Deliberations On and Myths About OBRA ’87 Psychopharmacological Medication Regulations

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Editor’s note: The author was employed as a pharmacy consultant by the Healthcare Financing Administration (now the Centers for Medicare and Medicaid) until his retirement in 1999. He was one of the few officials who consulted with professional organizations outside government in the process of developing those regulations.

The Omnibus Budget Reconciliation Act of 1987 (OBRA ’87) resulted in regulations and guidelines governing the use of psychopharmacological medication in nursing homes. How were they developed? Was a commission used to address this issue? Did the FDA write them? Did Congress write them?

INSTITUTE OF MEDICINE REPORT

It might surprise you to know, that the psychopharmacological regulation and guidelines were developed by the Health Care Financing Administration (HCFA). The Institute of Medicine (IOM) played a critical role in the reform of nursing homes. It was IOM report in 1986 that stimulated nursing home reform through congressional action. But the IOM only mentioned psychopharmacological drugs twice. These two mentions were both in the context of excessive use of such drugs being an indicator of poor nurse staffing. The IOM did not have specific recommendations concerning the regulation of psychopharmacological medications. But HCFA, and Congress, did!

HCFA PROPOSED RULES

When the IOM report was released, HCFA immediately began writing proposed regulations, that were published on October 16, 1987. This proposal called for the regulation of antipsychotic drugs, and unnecessary drugs.

ANTIPSYCHOTIC DRUG

The October 16 proposed regulation would restrict the use of these drugs to residents with a “specific condition” as diagnosed and documented in the clinical record. The term “specific condition” was not created by HCFA. We (The term “we” is used to describe the entire HCFA chain of administrative and legal approvals, as well as, the medical and pharmacy associations who assisted us in writing the regulations.) used the term “psychosis” in the proposed regulation primarily because we were not, as yet, well schooled in the Diagnostic and Statistical Manual, Third Ed. (DSM-III). The term “psychosis” cleared HCFA and the Department of Health and Human Services (HHS) and was changed in the Executive Office of Management and Budget (EOMB) to “specific condition.” Although we thought this change was unnecessary, it turned out for the better because “specific condition” later allowed HCFA to include “dementia” in the scope of this regulation. This is because “dementia” is not strictly a “psychosis” according to DSM-IV-TR, since it is primarily defined by “cognitive loss” and not by “psychotic symptoms.”

We also proposed that residents that were using these drugs receive gradual dose reductions and behavioral interventions unless such interventions were “clinically contraindicated.” We did this specifically because we thought there was a reservoir of residents who continued to be on these drugs inappropriately, and who would potentially benefit from a trial gradual dose reduction to determine continued need.

UNNECESSARY DRUG

An unnecessary drug was defined as any drug when used

- in excessive dose (including duplicate therapy), or
- for excessive duration, or
- without adequate monitoring, or
- without adequate indications for use,
- in the presence of adverse consequences that indicate the dose should be reduced or discontinued, or any combination of the reasons above.

The important aspect of this regulation is that it is applicable to ANY drug. One might ask why the antipsychotic drug regulation was necessary when we were seeking such broad authority under the unnecessary drug provision. Antipsychotic drugs were singled out because it was determined that this class of drugs had the greatest potential for “chemical
restraint,” which was a term used largely by the lay press and numerous congressional inquiries.

OBRA 87

The next major event that occurred was the enactment of OBRA 87 on December 22, 1987. This law also endeavored to implement the IOM report. We did not expect that Congress would enact OBRA 87, and this is why we proceeded with the HCFA proposed regulation. OBRA 87 had two major provisions dealing with psychopharmacological medications: (1) chemical restraints, and (2) psychopharmacological drugs.

The chemical restraint statute says the resident has the right to be free from “chemical restraints” imposed for the purpose of discipline or convenience and not required to treat medical symptoms except when necessary to ensure the physical safety of the residents or other residents.

The psychopharmacological drug statute required that these drugs could only be used as part of a plan the facility designed to eliminate or modify the symptoms for which the drug was prescribed and only if the plan was reviewed for appropriateness at least annually by an independent outside resource.

COMPETING REMEDIES?

Our view of the OBRA 87 statute on psychopharmacological medications was ambivalent. On one hand, we were greatly pleased with statutes that basically endeavored to achieve the same objectives as the proposed rule. The chemical restraint statute relied, in part, on the existent of “medical symptoms” to limit use. The proposed regulation relied on a similar concept—the presence of a “specific condition.” The psychopharmacological drug statute called for a “plan to eliminate or modify the symptoms” for which the drug was prescribed, which was very similar to the antipsychotic drug proposed rule calling for “behavioral interventions.” But we anticipated problems with the implementation of the statute:

- We knew that it would be difficult for surveyors to determine if a drug was being used for “discipline” or “convenience,” since these words explored the “intent” behind the order for chemical restraints, and “intent” is very hard to determine and prove.
- The statute allowed the use of a chemical restraint in order to “ensure the physical safety of the resident or other residents” without regard to medical symptoms, environmental circumstances, and social circumstances. This would allow the use of a chemical restraint if the individual were harming himself or others due either to pain (a medical symptom), excessive heat, noise, or humidity (environmental circumstances), or physical or psychological abuse (social circumstances). The use of a chemical restraint in these circumstances would be appropriate only in an emergency, and only for the time until an accurate diagnosis could be made. But the statute makes no provision for such an emergency. The literal wording of the statute said that restraints could be used to: “ensure the physical safety of the resident or other residents.” We could not believe that Congress would allow the use of a “chemical restraint” (for more than a short period of time) if the patient were causing harm as a result of a treatable medical problem such as electrolyte imbalance, seizure disorder, or hyperglycemia. We hoped that we could address this question, and others, with a proposed regulation (to be discussed later) that would clarify the statute.
- The statute would not allow the use of a chemical restraint when a resident is harmful to the staff. The statute does not list harm to staff as a reason for using chemical restraints. There should be allowance for this in an emergency until the staff can accurately diagnosis and treat the cause for the behavior.
- The psychopharmacological drug statute only called for a review of the appropriateness of the plan by an “independent external consultant.” We were not interested in pursing another review of drug therapy in nursing homes, and we knew we would have great political difficulty defining the qualification of an “independent external consultant,” since there would be significant competition among health professionals who sought to claim this function for themselves.
- We had experience in using the term “chemical restraint” in regulations for Medicaid providers such as intermediate care facilities for the mentally retarded. We found the “chemical restraint” term was difficult to define and consequently was not a practicable means of regulating the inappropriate use of psychopharmacological drugs. As a result we had deleted this term from these and other regulations. We thought the unnecessary drug regulation would be better enforced through criteria such as excessive dose, excessive duration, without adequate indications, without adequate monitoring, or in the presence of adverse effects. These criteria are medical and would be better understood by state surveyors who are predominately registered nurses. Nurses are schooled and experienced in such criteria but were not as experienced with the “chemical restraint” criteria (ie, discipline and convenience). We thought the unnecessary drug criteria would be more successful, particularly if we could provide surveyors with specific guidance on dosing, duration, indication, and monitoring, and so forth.

THE RESOLUTION

When confronted with questions about the meaning of a statute, regulators usually refer to committee reports to learn about the debates that the Congress had in developing the statute. This is very often a better picture of the intent of Congress. This statute had Senate and House committee reports, but they were of little help in clarifying congressional intent since they merely repeated the statutory provisions.

We had to attempt to resolve the foregoing problems before we could promulgate a final rule on the statutes regarding chemical restraints and psychopharmacological drugs. But we faced some rather short deadlines for implementing OBRA 87 provisions. If we proceeded solely with the statute and withdrew the antipsychotic drug regulation, we faced the possibil-

SPECIAL ARTICLE
Kidder 269
ity that a poorly defined statutory term would result in poor enforcement and ultimately in a partial or complete failure to protect residents from misuse. As a consequence of these considerations and in an effort to resolve issues with the statutes, we decided to go ahead with implementation of the antipsychotic and unnecessary drug regulation and propose a separate regulation on chemical restraints and psychopharmacological drugs. This proposed rule was published February 5, 1992. By August of 1993, we had prepared the first draft final rule. But, by this time good data were becoming available on the results of the antipsychotic and unnecessary drug regulations. Consequently, HCFA management decided that the basic statutory outcomes were being achieved, and there was no need to finalize controversial rules on this subject. In one way, this was unfortunate because the draft final rule would have done much to reduce the number of terms (eg, antipsychotic drug, unnecessary drug, chemical restraint, and psychopharmacological drug) and eliminate confusion about the use and meaning of these terms.

**THE GUIDELINES**

The initial draft guidelines for antipsychotic drugs were developed with considerable assistance from a geriatric psychiatrist who directed us toward the DSM-III and subsequently the DSM-IV. There was fear that the regulation of antipsychotic drugs would result in shifts from antipsychotics to benzodiazepines that if given in high enough doses could also be used as “chemical restraints.” Consequently, the unnecessary drug regulation was needed to regulate potential prescribing shifts to other drug categories. Antidepressants were also included in the guidelines, but no specific guidelines were included for indications for use, dose, gradual dose reduction, or monitoring criteria. In fact, surveyors were told not to look for behavior monitoring charts documenting symptoms of depression because we did not want to erect paperwork barriers to the accurate diagnosis and treatment of depression. This was because a recent JAMA paper had documented the undertreatment of depression in nursing homes.

This package of guidelines was sent to all interested parties for review and comment including: medical, nursing, pharmacy, advocacy, and nursing home associations. After the guidelines were distributed to interested parties, I received word that the American Psychiatric Association was having a meeting with my supervisors and was bringing their lawyers to the bureaucracy, such meetings usually mean only one thing—a lawsuit or the threat of one. I told my wife that I would soon be spending more weekends with her instead of with these regulations. But at the meeting, Dr. Barry Rovner, a geriatric psychiatrist, said that the regulations and guidelines were basically “pretty good” but needed some adjustments. I was speechless with amazement! Dr. Rovner and many of his colleagues worked with me to improve the fairness and practicality of the regulations and guidelines. Dr. Steve Levenson and his colleagues in the American Medical Directors Association also became invaluable resources. I was grateful to all these individuals. We had debates, but I frequently deferred to them, saying that they were in the practice of geriatric psychopharmacology and I was not.

In the meantime, the proposed regulation and the OBRA 87 statute were “joined” into one regulation that basically contained the “word-for-word” OBRA 87 provisions and those elements of HCFA’s proposed rule not included in the OBRA 87 legislation. This “joining” included the proposed rules on antipsychotic and unnecessary drugs. Advocacy groups opposed this “joining” because they wanted the OBRA 87 provisions to be further detailed in regulations and not simply a repetition of the statute. The HCFA view was that the statute was detailed enough. The impasse was resolved by agreeing to publish the “joined” statute and proposed regulation as a final rule with requests for additional public comment. This document was published on February 2, 1989 as a “Final Rule with Requests for Comments.” A second final rule including changes resulting from public comment was published on September 26, 1991. There were considerable legal and political complications in establishing the effective date of the OBRA 87 regulations. But, in general, implementation of OBRA 87 regulations began October 1, 1990.

**OPPOSITION TO THE REGULATIONS**

Despite congressional support, opposition to these requirements was strong. Objections focused on the following arguments:

- A number of individuals and organizations believed that HCFA should not hold the facility responsible for psychopharmacologic drug misuse since it is the physician who prescribes the drugs. The HCFA response was to explain that the facility (in particular its governing body) is ultimately responsible for the quality of care provided. A physician who attends residents in a long-term care facility is essentially an outside professional resource, and the facility must assume responsibility for the quality of his or her services.
- A number of individuals also argued that the Secretary did not have statutory authority to enforce the unnecessary drug regulation. The response stated that the Secretary had the general authority, quite apart from the OBRA-87 statute, to promulgate regulations necessary to protect the health and safety of residents in these facilities.
- It was also argued that the unnecessary and antipsychotic drug regulations represented an “interference with the practice of medicine” since they required the nursing home to exercise medical judgments that would interfere with the physician’s treatment decisions. HCFA’s response explains that the facility was not to make medical judgments in place of the physician. But the facility is responsible for ensuring compliance with standards for drug therapy that had been established through extensive consultation with and agreement from physicians who were specialists in the field of geriatric psychopharmacology.
- Concern was also expressed over unlicensed regulators overriding the clinical judgment of the physician when citing the facility for an “unnecessary drug.” This, of
course, was of great concern. But only licensed pharmacists and nurses were used to apply the drug therapy regulations, and they had to use extensive drug therapy guidelines (eg, dose, duration, and indications for use) approved by a specialist in the field of gerontology. Moreover, surveyors were provided with written instructions and training urging them to only make deficiency decisions in obvious cases where the resident’s functional status was being impaired or was likely to be impaired.

- Others argued that the rules were unfair to nursing homes since these drugs (especially antipsychotic drugs) were also misused in the outpatient setting, as well as in hospitals, and constituted a systemic health care problem that encompassed hospitals, nursing homes and ambulatory care. Therefore, any attempt to correct the problem should be through a systemic approach. HCFA’s response stated that even though there may be a systemic problem, nursing homes should not be excused from doing their part in achieving improvements immediately. This debate began when a study by Dr. Judith Garrard showed that in Minnesota 16% of the patients entering the nursing home from hospitals had discharge orders for antipsychotic medication. Mr. Thurston, a nursing home administrator, was critical of HCFA in a letter to the editor for not regulating hospitals to the same degree as nursing homes relative to these medications. On December 19, 1997, HCFA proposed a hospital regulation that would require that patients discharged from a hospital with orders for psychopharmacologic medications be diagnosed with conditions that justify the use of these medications. This regulation, (as of 4/11/03) has not been finalized.

THE SYNERGY OF EDUCATION AND REGULATION

During the debate on the psychopharmacological medication regulations, we received a letter from the American Medical Association in opposition, urging HCFA to pursue a more educational approach. After more than 30 years of public complaints and professional concern culminating in an Act of Congress, we did not believe another purely educational approach would be effective, or allowed. We had also experienced less than successful efforts through educational approaches such as drug utilization review and drug regimen review. But we were committed to an educational as well as the regulatory approach, and shortly thereafter, an opportunity presented itself.

Vanderbilt University School of Medicine’s Department of Preventive Care developed and published a manual describing such techniques after OBRA 87 was implemented. This manual is entitled, Managing Behavioral Symptoms in Nursing Home Residents: A Manual for Nursing Home Staff, (Vanderbilt Manual). It describes the 10 most common behavioral symptoms encountered in nursing homes, discusses why these symptoms occur, provides practical “down to earth” ways to deal with behavioral symptoms if they do occur, and teaches common sense interventions staff can do to prevent occurrence. What made this manual unique was a study of its impact published in the Archives of Internal Medicine. In this study, use of the Vanderbilt Manual resulted in an experimental group of participating nursing homes experiencing a 59% greater reduction in the use of antipsychotic drugs (with no coinciding increase in behavioral symptoms). An unexpected positive by-product of the use of this manual was a 31% decrease in days of physical restraint use. This unexpected finding suggests that when nursing staff is trained to avoid one form of restraint (eg, chemical) the training is transferable to other forms (ie, physical). In June of 1995, the Health Care Financing Administration sent a copy of The Vanderbilt Manual and a copy of the Archives of Internal Medicine paper to every Medicare and Medicaid certified skilled nursing facility in the United States. It was hoped that this educational tool would provide them with the means to prevent and/or cope with behavioral disturbances and avoid use of restraints and the risk of regulatory sanction.

PSYCHOPHARMACOLOGICAL MEDICATION REGULATION MYTHS

Myth Number 1: Maximum Doses

The idea that the doses listed in the guidelines represent maximum doses is not true. The guidelines clearly state that these doses are: “not maximum doses.” Moreover, the text of the guideline clearly states, for each category of psychopharmacological medication, the following:

“A (long action benzodiazepine, short-acting benzodiazepine, hypnotic, antipsychotic) drug should not be used unless its use is less than, or equal to, the following listed total daily doses unless higher doses are necessary for the maintenance, or improvement in the resident’s functional status.”

Some health professionals have referred to these guidelines as being “maximum doses,” which, of course, they are not. This behavior is not unusual in my experience. I have often encountered individuals who would seek to enforce their own standards of care by falsely attributing their establishment to a standard-setting organization, such as the federal or state government. It makes life easier.

Myth Number 2: Prohibition of PRN Antipsychotic Orders

Unfortunately, some have perpetuated the idea that HCFA’s regulations and guidelines prohibit the use of PRN (“as needed”) antipsychotic orders. At one time this idea was suggested in the early drafts of the guidelines, but after public comments it was deleted. The original thought was that the conditions for which antipsychotic medication were used required long-term use, and when PRN use was employed, it was primarily for sedation (eg, chemical restraint). But we dropped this idea when a psychiatrist called and explained his use of PRN antipsychotic orders. He would maintain his patients on a routine low dose and avoided adverse effects. The PRN order allowed short-term increase in the dose in order to treat breakthrough symptoms. In the long run, the patient was maintained on a lower dose and experienced fewer adverse effects. Because we did not want to constrain such practices, we withdrew this proposal.
Myth Number 3: Drug Holidays

In the HCFA proposed rule (October 16, 1987), we proposed that patients using antipsychotic medication undergo “drug holidays” periodically. I was not enthused about this concept because I did not think a single drug holiday would be very useful. But it was the idea of one of my supervisors whom I could not dissuade. I waited for the public comments. As I anticipated, they were not favorable, and we dropped the idea in favor of emphasizing gradual dose reductions. But, because it was in the Federal Register (as a proposed rule) some thought was a HCFA final rule. This is another example of individuals who personally adopted this standard, but placed responsibility for it on another entity.

Myth Number 4: Gradual Dose Reductions for Individuals with Severe Mental Illness

In the first set of guidelines, we determined that the regulations/guidelines should be applicable to residents who were formerly in psychiatric care facilities. We reasoned that there would be a reservoir of these patients who were prescribed these drugs inappropriately and who are now residing in nursing homes. It was not long after implementation in October of 1990 that the letters and calls of objection arrived. Many of these residents were appropriately taking these medications, and the gradual dose reductions were contraindicated, despite the guideline stating that residents need not undergo a gradual dose reduction if their physician explained why a gradual dose reduction was clinically contraindicated. We quickly sent a letter to the HCFA regional offices and state survey agencies changing this guideline so all former psychiatric patients would be exempt.

RESULTS

As shown in Table 1, the regulation/guideline had its intended effect. These data indicate a significant decrease in antipsychotic and hypnotic medications, and an increase in antidepressant medications with little change in antianxiety medications. This outcome is very close to what HCFA and its advisors from the American Psychiatric Association and the American Medical Directors Association expected. But, the critical question is whether these changes were or were not accompanied by improvements in residents’ functional status. A number of studies conducted during this time period support the idea that reductions in use of psychopharmacological medications did improve the functional status of residents or, at least, did not cause decline.11,13–19

Efforts to achieve these same results would be difficult to achieve through educational efforts alone. According to one study that achieved positive results before OBRA 87, such efforts are “not inexpensive.”13 It would have been difficult to sustain in-service training efforts long enough to change long established and outdated nursing home medical model practices through the educational option alone. HCFA enforcement of regulations most likely created a stimulus for change that allowed a means for change to occur through the training materials that HCFA, state survey agencies, and many professional associations were providing to nursing facilities during this time. The Vanderbilt study summarized this social phenomenon best when it stated, “Synergy between regulation and education may be an effective method to improve prescribing of antipsychotics in nursing homes.”11

REFERENCES


Table 1. Psychopharmacologic Interventions in Nursing Homes

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Note: OBRA ’87 regulations began implementation on 10/1/90.