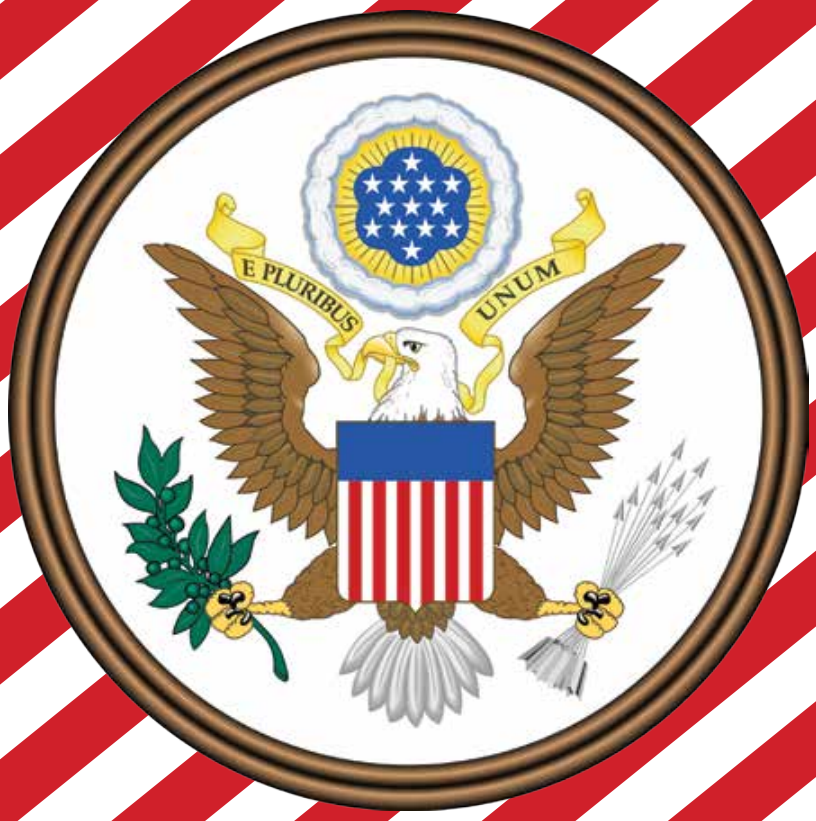

ABSTRACT

In 1990, the Omnibus Budget Reconciliation Act included requirements for Medicaid patients in an effort to save the federal government money. The requirements included a prospective drug utilization review, patient counseling, and maintenance of patient records. Subsequently, in 1993, when the pharmacy practice requirements went into effect, this federal regulation became the standard of care for pharmacists and part of their professional duty. This article suggests that the pharmacy should review all active pharmaceutical ingredients and excipients that are dispensed at the pharmacy and list all interactions or potential side effects in the review, so that a proper drug utilization review can be performed.

Drug Utilization Review: Our Patients Deserve Our Best

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In 1990, the Omnibus Budget Reconciliation Act (*OBRA, '90*), included requirements for Medicaid patients in an effort to save the federal government money. The requirements included a prospective drug utilization review (pro-DUR), patient counseling, and maintenance of patient records.[1,2] Subsequently, in 1993, when the pharmacy practice requirements went into effect, this federal regulation became the standard of care for pharmacists and part of their professional duty.[1,2]

Pharmacist and Attorney Nicholas J. Lynn, writes in a continuing education lesson, "A pharmacist should view the OBRA '90 requirements as more than rules that must be complied with; they are, in fact, a federally mandated risk management program."[3] Insurance companies and payors have also warned pharmacists to perform prospective DURs.[1,2]

The prospective DUR can only be appropriately performed if the pharmacist has first collected data from the patient, including but not limited to drug allergies, medical conditions (the present condition which requires the drug and any other medical conditions), and a list of prescription and non-prescription drugs that the patient is currently taking.[4]

While the DUR should be performed prior to transmitting a claim to a third party, in many cases, pharmacists do not discover an issue with dispensing a particular drug until the third-party payor alerts them. For compounded medications, common software systems available do not usually aid in the DUR process. The prescriptions are also usually paid for in cash, and there is no third-party review to aid the pharmacist. This makes it critical for a proper DUR to be performed when dispensing a compounded preparation.

In the author's experience, compounded medications can require more research,

"A pharmacist should view the OBRA '90 requirements as more than rules that must be complied with; they are, in fact, a federally mandated risk management program."

as there are no clinical trials or package inserts to review. A compounding pharmacist must be aware of the side effects, potential drug-drug, and drug-condition interactions for any active pharmaceutical ingredient (API) they are dispensing.

In some cases, there may be additional information that should be provided to the patient. For example, if the API has a black box warning, the pharmacist has a duty to warn the patient as to potential risks.

In addition to reviewing the collected patient data for any potential issues, the pharmacist needs to be aware of potential interactions that require the need to screen the patient for particular drugs or conditions.

For example, Feel Good Pharmacy (FGP) dispensed an intracavernosal erectile dysfunction medication (QuadMix) to patient NB, who was currently taking Trazadone at bedtime. Concomitant use of the two medications potentiates the risk of priapism[5,6] and NB subsequently ended up in the emergency room (ER) due to the combination. The pharmacist was unaware of this interaction.

FGP also dispensed Bi-est (a combination of estriol and estradiol) to patient GH who had a past medical history of Deep Vein Thrombosis. The prescription was written by her family practitioner. While the patient did not have any ill effects from the preparation, when GH visited the vascular specialist for her follow up, he was very concerned about the use of estrogen and let the pharmacist know that she should be paying more attention to her patients.

Another commonly compounded preparation is "Low-dose Naltrexone." The pharmacist should include in the counseling with the patient to discuss with the prescriber the need to discontinue the medication prior to any surgery. According to the website lowdosenaltrexone.org, "LDN users who are planning to have surgery performed generally discontinue taking LDN for one or two days prior to the scheduled procedure. They then are able to re-start it promptly after surgery, when they no longer need to take narcotics regularly."[7]

In addition to appropriately screening the patient's data at the time of reviewing the drug for appropriateness, an intervention

Compounding pharmacists, like all other pharmacists, are required to perform DURs and counsel patients. Patients are entitled to having the pharmacy staff collect their pertinent data and having the pharmacist review it prior to filling their prescription. Performing this task may make the difference in a hospital visit or potentially the patient's death.

is required when information yields any issue.[1,2] Interventions should include contacting the prescriber to discuss any necessary changes in the therapy (both drugs and dosages). Interventions should also include informing the patient of any potential issues to help them make informed decisions about using the medication.

Another thing to consider when counseling patients is to inform them of the overdose effects of certain compounded preparations. Several instances of patient harm with both liothyronine (T3) and clonidine are in the literature.[8-10] When a patient presented at the ER with severe abdominal cramps and diarrhea, it was determined that the patient had been overdosed with T3 due to a compounding error. Neither the patient nor the ER physician knew that this was an overdose symptom.[8]

Another very serious overdose in compounded preparations is the misuse of topical anesthetics.

Compounding pharmacists, like all other pharmacists, are required to perform DURs and counsel patients. Patients are entitled to having the pharmacy staff collect their pertinent data and having the pharmacist review it prior to filling their prescription. Performing this task may make the difference in a hospital visit or potentially the patient's death.

CONCLUSION

It is suggested for the pharmacy to review all APIs and excipients that are dispensed at the pharmacy and list all interactions or potential side effects in the review so that a proper DUR can be performed. This customized reference can be reviewed by the pharmacist performing the DUR to eliminate or reduce preventable errors.

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