveyors, publication of antipsychotic drug use on *Nursing Home Compare*, and promotion of alternatives to antipsychotic medications ("including potential approaches such as consistent staff assignments, increased exercise or time outdoors, monitoring and managing acute and chronic pain, and planning individualized activities").[8]

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[4] *Id.*

[5] On January 1, 2006, the costs of prescription drugs for nursing home residents who are eligible for both Medicare and Medicaid shifted from the Medicaid program to the Medicare program. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 (Dec. 8, 2003).

[6] Office of Inspector General, Department of Health and Human Services, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, page 21, OEI-07-08-00150 (May 2011), http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf.

[7] http://surveyortraining.cms.hhs.gov/pubs/VideoInformation.aspx?cid=1098

[8] CMS, "CMS Announces Partnership to Improve Dementia Care in Nursing Homes; Government Partnering with Providers, Caregivers, Patients to Ensure Appropriate Use of Antipsychotic Medications" (Press Release, May 30, 2012), http://www.cms.gov/apps/media/press/release.asp?Counter=4368&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date.

Our Methodology

A. Review of state survey reports

In this project, CMS selected seven states for review – Georgia, Illinois, Massachusetts, Missouri, Oregon, Pennsylvania, and Texas – reflecting states that use the traditional survey process and states that use the new Quality Indicator Survey process. CMS provided project staff with the entirety of the portions of the seven states' survey reports (2567s) for calendar years 2010 and 2011 that cited violation of antipsychotic drugs under 42 C.F.R. §483.25(l)(2)[9] F329,[10] unnecessary drugs. (In 2006, CMS collapsed a separate F-tag for antipsychotic drugs into F329.[11]) This Report does not disclose the identity of states in its state-specific analysis below, honoring the commitment made by project staff to state survey agency directors. The tables below identify the states in random order as State A through State J;[12] the sequence of states is the same in all three Parts of this Report.

Reviewing the F329 deficiencies in 2010 and 2011, the project found that the seven states cited unnecessary drug deficiencies under F329 in 602 surveys; 292 of the 602 F329 deficiencies (48.5%) involved, at least in part, the use of antipsychotic drugs in violation of the federal Requirements of Participation.[13]

The project also reviewed 14 chemical restraint deficiencies, 42 C.F.R. §483.12(a),[14] F222, cited by the seven states in three calendar years, 2010-2012.

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[9] Subsection (2) of 42 C.F.R. §483.25(l), "unnecessary drugs," addresses antipsychotic drugs:

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

[10] For survey purposes, CMS uses the term F-tags, which are correlated with one or more regulatory standards of care.

[11] CMS, "**Nursing Homes -** Issuance of Revised Surveyor Guidance for Unnecessary Medications (F329) and the entire Pharmacy Services section at §483.60 (collapsing current regulatory language into three tags (F425, F428, and F431) in Appendix PP, State Operations Manual, as well as medication related revisions in Appendix P Task 5 and Sub-Tasks 5A, 5C, and 5E: **REVISED**," S&C-06-09 (Sep. 15, 2006), http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter06-29.pdf.

[12] The seven states are labeled A, B, C, E, F, I, and J. The questionnaire to Surveyors (Part Two of this Report) includes Surveyors from three additional states whose State Survey Agency Directors asked that their Surveyors be included. Therefore, to maintain states' anonymity, project staff used the first 10 letters of the alphabet to identify states in all three Parts of this Report.

[13] Requirements of Participation are the standards of care that facilities must meet to participate in, and be eligible for reimbursement from, the Medicare and Medicaid programs. 42 C.F.R. Part 483.

[14] "The 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 the resident's medical symptoms."

II. How Seven States Cite Antipsychotic Drug Deficiencies under F329

The evaluation of antipsychotic drug deficiencies led to two key findings. First, states evaluate antipsychotic drug deficiencies in ways that are very different from state to state (and different even within states). Some states cite deficiencies for single incidents of care involving a single resident; other states cite deficiencies for multiple residents and multiple situations. Second, all states cite almost all deficiencies at an "isolated no-harm" level (level D),[15] regardless of the seriousness of the poor outcomes that residents suffer, regardless of the total number or proportion of residents who are affected by the facility's deficient practices, and regardless of the number of federal requirements that the facility violates.

A. Proportions of antipsychotic drug deficiencies under F329 (unnecessary drugs)

States varied considerably in the proportion of F329 deficiencies that cited antipsychotic drugs in whole or in part, as opposed to F329 deficiencies that were entirely unrelated to antipsychotic drugs (such as failure to monitor residents' Coumadin levels). The range of F329 deficiencies reflecting antipsychotic drugs was 20% of F329 deficiencies in one state, compared to 76% of F329 deficiencies in another state.

Table 1: Proportions of antipsychotic drug deficiencies cited under F329[16]

State	Number of F329 deficiencies	Number of antipsychotic drug deficiencies	Percentage of F329 deficiencies are for antipsychotic drugs
State A	197	148	76%
State B	55	11	20%
State C	57	30	53%
State E	44	26	61%
State F	129	48	37%
State I	20	8	40%
State J	100	24	24%
Total	602	295, as 292[17]	49%

[15] The federal enforcement system classifies deficiencies according to scope (isolated, pattern, widespread) and severity (substantial compliance, no actual harm with the potential for more than minimal harm, actual harm, and immediate jeopardy). 42 C.F.R. §488.408. CMS provided a visual depiction of the 12-option scope and severity grid in the preamble to the final enforcement rules. 59 Fed. Reg. 56116, 56183 (Nov. 10, 1994).

[16] State A survey cited a D-level deficiency as both a recertification and a complaint survey; a second State A survey cited an E-level deficiency as both a recertification and a complaint survey. Both State A deficiencies are counted once each in calculating the total number of deficiencies. State F cited an E-level deficiency from a combined recertification/complaint survey; the deficiency is counted once in calculating the total number of deficiencies.

[17] Three deficiencies (one in State F and two in State A) were counted twice in a combined recertification/complaint survey. Although these deficiencies were separately listed as recertification and complaint deficiencies, the total number of antipsychotic drug deficiencies is reduced by three.

B. Annual and complaint surveys

Most antipsychotic drug deficiencies under F329 were cited following annual recertification surveys, rather than following complaint surveys, although, as shown in Table 3, more F329 deficiencies with higher scope and severity levels are cited following complaint surveys than recertification surveys.

Table 2: Antipsychotic drug deficiencies cited under F329 in recertification and complaint surveys[18]

State	Total number of F329 antipsychotic drug deficiencies	Number cited in recertification surveys	Number cited in complaint surveys
State A	148	132 (includes 2 combined certification/complaint)	18 (includes 2 combined certification/complaint)
State B	11	11	0
State C	30	24	6
State E	26	23	3
State F	48	39 (includes 1 combined certification/complaint)	10 (includes 1 combined certification/complaint)
State I	8	8	0
State J	24	15	9
Total	295, count as 292	252, count as 249	46, count as 43

C. Scope and severity levels of antipsychotic drug deficiencies

Regardless of the proportions of antipsychotic drug deficiencies cited or the number of survey reports that included antipsychotic drug deficiencies, all seven states cited almost every antipsychotic drug deficiency at an isolated "no-harm" level. Of the 295 survey reports with F329 deficiencies addressing antipsychotic drugs, 278 of them (95%) coded the deficiency at level D (isolated no harm) or level E (pattern no harm). Only three states cited any G-level (isolated harm) deficiencies; four states cited no G-level deficiencies. No state cited any antipsychotic drug deficiency at a level higher than G in calendar years 2010 and 2011.

- 198 (67.8%) are cited at level D (167 as a result of recertification surveys; 32 as a result of complaint surveys);[19]

- 82 (28.0%) are cited at level E (75 as a result of recertification surveys; 9 as a result of complaint surveys);[20]

[18] One State A survey cited a D-level deficiency from a combined recertification/complaint survey; a second State A survey cited an E-level deficiency from a combined recertification/complaint survey. Both State A deficiencies are counted once for the total number of deficiencies, and one each in the recertification and complaint columns. State F cited an E-level deficiency from a combined recertification/complaint survey; the deficiency is counted once for the total number of deficiencies, and once each in the recertification and complaint columns.

[19] A State A survey cited a D-level deficiency in a combined recertification/ complaint survey. Consequently, there were 198 D-level deficiencies, not 199.

- 15 (5.1%) are cited at level G (7 as a result of recertification surveys; 8 as a result of complaint surveys).

Although only a limited number of deficiencies were cited above the no-harm (D-E) level, a higher proportion of harm deficiencies (level G) were cited following complaint surveys than recertification surveys. Eight of 15 G-level deficiencies (53%) were cited following complaint surveys.

Table 3: Scope and severity levels of antipsychotic drug deficiencies cited under F329[21]

State	Total number of antipsychotic drug deficiencies	Recert. Survey D	Recert. Survey E	Complaint Survey D	Complaint Survey E	Other
State A	148	99 (includes 1 cited as both certification and complaint)	26 (includes 1 cited as both certification and complaint)	11 (includes 1 cited as both certification and complaint)	3 (includes 1 cited as both certification and complaint)	Cert G: 7 Complaint G: 4
State B	11	6	2	3	0	0
State C	30	20	4	3	0	Complaint G: 3
State E	26	17	6	3	0	0
State F	48	7	32 (includes 1 cited as both recertification and complaint)	4	5 (includes 1 cited as both recertification and complaint)	Complaint G: 1
State I	8	8	0	0	0	0
State J	24	10	5	8	1	0
Totals	295, as 292	167	75	32	9	15

[20] States A and F cited an E-level deficiency in a combined recertification/complaint survey. Consequently, there were 82 E-level deficiencies, not 84.

[21] One State A survey cited a D-level deficiency from a combined recertification/complaint survey; a second State A survey cited an E-level deficiency from a combined recertification/complaint survey. State F cited an E-level deficiency from a combined recertification/complaint survey; the deficiency is counted once for the total number of deficiencies, and once each in the recertification and complaint columns.

D. Number and proportion of antipsychotic drug deficiencies cited at a harm level

Four states cited only no-harm (levels D and E) deficiencies. Three states cited harm (level G) deficiencies, ranging from 2% to 10% of the antipsychotic drug deficiencies that they cited. As noted in Table 3 below, State A cited 11 of the 15 harm deficiencies (73%).

Table 4: Number and proportion of antipsychotic drug deficiencies cited under F329 at a harm level (level G)

State	Number of no-harm deficiencies	Proportion of deficiencies at no-harm level	Number of harm deficiencies	Proportion of deficiencies at harm level
State A	137	93%	11	7%
State B	11	100%	0	0%
State C	27	90%	3	10%
State E	26	100%	0	0%
State F	47	98%	1	2%
State I	8	100%	0	0%
State J	24	100%	0	0%

E. Numbers of survey reports with antipsychotic drug deficiencies cited under F329

Some states cited very few antipsychotic drug deficiencies, and other states, larger numbers. One state cited only eight antipsychotic drug deficiencies in the two-year period; another state cited 148 antipsychotic drug deficiencies. These differences are not explained by the number of facilities in the states.[22] The lowest-citing state cited one antipsychotic drug deficiency for every 42.2 nursing facilities in the two-year period; the highest-citing state cited one antipsychotic drug deficiency for every 5.3 nursing facilities in the two-year period.

Table 5: Survey reports with antipsychotic drug deficiencies cited under F329

State	Number of F329 deficiencies for antipsychotic drugs	Frequency of antipsychotic drug deficiencies in surveys
State A	148	1 for every 5.3 facilities
State B	11	1 for every 39.0 facilities
State C	30	1 for every 4.6 facilities
State E	26	1 for every 19.7 facilities
State F	48	1 per every 24.8 facilities
State I	8	1 per every 42.2 facilities
State J	24	1 for every 29.7 facilities

[22] The number of nursing facilities in each state was reported by Kaiser. http://www.statehealthfacts.org/comparemaptable.jsp?cat=8&ind=411. This Report does not identify the number of facilities in each state in order to maintain the anonymity of the states.

F. Percentages of residents receiving antipsychotic drugs, F329

Deficiency rates for antipsychotic drug use are also not explained by the percentages of residents receiving antipsychotic drugs in the seven states. Rates of antipsychotic drugs reported to CMS by nursing facilities, and then publicly reported, by state, by CMS, do not show significantly different rates across states in two relevant measures: the overall prevalence of antipsychotic use in the absence of psychotic or related conditions and the prevalence rate for residents at high risk (defined as residents with both cognitive impairment and behavior problems).

In a representative timeframe for this study, the third quarter of 2010 (July-September), CMS reported similar rates of antipsychotic drug use for both measures in the seven states.[23]

Table 6: Antipsychotic Drug Use Rates, by State

State	Measure 10_1_Overall Prevalence of Antipsychotic Use, in the Absence of Psychotic or Related Conditions	Measure 10_1_HI Prevalence in the Absence of Psychotic or Related Conditions; High Risk Residents
State A	22.6%	37.9%
State B	20.2%	36.6%
State C	18.5%	38.4%
State E	21.5%	44.4%
State F	20.0%	39.0%
State I	22.8%	41.8%
State J	16.2%	36.8%
Average	**20.2%**	**39.3%**

State E, the state with the highest rate of antipsychotic drug use for residents at high risk (residents with both cognitive impairment and behavior problems) (Table 6), cited no deficiencies at a harm level (Table 4). State A, which cited 11 of the 15 harm-level deficiencies cited nationwide (73%) (Table 4), had a lower rate of antipsychotic drug use among residents at high risk than the average rate for the seven states (Table 6).

III. Which factors states cite in antipsychotic drug deficiencies under F329

Despite the federal survey protocol setting out how Surveyors should identify and cite all deficiencies, state survey teams vary considerably in how they evaluate, discuss, and document antipsychotic drug deficiencies. Each state appears to have its own approach about how Surveyors evaluate the regulatory requirements, which specific factors they evaluate, and whether they evaluate the impact of the antipsychotic drugs on the residents.

Some survey reports (2567s) are lengthy, discussing several residents and including record citations to residents' medication (and other) records and multiple staff and family interviews.

[23] CMS, Psychotropic Drug Use – July/September 2010, http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/MDSPubQIandResRep/qmreport.html.

Other survey reports are short and comparatively cursory, reflecting a single incident or a single resident.

Some state Surveyors consider whether the facility identified a diagnosis or justification for the drug; others do not.

Some state Surveyors determine whether facility staff monitored the resident for specific targeted behaviors for which the drugs are prescribed and administered; others do not.

Some state Surveyors question whether the facility monitored the resident for side effects, whether the drug dosage was excessive, whether residents received duplicate therapy (more than one drug in the same class), whether the facility tried gradual dose reductions, or whether the facility tried a behavioral intervention before administering a drug (particularly for as-needed (PRN) antipsychotic drug orders).

No states' Surveyors considered, and surveyed for, all of these regulatory requirements.

Some states cite violations of the facility's antipsychotic drug policy; others do not.

Some state Surveyors cite the Food and Drug Administration's (FDA's) Black Box warnings about the use of antipsychotic drugs with residents who have dementia or other pharmacologic or nursing reference work. Some states never cite any governmental or external authority.

Some state Surveyors evaluate the poor outcomes for residents, such as weight gain or loss, or lethargy/sleepiness, abnormal involuntary movements, hospitalizations, or death; other states do not identify resident outcomes in deficiency reports.

Many survey reports do not identify resident outcomes. While citing one or more issues of non-compliance with federal Requirements (impermissible reason for drug; duplicate therapy; excessive dosage; failure to monitor resident; failure to assess resident; failure to try gradual dose reductions; violation of facility policy; failure to attempt behavioral interventions before using drugs), survey reports often do not cite how the resident(s) reacted to the antipsychotic drugs they were given. Moreover, even when states document poor resident outcomes, they are still likely to categorize the deficiency as causing no harm (level D or E).

IV. Examples of antipsychotic drug deficiencies cited under F329

The following summaries of antipsychotic drug deficiencies are samples of deficiencies from each of the seven states. The description of the deficiency is quoted from the survey reports' initial statement, followed by a summary of the deficiency written by project staff. Additional language quoted from subsequent parts of the survey report is identified by quotation marks. The summaries describe the type of survey (recertification, complaint, or both), date of survey, and the number of pages in the survey report for the F329 deficiency.

A. Examples of level D (no harm) deficiencies for antipsychotic drugs cited under F329

State A

Recertification survey (July 14, 2011), 2½ pages: "The facility failed to attempt a reduction in antipsychotic medication for three of five residents (R26, R23, and R2) reviewed for antipsychotic medications in a sample of thirty."

Two of the residents lived in the facility's secure dementia unit. The facility's Memory Care Coordinator "was not aware of Seroquel's contra-indication in the case of use for dementia-related behavioral disorders." The Memory Care Coordinator stated that there were no documents "or written indications to diagnostically or clinically support the use or continued use of Seroquel" for the third resident.

State A

Recertification survey (April 20, 2011), 5½ pages: "The facility failed to show justification for the use of antipsychotics and for the use of dual drug therapy and failed to assess and reduce the antipsychotic medications for three of ten residents (R1, R12, R13) reviewed for antipsychotic medications in the sample of 16."

R13 was diagnosed with dementia with behavioral disturbances. His behaviors included wandering, episodes of agitation, striking out at staff, and needing redirection. He had 20 falls. He was given Zyprexa and, "for behaviors of resisting care and refusing medications," Seroquel. R13's family expressed concern about the large number of medications R13 was given, which they said made him more anxious and agitated. The consultant pharmacist twice made recommendations to reduce the Zyprexa and reevaluate the medications; the physician declined both recommendations. R1, diagnosed with bipolar affective, diabetes, and depression, was given Risperdal, Seroquel, and Depakote. The consultant pharmacist made two recommendations about the duplicative drug therapy, which the physician declined. R1 was not assessed for pain, and was observed with her eye closed while being fed. Surveyors observed her jaw moving constantly, although the facility's Abnormal Involuntary Movement Scale documented no abnormal body movement. R12, diagnosed with Schizophrenia, was given Seroquel, Zyprexa, and PRN Haldol intramuscularly, with Seroquel and Zyprexa "above the daily recommended dosage."

State A

Recertification survey (Feb. 16, 2011), 3½ pages: "The facility failed to assess and recognize the side effect of abnormal involuntary movements, failed to assess the medication usage in regards to falls, and failed to provide justification for the use of an antipsychotic for 1 of 3 residents (R10) on the sample who are receiving antipsychotic medications in the sample of 13. R10 developed moderate to extreme abnormal involuntary movements of the face, upper and lower extremities, and body trunk after starting the antipsychotic medication. These movements effect R10's ability to independently perform activities of daily living. The facility failed to notify the

physician of the pharmacy recommendations for 1 of 7 sampled residents (R12) on anxiolytics in the same of 13 residents."

R10, diagnosed with dementia with agitation, was admitted in November 2007 with Risperdal for visual hallucination and agitation. Risperdal was discontinued in January 2010 and R10 was given Seroquel, beginning June 8, 2010, for "becoming combative with staff." R10 became combative when he "was not wanting to stay in bed, was wanting to get up out of bed, to get up and walk." In July, PRN Haldol was added to R10's drug regimen. The Alzheimers Unit Coordinator told Surveyors in February 2011 that "behavior tracking records are not kept," that R10 had not had any behaviors since June 2010, and that she "is not sure why R10 is still receiving antipsychotics." She described R10's "severe abnormal involuntary body movements and seizure like movements at times" and reported that R10 cannot ambulate and has had "falls from sliding out of wheelchair." He was on hospice care and was receiving Depakote for seizure movements. The facility did one assessment of abnormal involuntary body movements in August 2010 and then not again until the survey, at which time "R10 was observed to have moderate rigidity to body, extrapyramidal movements to upper extremities and facial movements including tongue upon protrusion." The 2011 assessment "documents significant change in the area of incapacitation of this resident." The physician, pharmacist, and hospice organization were contacted and the dosage for Seroquel was reduced and Haldol was discontinued. The other resident cited in the deficiency had a different drug issue.

State B

Recertification survey (June 16, 2011), 2 pages: "The facility failed to ensure the drug regime for 1 resident (#13) in a total sample of 15 residents, was free from unnecessary drugs."

The resident's Seroquel had been reduced but was increased "secondary to the resident acting out, being impulsive and making staff accusations" – the resident "made an allegation of abuse by staff." P. 373 #156

State C

Recertification survey (Jan. 7, 2011), 1½ pages: "The facility failed to have physician orders, failed to assess incidents of agitation, attempt non-pharmacological interventions and/or have indications for use prior to PRN antipsychoactive medication administration for 2 of 6 sampled residents (#s 7 & 10) who received PRN psychoactive medications."

R7 was diagnosed with dementia with behaviors. She was given PRN Haldol for agitation, but staff did not document how she demonstrated agitation or what non-pharmacological interventions they tried before administering the drug. "When asked why Haldol was given without a physician order, rather than the ordered Ativan, Staff 4 stated that the Haldol was still in the medication cart and the LN had reported 'it works for her.'" R10 received drugs other than antipsychotic drugs.

State C

Recertification survey (Sep. 24, 2010), 3+ pages: "The facility failed to provide comprehensive assessment and/or ongoing monitoring for the use of antipsychotic medications for 3 of 5 sampled residents (#s 1, 12 and 13) who received antipsychotic medications."

R1, admitted in July 2010 with Alzheimer's dementia, began receiving Haldol in August when staff documented "'increasing aggression with any nursing care.'" A certified nurse assistant who knew R1 when she lived in the facility's Alzheimer's Care Unit said R1 always resisted care and that the issue was not new for her. Staff did not use the Abnormal Involuntary Movement Scale (AIMS) to evaluate R1 until the survey. R13, who had a diagnosis of schizophrenia on admission, received Zyprexa each night at bedtime, but, in violation of facility policy, staff did not address her psychotropic drug use in either her assessment or care plan. Staff said R12 was given Seroquel "for being non-compliant related to refusing to allow staff to test her blood glucose or give insulin when required." Staff did not assess R12 for the adverse effects of the drug, as required by facility policy. R12 wanted to leave the facility. A CNA told Surveyors that R12 "did better when she was able to sleep as long as she wanted and get up on her own. Staff 11 thought the resident felt more in control then."

State C

Complaint survey (April 28, 2010), 3 pages: "The facility failed to prevent an excessive dose of an antipsychotic medication and continued the medication in the presence of adverse effects for 1 of 3 sampled residents (#1) with antipsychotic medications."

R1 lived in the secure dementia unit. When nursing notes dated January 31, 2010 reported that R1 had "increasing behaviors and aggressiveness toward staff and other residents, urinated in inappropriate places and made paranoid statements," the physician ordered Risperdal on February 1. A facility report of aggression on February 8 led to an increased dosage of Risperdal on February 9. On February 10, nursing notes reported, "'Res. Was anxious [about] 'being locked in jail,' so staff brought him out to walk around the rest of the building, made him a snack [and] reassured him he is not a prisoner. This did seem to make him feel better and it might be worth looking into having him come down to the main dining room for meals.'" Many reports between February 11 and 24 indicated no agitation or problems. However, an incident on February 22 led to another increase in Risperdal on February 23. On April 8, R1 was found on the floor, complaining of pain. He was sent to the emergency room for evaluation. Staff told Surveyors that R1 "liked to be helpful and he urinated in inappropriate places."

State E

Recertification survey (Dec. 3, 2010), 7 pages: "The facility failed to document ongoing assessment/monitoring of behaviors that required the continued use of psychoactive medication (a medication that directly and chemically affects a person's mental state) for four residents (Resident #1, #11, #15, #21) who received psychoactive medications. The facility identified 74 residents who received psychoactive medications. Twenty-one residents were selected for review. The facility had a census of 118 residents."

The report includes detailed discussions of record reviews and interviews. Facility staff contacted R15's physician after an incident on November 2 when the resident became agitated with a nurse, grabbed the nurse's hair and wrist, refused to allow care, and yelled. The physician ordered Haldol. Surveyors found no diagnosis supporting R15's order for Seroquel.

State E

Complaint survey (June 14, 2011), 5+ pages: "The facility failed to show one resident (Resident #1) of three sampled residents received specific behavioral interventions or other non pharmaceutical interventions, including identification of triggers and development of a comprehensive plan of care to address individualized interventions for behaviors, prior to administering antipsychotic intramuscular (IM) and PO (by mouth), medications of Haldol and Ativan (hypnotic/antianxiety medications). The resident received 14 doses of the medications within an approximate six week period of time for physical aggression, verbal aggression, not following staff directions and staff noting the resident as not redirectable. The census was 165."

The survey report documents repeated instances of staff giving R1 a "calm cocktail" (Ativan and Haldol) and using its CALM (Crisis-Alleviation-Lessons and Method) protocol when the resident became verbally and physically aggressive. In one instance, on March 29, 2011, R1 became "physically aggressive with staff wanting a snack." The facility called a "code green" and "the resident [was] taken to the floor in a safe manner according to CALM protocol." The resident was given Ativan/Haldol intramuscularly and "was held on the floor for 15 minutes then released and assisted to bed." In an interview on May 15, a certified nurse assistant said R1 had shown an increase in behaviors in the last few months. The Director of Nurses said injections should be a last resort "and should only be given if the resident was showing signs of critically harming self or others." She said that PRN orders had been discontinued for R1, but did not know when. R1 developed "orofacial dyskinesia (abnormal involuntary repetitious movement of the muscles of the face)." The facility did not attempt other interventions before using its CALM protocol or calling a code green.

State E

Certification survey (March 2, 2011), 5½ pages: "The facility failed to ensure the drug regimen of one of 27 sampled residents (Resident #20) remained free from excessive doses and non-drug behavioral interventions were attempted when indicated, instead of or in addition to medications. The census was 271 with 215 in certified beds."

R20 was given Haldol, sometimes intramuscularly, sometimes PRN, beginning in October 2010 and, as a consequence, R20 fell frequently, breaking several teeth in a fall; declined in activities of daily living ("from requiring limited assistance with ADLs to requiring total care," becoming incontinent of bowel); and slept frequently (in the dining room, on the floor).

State F

Certification survey (Sep. 3, 2010), 5 pages: "The facility failed to ensure one of nine residents (Resident #6) sampled to psychoactive medications, did not receive unnecessary drugs as evidenced by: a. the facility failed to ensure that Resident #6 was not given (Haldol), unless antipsychotic drug therapy was necessary to treat a specific condition as diagnosed and documented in the clinical record. This drug, Haldol, has a black box warning for the elderly. b. the facility failed to document adequate monitoring for the use of the antipsychotic drug, or intervene with behavioral interventions before administering the antipsychotic drug. The facility's failure to assess a psychoactive drug with a 'black box' warning for the elderly placed Resident #6 at risk for oversedation and even death."

R6, a resident with "dementia with behavior disturbances," was given PRN Haldol intramuscularly on June 9, 2010, although Haldol was not prescribed for R6 until June 29. He received four doses of Haldol that had expired. R6 left the facility on June 13. "It took 6 staff to get him to reenter the facility." Staff wrote, "'. . . cont. to want to leave or wanting a cigarette . . . Haldol 2mg. given per Dr. orders to right hip.'" On July 2, R6 "'became agitated with staff getting him out of bed for a shower and ADL care'" at 6:30 a.m.; he was given Haldol by injection. On July 2, R6 was diagnosed with a urinary tract infection (UTI). His responsible party told Surveyors that R6 gets confused when he has a UTI. Nursing notes on July 7 indicated that the UTI could have contributed to R6's confusion. Surveyors documented additional incidents when R6 was given Haldol intramuscularly when he left the facility, tried to hit nurses, and flailed his arms. R6 expressed feelings of depression and sadness, which the facility did not address.

State F

Complaint survey (Aug. 25, 2011), 5 pages: "The facility failed to ensure one (Resident #1) of nine residents' drug regimens was free of unnecessary drugs.
Resident #1 was a 65-year-old female with multiple medical disorders, who had physician's orders for more than nine drugs, including the antipsychotic drug Seroquel, the anticonvulsant drug Depakote (prescribed for diagnosis of psychosis), the antianxiety drug Buspar, the antianxiety drug Ativan, the antidepressant drug Cymbalta, the antidepressant drug Desyrel, and the anticholinergic drug Cogentin.
Resident #1 experienced a fall on 7/30/11 with no apparent injury, a fall on 8/01/11 with no apparent injury, a fall on 8/03/11 with no apparent injury, a fall on 8/06/11 with no apparent injury, a fall on 8/07/11 with no apparent injury, and two falls on 8/09/11 with injury. Facility staff did not recognize and assess the potential contribution of Resident #1's drug regimen to her newly emerging and worsening symptoms and modify the drug regiment as appropriate. The facility failed to address and eliminate or reduce underlying causes of Resident 1's falls. Subsequently Resident #1 was hospitalized on 8/10/11, more than 24 hours after her last fall, with diagnoses including Altered Mental Status, Urinary Tract Infection, Metatarsal Fractures, and Dementia.
As a result of these failures, Resident #1 received duplicate pharmacotherapy without proper psychiatric assessment and diagnosis, which results in adverse drug effects and placed her at

increased risk of injury, morbidity, and mortality. These failures could affect the 76 of 102 residents, including Resident #1, who received psychoactive drugs."

When she was admitted on May 17, 2011, R1 was independent in mobility, transfers, eating, and toileting. Seroquel was begun July 20 and R1 began falling. R1's psychiatrist was aware of R1's falls but, on August 8, continued her medication regimen. The social worker told Surveyors she was concerned that R1's decline in ADLs had been due to the medications.

State F

Recertification survey (Sep. 16, 2011), 1 page: "The facility failed to ensure that one of 24 sampled residents drug regimen was free of unnecessary drugs and that adequate monitoring of psychotropic medications was done. (Resident #20) – Resident 20 received Seroquel 300 mg every eight hours without psychiatrist consult and monitoring. These failures affected one resident and placed 129 residents at risk for adverse reactions to medications and a decline in status."

R20 received more than the acceptable recommended dose of Seroquel. The psychiatric nurse practitioner said she increased the dosage because the resident was agitated and that she gave R20 Cogentin to counteract the side effects of the Seroquel. Surveyors observed R20 sleeping.

State I

Recertification survey (Feb. 24, 2011), ½ page: "The facility failed to ensure that residents had appropriate diagnosis, gradual dose reduction and behavioral interventions for antipsychotic medications for one resident, resident #90 on a sample of thirty-seven (37) residents."

One of 37 residents in the sample was given Risperdone for yelling out and fear of other residents. The resident did not have a diagnosis of a psychosis but had depression, anxiety, and Alzheimer's Disease. The consultant pharmacist recommended decreasing or discontinuing the antipsychotic drug; the physician rejected the recommendation. Surveyors cited failure to try dose reductions, absence of a diagnosis, and failure to try behavioral interventions. No resident outcomes were listed.

State J

Complaint survey (Nov. 9, 2011), 2½ pages: "The facility failed to ensure that residents were not prescribed medications in the presence of adverse consequences which indicated the dose should be reduced or discontinued for one of three residents reviewed (Resident R1)."

R1, who had dementia but no diagnosis of psychosis, was admitted from the hospital on October 20, 2011. By the time of the November 9 survey, she had fallen twice. Staff told Surveyors that they thought R1 had "a shuffling gait, slow movements of the extremities, and an unsteady balance" at the time of her admission. The psychiatrist who prescribed Risperdal Consta told Surveyors that he had not seen R1 since her admission, that staff said she was "'all right,'" and

that he was "not aware that she had a shuffling gait, was moving her extremities slowly, had a flat effect, and was sleeping all the time."

State J

Recertification survey (June 16, 2011), 1 page: "The facility did not ensure that non-pharmacological interventions were attempted prior to the administration of an antipsychotic medication for one of 24 residents reviewed (Resident R112)."

Staff obtained an order for Haldol for R112 "because the resident was uncooperative." A nurse told Surveyors "'We had to get the EKG done.'"

B. Examples of level E (no harm) deficiencies for antipsychotic drugs cited under F329

State A

Recertification survey (Dec. 22, 2011), 3½ pages: "The facility failed to show the justification or behaviors warranting the use of an antipsychotic and failed to attempt a reduction for an antipsychotic for four of five residents (R1, R2, R20, R21) receiving antipsychotics in the sample of 16. The facility failed to show the justification for an antipsychotic and psychoactive medication that is above the recommended dose for the elderly for one of five residents (R20) receiving antipsychotics and psychoactive medication in the sample of 16."

Three of the residents (R4, R20, R21) experienced falls; R4 fell eight times in four months. R20, who was given an excessive dose of Haldol for yelling and resisting care, was receiving hospice care. Surveyors found no documentation that the facility had "assessed R20's behaviors related to pain and for the possible need to increase pain medication." R1, diagnosed with Alzheimer's dementia and depression, was given Zyprexa for behaviors of rejecting care and delusions. She cried out and was confused. R1 had a Stage 4 pressure sores and, according to the LPN, cried out in pain, "especially when trying to move her."

State A

Recertification survey (August 15, 2011), 4 pages: "The facility failed to adequately monitor five of five residents reviewed for antipsychotic medications (R13, R1, R5, R6, R12), in the sample of 15. Staff failed to complete assessments which identified targeted behaviors and addressed the response to or effects of the antipsychotic. Staff failed to document indications for use of antipsychotics and failed to have documented justification for excessive dosage of antipsychotics. Staff failed to maintain quantitative behavioral documentation to support the use of antipsychotics."

R13, who had severe cognitive/memory problems but no symptoms of psychosis, was given Risperdal and PRN Haldol intramuscularly. Behaviors warranting the drugs included yelling and hitting, but there was no behavior tracking. Staff reported, and Surveyors observed, the resident

sleeping. The physician declined the consultant pharmacist's recommendation to change the antipsychotic drugs for R12, who was "spending all her time in bed."

State A

Complaint survey (Feb. 10, 2011), 3+ pages: "The facility failed to monitor and evaluate the effects of Antipsychotic and Antianxiety medications for 4 of 4 sampled residents (R2, R5, R6, R4), in a sample of 6. The facility failed to document the rationale for use, to monitor, recognize and act on side effects for 1 of 4 sampled residents receiving 2 Antipsychotic medications concurrently."

R2, who had dementia-related psychosis, was legally blind and had significant hearing impairment. R2 was given Zyprexa for physical aggression during cares and for yelling. The social services questioned "if some of his aggressive behavior during cares is due to communication difficulties." The Director of Nursing told Surveyors, "'there are no assessments for psychoactive medications for anyone.'"

State A

Recertification survey (Nov. 10, 2011), 5½ pages: "The facility failed to ensure that residents receiving antipsychotic medications had appropriate indications for use, received gradual dose reductions, unless clinically contraindicated, and had adequate monitoring, and non-pharmacological interventions. This affected three of nine residents who received antipsychotic medication, (R10, R14, and R15) from a sample of twenty-six residents. Additionally: the Facility failed to follow their Psychotropic Medications Use of Psychotropic Medications Policy and Procedure."

The facility roster provided to Surveyors indicated that 44 of the 66 residents on the locked unit routinely received antipsychotic medications. R14, admitted April 15, 2001 with Alzheimer's dementia, spoke only Greek and no one on staff spoke or understood Greek. R14's April 21 assessment reported, "'communication problems may be mistaken as cognitive impairment. Will not develop Care Plan. Reason: No special interventions needed.'" R14 was given Risperdal for "'agitation/aggression/dementia/psychosis'" and received electro-shock therapy "for his diagnosis and history." R15, who was also identified as not speaking English, was given Risperdal for "'behavior disturbance/agitation," but the behavior logs for R15 did "not document any behavioral issues." R10 was given Seroquel for resisting care, conflict, and Alzheimers. In the ten months between R10's admission and the survey, staff documented three instances of combative behavior, all during toileting.

State B

Recertification survey (Dec. 22, 2011), 4+ pages: "The facility failed to ensure that residents did not receive unnecessary drugs. For Resident #10, the facility administered a daily dose of antipsychotic medication that had been discontinued. For Residents #8 and 14, the facility failed to attempt a gradual dose reduction for 2 of 9 sampled residents (#8, 10 and 14 [sic]) who received antipsychotic drugs in a total sample of 22 residents."

R10's health care proxy had refused Seroquel, but R10 continued to receive the antipsychotic drug for six weeks, until the time of the survey. The survey report did not identify outcomes for any of the residents.

State E

Recertification survey (Dec. 17, 2010), 5 + pages: "The facility failed to document ongoing assessment/monitoring of behaviors that required continued use of psychoactive medication (a medication that directly and chemically affects a person's mental state) for three residents (Residents #3, #6, and #13) and failed to obtain the diagnosis for one resident (Resident #6) who received a psychoactive medication. The facility identified 55 residents who received psychoactive medications. Thirteen residents were selected for review. The facility had a census of 65 residents."

In violation of the facility's antipsychotic medication use policy, cited by Surveyors, R3, who was on hospice care, received Haldol at night and five anti-anxiety medications for anxiety. Behavioral monitoring was started the day of the survey. R13 "had increased sexually inappropriate behavior and started on Risperdal."

State F

Recertification/Complaint survey (April 1, 2010), 6½ pages: "The facility failed to ensure 12 residents (Residents #1, #2, #4, #5, #6, #7, #11, #16, #18, #20, #21 and #24) of 12 residents, reviewed for being administered psychoactive medications, were adequately monitored for behaviors and/or side effects of the medications to ensure the necessity and effectiveness of the medications."

Six of the 12 residents received antipsychotic medications. Staff did not monitor for specific targeted behaviors for all six residents and failed to monitor for side effects for four residents. Sixty-eight residents in a resident census of 116 were taking psychoactive medications.

State F

Complaint survey (March 31, 2011), 7½ pages: "The facility failed to ensure each resident's drug regimen was free from unnecessary drugs for one (Resident #1) of two residents, who were administered the antipsychotic medication Seroquel, and did not receive proper monitoring and re-evaluation of the appropriateness of treatment, once adverse side-effects such as increased lethargy, sedation, agitation, restlessness, and falls became apparent."

On February 9, 2011, R1's physician gave orders to begin Seroquel, increasing the dosage every three days "with an ultimate dose of 600 mg" by February 23. R1 became increasingly lethargic, restless, and agitated as the dosage increased. The occupational therapist documented R1's increasing drowsiness and attributed her drowsiness to the medication. R1 had been making good progress in physical therapy until the dosage of Seroquel was increased. A certified nurse assistant also told Surveyors that R1 had been independent in all of her activities of daily living

at admission, but "changed after being at the facility and became confused, and she seemed like she was 'drugged up.'" The Assistant Director of Nursing said that Seroquel was begun because R1 cursed and yelled at times and "on one occasion tried to go into another resident's room." R1's psychiatrist told Surveyors that "part of the reason he started the resident on Seroquel was due to the family members, to include a husband and son, being concerned and upset with an intimate relationship she had started with another resident at the facility." R1 began falling as the dosage of Seroquel was increased and, on March 12, she fell, "sustaining a left hip fracture requiring hospitalization and surgery." Surveyors cited Lexi-Comp's Geriatric Dosage Handbook, the Food and Drug Administration's warning, and the drug manufacturer's warning for Seroquel.

State F

Recertification survey (Dec. 3, 2010), 4½ pages: "The facility failed to ensure for one (Resident #12) of nineteen residents reviewed: Resident #12 was not given an antipsychotic drug unless antipsychotic drug therapy was necessary to treat a specific condition as diagnosed and documented in the clinical record and received behavioral interventions in an effort to discontinue these drugs."

R12, admitted to the facility on November 10, 2010 with a diagnosis of senile dementia with delirium, had no diagnosis supporting the November 20, 2010 order for Seroquel. The November 9 order for a geriatric psychiatry/psychology consultation was never implemented. Asked why R12 was started on Seroquel, an LVN described R12's decline in condition, identified R12 as a fall risk, and reported that R12 said he wanted to go home. The LVN asked Surveyors if Seroquel was an antidepressant. Surveyors cited the discussion of Seroquel in Lexi-Comp's Geriatric Dosage Handbook.

C. Examples of level G (harm) deficiencies for antipsychotic drugs cited under F329

State A

Complaint survey (June 1, 2011), 3½ pages: "The facility failed to provide adequate monitoring with indications for use, diagnoses, behavioral tracking and interventions for 2 (R3, and R4) of 4 residents reviewed for medication in a sample of 7. This failure resulted in a decline in condition, and hospitalization for change in mental status and dehydration for R4."

R4 was admitted to the facility on February 9, 2011; she had "communication problems due to hearing and vision deficits." Her husband died at the facility on March 16 and nurses' notes documented that she cried when she talked about him. The physician prescribed Seroquel for "'agitation'" on April 6. R4 lost a significant amount of weight and was hospitalized on April 20 with diagnoses of mental status changes, dehydration, acute renal failure, urinary tract infection, and volume depletion. She was discharged back to the facility on April 27 for comfort care and died April 30. R3, recently widowed, was given Seroquel for agitation and paranoia. She was combative and attempted to leave the facility. After R3 was observed striking her roommate on May 10 (the first time R3 had ever hit anyone at the facility, according to the social worker), the facility told R3's Power of Attorney to find an alternate placement for her. The family

transferred R3 to another facility on May 12. Surveyors contacted the administrator at the second facility, who said she was aware of R3's history at the prior facility. The administrator told Surveyors that the second facility had ordered a complete medical workup of R3 "and found R3 had a urinary tract infection." The second facility had "no problems" with R3, according to the administrator.

State A

Recertification survey (July 28, 2011), 3½ pages: "The facility failed to attempt a reduction for two of ten residents (R8, R15) reviewed for antipsychotic medications in a sample of seventeen. R8 has developed an inability to sit or lay still in bed to rest. R8 is in constant motion and has developed a large abrasion to right back due to this constant motion. This failure resulted in the decline of R8 ability to function normally. R15 is unable to stay awake to eat or participate in activities."

R8, ambulating independently on admission in November 2009, had Alzheimer's Dementia, depression, anorexia, and anxiety. She was given Risperdal for yelling out and for being verbally abusive and resistive to care. The facility documented some of her involuntary movements. Surveyors observed R8 in "constant motion." The Director of Care Delivery told Surveyors there was "no clinical justification for the use of Risperdal." R8's physician declined the consultant pharmacist's recommendation to consider gradual dose reduction for Risperdal, saying "'patient doing very well as is. See no good reason to change treatment.'"

State C

Complaint survey (March 31, 2011), 3 pages: "The facility failed to ensure a drug regimen was free from unnecessary drugs for 1 of 1 sampled residents (#2). Resident 2 was observed to be drowsy, lethargic and somnolent at times."

R2 received Zyprexa, Depakote, and an excessive dose of PRN intramuscular Haldol. Surveyors cited considerable documentation of R2's sleeping and not being able to be roused for meals. Staff did not assess R2 for possible pain.

State F

Complaint survey (March 5, 2010), 3½ pages: "The facility failed to ensure that the resident's drug regimens were free from unnecessary drugs used in excessive doses and without adequate monitoring of possible adverse reactions for 2 of 11 sampled residents. (#3 and #2)."

R3 was given antipsychotic drugs when she was hospitalized in January 2010 for a psychiatric evaluation. Returning to the facility, she was "different" and "only wanted to sleep." The physician ordered that the prescribed dosage of Seroquel be reduced from 200 mg to 100 mg on February 16 and to 50 mg on February 18, 2010, but R3 continued to receive 200 mg (four times the prescribed dose) and "was hospitalized on 2/21/10 with altered mental status." R3's admission orders for her second hospitalization identified an "adverse reaction of meds" and indicated that R3 was allergic to Seroquel. During her second hospitalization, R3 was taken off

Seroquel and a family member reported that R3 "was returning to normal and becoming more like her old self." Surveyors cited Mosby's Nursing Drug Reference's description of Seroquel. R2 was given other drugs.

V. How Seven States Cite Antipsychotic Drug Deficiencies under F222

Some states cite antipsychotic drug deficiencies under chemical restraints, 42 C.F.R. §483.13(a), F222.

A. Proportions of antipsychotic drug deficiencies cited under F222

Four of the seven states cited a total of 14 antipsychotic drug deficiencies under F222 in 2010, 2011, and 2012 out of a total of 29 F222 chemical restraint deficiencies.

Table 7: Proportions of antipsychotic drug deficiencies cited under F222

State	Number of F222 deficiencies	Number of antipsychotic drug deficiencies	Percentage of F222 deficiencies for antipsychotic drug
State A	11	5	45%
State B	0	0	0
State C	0	0	0
State E	4	2	50%
State F	5	1	20%
State I	0	0	0
State J	9	6	66%
Total	29	14	48%

B. Recertification and complaint surveys

Half of the antipsychotic drug deficiencies cited under F222 were cited following recertification surveys, half, complaint surveys.

Table 8: Antipsychotic drug deficiencies cited under F222 in recertification and complaint surveys

State	Total number of F22 antipsychotic drug deficiencies	Number cited in recertification surveys	Number cited in complaint surveys
State A	5	3	2
State B	0	0	0
State C	0	0	0
State E	2	2	0
State F	1	1	0
State I	0	0	0
State J	6	1	5

Total	14	7	7

C. Scope and severity levels of antipsychotic drug deficiencies

Twelve of the 14 antipsychotic drug deficiencies (86%) were cited at no harm levels (levels D and E); two (14%) were cited at level G.

Table 9: Scope and severity levels of antipsychotic drug deficiencies cited under F222

State	Total number	Recertification Survey D	Recertification Survey E	Complaint Survey D	Complaint Survey E	G
State A	5	2	1	1	0	1 (complaint)
State B	0	0	0	0	0	0
State C	0	0	0	0	0	0
State E	2	2	0	0	0	0
State F	1	0	1	0	0	0
State I	0	0	0	0	0	0
State J	6	0	4	0	1	1 (certification)
Total	14	4	6	1	1	2

VI. Examples of antipsychotic drug deficiencies cited under F222

Surveyors' descriptions of F222 deficiencies are similar to their descriptions of F329 deficiencies.

A. Level D (no harm) deficiencies for antipsychotic drugs cited under F222

State A

Complaint survey (March 25, 2010), 1 page: "The facility failed to use other interventions prior to giving Haldol, failed to obtain a written or verbal consent, or have a diagnosis to warrant the use of Haldol with 1 of 3 residents on the sample reviewed for Psychotropic medication use, (R4)."

R4 had Alzheimer's and dementia. Transfer orders from the hospital included Seroquel at bedtime and Haldol intramuscularly every 4 hours PRN. When R4 returned from the hospital at 8:00 a.m. on March 17, he said he did not want to go to bed "and the nurses immediately gave R4 a Haldol injection." The nurse told Surveyors "that R4 was not being combative nor causing any major problems but just did not want to go to bed." The Director of Nursing told Surveyors that the nurse was no longer at the facility "and that this had been a problem with this nurse."

State E

Certification survey (June 1, 2012), 3½ pages: "The facility failed to appropriately assess, intervene and utilize other interventions before a chemical restraint was administered for one of 19 sampled residents (Resident #9). The census was 110."

R9 had dementia and Alzheimer's disease, seizure disorder anxiety and depression. Surveyors found no diagnosis documenting the need for Haldol, but there was a physician order for PRN Haldol. Nursing notes indicated that at 7:00 p.m. on May 23, R9 kept standing up from his/her wheelchair, which triggered the personal safety alarm (PSA). Nursing notes report, "The resident continues to trigger the PSA. Haldol 2 mg given then the resident was sent to bed." Medication administration records indicated multiple times when R6 was given PRN Haldol, but no behaviors or interventions were noted. On May 24, Surveyors observed a licensed practical nurse telling R6 that she had a vitamin for her. R6 at first said he/she did not want a pill, but the LPN said the pill would help get R6 strong and keep her standing. R6 took the pill, which was Haldol, not a vitamin.

State J

Complaint survey (April 4, 2011), 1 page: "The facility failed to ensure that one of nine residents reviewed (Resident R7) had the right to be free from chemical restrains used for staff convenience."

R7, who had diagnoses of alcohol induced dementia, anxiety and encephalopathy, preferred a bed bath and was dependent for bathing. His care plan indicated that he should be offered a bed bath "if he refused a shower or tub bath" and that staff should "leave the resident and return at a later time, offer an alternative caregiver, and explain the risks of refusing." The physician ordered PRN Haldol for agitation. The licensed practical nurse told Surveyors that R7 "would fight the girls before a shower; therefore, she gave him Haldol to make him more compliant." The Director of Nursing told Surveyors she did not know that Haldol was being used as a chemical restraint and contacted the physician during the survey to get the use of Haldol on shower days discontinued.

B. Level G deficiencies for antipsychotic drugs, F222

State J

Recertification survey (Feb. 7, 2012), 2½ pages: "The facility failed to assure that less restrictive interventions were attempted prior to the administration of an anti-psychotic medication by injection to four out of 24 residents reviewed (Residents: G13, G2, C6, and C23), resulting in actual harm to resident C6."

Facility policy for Behavior Management Guidelines require a physician order, including diagnosis and targeted behavior, prior to the initiation of antipsychotic drugs. The policy also provides that "antipsychotic drugs will not be used if the only indication is one or more of the

following: restlessness, anxiety and agitated behaviors that do not represent danger to the resident or others." Resident C6 had diagnoses of depression and anxiety. He was given Seroquel at bedtime. On November 3, when he became combative and struck a staff member, staff called the physician, who ordered intramuscular Haldol PRN for agitation and combative behavior. He was given intramuscular Haldol at12:00 a.m. and 5:30 a.m. (and Ativan at 6:00 a.m.) and at 11:24 a.m., he "was found to be very catatonic, rigid, with his neck tight and upper extremities tight and contracted." No interventions had been tried before the Haldol was administered. A similar incident occurred on November 15, when C6 was given Haldol and Ativan and then found again in a catatonic state. The three other residents were given Haldol or Haldol and Risperdal without evidence that residents' behavior warranted the drugs or that staff attempted less restrictive interventions.

C. Little overlap in deficiencies cited under F329 and F222

State A cited both F329 and F222 in a single survey, classifying both deficiencies at level E. State J cited F222 in one survey and F329 six months later in another survey, both at level D. Aside from these two examples, there was no overlap in states' use of F329 and F222 for antipsychotic drugs.

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