DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Psychotropic Drug Use in Nursing Homes

Supplemental Information - 10 Case Studies



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OVERVIEW

PURPOSE

To provide supplemental information to our main report "Psychotropic Use in Nursing Homes" by describing 10 nursing homes' use and monitoring of psychotropic drugs.

BACKGROUND

This report supplements our main inspection on the use of psychotropic drugs in nursing homes, which found that these drugs are generally used appropriately. The Senate Special Committee on Aging requested that the Office of Inspector General look at the extent to which psychotropic drugs are being used as inappropriate chemical restraints in nursing homes. 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 drugs. The Centers for Medicare & Medicaid Services established guidelines for the appropriate use of these drugs in nursing homes.

We selected 10 different nursing homes for site visits based on their psychotropic drug usage rates, geographical variation, facility size, and ownership category. These facilities are in California, Florida, Idaho, Maryland, Massachusetts, Missouri, New York, Ohio, Texas, and Wisconsin. In each nursing home we conducted interviews with administrative and direct care staff, toured the nursing home, and spoke with residents. We present a 10 case summary and individual nursing home case studies.

10 CASE SUMMARY

In the main report, our medical record review determined that psychotropic drug use in nursing homes is generally appropriate. This supplemental information describes nursing homes' self-reported approaches for managing residents taking these drugs. It is intended to assist the reader in better understanding the findings of the main report and to instruct individuals interested in this topic.

Psychotropic Drug Treatment Protocols

A drug treatment protocol consists of the general practices used to manage residents' drug therapy, which are important given that our main report found at least one third of our sample nursing home residents entered the facility already on their medication. Respondents in all 10 nursing homes describe using similar practices for managing residents' psychotropic drug therapies, including resident physical and/or psycho-social evaluations, behavior monitoring programs, tracking of side effects and adverse reactions, and dose reductions. All 10 nursing homes say they evaluate residents prior to starting drug therapy in order to rule out non-psychiatric causes of their behavior; most facilities also believe a philosophy of "start low and go slow" is the best practice. All 10 facilities also report beginning behavior monitoring at the time of admission for residents already taking psychotropic drugs. Finally, many nursing home respondents use the Drug Regimen Review conducted by their consultant pharmacist as an important element for monitoring psychotropic drug use, and many also use interdisciplinary review committees for this purpose.

Non-Pharmacologic Alternatives

All 10 nursing homes we visited discuss using alternative non-pharmacologic interventions for psychiatric disorders and problem behaviors. The staff say that they most often try interesting the resident in something else (redirecting); providing intensive one to one direct care (one-to-one); letting the resident have time alone (time out); talking to the resident about what is bothering them (emotional support); removing the resident to a different area in the nursing home (relocating); and leaving the resident and returning at a later time (re-approaching). Nursing homes may also get the family involved in residents' day to day life at the nursing home and have the same staff person care for the same resident in order to establish an ongoing relationship between the two.

Appropriate Use of Chemical Restraints

We asked all respondents about the appropriate use of chemical restraints in their nursing home. Overall, respondents express a general reluctance to use a psychotropic drug solely as a chemical restraint. However, eight explain that they may use a psychotropic drug when residents' behavior is harmful to themselves or to others; the other two say they have not had a need to use a restraint. For example, respondents in one facility say they would use a restraint if a resident was striking other residents or staff. At another facility, respondents provide a specific example of using a restraint when a resident was continually throwing herself from her bed to the floor.

Staff Structure and Training

All 10 nursing homes have access to psychiatric staff, such as a "psych team" or consultant psychiatrists and psychologists. Also, in a few homes with specialized units for residents with dementia or Alzheimer's disease, the nurses and certified nurse aides work only in that unit and are often given specialized training to care for these residents. Additionally, many nursing homes offer some type of training to direct care staff, such as behavior management techniques. However, some aides say that there is not enough direct care staff to care for psychiatric residents.

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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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.

Omnibus Budget Reconciliation Acts of 1987 and 1990

In 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, the nursing Home Reform Act limits the use of "as needed" (PRN) 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 involve pharmacists more actively in resident 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 & Medicaid Services Regulations

To implement the requirements of OBRA 1987, on February 2, 1989, the Centers 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; or
- in the presence of adverse consequences, which indicate the dosage should be reduced or discontinued.

In addition, the CMS regulations state that residents who have not previously used antipsychotic 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."

Methodology

We selected a purposive sub-sample of 10 nursing homes in different States to visit onsite. These 10 nursing homes were selected based on five criteria:

- geographical location
- number of residents in November 2000
- psychotropic drug usage rate in November 2000
- urban/rural location, and
- 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, based on census data, eight of the nursing homes were located in an urban area while two were rural. 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 how they 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 or meal.

In addition to reporting each nursing home's case study individually, we conducted a cross case analysis of the inspectios team's observations and interviews with nursing home staff. We used a summary matrix to identify four approaches the nursing homes use to manage residents taking psychotropic drugs. These are: psychotropic drug treatment protocols; non-pharmacologic alternatives; appropriate use of chemical restraints; and staff structure and training. The results of this cross case analysis are reported in the cross case summary.

Limitations

This methodology has several limitations. First, the approaches we describe are based on self-reported information that we did not independently validate. This information is based primarily on a description of policies and not necessarily of direct practices. Our intention is not to endorse these policies but rather to describe a cross section of nursing home approaches to managing residents taking psychotropic drugs. Finally, we did not examine overall quality of care in any of the 10 nursing homes.

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

10 CASE SUMMARY

In the main report, our medical record review determined that psychotropic drug use in nursing homes is generally appropriate. This supplemental information describes nursing homes' self-reported approaches for managing residents taking these drugs. It is intended to assist the reader in better understanding the findings of the main report and to instruct individuals interested in this topic.

Based on the analysis of our interviews and the inspection team's observations, we identified four similarities in the 10 nursing homes' approaches. These are:

- 1. Psychotropic drug treatment protocols
- 2. Non-pharmacologic alternatives
- 3. Appropriate use of chemical restraints
- 4. Staff structure and training

Psychotropic Drug Treatment Protocols

A drug treatment protocol consists of the general practices used to manage residents' drug therapy. Such protocols are important given the growing prevalence of psychotropic drug use among nursing home residents. In fact, our main report, "Psychotropic Drug Use in Nursing Homes," found that at least one third of the nursing home residents in our sample entered the facility already on their psychotropic medication. Also, most of our case study respondents say that many residents are already taking a psychotropic drug at their time of admission.

Respondents in all 10 nursing homes describe using similar practices for managing their residents' psychotropic drug therapy. These include resident physical and/or psychosocial evaluations, behavior monitoring programs, tracking of side effects and adverse reactions, and dose reductions. In fact, the results of our medical record review from the main report show that nearly all the psychotropic drugs being used by residents in our sample are being used without adverse consequences and with adequate monitoring.

Respondents in all 10 nursing homes say they evaluate residents prior to starting psychotropic drug therapy in the nursing home in order to rule out non-psychiatric causes of their behavior. This is supported by the results of our medical record review, that found that in most cases, residents' behavioral symptoms are not being caused solely by environmental stress or medical conditions. Most respondents mention that they give residents a physical work-up when a change in their behavior occurs; respondents say identifying what might be precipitating the problem behavior and removing it is important. Several respondents also mention assessing residents' spiritual, social, and

pain status. When other causes are ruled out and drug therapy is initiated, most facilities believe a philosophy of "start low and go slow" is the best practice. This means that the drug therapy is initiated at the lowest possible dose with incremental increases when necessary.

All 10 facilities say they begin behavior monitoring at the time of admission for residents already taking psychotropic drugs. In three of the 10 homes, respondents say they begin behavior monitoring for all new admissions. Respondents say that behavior monitoring allows a more accurate understanding of how residents are responding to their psychotropic drug therapy and whether they are appropriate candidates for dose reduction. Some nursing homes document behavior monitoring in the medication administration record (MAR) and others have developed specialized behavior monitoring sheets.

Most of the nursing homes use the Drug Regimen Review (DRR), conducted by their consultant pharmacist, as an important element for monitoring psychotropic drug use. They say that the monthly DRR is helpful for identifying problems or potential problems. Some facilities report using the DRR as a tracking tool when monitoring for dose reduction, side effects, dosage appropriateness, and adequate documentation in the resident's medical record.

The importance attributed to DRRs by our case study respondents is supported by our review of all nursing homes' DRRs in our main report, "Psychotropic Drug Use in Nursing Homes." The DRRs we reviewed for that study 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.

Nursing home respondents also report other methods for managing their residents' psychotropic drug therapy. These include daily or weekly monitoring in nurses' notes, periodic psychiatrist assessments, and corporate reviews of psychotropic drug therapies.

Finally, seven nursing homes report using interdisciplinary review committees to monitor the use of psychotropic drugs, including monitoring for side effects and adverse reactions. A few of these committees are part of periodic quality assurance team meetings. Attendees at these committees can include: the medical director, administrator, director of nursing, department heads, consultant pharmacist, MDS RN coordinator, social worker, psychiatrist, psychologist, and other direct care staff. The administrator of a nursing home with many mentally ill residents believes a multi-disciplinary approach results in quality of care for all residents, saying "we focus on a coordination of services."

Non-Pharmacologic Alternatives

All 10 nursing homes we visited are using alternative non-pharmacologic interventions for residents with psychiatric disorders and problem behaviors. The staff at all 10 report using similar behavior management techniques to care for residents who are acting out, are confused or agitated, or who exhibit other behavioral symptoms. These include interesting the resident in something else (redirecting); providing intensive one-to-one direct care (one-to-one); letting the resident have time alone (time out); talking to the resident about what is bothering them (emotional support); removing the resident to a different area in the nursing home (relocating); and leaving the resident and returning at a later time (re-approaching). In fact, during several of our visits, we observed some of these techniques, such as individual staff members spending time with residents who seemed disturbed or agitated and staff redirecting residents to other activities or locations.

Nursing home respondents also try other non-pharmacologic approaches. They may try to get the family involved in the resident's day-to-day life at the nursing home. In addition, staff also note the importance of having the same staff person care for the same resident in order to establish an ongoing relationship between the two. However, they will also consider changing staff if a resident does not get along with that individual. A few respondents also say that for residents whose problem behavior occurs suddenly, it could be the timing of an activity or physical care that is causing the problem; a change in timing can therefore be helpful. Several respondents also told us that environmental modification, such as keeping the nursing home free of confusing objects, contributes to residents' emotional wellbeing. Finally, some nursing homes try innovative approaches such as pet therapy, recreational activities, or massage therapy.

Appropriate Use of Chemical Restraints

We asked all respondents about the appropriate use of chemical restraints in their nursing home. Overall, respondents express a general reluctance to use a psychotropic drug solely as a chemical restraint. However, eight explain that they may use a psychotropic drug when residents' behavior is harmful to themselves or to others; the other two say they have not had a need to use a restraint. For example, respondents in one facility say they would use a restraint if a resident was striking other residents or staff. At another facility, respondents provide a specific example of using a restraint when a resident was continually throwing herself from her bed to the floor. Medical directors and administrators at a few nursing homes describe using Risperdal and Zyprexa, two antipsychotic medications, as chemical restraints in residents who are extremely combative with care or hallucinating. Respondents at other nursing homes say Ativan, an anti-anxiety drug, will be given for escalating behaviors.

Staff Structure and Training

All 10 nursing homes have access to psychiatric staff, typically on a consultant basis. For example, in one nursing home with a high proportion of mentally ill residents, they contract with a company to provide a "psych team," whose members could include psychiatrists, psychologists, geriatric nurse practitioners, and other geriatric specialists. This team evaluates and manages residents. Other nursing homes may use individual psychiatrists and/or psychologists on a consultant basis. These consultants may assess residents taking psychotropic drugs and/or who are enrolled in behavior management programs. Lastly, in all of the nursing homes, residents may also have their own private physicians who manage their psychotropic drugs.

Nursing homes may structure their direct care staffing assignments for residents taking psychotropic drugs in different ways. In a few homes with specialized units for residents with dementia or Alzheimer's disease, the nurses and certified nurse aides (CNAs) work only in that unit and are often given specialized training to care for these residents. Additionally, many nursing homes offer some type of training to direct care staff, such as behavior management techniques. Further, a few homes provide in-service education to nursing staff on psychotropic drug therapy.

We also asked CNAs about caring for residents taking psychotropic drugs. A majority of CNAs say that when a resident in their care requires full assistance, care duties for other residents in their care will be shifted to another CNA. Some also say that there is not enough direct care staff to care for psychiatric residents. Despite these concerns, however, when CNAs were asked what they like most about their jobs, they overwhelmingly responded "the residents."

INDIVIDUAL CASE STUDIES

BELOIT HEALTH AND REHABILITATION CENTER

- Located in Beloit, Wisconsin, a small town in southern Wisconsin
- For-profit nursing home
- 148 beds (60 Medicare certified, 148 Medicaid certified)

Facility Profile

Beloit Health and Rehabilitation Center caters to long term residents, most of whom have dementia and other mental disorders. These residents also tend to be clinically complex, with multiple medical problems requiring intensive daily assistance. Beloit Health and Rehabilitation Center also has a separate Alzheimer's Unit, one of the few nursing homes in the area to have such a unit. Despite their high proportion of residents with mental disorders, their psychotropic drug use has been decreasing over the past several years. Currently, they have a moderate rate of 22 percent.

Approach to Psychotropic Drug Therapy

The Beloit Health and Rehabilitation Center follows a "start low, go slow" protocol for their residents' use of psychotropic drugs, meaning they will initiate drug therapy on a low dose and make gradual modifications. They will first rule out metabolic causes for problematic behaviors before using a drug. A daily clinical review is conducted for all residents on psychotropic drugs and any changes in medication are reviewed by both the director of nursing and the case manager before being implemented. The facility generally follows dosage guidelines established by its corporate office; these are more stringent than Federal guidelines.

This nursing home also utilizes a strong interdisciplinary approach in monitoring psychotropic drugs. One staff member, stressing the importance of a team approach, states, "If [the] pharmacist is the only person tracking drugs, [the drugs] can't be effective." A behavior management program for each resident is established by the case manager and team meetings are held at regular intervals to review each resident's progress and drug use. These meetings are typically attended by the consultant pharmacist, the director of nursing, case manager, and psychologist, as well as other staff members. Further, residents are also referred to a geriatric psychiatrist at a nearby hospital for evaluation and monitoring.

Alternative Interventions

Since staff at Beloit Health and Rehabilitation Center express a strong belief that psychotropic drugs should only be used if every other intervention has failed, they use various non-pharmacologic interventions for handling problematic behaviors. They will try intensive "one-on-ones", in which a staff member is assigned to an individual resident for 24 hours a day, until a resident's problem behavior is modified or controlled. Staff at the nursing home say they are willing to accept some combative behavior in residents as long as the behavior is not dangerous for the resident or others in the facility. In fact, during our visit, we observed staff interacting with and comforting residents who were out in the hallways and/or appeared distressed by speaking to them in soft, quiet tones and trying to re-direct them to their room or some other activity. Other non-pharmacologic interventions used in the nursing home include small group activities, removal or redirection of a resident who is displaying problem behaviors, and the assignment of new staff to care for a resident. Lastly, a psychologist is actively involved in the nursing home's activities by providing training to staff, consulting on aggressive behavior, conducting psychological evaluations, and providing therapy for some residents with mild Alzheimer's disease or dementia.

BLAIR HOUSE OF WORCESTER

- Located in Worcester, Massachusetts, a small industrial city near Boston
- For-profit nursing home
- 75 beds (75 Medicare certified, 75 Medicaid certified)

Facility Profile

Blair House of Worcester cares exclusively for residents with dementia. The residents are in various stages of dementia and about 30 to 50 percent have a history of mental illness. Since this home is the only one of its kind in the area, it serves residents from both rural and urban Massachusetts and Connecticut. Further, Blair House accepts residents who have failed in other nursing homes.

This nursing home has a higher psychotropic drug usage rate (66 percent) than the others in our sample. One of the home's medical staff explains this rate by saying that, "dementia is a disease that causes people to act just on raw impulse. The anti-psychotic drugs slow them down and help them to deal with their impulses."

Approach to Psychotropic Drug Therapy

Blair House has established a process which staff follow before prescribing a psychotropic drug. For the first 48 hours that residents are in the facility, the staff record their behaviors on a standardized behavior monitoring sheet. Then the social worker develops a specialized behavior management plan and monitoring sheet. If it is needed, they ask the psychiatric team, consisting of the psychologist, psychiatric nurse practitioner, and psychiatrist, for a consultation which may result in revision of the behavior management plan. If after several weeks the resident's behavior has not improved, the psychiatric nurse practitioner may prescribe a low dosage of a psychotropic medication.

When initiating psychotropic drugs as a new therapy or when a change in condition occurs, staff at Blair House try to start with a low dosage and gradually increase until the resident improves. Staff make it a point to allow time for a new resident to adjust to the facility before prescribing medication. A similar process is followed when a resident develops a behavior in the facility. Staff also rule out physical problems, such as urinary tract infections, before using drugs.

Blair House uses several methods to monitor and minimize psychotropic drug usage. Nurses monitor behavior episodes and the side effects of the psychotropic drugs on monitoring sheets. The consultant pharmacist will recommend reductions when the resident has exhibited none of the targeted behaviors for three to four months. Otherwise, staff attempt a reduction at least every six months. In addition, when possible they try to prescribe the lowest possible dose of anti-psychotics by combining it with another medication, such as an anti-depressant.

Alternative Interventions

The facility's staff use behavior management techniques instead of or in combination with psychotropic drugs. Specifically, the staff use the techniques of redirection and reassurance. For example, a staff member may bring a distraught resident to a quiet place for milk and cookies or call a family member to speak to the resident. In addition, staff will redirect disruptive behavior. They also do not attempt to reorient delusional residents. For example, we observed one resident calling out the name of her sister, who had passed away years ago. The resident wanted her sister's assistance. Part of the behavior management plan for this resident was for staff to tell her that her sister "would be here soon." Further, Blair House trains all staff about handling the behaviors of residents with dementia. The administrator believes this training, along with the specialized experience of the nurses and certified nurse assistants, is advantageous to the residents. During our site visit, we observed that most of the residents in this facility were active; many were walking throughout the hallways and interacting with staff. Other residents were participating in a group activity.

CROWN CENTER AT LAUREL LAKE

- Located in Hudson, Ohio, a suburb of Cleveland
- Non-profit nursing home
- 75 beds (75 Medicare certified, 0 Medicaid certified)

Facility Profile

Crown Center at Laurel Lakes is part of a larger campus that offers assisted and independent living to its residents. The nursing home shares services, such as recreational activities and physical therapy, with the assisted living unit. About 75 percent of the nursing home residents come from the assisted or independent living units. The nursing home has a mix of both short-term and long-term residents with a variety of needs. In addition, residents from the independent living and assisted living volunteer in the nursing home by visiting and sometimes sitting with an upset resident. According to the staff, the nursing home residents in this facility are of a higher socio-economic class, education level, and have higher family involvement than average.

Crown Center has a drug usage rate of 25 percent, which is moderate in comparison to the other homes in our sample. The medical director attributes this rate to standing "as needed" orders for sleeping medications that are rarely used. He explains that many of the residents in the home are privately funded and pay for their own sleeping medication; therefore, the nursing home is hesitant to cancel the order, even when the drugs are not used regularly.

Approach to Psychotropic Drug Therapy

Crown Center's policy is "to encourage safe and effective" drug therapy. They use psychotropic drugs for both short-term and long-term treatment. According to staff, these drugs are used in the short-term to treat psychological problems due to: illness (such as a stroke), the death of spouse or roommate, or depression when first coming to the nursing home. Staff also report that for long-term therapies, psychotropic drugs such as anti-anxieties are sometimes used in conjunction with anti-depressants to treat depression. Also common in this facility are "as needed" orders for residents who need occasional sleep aids. According to staff, "if a resident comes to the facility already using a psychotropic drug and the diagnosis is appropriate, we continue [the drug]." If a new problems arises, the nursing staff chart the resident's behavior for three days and consult the resident's personal physician. The psychologist from the psychological services team reports also providing consultation to the staff and making recommendations for medications.

Residents on psychotropic drugs are monitored in several ways. Nurses monitor the day-to-day effectiveness of the drugs with a standardized "behavioral monthly flow chart". On this chart, nurses record during each shift the frequency of behavior episodes and side effects. They also record the type of behavior and the intervention as well as the type of side effect and the action taken. The MDS RN coordinator performs a test for side-effects on all residents taking anti-psychotic medications. In addition, the consultant pharmacist reports recommending appropriate dose reductions.

Alternative Interventions

Staff at Crown Center at Laurel Lake also use various behavior management techniques. The administrator reports that "psychotropics are not the first route to go." When a resident is acting out aggressively, staff report trying to calm the resident by diverting or redirecting them. They may call the family to come in or ask a volunteer to sit with the resident. They may give them food, a book of pictures they like, or massage therapy. One nurse remarked that "if you are with a patient every day you can figure out what they want. Staff here take steps to modify behavior." Lastly, the nursing home also contracts with a psychological consulting company for psychotherapy and behavior management advice.

GRACEWOOD NURSING CENTER, INC.

- Located in Pinellas Park, Florida, a suburban retirement community
- For-profit nursing home
- 120 beds (120 Medicare certified, 120 Medicaid certified)

Facility Profile

At the time of our visit to Gracewood Nursing Center, Inc. a transfer of ownership was in progress. This nursing home has plans to add a specialized orthopedic rehabilitation unit but presently most of the residents are long-term care and 65 and older. Many are bed bound, others are wheelchair bound, and few are ambulatory. A few younger residents with chronic disabling conditions also live at the home. Previous to the change in ownership, the facility had received many deficiency citations in the last three surveys, including a 'G' level in the most current survey. An interim administrator has been hired by the corporation during the transition to improve conditions. Gracewood Nursing Center has a moderate psychotropic drug usage rate of 18 percent.

Approach to Psychotropic Drug Therapy

Gracewood Nursing Center, Inc., has instituted new guidelines and protocols for all residents who come into the facility already taking one or more psychotropic medications and for residents who begin such therapy after admission. First, they will rule out a medical cause for problematic behaviors and evaluate residents for other unmet needs such as dietary dislikes and personality clash with care-givers or roommates. Then, a behavior monitoring program is initiated. For those residents taking anti-psychotics, a bi-annual Abnormal Involuntary Movement Scale (AIMS) test is given.

The nursing home's new guidelines include interdisciplinary strategies to maintain residents at an optimum behavioral level and to monitor the use of psychotropic drugs. Bi-monthly behavior management meetings are conducted during which eight residents are selected for a full medical record review. A monthly "pro psychoactive drug review" is conducted by RN staff who partner with the consultant pharmacist and gerontologist in an effort to reduce dosage when appropriate and/or taper dosage with a goal to discontinue the drug. As one RN respondent says, "We rely heavily on the drug regimen review to identify any problems." The consultant pharmacist also meets with the director of nursing bi-monthly to review charts.

Alternative Interventions

The staff at Gracewood Nursing Center, Inc. have a strong belief that alternative non-pharmacologic interventions are dependent on their knowledge and understanding of the

resident. They describe several approaches to manage a resident's behavioral symptoms as supportive of the resident, especially when an acute and sudden onset of a behavior occurs. If the resident is aggressively acting out they generally will use one-to-one monitoring. The director of nursing emphasizes that "staff are instructed to talk to the resident in an effort to determine what might be upsetting to them [and] thereby triggering the behavior." One CNA says "if the behavior occurs in the first week of admission, we usually don't consider this a real change in condition but will continue to monitor [the behavior]." Other alternative interventions used in the nursing home include small group day trips outside the facility, touch therapy, and counseling by a member of the clergy.

We noted little activity at this nursing home except for a smoking area in an open center courtyard, where a few of the younger ambulatory residents gather to smoke. During the five hours we were at the nursing home we did not see any planned activities for residents in the multi-purpose common room. One resident, a woman in her early forties who has been living in the home for twelve years and was one of the three residents randomly selected for a medical record review, complained about the care she receives, claiming that the staff is slow to respond to residents' needs and requests.

MACON HEALTH CARE CENTER

- Located in Macon, Missouri, a rural farming community in northeastern Missouri
- For-profit nursing home
- 120 beds (52 Medicare certified, 50 Medicaid certified)

Facility Profile

Macon Health Care Center is located near the town's community hospital, which accounts for its emphasis on long term specialized care. Many residents require a high level of skilled care, such as tube feedings, tracheotomy care, and intravenous drug therapy. Other specialities include stroke rehabilitation as well as mental illness and advanced dementia. Accordingly this nursing home has a high psychotropic drug usage rate of 46 percent. Additionally, many of the residents have a diagnosis of psychosis, schizophrenia, or retardation. Within their parent corporate organization, Macon Health Center is one of nine facilities in Missouri that cares for residents with mental illnesses. These residents are meshed into the general nursing home population.

Approach to Psychotropic Drug Therapy

Respondents at Macon Health Care Center describe residents taking long term psychotropic drugs as having been admitted into the nursing home from a psychiatric institution with a prior history of such drug therapy. However, the administrator says the admission protocol for all residents "requires a full physical assessment by the MDS RN coordinator," and, "if admitted on a psychotropic drug, an assessment of appropriateness for reduction is also done." If a behavior develops after admission several steps are taken before initiating drug therapy. If the behavior is aggressive, one-to-one care is started. Staff evaluate the resident for pain and a full medical work-up follows. When these steps do not indicate the reason for the behavior, the resident is given a psychological evaluation.

At Macon Health Care Center, monitoring of residents' drug therapies includes quarterly and annual assessments by the MDS RN coordinator. The medical director or nurse practitioner reviews these assessments. Also, the nursing home has weekly interdisciplinary behavior team meetings and monthly quality assurance meetings that most attending physicians and all department heads attend. Additionally, the director of nursing has developed a tracking system using the consultant pharmacist's DRR to follow trends and dosage for residents on all categories of psychotropic drugs. The regional consulting nurse also conducts a "corporate" review of residents on psychotropic drug therapy.

Alternative Interventions

All direct care staff interviewed describe staff education as an important piece in the successful behavioral management of residents with mental illness. Additional special sessions for staff working in the Special Needs Unit address the challenge of working with this resident population, as does an "alternative program" that sends direct care staff to the facility's regional office for training. Nursing home staff say this training keeps their behavior management skills up to date.

Approaches to moderate resident behaviors include innovative and creative strategies. For example, the facility has instituted pet therapy - birds, rabbits, cats and a dog, "are wonderful diversions for the residents," says one RN. In fact, during our visit, we observed residents happily greeting a dog that was scampering through the hallways. The administrator credits the social worker and nursing staff as a limitless source of creative thinking.

MANOR CARE HEALTH SERVICES

- Located in Silver Springs, Maryland, a suburb of Washington D.C.
- For-profit nursing home
- 130 beds (28 Medicare certified, 130 Medicaid certified)

Facility Profile

The majority of residents at Manor Care Health Services are long term care residents, many of whom have dementia and other chronic illnesses. The nursing home also has a separate Alzheimer's Unit. This facility has a psychotropic drug usage rate of 38 percent. Many residents at Manor Care come from an assisted living center that is adjacent to the nursing home, particularly as their Alzheimer's disease or dementia becomes more severe.

Approach to Psychotropic Drug Therapy

Manor Care Health Services will generally start residents on low psychotropic drug dosages when beginning a new drug therapy. They also generally obtain pharmacist and psychiatrist input when initiating or making a change in psychotropic drug medication. They will try to monitor new residents for at least one week before prescribing a psychotropic drug, although the staff may use a psychotropic drug on a short term basis to control a resident's agitation and yelling, especially if the resident is a new admission. Each resident in the facility also has a behavior tracking chart that is periodically updated, and a psychologist and psychiatrist are also available for ongoing consultation.

Manor Care Services has a psychotropic drug committee that meets monthly to monitor how the drugs are used. This committee is comprised of the director of nursing, unit manager, consultant pharmacist, and social worker. During their meetings, the members discuss the residents' behavior, response to the drugs, and possible side effects. The social worker at the facility stresses the importance of such monitoring since there are "more patients with psychiatric problems in nursing homes today than ever before." In fact, we observed several residents in the hallways and common rooms that appeared confused and/or were yelling and moaning. Staff comforted these residents by speaking to them in quiet tones or holding their hands; in some cases, they redirected the resident to another location.

The staff express a belief that decisions on when and how to use drugs are unique to each individual and his or her needs. The director of nursing states, "[We] treat patients on an individual basis."

Alternative Interventions

Staff at Manor Care Services attempt various non-pharmacologic approaches to handle behavioral issues. These include: redirecting residents to new activities or locations; changing roommates if that is an issue; changing the timing of direct care activities (such as bathing); talking to residents about their care; and assigning the same staff person to care for the same resident. One of the CNAs we spoke with says that when residents act out aggressively, she may leave them for a short period of time or ask them what is bothering them. Her approach was typical of the care we observed while touring the facility.

MISSION NURSING AND REHABILITATION CENTER

- Located in Mission, Texas, a large suburban town in the Rio Grande Valley
- For-profit nursing home
- 120 beds (30 Medicare certified, 67 Medicaid certified)

Facility Profile

Mission Nursing and Rehabilitation Center admits mostly long term residents and recently discharged hospital patients requiring highly skilled care. Additional specialties include dementia care, orthopedic rehabilitation, and a 20 bed Alzheimer's Unit (the second such unit in the area for which there is usually a waiting list for beds.) Because of a forced closure of a nearby psychiatric nursing facility and this nursing home's reputation for specialized psychiatric care, many recent referrals have a history of mental illness. Despite a high proportion of residents with mental disorders, this nursing home has a low psychotropic drug rate of 16 percent. Many of the residents are Spanish speaking, as are the staff who care for them.

Approach to Psychotropic Drug Therapy

Respondents at Mission Nursing and Rehabilitation Center believe their low psychotropic usage rate is reflective of a policy to avoid the use of such drugs if possible. The pharmacological approach for all residents admitted into the facility already taking a psychotropic drug includes initiation of behavior monitoring and a consultant pharmacist check for appropriate psychiatric diagnosis and dosage suitability. Behavior monitoring is also initiated for all new admission to help direct care staff develop an understanding of the resident.

In an effort to ensure the effectiveness of drug therapies, this facility conducts daily interdisciplinary reviews of all residents who have experienced a change in condition or medication. All department heads are required to attend. The director of nursing also conducts daily medication order reviews. Behavior management programs are developed by an in-house psychology team, to which all staff may refer a resident. This team is made up of a clinical nurse geriatric specialist, psychologist, and psychiatrist. The consultant psychiatrist is also available to assist staff on an as-needed basis.

Staff also describe a corporate belief in specialized training. All staff receive annual psychotropic drug training and satellite training sessions are broadcast via the corporation's "Long Term Care Network." This training is mandatory for all staff, who are then tested on program content.

Alternative Interventions

Mission Nursing and Rehabilitation Center's policy to avoid the use of psychotropic drugs is reflected in the staff's commitment to try alternative interventions for a resident whose onset of behavioral symptoms begin after admission. These alternative interventions include: emotional support of the resident, encouragement of the resident to verbalize what is wrong, time out, and redirection. To manage aggressive residents, staff use calming techniques such as a decrease in sensory stimulation, redirection (especially if the resident is confused), bringing the resident into his/her room, encouraging the resident to verbalize what is bothering him or her, and activity therapy. If none of these methods are successful, the physician is called. Residents whose behavior poses a threat to self or others and who cannot be maintained with either pharmacologic or non-pharmacologic treatment, are transferred to a local psychiatric facility for evaluation and treatment.

MISSION TERRACE CONVALESCENT HOSPITAL

- Located in Santa Barbara, California, a city in southern California
- For-profit individually owned nursing home
- 138 beds (138 Medicare certified, 0 Medicaid certified)

Facility Profile

Mission Terrace Convalescent Hospital's specialties include orthopedic and medical rehabilitation, wound care, and hospice care. According to the administrator, who owns this facility as well as a sister facility with assisted living, the nursing home is becoming "more of a rehabilitation center and less a long term setup;" she also says she "avoids a dementia speciality." The director of nursing describes the resident population as having more family involvement and a higher socio-economic class and education level than most other nursing homes.

Mission Terrace Convalescent Hospital has a moderate psychotropic drug usage rate of 33 percent. The director of nursing says that "although few residents have psychiatric diagnoses and/or dementia., many hospice patients require anti-anxiety drug therapy as part of end of life care. [Additionally], many transitional patients, such as the robust 65 year old who has just undergone hip replacement, usually want a sleeping pill while they are here."

Approach to Psychotropic Drug Therapy

This nursing home has developed separate procedures for residents coming into the nursing home already taking a psychotropic drug and for residents whose drug therapy begins after admission. The MDS RN coordinator says, "for residents admitted and already taking a psychotropic [drug] we determine the behavior [necessitating the drug therapy], monitor and calculate, then work toward reduction." She also describes the steps taken when a resident's behavioral symptoms begin after admission. Firstly, the premedication behavior is identified and a medical work-up is done. Then a behavior management program is started. The MDS RN coordinator believes that: "perhaps as many as 80 percent of the time [the work-up] rules out and diverts the use of a psychotropic drug, especially for urinary tract infections, which can cause aberrant behaviors in the elderly, such as agitation, aggression, confusion, and hallucinations."

At Mission Terrace Convalescent Hospital, the consultant pharmacist monitors psychotropic drugs by reviewing the drug treatment plans and reporting to the director of nursing monthly. These reports are also placed in the residents' medical record. Residents who take more than one psychotropic medication or who are undergoing

dosage reduction are followed by a psychiatrist, while others are managed by the attending physician.

The nursing staff also utilizes a behavior management program developed by the director of nursing. This system is color coded by behavior type and includes a daily tally of behavior episodes observed in the resident and any circumstances that appear to be related to the behavior. This account is kept in the resident's medical record and reviewed by the director of nursing as part of her weekly assessments. Additional discussions about residents taking psychotropic drugs occur at weekly rehabilitation meetings attended by the administrator, medical director, department heads, and other direct care staff.

Alternative Interventions

Mission Terrace Convalescent Hospital will generally attempt alternative interventions for residents with behavioral disturbances. They first rule out medical causes for the behavior and assess the resident for spiritual, social, dental needs, and for the presence of pain. Staff say they utilize one to one, redirection, emotional support, and other behavior management techniques. One registered nurse we interviewed, who is the staff trainer, says "we underestimate the impact of life altering scenarios... these patients feel very threatened over the loss of control. The usual response is to give [the resident] a pill." The director of nursing believes: "for the resident who wanders, or is anxious and confused about where they are and why they are here... a loss of independence is too often overlooked by nursing home care-givers. We encourage all of our staff, from housekeepers to RNs, to offer emotional support to the patient to reduce their [residents] anxiety." Similarly, a charge nurse says, "We try to find other methods, other than drugs."

MOUNTAIN VALLEY CARE AND REHABILITATION

- Located in Kellogg, Idaho, a small town in rural Northwestern Idaho
- For-profit nursing home
- 68 beds (68 Medicare certified, 68 Medicaid certified)

Facility Profile

Mountain Valley Care and Rehabilitation is one of only two nursing homes in the local area. Most of the residents in this nursing home are long-term, although some are short-term, requiring orthopedic and stroke rehabilitation. The majority of the residents are over 70 years old and only a very limited number are independent. This nursing home has a low drug usage rate of 9 percent.

Approach to Psychotropic Drug Therapy

According to the administration, most of the residents on psychotropic medications came to the facility already taking the drugs. Occasionally an in-house resident may be prescribed a psychotropic drug, such as a resident with Alzheimer's disease who begins to hallucinate. However, before medication is prescribed, the staff takes several steps. They assess the resident for medical problems to determine if the behavior is being caused by pain or another physical problem, such as a urinary tract infection. Also, staff record each resident's behavior, noting the type of behavior, the time of day, and what precipitated the behavior. The charge nurse explains that, "We try to establish what behaviors they [residents] demonstrate and develop interventions before we start medications." If none of these interventions work, they will consult the psychiatrist and start a medication.

The nursing home staff reports monitoring residents taking psychotropic medications in several different ways. The charge nurse explains that "once [the resident is] on the med[ication] we do behavior monitoring sheets and continue to look for interventions." The nurses also record any side effects they observe by placing 'side effect' stickers in the resident's medical chart. Once a month, the consultant pharmacist reviews the medications. The psychotropic drug group, consisting of the psychiatrist, director of nursing, MDS RN coordinator, and social services, meets monthly to review charts and behavior sheets and to assess whether or not the drug is effective.

Alternative Interventions

In an interview, the medical director told us that he is the personal physician of most of the residents in the facility and that he has an "aversion to these drugs." He explained that he is concerned about the side effects of psychotropic drugs as well as the regulations surrounding their use. Instead, he advocates alternatives, such as behavior management.

Staff also explain that the consulting psychiatrist has made this easier with his ideas for alternative treatments and his experience with using the different drugs.

The nursing home uses several non-pharmaceutical techniques to control residents' behavior. As described above, staff monitor and record the circumstances of residents' targeted behaviors. They graph these behaviors over time and record in the chart which interventions were successful in order to identify what precipitates the behavior and remove it. For example, we met one resident who had been acting out aggressively towards other residents until staff discovered it was because he felt territorial of the space in front of his door. To alleviate some of his anxiety, the staff placed a small rug in front of his door to remind other residents not to stand there. The nursing home also uses pet therapy (cats, birds, and dogs) to calm residents. In addition, they have allowed a local child day care center to build a playground on their grounds. Staff say the nursing home residents enjoy watching the children play.

PARK NURSING HOME

- Located in Rockaway, New York, in the borough of Queens, New York City
- For-profit nursing home
- 196 beds (196 Medicare certified, 196 Medicaid certified)

Facility Profile

Park Nursing Home has a high proportion of mentally ill residents. The age range of the entire resident population is from 36 to 90, with an average age between 60 and 70 years. Most are long term care and many have a long standing diagnosis of schizophrenia or advanced dementia. As soon as the inspection team entered the facility, we observed intense activity and noise levels, with some confused residents wandering throughout the facility. However, the staff used a firmly directive yet gentle approach that was non-threatening and non-confrontational to guide residents.

Park Nursing Home actively seeks out residents with a history of mental illness. The administrator credits a contract with the New York State Mental Health Authority as keeping the facility competitive while also providing a much needed public service to a marginal population; he explains that State psychiatric institution closures have displaced many patients.

Approach to Psychotropic Drug Therapy

Park Nursing Home uses a highly systemized approach for residents taking psychotropic drugs, starting with an automatic psychiatric consultation for all residents coming into the nursing home already taking psychotropic medications. Staff attempt to discontinue the drugs for these residents. Whether or not the resident is newly prescribed or has a history of taking such drugs, the drug therapy plan is developed by the psychiatrist, who determines a pharmacologic versus behavior modification approach, or a combination of the two. The director of nursing believes that only by "individualizing the resident's plan of care with input from a multi-disciplinary team, can there be a successful outcome." Further, the medical director conducts weekly chart reviews for those residents who have had a change in condition and physically examines any newly admitted resident. Beyond the monthly DRR, a consultant pharmacist also reviews three to eight medical records a week and makes necessary recommendations to the physician of record.

Quality control for all residents taking a psychotropic drug includes a behavior monitoring record, weekly RN psychotropic drug notes, interdisciplinary notes evaluating the resident's current behaviors and response to all interventions, and a weekly psychiatrist note that includes an assessment for side effects and efficacy of continued treatment. When a resident experiences a change in condition or behavior, an automatic

psychiatric consult is stimulated. Finally, all residents with a mental illness diagnosis are seen by the psychiatrist once a year or if not stable, every three months. Because of the high proportion of residents with mental illness, Park Nursing Home maintains 24 hour and 7 day psychiatric consultation coverage.

Alternative Interventions

The Park Nursing Home administrator believes the first step to successful alternative management is to observe all new admissions into the facility on a one to one basis. They also use activities therapy and psychiatric therapy and an innovative redirection approach that places diversionary objects in common areas. For example, a dresser with its drawers filled with fabrics and other safe objects allows the residents the opportunity to open the drawers, pull out the fabric, and begin unfolding and re-folding the material.

Continuity of care staff is also cited by all nursing home staff as integral to modifying residents' behavior. The administrator describes staff retention as "extremely important to us; we try to accommodate [staff's] personal needs as much as possible." Almost all of the CNAs at this nursing home are long term employees who have established relationships with both the residents and their families. The charge nurses in the care units make every effort to resident assignments unchanged from day to day. The three CNAs we interviewed say that the change in the nursing home resident population over the last two years has been a difficult adjustment for them. As one stated, "These patients are a lot of work. As soon as you finish giving care to one, get them bathed and dressed, and you move on to the next, the first has already taken off his clothes and you have to start all over."



Comments on the Draft Report

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

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Health Care Financing Administration

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Deputy Administrator Washington, D.C. 20201

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OFFICE OF INSPECTOR GENERAL

TO:

Janet Rehnquist

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FROM:

Ruben J. King-Shaw Jr.

Chief Operating Officer and Deputy Administrator Centers for Medicare & Medicaid Services

Office of Inspector General (OIG) Draft Report: Psychotropic Drug Use in SUBJECT:

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.

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 & Medicald Services (CMS). We are exercising fiscal restraint by exhausting our stock of stationary.

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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 (<u>www.hcfa.gov/medlearn</u>). 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