

IN A STUPOR

WHAT CALIFORNIA'S ANTIPSYCHOTIC DRUG COLLABORATIVE REVEALS ABOUT ILLEGAL NURSING HOME DRUGGING

A SPECIAL REPORT BY:

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Executive Summary

Over 25,000 residents of California nursing homes – nearly one in four – receive an antipsychotic drug. The vast majority of these administrations are “off-label” for dementia, meaning they have not been approved by the FDA for that purpose.¹ More critically, antipsychotic drugs have an FDA-mandated Black Box warning label telling people with dementia that the drug increases (almost doubles) their risk of death.

The misuse of antipsychotic drugs is a leading form of elder abuse in nursing homes. Far too often, nursing homes use these powerful drugs as a substitute for needed care with the purpose of sedating or subduing residents who have dementia. Dozens of clinical studies, reports, and media stories have raised serious concerns that these drugs are endangering the lives of elderly nursing home residents.² In response, CANHR has launched a campaign to stop the use of chemical restraints in nursing homes.³

After years of CANHR pleading with California state officials to take action on this epidemic of dangerous drugging, the Department of Public Health (“DPH”) launched an Antipsychotic Drug Collaborative to inspect selected facilities with potential drugging problems. The results have been stunning, finding 147 violations in 24 facilities, an average of 6.1 deficiencies per facility.

The extent of the violations found by the Collaborative is extremely troubling. Forty-one different regulatory rules were violated, ranging from failure to ensure residents have physicians to deficient patient records. Most violations, however, fell within three categories:

- Failure to obtain informed consent from residents or their responsible parties for drugs;
- Use of unnecessary drugs or drugs in excessive dosage; and
- Deficient pharmaceutical consultant services.

The deficiencies found in each of these three classes demonstrate a nursing home industry with a terrible drug problem. Rules intended to protect residents from unnecessary or dangerous drugs go unheeded and, in some cases, nursing home staff members were oblivious to the rules in the first place. In other cases, staff members flat-out lied about having obtained consent before administering drugs.

The extent of antipsychotic drug misuse is not solely the fault of nursing homes. For nearly a generation, DPH has overlooked, ignored, and apologized for providers that inappropriately drugged residents. Fewer than four citations are issued per year for illegal drugging and virtually no disincentives exist to force providers to abide by resident protections. Quite simply, DPH has done virtually nothing to reduce the number of illegally drugged residents in California. Its Collaborative findings are a cry for further state action. We call on DPH to use its significant tools for enforcement, policy, and education to immediately and finally address this crisis of chemical restraints.

Citations vs. Deficiencies – What’s the Difference?

When a nursing home has violated an applicable rule, DPH has discretion regarding what enforcement action it will take. Citations are issued when DPH determines that the health, safety, or security of a resident was significantly affected. Citations include a monetary fine to discourage future wrongful conduct. Deficiencies are issued when a state rule violation is found but is determined not to have threatened the health, safety, or security of a resident. No monetary fines are issued. The Collaborative so far has issued 147 deficiencies but no citations.

1. A May 2011 U.S. Office of the Inspector General Report found that 83% of nursing home residents who received an atypical antipsychotic received it for an off-label use (the report is available at <http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>).

2. Information on studies and news reports are posted at: <http://www.canhr.org/stop-drugging/news-and-resources>.

3. Information on the campaign is available at CANHR’s stop-drugging website: www.canhr.org/stop-drugging/.

The CDPH/DHCS Long-Term Care Antipsychotic Drug Utilization Collaborative

In 2010, DPH – the agency tasked with licensing and monitoring nursing homes in California – initiated its Collaborative with the Department of Health Care Services (“DHCS”). The stated goal of the Collaborative is to “identify facilities where inappropriate antipsychotic medication is being used and once identified, [ensure] corrective action is implemented.” DPH agreed to investigate the propriety of antipsychotic use involving specific Medi-Cal beneficiaries identified by DHCS, primarily those who were receiving more than one antipsychotic drug that was paid for by Medi-Cal, California’s Medicaid program.⁴

By July 2011, DPH had completed 32 investigations at 24 facilities (some facilities were investigated twice), reviewing approximately 86 resident cases. As a result of the investigations, 147 deficiencies were issued, finding fault in all phases of antipsychotic drug administration - from insufficient indications for use to failure to implement long-term dose reductions. Every investigated facility received at least one deficiency, indicating that illegal drugging is as widespread as it is deep.

What is it About Antipsychotics that Merits These Investigations?

Antipsychotic medications are the current treatment of choice for severe psychiatric conditions like schizophrenia. Antipsychotics are not approved for treating dementia by the FDA. Despite this lack of approval, people with dementia - particularly those living in nursing homes - are drugged with antipsychotics at an alarming rate. In California, over 25% of all nursing home residents receive an antipsychotic drug.⁵ A recent federal Office of the Inspector General (“OIG”) report found 83% of all residents who received atypical antipsychotics paid for by Medicare receive them for an “off-label” use, reinforcing the notion that antipsychotics are often given to residents without clinical justification.

The extremely high rate of usage is especially alarming because antipsychotics have severe side effects for elderly people with dementia. In fact, the use of antipsychotics nearly doubles their risk of death. The increased mortality prompted the FDA to require a Black Box warning label on all antipsychotics, intended to tell users of the risk of death. Unfortunately, nursing home residents and their representatives rarely see these warnings and usually are not told about them.⁶

Another reason why antipsychotic use in nursing homes deserves scrutiny is the drugs are often administered as chemical restraints, i.e., they are given to control nettlesome behaviors and render residents more “manageable” instead of treating clinically indicated conditions. Although state and federal laws require that psychotropic drugs only be used if other less severe alternatives are impractical or unsuccessful, antipsychotics are often used as the first line of treatment whenever behavioral issues arise for a person with dementia.⁷

Title 22 of the California Code of Regulations Section 72018 defines a CHEMICAL RESTRAINT as:

*“a drug used to control behavior and used in a manner **not required** to treat the patient’s medical symptoms.”* [emphasis added]

All residents have a right to be free from the use of chemical restraints. (42 CFR §483.13(a); 22 CCR §72527(a)(23); 22 CCR §72319)

4. Of course, Medi-Cal does not pay for most antipsychotic drugs in California nursing homes. Medicare, through its Part D prescription drug benefit, pays for most antipsychotic drugs.
5. For more information about the rate of antipsychotic drug use in California nursing homes, including each individual facility’s rate, go to www.canhr.org/stop-drugging.
6. The recent OIG report found 88% of residents on atypical antipsychotics paid for by Medicare receive them contrary to the Black Box warning label.
7. Antipsychotic usage is receiving increased federal scrutiny. Senator Herb Kohl recently introduced a bill that would require physicians to complete a written certification form before prescribing atypical antipsychotics for nursing home residents. This requirement is expected to guard against unnecessary, costly antipsychotic prescriptions.

Analyzing the Collaborative’s Findings

Informed Consent is Often Neglected and Occasionally Outright Fabricated.

Informed consent is a key legal right that requires doctors to respect the decisions of their patients. Informed consent requires doctors and health facilities to inform patients about the purpose, risks, benefits, and alternatives to a proposed treatment and then allow them to accept or reject it. The right to informed consent is supported by nearly a century of legal rulings and more recent laws and regulations, including specific rights of nursing home residents to informed consent before psychotropic drugs are used.⁸ If a patient is unable to provide informed consent due to a cognitive disability, the right must be exercised by a surrogate.

The Collaborative investigations revealed that 15 of the 24 sampled nursing homes had violated at least one rule regarding informed consent. The most common violation was the failure to obtain the consent of the resident or a surrogate before administering a psychotropic drug (10 facilities). Another common violation was the failure to involve the resident’s physician in the informed consent process. Staff members typically identify the condition to be treated, initiate a request for a medication, and then await approval. In the interim, the physician makes her prescription based on information provided by the staff and does not actually observe the condition at issue. The physician often writes the prescription with no regard for informed consent, at best relying on inadequately trained nursing home staff to obtain informed consent. In these cases, informed consent is often incomplete; in other cases, it is simply not obtained at all.

Perhaps the most striking revelation of the Collaborative findings is the incidence of outright informed consent fraud. In three facilities, staff members were trained to reflexively falsely enter a notation into residents’ medical records that informed consent had been obtained before administering psychotropic drugs. In another facility, informed consent was a total farce: a physician signed a form indicating she had obtained informed consent almost two months after initiating an antipsychotic prescription. The name of the medication, the name of the resident, and the signature of the surrogate decision maker were all blank on the form.

Taken together, the myriad informed consent violations show that the clinical and policy goals of the legally mandated informed consent process are not being satisfied. Residents or their surrogates are not given a meaningful chance to weigh the costs and benefits of proposed psychotropic drugs and the values of the patient are not reflected in their course of treatment. As a result, residents are being involuntarily and dangerously drugged.

Collaborative Findings – INFORMED CONSENT

<u>Regulation (Title 22)</u>	<u>Description</u>	<u># of Facilities in Violation</u>	<u>% of Facilities Investigated</u>
72527(a)(5); 72527(e)(1)	No facility policy regarding informed consent	3	13%
72528(a)	Incomplete informed consent forms (no Black Box warning information); physician did not obtain informed consent; or informed consent was fraudulent	11	46%
72527(e)(2); 72528(c)	Informed consent not obtained prior to antipsychotic administration	10	42%
TOTALS	Informed Consent	15	63%

8. Title 22, California Code of Regulations, Section 72528. DPH has recently issued a policy declaration clarifying the role of nursing homes in verifying informed consent (see <http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-11-08.pdf> and <http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-11-31.pdf>)

Sample Informed Consent Violations:

1) Fraudulent Informed Consent - American River Care Center, Investigation #CA00228746

“During a telephone interview on 5/18/10 at 1 p.m., Resident 4’s wife indicated that she had not been contacted by Resident 4’s physician on 4/12/10 regarding information related to Seroquel, including potential adverse effects, alternative treatments available or potential benefits.

During an interview at 1:55 p.m., AS [administrative staff] 2 confirmed the medical record findings and acknowledged that Resident 4’s physician had not obtained informed consent prior to initiating Seroquel on 4/12/10. AS 2 further acknowledged that Resident 4’s wife should have been contacted by his physician to obtain informed consent. *AS 2 was unable to explain why the licensed nurse had documented Resident 4’s physician obtained informed consent on 4/12/10.*” [emphasis added]

2) Physician Not Involved in Informed Consent - Gilroy Healthcare and Rehabilitation Center, Investigation #CA070000040

“[Doctor] explained that informed consents were obtained by the facility, explaining, ‘I don’t do informed consents.’”

Unnecessary and Excessive Drugging

Nursing homes are prohibited from administering psychotropic drugs in excessive doses or when not clinically indicated. Such an administration is often called a “chemical restraint.” Several state laws and regulations are intended to prevent unnecessary or excessive use of psychotropic drugs in nursing homes.

The Collaborative’s 32 investigations demonstrate that, despite restrictive prescribing guidelines and prohibitive state regulations, nursing homes frequently administer antipsychotic drugs to residents in a manner that is sloppy, inappropriate, and unsafe. Over two-thirds of the investigated facilities were faulted for at least one violation of a chemical restraint regulation. The nature of the violations indicate that antipsychotics are used without specified objectives (nine facilities) or for inappropriate purposes such as to control behaviors that are not indicative of physiological brain problems (seven facilities). In one case, a resident who was dying and receiving hospice care was drugged with Haldol three times a day for having told a staff member to “shut the heck up.”⁹ Once the drugs are initiated, they are often poorly monitored for side effects and are not assessed for efficacy (12 facilities – half of those surveyed).

Upon examination of the Collaborative findings, one can only conclude that misuse of antipsychotic drugs is rampant in California nursing homes. Over half of the facilities investigated were found deficient with respect to at least one regulation intended to prevent unnecessary or excessive drugging. As a result, residents are being unnecessarily drugged with dangerous and often contra-indicated antipsychotics.

Collaborative Findings – Unnecessary and Excessive Drugging

<u>Regulation (Title 22)</u>	<u>Description</u>	<u># of Facilities in Violation</u>	<u>% of Facilities Investigated</u>
72311(a)(1)	No stated objectives to be accomplished by antipsychotic administration	9	38%
72319(j)	Failure to evaluate drug effectiveness and adverse reactions	10	42%
72375(c)	Inappropriate antipsychotic use; failure to properly assess efficacy or consider gradual dose reduction	8	33%
TOTALS	Unnecessary and Excessive Drugging	17	71%

9. Applewood Care Center, Investigation #CA030000089

Sample Unnecessary Drugging Violations:

1) Inappropriate / No Indications for Antipsychotic Use - Empress Care Center, LLC, Investigation #CA070000050: “A review of the clinical record on 06/14/11 at 12:30 P.M. indicated the Zyprexa indication was for resisting care. The nursing supervisor stated that resisting care meant Patient 3 refused to shower, dress, and be groomed (activities of daily living). She said poor self-care would be resisting care.”

2) Inappropriate / No Indications for Antipsychotic Use - Herman Health Center, Investigation #CA070000057: “A review of the clinical record indicated the following psychotropic indications:
Seroquel indication wandering
Thorazine indication wandering
According to the facility policy wandering would be an inadequate indication.”

Consultant Pharmacists

The third set of nursing home rules regarding antipsychotic drug use that are violated with striking regularity involve consultant pharmacists. These pharmacists are intended to ensure the safe and effective use of medications in the nursing home by reviewing residents’ drug records on a monthly basis and advising facility staff and physicians of unnecessary use, harmful interactions, drug irregularities, and dosing and duration concerns.

Notwithstanding their vital role, the Collaborative investigations found that consultant pharmacists almost universally failed to protect residents from inappropriate use of antipsychotics. In 18 of 20 nursing homes where antipsychotics were misused – 90% of the cases – DPH found that the consultant pharmacists failed to identify the inappropriate use.

The consultant pharmacists’ abysmal failure to protect residents from chemical restraints is directly tied to their lack of independence. Independence is critical to the effectiveness of consultant pharmacists. If the consultant has financial ties to the facility or a pharmaceutical manufacturer or distributor, her oversight may be compromised by financial incentives. In such a case, the consultant may recommend drug use that is more consistent with profit than with positive patient outcomes.¹⁰ To limit the possibility of outside financial influence, California regulations require nursing homes to pay market rates for consultant pharmacy services.¹¹ Services provided below cost may be used as an enticement to nursing homes to enter into pharmacy contracts and the provider makes up the difference by providing or recommending certain drugs.

The Collaborative investigations found pervasive evidence that consultant pharmacists lack independence. Three-fourths of the reviewed nursing homes were found to have pharmacy services provided below cost, suggesting consultant independence is highly compromised in California. Some consultants were paid substantially less than half of the prevailing market rate. Consultant pharmacists seem to be working against the interests of the residents they are charged with protecting, undertaking their task with financial conflicts of interest and acting as drug enablers.

10. The concern regarding consultant pharmacist independence is so great the Center for Medicare Services recently issued a Notice of Proposed Regulation to require nursing homes use consultant pharmacists who are unaffiliated with a long-term care pharmacy. The proposed regulation points out the enormous risk to patient safety posed by financial influence among consultants. In support of the notion that consultant integrity is unacceptably compromised, CMS points out the high rate of antipsychotic drug use in nursing homes for residents with dementia. Despite FDA Black Box warning labels and reports of rampant misuse, administration of antipsychotics in nursing homes continues unabated. CMS states “it is reasonable to presume that the incentives present in the relationships among consultant pharmacist, LTC pharmacies and drug manufacturers can influence the prescribing practices reflected [by the rate of misuse].” (76 Fed. Reg., No. 196, p. 63072)

11. Title 22, California Code of Regulations, Section 72353.

Collaborative Findings – Pharmaceutical Service

<u>Regulation (Title 22)</u>	<u>Description</u>	<u># of Facilities in Violation</u>	<u>% of Facilities Investigated</u>
72525	Defective pharmaceutical service committee	4	17%
72353	Pharmaceutical services provided below cost	18	75%
72375	Failure to note drug irregularities	15	63%
TOTALS	Pharmaceutical Service	19	79%

Sample Consultant Pharmacist Violations - Failure to Note Drug Irregularities:

1) Windsor Care Center of Sacramento, Investigation #CA030000160: “The consultant pharmacist failed to identify drug therapy irregularities . . . related to

1. Resident 1 failed to receive his diabetic medication . . . for over two months.
2. Resident 2 was receiving ‘as needed’ Haldol (an antipsychotic medication) for an indication not in accordance with the facility’s policies and procedures [or federal guidance].”

2) Hillcrest Manor Sanitarium, Investigation #CA080000064: The consultant pharmacist failed “to notify the Director of Nurses and Administrator of the concurrent use (used together at the same time) of contraindicated drugs (drugs with explicit warnings against their concurrent use). Patient 1 was placed at risk of experiencing a potentially serious adverse drug event.”

3) Hillside Senior Care, Investigation #CA020000101: When the consultant pharmacist was asked why he failed to identify the lack of clinical rationale for administering two antipsychotic medications, “he said he would respond at a later time.” He also failed to note that “gradual dose reduction for either of the antipsychotic medications were conducted, attempted, or contra-indicated.”

*Windsor Care Center of Sacramento, Hillcrest Manor Sanitarium, and Hillside Senior Care were all issued deficiencies for accepting pharmacy services below cost.

Conclusions

The Collaborative Results Demonstrate California Nursing Homes Have a Huge Drug Problem.

The results of the Collaborative investigations demonstrate that nursing homes do not comply with state rules meant to protect residents from unsafe drugging or from the use of psychotropic drugs as a form of chemical restraint. Informed consent violations were rampant in many facilities, meaning residents were often given powerful antipsychotic medications (in these cases more than one) without being told about the significant risks involved or even what they were being given. Over 70% of the surveyed facilities were guilty of unnecessary or excessive drugging, showing an epidemic of misuse of antipsychotic drugs, often as a blatant chemical restraint. Finally, more than three-quarters of nursing homes were found to have regulatory deficiencies in their pharmaceutical services, revealing pharmacist consultants with potentially compromised integrity and very poor job execution. Overall, nursing home use of antipsychotic drugs is marked by failure and mistreatment, leaving residents vulnerable to decreased quality of life and even unwitting physical danger.

A Little DPH Energy Goes a Long Way.

The Collaborative is remarkable for two reasons. One, its investigations revealed rampant rule-breaking among nursing homes regarding the use and misuse of antipsychotic drugs. But another significant aspect is that the Collaborative happened at all. Although California rates of antipsychotic use in nursing homes have been unacceptably high for decades, roughly seven times the use of physical restraints, DPH has shown little interest in meaningfully addressing misuse. Citations for misusing psychotropic drugs remain rare and meaningful attention like that of the Collaborative have been virtually nonexistent. This head-in-the-sand attitude has enabled many nursing homes to inappropriately drug an entire generation of residents.

In the case of the Collaborative, DPH finally dedicated some of its resources to focus on antipsychotic drug use. For this, DPH and the employees who conducted the investigations should be commended. It is evident the employees were well-versed in state regulations and took their charge to carefully examine individual records quite seriously. By looking at a mere estimated 86 resident files, the investigators identified 147 violations, some of which included facility-wide practices. The good work of these investigators has confirmed that antipsychotic drug use in California nursing homes is indeed a crisis that DPH should finally treat as a top priority.

The essential work of the Collaborative is tempered by the handicaps set upon it. The scope of the Collaborative was much more narrow than it should have been.

- The investigations examined drugging practices at less than 3% of California nursing homes.
- DPH has not enforced any of its findings with citations and monetary fines.
- DPH has not posted its findings, or antipsychotic use rates by nursing homes, virtually hiding this information from the general public.
- Only records of residents whose antipsychotic medication was paid for through the Medi-Cal program were reviewed. Since the Medicare prescription drug benefit was created in 2004, most nursing home resident drugs are paid for by Medicare.
- The Collaborative ignored federal rules regarding antipsychotic drug use in its investigation. Inexplicably, the Collaborative chose to narrow its application of medication standards to state regulations, foregoing an ample and perhaps more demanding body of applicable law and preventing its findings from becoming part of the facility ratings on the federal Nursing Home Compare website.
- Residents with two or more antipsychotics - the primary target of the Collaborative - are more likely to have a diagnosis of mental illness and have arguably more clinical justification for use than a person with dementia for whom antipsychotic use is considered off-label.

Despite the limitations imposed on the Collaborative investigators, they have confirmed the chemical restraint crisis in California nursing homes. Statewide data have long demonstrated the high quantity of residents receiving antipsychotic drugs but the Collaborative has exposed the low quality of the prescribing practices, revealing a system where drugging is often performed haphazardly and unsafely.

Recommendations

The striking Collaborative findings can and should spur statewide efforts to reduce the misuse of antipsychotic drugs. DPH needs to take immediate action to prevent further resident abuse. CANHR makes the following recommendations to DPH to achieve this goal.

1. Submit a report to Governor Brown summarizing the Collaborative findings and making recommendations for action to remedy the antipsychotic drug epidemic. The report would be consistent with DPH's directive from former Governor Schwarzenegger in his veto message for SB 303.¹² Copies of the report should be sent to the Senate and Assembly Health and Aging Committees.
2. Post the Collaborative findings on the DPH Consumer Information System (CIS) website, so residents, prospective residents, and their family members can more comprehensively review a facility's enforcement history and quality of care offered. In addition, the facility-specific rates of psychotropic drug use should also be posted.
3. Conduct Collaborative-style investigations on every nursing home that has an antipsychotic use rate of 50% or more. The focus of the Collaborative thus far has been anchored to individual residents – primarily those receiving more than one antipsychotic paid for by Medi-Cal. In the future, the Collaborative may be more effective if it focused on facilities with exceptionally high rates of antipsychotic drug use.
4. Adopt CANHR's proposed procedures for investigating compliance with informed consent requirements during facility annual inspections. In a nutshell, CANHR's procedures guide surveyors to review the records of five residents receiving antipsychotic drugs for compliance with applicable informed consent regulations and audit compliance directly with the affected resident. (CANHR's proposed protocol can be found at <http://canhr.org/ToxicGuide/PDFs/InformedConsentProtocol.pdf>)
5. Take real enforcement action that creates an actual disincentive to misusing psychotropic drugs. When confronted with egregious regulatory violations like fraudulent informed consents, blatant chemical restraints, and total failure to have policies and procedures regarding psychotropic drug use, the Department should issue citations accompanied by monetary fines. Issuing state-level deficiencies that stay tucked away in a facility's file and not reported to public consumer information systems do not encourage improved behavior nor inform consumers. Real enforcement action, in the form of citations and federal action, is needed.
6. Support legislation that would render the delivery of antipsychotics to nursing home residents without informed consent an automatic A or AA-level citation, with a minimum \$10,000 fine.
7. Provide educational outreach to providers. The Department has uncovered a shocking level of poor practice regarding the use of psychotropic drugs. Education is needed in addition to enforcement. Educational efforts could include sample informed consent forms or policies and procedures as well as teaching non-pharmacological alternatives for treating dementia symptoms. CANHR invites the Department to join us in promoting the least medicating approach to providers throughout the state.
8. Ensure the independence of pharmaceutical consultants. A striking aspect of the Collaborative findings is the overwhelming failure of pharmaceutical consultants to carefully audit psychotropic drug use. The rules regarding consultants need real reform. Recently proposed federal regulations are seeking to “sever” the relationship between consultants and the pharmacy, drug manufacturers and distributors to ensure financial arrangements do not influence consultant decisions. DPH should support the adoption of the regulations and educate the Center for Medicare Services about the state's trouble with pharmaceutical consultants.

12. The Governor's veto message stated, in part: “I have instructed [DPH] to identify providers that may be inappropriately prescribing these medications and thereby posing a threat to the health and safety of residents in skilled nursing facilities. If the department's analysis indicates that such inappropriate prescribing behavior is occurring and recommends statutory changes in this area, I ask the Legislature to immediately seek changes to correct it.” (for the full veto message, go to http://www.canhr.org/stop-drugging/wp-content/uploads/2010/07/SB303_Alquist_Veto_Message.pdf)