Office of Inspector General: U.S. Department of Health and Human Services

Overmedication of Nursing Home Patients Troubling

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With 46 million beneficiaries, any issue facing Medicare is a cause for concern.

A government report this week has documented a problem regarding the use of antipsychotic drugs in nursing homes. Too many of these institutions fail to comply with federal regulations designed to prevent overmedication, giving nursing home patients antipsychotic drugs in ways that violate federal standards for unnecessary drug use.

The report also found that these powerful, at times dangerous drugs were often prescribed for uses that are not approved by the Food and Drug Administration and do not qualify as medically accepted for Medicare coverage. Potentially most alarming, 88 percent of the time these drugs were prescribed for elderly patients with dementia, a population the FDA has warned faces an increased risk of death from this class of drugs.

Despite the fact that it is potentially lethal to prescribe antipsychotics to patients with dementia, there's ample evidence that some drug companies aggressively marketed their products towards such populations, putting profits before safety.

Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged - and seek solutions.

The Department of Health and Human Services initiated the report when a member of Congress questioned how many nursing home residents received a class of antipsychotic drugs introduced in the 1990s, among them risperidone and olanzapine. These drugs, known as "atypical" or "second generation" antipsychotics, replaced (at much higher cost) antipsychotic drugs introduced in the 1950s and 1960s to treat schizophrenia.

The FDA approves these and other drugs based on scientific proof of safety and effectiveness for specific uses. The agency also reviews scientific evidence to determine what warnings a drug must carry.

For atypical antipsychotics, the FDA imposes its strongest safety warning, often called a "black box warning," emphasizing an increased risk of death when used in elderly people with dementia. Physicians can use their medical judgment to prescribe drugs for uses unapproved by the FDA, including to patients for whom the boxed warning applies. Ideally, however, physicians who prescribe in such ways first determine that the benefits outweigh the risks.

The report also found:

- About 14 percent of nursing home residents, or nearly 305,000, had Medicare claims for these antipsychotic drugs.
- A little more than half of the antipsychotic drug claims for which Medicare paid should not have been covered because the claimed drugs were not used for medically accepted indications or not documented as provided to patients.
- For one in five residents, nursing homes dispensed these drugs in a way that violated the government's standards for their use. For example, the prescribed dose was too high or residents were on medication for too long.

Obviously, millions of taxpayer dollars are misspent if the Medicare program is paying for thousands of nursing home residents to get these drugs in violation of program requirements.

And although most physicians and nursing homes dispense antipsychotic drugs with the best interests of patients in mind, it is of great concern that so many nursing home residents are prescribed these drugs in the first place. The report didn't explore this issue, but a series of lawsuits and settlements that DHHS helped bring about suggest that many pharmaceutical companies have improperly promoted these drugs to doctors and nursing homes for many years.

For example, Eli Lilly pled guilty to criminal charges associated with illegally marketing its drug Zyprexa (olanzapine), including to doctors that treat elderly nursing home patients. Several other pharmaceutical companies -- Bristol-Meyers Squibb, Astra Zeneca and Pfizer -- settled government allegations that they improperly promoted their antipsychotic drugs for unapproved uses. Federal prosecution is pending against Johnson & Johnson for allegedly paying millions of dollars in kickbacks to induce Omnicare, the nation's largest long-term care pharmacy, to recommend the use of Risperdal in treating nursing home patients, many of whom

had dementia.

The drug companies have paid billions to resolve these civil and criminal liabilities under federal health and safety laws. But money can't make up for years of corporate campaigns that market drugs with questionable benefits and potentially deadly side effects for vulnerable, elderly patients.

To solve this problem, everyone has a role to play.

Doctors should base prescribing decisions on their best medical judgments, weighing scientific evidence and an especially careful analysis when they are prescribing drugs for off-label use.

Nursing homes and pharmacies that serve the elderly should base drug-dispensing decisions on the best interest of the patient, not on improper influence of drug companies.

Family members of nursing home residents must ask questions about medications that their loved ones take, learning the reasons for their use, proper dosages and possible side effects.

Government must uphold patient safety standards established for nursing homes and combat off-label promotion of these powerful and potentially lethal drugs.

And drug companies should follow laws designed to protect patients and not promote drugs for unapproved uses -- or pay kickbacks to doctors and institutions to influence their prescribing.

As the huge Baby Boom generation ages, 10,000 Americans a day for the next 18 years will become newly eligible for Medicare. The future is challenging enough; we must not leave unaddressed the current, urgent problem of antipsychotic drug use among nursing home patients.