DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Psychotropic Drug Use in Nursing Homes

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EXECUTIVE SUMMARY

PURPOSE

To assess the extent and nature of inappropriate psychotropic drug use in nursing homes and how it relates to chemical restraints.

BACKGROUND

The Senate Special Committee on Aging requested that the Office of Inspector General look at the extent to which psychotropic drugs in nursing homes are being used as inappropriate chemical restraints. Usage rates for these drugs have been increasing since 1995. A chemical restraint is the use of a drug to control an individual's behavior and is legally appropriate only if used to ensure the physical safety of residents or other individuals.

Psychotropic medications are drugs that affect brain activities associated with mental processes and behavior. They are divided into four broad categories: anti-psychotic; anti-depressant; anti-anxiety; and hypnotic medications. The Centers for Medicare & Medicaid Services established guidelines for the appropriate use of these drugs in nursing homes. Several programs exist to monitor the quality of care in nursing homes, including the appropriate use of psychotropic drugs. These include the nursing home survey and certification process and the State Long Term Care Ombudsman program.

We combined five methods for this inspection: 1) a medical record review of 485 nursing home residents taking psychotropic drugs; 2) an analysis of survey and certification and ombudsman program data; 3) an assessment of 135 nursing home Drug Regimen Reviews; 4) on-site visits to 10 nursing homes; and 5) a telephone survey of 20 survey and certification and ombudsmen staff. We excluded anti-depressants from our review.

FINDINGS

Psychotropic drug use in nursing homes is generally appropriate

Eighty-five percent of residents' psychotropic drugs use is medically appropriate. Nearly all have the potential to benefit functionally from their drug therapy and are using the drugs within Medicare guidelines for appropriate use.

Another 8 percent of residents are using psychotropic drugs inappropriately. These drugs are inappropriate for one or more of the following reasons: the dose is too high because

appropriate dose reductions are not followed; there is unjustified chronic use of the drug; there is no documented benefit to the resident; the wrong type of drug is being given for a particular diagnosis; and there is unnecessary duplicate drug therapy. The use of psychotropic drugs as an inappropriate chemical restraint does not appear to be widespread; our medical record reviewers could not conclusively determine that any of the inappropriate drug use was a chemical restraint. Finally, for 7 percent of residents, reviewers could not determine the appropriateness of their psychotropic drug use due to insufficient medical record documentation.

Data from survey and certification and ombudsman programs support the findings of the medical record review

Deficiencies from the Online Survey Certification Reporting System that directly cite the misuse of chemical restraints and psychotropic drugs are not common. Deficiency tag F222, (inappropriate chemical restraints) comprises 0.08 percent of all deficiencies in the current survey and has decreased slightly over the past four surveys. Further, tag F329 (unnecessary psychotropic drugs) comprises 2 percent of all deficiencies in the current survey and has remained constant. Also, most surveyors in our sample States concur that inappropriate chemical restraints are not common.

Similarly, Ombudsman complaints specific to the inappropriate use of chemical restraints and psychotropic drugs are not prevalent. In 1999, complaints about physical and chemical restraints accounted for 1 percent of all nursing home complaints, while those about the use of psychoactive drugs comprised just 0.25 percent of the total.

A growth in the proportion of nursing home residents with mental disorders may contribute to increasing psychotropic drug rates

Data from the Online Survey Certification Reporting System show that from 1995 to 1999 the overall national drug usage rate for anti-psychotics grew from 16 to 19.4 percent. During this time period, anti-anxiety drug rates increased from 14.3 to 15.7 percent. At the same time, data from this system show that over the last four surveys the proportion of residents with a documented psychiatric disorder, excluding dementia, increased from 13 to 16 percent and the proportion with behavioral symptoms grew from 29 to 31 percent. Further, numerous articles have linked the increasing prevalence of mental disorders among nursing home residents to higher psychotropic drug rates.

CONCLUSION

In response to concerns expressed by the Senate Special Committee on Aging about the use of psychotropic drugs as inappropriate chemical restraints in nursing homes, this report finds that these drugs are generally being used appropriately. While drug usage

rates for anti-psychotic and anti-anxiety medications have been rising, most psychotropic drug use in nursing homes is medically appropriate. Where it is inappropriate, the problems do not appear to be related to inappropriate chemical restraints but rather to inappropriate dosage, chronic use, a lack of documented benefit to the resident, and inappropriate duplicate drug therapy. We do note, however, that lack of adequate documentation for residents' psychotropic drug use is of some concern. The Centers for Medicare & Medicaid Services may consider educating providers to better document the appropriate use of these drugs.

AGENCY COMMENTS

We received comments on the draft report from the Centers for Medicare & Medicaid Services. They believe that the report will contribute to a better understanding of psychotropic drug use in nursing homes and in identifying areas for further focus. The CMS also notes that training related to psychotropic drug use and related documentation issues is already underway or planned.

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INTRODUCTION

PURPOSE

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BACKGROUND

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We are also releasing a companion report entitled "Psychotropic Drug Use in Nursing Homes Supplental Information - 10 Case Studies," OEI-02-00-00491, which presents information from on-site visits to ten nursing homes.

Psychotropic Medications

Psycho-pharmacologic medications are drugs that affect brain activities associated with mental processes and behavior. These drugs are also called "psychoactive" or "psychotherapeutic" medications. For clarity, we will refer to this class of drugs throughout our study as "psychotropics." Psychotropic medications are divided into four broad categories: anti-psychotic; anti-depressant; anti-anxiety; and hypnotic medications.

Anti-psychotic Drugs. Anti-psychotic medications are used to treat various psychoses and neurologic conditions. These include schizophrenia, schizoaffective disorder, delusional disorder, psychotic mood disorder, acute psychotic episode, Tourette's syndrome, and Huntington's disease. Other indications for long-term anti-psychotic use in the elderly are organic mental syndromes (including dementia with associated psychotic and/or agitated features defined by "certain behaviors" that are harmful to self or others) and mood disorders with psychotic features.

Anti-psychotics are classified as either "conventional" or "atypical." Conventional anti-psychotics have several serious side effects. These side effects prompted the development of newer drugs called atypical anti-psychotics, which came onto the market

in the mid 1990s. Clinical trials have demonstrated their effectiveness for a variety of disorders in the elderly, including schizophrenia and other psychoses. Although atypical anti-psychotics elicit fewer adverse reactions, other characteristics of these drugs, such as the effects on resident's cognition, have not been thoroughly tested.[1]

Anti-depressant Drugs. Anti-depressant drugs are usually used in the treatment of depression and agitation. Anti-depressants in low dosages are also used to treat insomnia. Side effects include excessive sedation, anti-cholinergic effects (dry mouth, constipation, urinary retention, blurred near vision, rapid heart rate, confusion, and disorientation), orthostatic hypotension (which can predispose a resident to falls), and electro cardiographic changes. Most anti-depressants have a long enough half-life that the elderly, who have lower tolerance levels for most drugs, require smaller and less frequent doses.

Anti-anxiety and Hypnotic Drugs. Anti-anxiety drugs are used for the short-term management of anxiety and insomnia. Hypnotics are medications used for short-term sleep aids. However, even lower dosages of these two categories of drugs in the elderly population are associated with impairment of daytime functioning and may in some cases increase confusion and disorientation, which may in turn exacerbate problem behaviors.[2]

Omnibus Budget Reconciliation Act of 1987

On December 22, 1987, Congress enacted comprehensive nursing home reform with the Omnibus Budget Reconciliation Act (OBRA) of 1987 (P.L. 100-203). As part of OBRA 1987, Congress passed the comprehensive Nursing Home Reform Act (NHRA). This Act mandates that residents be free from "physical or chemical restraints imposed for the purposes of discipline or convenience." It also states that restraints may only be imposed to ensure the physical safety of the resident or other residents and only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used. Further, NHRA limits the use of "as needed" (P.R.N.) orders and requires efforts to withdraw the drug or decrease dosage be made for residents who are receiving psychotropic drugs.

Additionally, the Omnibus Budget Reconciliation Act (OBRA) of 1990 requires the regulation of certain drugs in nursing homes and the establishment of Drug Regimen Reviews for nursing home residents. The provisions of Section 4401 of OBRA 1990

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[1] Cohen, Lawrence, J., Burke, William, J. (1999) "Appropriate Use of Anti-psychotics for Residents with Dementia in the Long-Term Care Setting," Consultant Pharmacist 14, (2).

[2] Stimmel, Glen (1996) "Use of Sedation in Patients with Behavioral Disturbances of Dementia," Consultant Pharmacist 11, (Supplement D): 9-11.

involve pharmacists more actively in patient care by refocusing pharmacists from a product oriented role to one involving clinical practice responsibilities for reducing potential drug therapy problems.

The Centers for Medicare and Medicaid Services Regulations

To implement the requirements of OBRA 1987, on February 2, 1989, the Center for Medicare & Medicaid Services (CMS), formerly known as the Health Care Financing Administration, finalized regulations (42 C.F.R §483.25(1)) on anti-psychotic medications and unnecessary drugs. These regulations were further refined in 1991. The CMS regulations state that each resident's drug regimen must be free from unnecessary drugs and define what is considered an unnecessary drug. An unnecessary drug is any drug used:

- in excessive dose;
- for excessive duration;
- without adequate monitoring or without adequate indications for its use;
- in the presence of adverse consequences, which indicate the dosage should be reduced or discontinued; or
- without specific target symptoms.

In addition, the CMS regulations state that residents who have not previously used anti-psychotic drugs should not be given these drugs unless anti-psychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record. Further, the regulation mandates that residents who use anti-psychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

In July 1995, the CMS completed the final step in the implementation of OBRA 1987 by introducing new tasks into the nursing home survey process. Further refinements to survey procedures and interpretive guidelines were implemented on July 1, 1999. Some of these are specific to psychotropic drug therapy, including: new investigative protocols and the incorporation of quality indicators (QIs) based on the Minimum Data Set (MDS) into the off-site survey process; an update to the list of anti-psychotic drugs that can be cited as unnecessary or misused under tag number F329; the addition of drug therapy guidelines; and a revised definition of medication error. Additionally, the updated CMS regulations change some anti-psychotic dosing restrictions and list medications considered potentially hazardous to the elderly.

Nursing Home Monitoring Programs

Several programs exist to monitor the quality of care in nursing homes. These programs can act as a safeguard against the use of psychotropic drugs as inappropriate chemical

restraints and provide a venue for receiving and handling complaints about such misuse.

Nursing Home Survey and Certification. All Medicare and/or Medicaid participating nursing homes must be certified in meeting certain Federal requirements. Nursing home certification is achieved through routine surveys. The CMS contracts with States to perform these surveys for Medicare and dually-eligible nursing homes. All nursing homes are subject to an unannounced standard survey "no later than 15 months after the date of the previous standard survey." If during the standard survey a nursing home is found to have provided substandard quality of care, an additional extended survey will be conducted within 2 weeks. During either type of survey, a surveyor may cite the nursing home for a deficiency if that facility fails to meet specific requirements.

Survey deficiencies are categorized, collected, and reported in the Online Survey Certification and Reporting System (OSCAR). Several deficiencies relate directly to pyschotropic drug misuse. For example, tag number F329 is cited for all unnecessary drugs including: anti-anxiety, anti-depressant, anti-psychotic, and hypnotic drug use. Tag number F330 is specific to anti-psychotic drug use in residents who do not have a specific condition as diagnosed and documented in the medical record, and tag number F222 is cited for inappropriate chemical restraints. In addition, other tags that address quality of care, resident's rights, and drug regimen reviews also indirectly relate to the misuse of psychotropic drugs.

Ombudsman Program. The State Long Term Care Ombudsman program was established in 1978 by the Older Americans Act to ensure quality of care and advocacy on behalf of long term care residents. It requires that each State have an Ombudsman program, which are run by States and local communities and use both paid and volunteer staff. The programs have multiple functions including: identifying, investigating, and resolving complaints made on behalf of residents; protecting the legal rights of residents; and providing information and consultation to residents and families.

All of the States systematically collect and report data relating to their Ombudsman Program under the National Ombudsman Reporting System (NORS). Two of the complaint categories in NORS specifically relate to the use of psychotropic drugs - one for chemical and physical restraints and the other for psychotropic drug assessment, use, and evaluation. Other categories indirectly address this problem, such as weight loss, assistance in eating, and functionality.

METHODOLOGY

We combined five methods for this inspection: 1) a medical record review of residents taking psychotropic drugs; 2) an analysis of nursing home survey and certification and

ombudsman program data; 3) an assessment of nursing home Drug Regimen Reviews; 4) on-site visits to 10 nursing homes; and 5) a telephone survey of State survey and certification and ombudsmen staff. The findings of the on-site visits are presented in a companion report, "Psychotropic Drug Use in Nursing Homes Supplemental Information - 10 Case Studies," OEI-02-00-00491.

We excluded anti-depressants from our review because depression in nursing home residents has historically been under-diagnosed and under-treated. Therefore, the increase in anti-depressant use is generally considered to be appropriate.

Nursing home and resident sample

We used a two-stage cluster sample for this inspection. In the first stage of sampling, we used the OSCAR current survey file to select a random sample of 203 nursing homes. For each of the nursing homes in our sample, we requested their enrollment census for the month of November 2000. From this census, we asked the nursing homes to identify which residents received a psychotropic drug and what type (anti-psychotic, anti-anxiety, hypnotics, and/or anti-depressants) they received. We obtained a response from 196 of the 203 nursing homes, for an overall response rate of 97 percent.

In the second stage of sampling, we selected a random sample of 587 nursing home residents. From each of the 196 nursing home enrollment lists we randomly selected 3 residents who received either an anti-psychotic, anti-anxiety, and/or a hypnotic during November 2000 (we excluded residents solely on anti-depressants). One nursing home had only two residents who met these criteria and we sampled both residents.

Medical record review

For each of the residents in our sample, we requested their complete clinical records for May 2000 through November 2000. Among the documentation we requested were admission sheets, plans of care, nurses' and physicians' notes, medication administration records, psychiatric and neurological assessments, behavior management records, and physician orders.

We received 574 of the 587 medical records that we requested, for a medical record response rate of 98 percent. If we had obtained a response from all 203 nursing homes in our first stage of sampling and had sampled 3 residents from each one, our overall response rate for medical records would have been 94 percent. Of the 574 medical records we did receive, we sent 485 for medical record review. The other 89 residents did not meet our sampling criteria and were excluded from the medical record review. While they were identified by their nursing home as having received a psychotropic drug in November 2000, their record showed no evidence that they had actually used the drug. Many of these residents had PRN ("as necessary") orders that were not administered in November. Other residents were taking these drugs for non-psychiatric reasons.

We used an independent contractor to conduct the medical record review. First, together with the contractor, we developed a screening instrument to review the residents' records. The screening instrument was based on the CMS guidelines for the appropriate use of psychotropic drugs. We also obtained input on this instrument from the American Association of Geriatric Psychiatrists and the American Medical Directors Association. Nurse screeners with geriatric experience initially reviewed all the records; the cases that did not pass this initial screening were passed on for second level review.

Both a geriatric psychiatrist and a consultant pharmacist conducted the second level review. These reviewers determined a drug to be inappropriate if, based on the clinical documentation in the medical record, the drug was not medically necessary or reasonable. See Appendix A for confidence intervals on key findings of the medical record review.

Analysis of nursing home survey and certification and ombudsman program data

We examined data from both the OSCAR and NORS. In OSCAR, we looked at nursing home deficiencies for chemical restraints (F222), unnecessary psychotropic drugs (F329), and psychotropic drug use in the absence of a documented diagnosis (F330). In NORS, we looked at complaints made to Ombudsman about physical and chemical restraints (H60) and psychoactive drugs (H62). For both sets of data, we looked at both the prevalence of and changes over time for each of the specific deficiencies and complaints.

Assessment of Drug Regimen Reviews

From the 196 nursing homes that responded to our request for an enrollment list, we requested 6 months of drug regimen reviews (DRRs). Overall, 135 nursing homes submitted these DRRs. We did not follow-up with the other 61 nursing homes. We reviewed a selection of these DRRs to determine how they assure that psychotropic drugs are being used appropriately.

Site visits

We selected a purposive sub-sample of 10 nursing homes in different States to visit on-site. These 10 nursing homes were selected based on five criteria: 1) geographical location, 2) number of residents in November 2000, 3) drug usage rate, 4) urban/rural location, and 5) ownership status. We chose nursing homes in California, Florida, Idaho, Maryland, Massachusetts, Missouri, New York, Ohio, Texas, and Wisconsin. Five of the facilities were large (more than 100 residents), four were medium (61-99 residents), and one was small (less than 60 residents). Also, four of the homes had a high psychotropic drug usage rate (greater than 34 percent), four had a moderate rate (18 to 34 percent), and two had rates of less than 18 percent. Lastly, eight of the nursing homes were located in an urban area while two were rural, and nine were for-profit while one was non-profit.

While on-site at these 10 facilities, we interviewed both administrative as well as direct care staff. Our administrative interviews included discussions with nursing home

administrators, directors of nursing, medical directors, consultant pharmacists, psychiatrists, social workers, and psychologists. We spoke with these respondents about how psychotropic drugs are being used and monitored in their facility.
We also interviewed nurses and certified nurse aides in each facility separately from administrative staff about how they care for and monitor residents on psychotropic drugs and handle aggressive residents. Lastly, while on-site we spoke with and observed the residents in our sample and toured the facility, including observing at least one structured activity and meal time.

Telephone interviews with State surveyors and ombudsmen

For the States represented in our purposive sub-sample, we conducted two structured telephone interviews - one with the State ombudsman and the other with the State survey and certification director or other manager. During these interviews, we discussed with respondents how pyschotropic drugs are being used by nursing homes in their State, the nature and extent of inappropriate chemical restraints, and the processes that their State has in place to handle such complaints.

Limitations

Our methodology has two main limitations. First, we assessed the appropriateness of psychotropic drugs based solely on a medical record review and not on in-person clinical assessments of the residents in our sample. For example, our reviewers state that they could not conclusively determine if any inappropriate drug use was an inappropriate chemical restraint without a physical examination of the resident. Second, the nursing homes in our sample self-identified the residents that were receiving psychotropic drugs in November 2000.

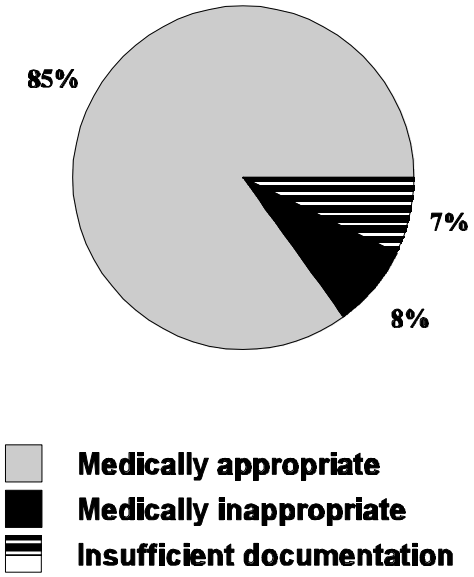
This inspection was conducted in accordance with the **Quality Standards for Inspections** issued by the President's Council on Integrity and Efficiency.

FINDINGS

Psychotropic drug use in nursing homes is generally appropriate

Our medical record review shows that 85 percent of nursing home residents who take psychotropic drugs are taking drugs that are medically appropriate. Another eight percent are using psychotropic drugs inappropriately, and for seven percent our reviewers could not determine the appropriateness of their psychotropic drug therapy due to insufficient medical record documentation. See Graph 1 below.

Graph 1
Nursing Home Residents' Psychotropic Drug Use



Source: Medical Record Screening Instrument, 2001

Eighty-five percent of residents' psychotropic drug use is medically appropriate

Most nursing home residents taking psychotropic drugs are taking drugs that are medically appropriate. Nearly all of these residents have the potential to benefit functionally from their drug therapy and there is evidence that, for most, their therapeutic goal has been or can be achieved. Also, in accordance with the CMS guidelines, in most cases the psychotropic drugs are being used at appropriate dosages and duration and not as inappropriate duplicate therapy. The drugs are also generally being used with adequate indications and monitoring and without adverse consequences.

Nearly all residents taking anti-psychotic drugs (95 percent) or anti-anxiety drugs (93 percent) have a documented diagnosis of mental illness. More specifically, among residents on anti-psychotic drugs, the most common diagnosis is dementia with associated psychotic or agitated behaviors (71 percent), while 14 percent have a diagnosis of schizophrenia. Close to half of residents taking anti-anxiety drugs (43 percent) have a diagnosis of dementia of the Alzheimer's type with behavioral disturbance. For the few residents with no documented mental health diagnosis, most are appropriately taking an anti-psychotic or anti-anxiety drug due to an acute problematic behavior.

We noted several features of nursing homes' Drug Regimen Reviews (DRRs) that may help to assure that psychotropic drugs are used appropriately. These DRRs are conducted on a monthly basis by pharmacists to assess residents' drug treatment plans. Many of the DRRs we reviewed include the pharmacist's recommendation to change a medication in order to improve the management of a resident's behavioral symptoms, as well as a recommendation to re-evaluate or discontinue PRN ("when necessary") drug orders. The DRRs also commonly include a suggestion to decrease dosage, a reminder that reduction attempts are past due, or an identification of medication errors, such as when inappropriate duplicate drugs are being given. In many cases, the resident's physician concurs with the pharmacist's recommendation and indicates this agreement on the DRR.

Eight percent of residents are using psychotropic drugs inappropriately

Eight percent of residents who take psychotropic drugs are using these drugs inappropriately. These drugs are inappropriate for one or more of the following reasons: the dose is too high because appropriate dose reductions are not followed; there is unjustified chronic use of the drug; there is no documented benefit to the resident; the wrong type of drug is being given for a particular diagnosis; and there is inappropriate duplicate drug therapy. For example, in a few cases an additional anti-psychotic drug is being given to treat symptoms without dose adjusting on the first drug to a level that would effectively treat the resident. In many instances there is no clear documentation to support continued need for duplicate or triplicate drug therapy. Residents on more than one psychotropic drug are more likely than residents on just one psychotropic drug to be taking a medication inappropriately.

There do not appear to be any nursing home characteristics associated with inappropriate use. Neither ownership type nor urban or rural setting are linked with inappropriate use of these drugs. Also, nursing homes with higher psychotropic drug usage rates are not more likely than homes with medium and low rates to inappropriately use these drugs. However, nearly all nursing home surveyors and some ombudsmen we interviewed say that inadequate nursing home staffing ratios, training, and experience may be associated with a greater likelihood of inappropriate drug use.

Inappropriate chemical restraints do not appear to be widespread. Our medical record reviewers could not conclusively determine that any of the inappropriate drug use was an inappropriate chemical restraint. In follow-up discussions with reviewers, all agree that

based on their medical record review, the use of psychotropic drugs as inappropriate chemical restraints, solely for the convenience of staff, does not appear to be common.

Seven percent of residents' medical records lack sufficient documentation to determine the appropriateness of their psychotropic drug use

Seven percent of residents we sampled have such inadequate records that our medical record reviewers are unable to determine if their drug use is appropriate. Some of these residents' records lack information about their mental health history, while others' lack physician notes on the medical rationale for why the drug is being used. For example, several residents were taking hypnotic drugs without any note of sleeping problems in their records. However, based on their clinical judgement and other documentation in the record, our reviewers believed that these drugs may have been appropriate.

There are two other ways in which nursing home documentation for these drugs is insufficient. Of the records that went for second level review, there was not always adequate documentation to explain why residents were taking psychotropic drugs outside of the CMS dosage guidelines (even though the medical reviewers determined that the dosage was appropriate). Also, some records do not have adequate documentation to support the duration of time the resident has been receiving the drug. In fact, our medical reviewers cite this as one of the biggest documentation problems. They state that documentation to justify the appropriateness of chronic use of pyschotropic drugs is often lacking since residents' records commonly lack physician notes to support ongoing drug therapy.

Data from survey and certification and ombudsman programs support the findings of the medical record review

The OSCAR deficiencies that directly cite inappropriate psychotropic drugs and chemical restraints are not common. Deficiency tag F222, cited for inappropriate chemical restraints, comprises 0.08 percent of all deficiencies in the current survey, and the number of these deficiencies has been decreasing slightly over the past three surveys. Further, tag F329, cited for unnecessary psychotropic drugs, comprises 2 percent of all deficiencies in the current survey; the number of these deficiencies has remained constant. Lastly, tag F330, cited for the use of a psychotropic drug in the absence of a documented diagnosis, accounts for 0.13 percent of all deficiencies; these deficiencies have also seen a small decrease. It should be noted that other deficiencies, such as pressure sores and weight loss, may indicate that psychotropic drugs are being used as inappropriate chemical restraints.

Similarly, ombudsman complaints specific to the inappropriate use of psychotropic drugs and chemical restraints are not prevalent. In 1999, complaints about physical and chemical restraints accounted for 1 percent of all nursing home complaints, while those about the use of psychoactive drugs comprised just 0.25 percent of the total.

Furthermore, the number of these complaints, while increasing slightly from 1996 to 1998, have decreased from 1998 to 1999.

Also, most surveyors and some ombudsmen in our sample States concur that inappropriate chemical restraints are not common. Most of the 10 surveyors we interviewed say that use of psychotropic drugs as inappropriate chemical restraints is uncommon. While fewer ombudsmen agree, most say that only a small number of nursing homes are using the drugs inappropriately. Further, a majority of both surveyors and ombudsmen in our sample report that over the past three years, the inappropriate use of these drugs as inappropriate chemical restraints has decreased or remained the same.

Several respondents in our sample States say that chronic drug use may be more of a problem. One surveyor says: "The decision to use the drug might be right but [nursing homes] might not handle it correctly as [they] go along." An ombudsman agrees: "[It] may have been appropriate to use the drug at the start, but not keep the resident on the drug for 5 years."

A growth in the proportion of nursing home residents with mental disorders may contribute to increasing psychotropic drug rates

More residents are taking psychotropic drugs

Since 1995, nursing home psychotropic drug usage rates have increased. This increase occurred after initial drops in usage rates following the implementation of OBRA 87. The largest increase has occurred with the use of anti-psychotics. Based on OSCAR data, from 1995 to 1999 the national rate for anti-psychotics grew from 16 percent to 19.4 percent, and anti-anxiety drug rates increased from 14.3 percent to 15.7 percent.[3] However, hypnotic drug rates have remained relatively steady at 5 percent for this time period.

Based on our sample, which excluded residents taking only anti-depressants, anti-psychotics appear to be the most prevalent of the different groups of psychotropic drugs. Sixty-seven percent of residents on psychotropic drugs are taking an anti-psychotic medication, while 42 percent are taking an anti-anxiety drug, and far fewer (17 percent) are taking a hypnotic medication. Overall, more than half of these residents are taking two or more psychotropic drugs.

Nursing homes have a higher proportion of residents with mental disorders

The population of residents with mental disorders in nursing homes has also been growing. Data from OSCAR show that the proportion of all residents with a documented

[3] American Society of Consultant Pharmacists Fact Sheet, September (2000).

psychiatric disorder, excluding dementia, increased from 13 percent to 16 percent over the last four surveys. Also, the proportion of all residents with behavioral symptoms grew from 29 percent to 31 percent over the same period. Further, in our telephone interviews two ombudsmen say they are seeing more problem behavior and dementia among nursing home residents in their States. Lastly, one of our medical record reviewers, a geriatric psychiatrist, mentions that nursing homes are different now than they were when OBRA 87 was first implemented, due to the higher proportion of psychiatric residents.

Numerous articles have also documented the increasing prevalence of mental disorders among nursing home residents. In one article examining the effects of OBRA 87 on psychotropic prescribing rates, the authors argue that "the prevalence of psychiatric disorders in long-term care facilities is formidable, and nursing homes have become defacto mental health facilities."[4] When discussing the impact this has had on psychotropic drug use, they caution against "trends that equate low utilization ... with high-quality care, without considering other factors such as improvements in the quality of life associated with appropriate use of psychotropic medications."[5] In another article from the Consultant Pharmacist, the authors state that "the small but meaningful increase in usage seen in several categories ... may be explained by an increase in [behavioral] acuity of patients."[6]

Lastly, nursing homes appear to be accepting more residents with a history of psychotropic drug use. At least one third of the residents in our sample entered the nursing home already on their medication. Several of our medical record reviewers point out that hospitals' common use of these drugs results in new nursing home admissions who already have a prior history of taking psychotropic medications. Finally, a few of the administrators at the nursing homes we visited say that they try to reduce drug levels for residents entering the home already taking high dosages.

Four of the 10 nursing homes we visited are actively seeking out psychiatric patients

Four of the 10 nursing homes we visited specifically target psychiatric patients. All four have psychotropic drug usage rates that are above the national average. These nursing homes actively seek out such patients because they have developed the expertise and staffing structure necessary to care for residents with a mental illness. Some

[4] Lantz, Melinda, Giambanco, Vincent, and Buchalter, Eric. (1996) "A Ten-Year Review of the Effect of OBRA-87 on Psychotropic Prescribing Practices in an Academic Nursing Home," Psychiatric Services.

[5] Lantz, (1996).

[6] Tobias, Dianne and Pulliam, Charles. (1997) "General and Psychotherapeutic Medication Use in 878 Nursing Facilities: A 1997 National Survey," Consultant Pharmacist.

administrators mention that in order to remain financially viable, they need to target this segment of the nursing home population; residents with lesser care needs or with less advanced dementia or Alzheimer's disease are increasingly going to other long term care settings, such as assisted living centers.

CONCLUSION

In response to concerns expressed by the Senate Special Committee on Aging about the use of psychotropic drugs as inappropriate chemical restraints in nursing homes, this report finds that these drugs are generally being used appropriately. While drug usage rates for anti-psychotic and anti-anxiety medications have been rising, most psychotropic drug use in nursing homes is medically appropriate. Where it is inappropriate, the problems do not appear to be related to inappropriate chemical restraints but rather to inappropriate dosage, chronic use, a lack of documented benefit to the resident, and inappropriate duplicate drug therapy. We do note, however, that lack of adequate documentation for residents' psychotropic drug use is of some concern. The Centers for Medicare and Medicaid Services may consider educating providers to better document the appropriate use of these drugs.

AGENCY COMMENTS

We received comments on the draft report from the Centers for Medicare & Medicaid Services. They believe that the report will contribute to a better understanding of psychotropic drug use in nursing homes and in identifying areas for further focus. The CMS also notes that training related to psychotropic drug use and related documentation issues is already underway or planned.

APPENDIX A

Confidence Intervals for Key Medical Record Review Findings

We calculated confidence intervals for the medical record review key findings. The point estimate and 95% confidence intervals are given for each of the following:

KEY FINDINGS	POINT ESTIMATE*	CONFIDENCE INTERVAL
Nursing home residents who are taking psychotropic drugs that are medically appropriate	85 %	81 % - 89%
Nursing home residents who are taking psychotropic drugs that are medically inappropriate	8%	5 % - 11%
Nursing home residents whose medical records lack sufficient documentation to determine the appropriateness of their psychotropic drug use	7 %	4 % - 10 %

* N = 485

APPENDIX B

Comments on the Draft Report

In this appendix, we present in full the comments from the Centers for Medicare & Medicaid Services.

DEPARTMENT OF HEALTH & HUMAN SERVICES

RECEIVED
2001 SEP -4 PM 3:09
OFFICE OF INSPECTOR GENERAL

Health Care Financing Administration
Deputy Administrator
Washington, D.C. 20201

DATE: AUG 30 2001

TO: Janet Rehnquist
Inspector General
Office of Inspector General

FROM: Ruben J. King-Shaw Jr.
Chief Operating Officer and Deputy Administrator
Centers for Medicare & Medicaid Services

IG ✓
EAIG
PDIG ✓
DIG-AS
DIG-EI ✓
DIG-OI
DIG-MP
OCIG
ExecSec
Date Sent 9/5/01

SUBJECT: Office of Inspector General (OIG) Draft Report: *Psychotropic Drug Use in Nursing Homes*, (OEI-02-00-00490) and *Psychotropic Drug Use in Nursing Homes: Supplemental Information – 10 Case Studies*, (OEI-02-00-00491)

Thank you for the opportunity to review and comment on the above-referenced draft report. The information gathered by OIG will help the Centers for Medicare & Medicaid Services (CMS) make sound policy decisions about how best to protect the interests of residents in nursing homes. The report's findings that psychotropic drug use in nursing homes is generally appropriate and that these drugs do not appear to be used as chemical restraints are encouraging. This report is valuable in contributing to our understanding of psychotropic drug use in nursing homes and in identifying areas for further focus.

Since the passage of the Omnibus Budget Reconciliation Act (OBRA) of 1987, CMS has worked towards reducing the inappropriate uses of chemical restraints and the unnecessary use of drugs in nursing homes. Psychotropic drug use by nursing home residents has been our concern because of the potential risks associated with psychotropic therapy and the use of psychotropic drugs as chemical restraints imposed for the purposes of discipline or staff convenience. Certain anti-psychotic agents are associated with potentially irreversible adverse effects. The risk of potentially adverse effects warrants the use of guidance for these medications.

The conclusion of this report suggests the need for additional training. It is expected that already planned training sessions in psychotropic medication use and related documentation issues for patient medical records will have a positive impact on the quality of care of our nursing home residents.

OIG Recommendation:

The Centers for Medicare & Medicaid Services may consider educating providers to better document the appropriate use of these drugs.

CMS Response:

In an effort to continue the positive trend toward effective medication use in our nursing home residents, we are currently revising the State Operations Manual, (SOM) Appendix PP regarding

The Health Care Financing Administration (HCFA) was renamed to the Centers for Medicare & Medicaid Services (CMS). We are exercising fiscal restraint by exhausting our stock of stationery.

monitoring of chemical restraints and unnecessary drug use in nursing homes. More information will be given on medication use. Part of this revision will include additional guidance on the use of atypical anti-psychotic medications which the report mentions as being effective for a variety of disorders in the elderly.

Additionally, the revision to the SOM will include guidance on the use of anti-depressant drugs. This report excluded residents who were receiving only an antidepressant medication because it was believed that depression is under-diagnosed and under-treated in the elderly. This statement is true. However, we believe that guidance is needed for the newer anti-depressant agents that are frequently used by our elderly nursing home residents. The newer anti-depressant agents, like many other medications, are associated with certain risks as well as benefits.

Furthermore, in an effort to maintain or improve the quality of care that our nursing home residents receive, we have planned two national training sessions. One training session will be a satellite broadcast dealing with the use of unnecessary drugs and chemical restraints. The other training session will be a conference to provide further guidance regarding monitoring of medication use through the survey process, and psychotropic medication documentation issues in patient medical records. The target audience for both training sessions will be regional office surveyors, state agency surveyors, and facility providers. These training sessions will serve to educate individuals about the revisions to the SOM concerning medication use and its impact on the survey process, and about the inappropriate use of psychotropic medications in nursing homes.

Along with the above-mentioned training sessions, CMS will also provide the following provider education services:

- A Web-based training module to educate providers on the issues of medical record documentation.

- The design of a Web page to be located on the Medlearn Web site, which is the learning resource for providers (www.hcfa.gov/medlearn). This Web page will provide information to providers on medical documentation for psychotropic drug use in nursing homes, and will include links to: Medicare regulations, carrier and fiscal intermediary Web sites, program memoranda, Surgeon General reports, and OIG reports.

- The design and development of articles that will educate providers on the issues regarding medical documentation related to psychotropic drug use in nursing homes. These articles can be placed in contractor bulletins and posted on the MedLearn Web site. The contractor bulletins have an estimated circulation of 1 million physicians and other providers.

Attachment