

Drug Diversion Toolkit

Patient Counseling—A Pharmacist's Responsibility to Ensure Compliance





Content Summary

This booklet educates pharmacy personnel about the requirements surrounding patient counseling standards. Pharmacists will understand the Federal requirement under the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to offer patient counseling to Medicaid patients. Pharmacists will understand that laws established by each State may differ and will recognize the importance of compliance with State regulations. This booklet provides guidance on when counseling may not be required as well as alternative methods to offer counseling when a patient is not present in the pharmacy or when language barriers exist. Finally, this booklet discusses the provision of written materials to supplement patient counseling and the importance of documentation to demonstrate compliance with the requirement.

A patient's complete understanding of how to use a prescription medication is critical to successful adherence to medication therapy. An effective counseling session between patient and pharmacist ensures that the patient receives essential educational information related to the medication and provides an opportunity for the patient to ask questions. Not only is patient counseling the right thing to do, it is mandated by law in most States. It is vital to document this care provision to validate compliance.

The Omnibus Budget Reconciliation Act

Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) was enacted by Federal lawmakers to ensure fiscally responsible spending of Federal funding while concurrently ensuring safe and effective therapeutic outcomes for Medicaid patients. OBRA '90 includes three key drug utilization review (DUR) components that impact the practice of pharmacy: prospective drug utilization review, record-keeping requirements, and a requirement to offer counsel.[1] OBRA '90 further outlines specific information that the pharmacist, while exercising professional judgment, should discuss with the patient when the offer to counsel is accepted, such as:

- Name of the drug (brand name, generic, or other descriptive information);
- Intended use and expected action;
- Route, dosage form, dosage, and administration schedule;
- Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including how to avoid them and the action required if they occur;
- Techniques for self-monitoring of drug therapy;
- Proper storage;
- Potential drug-drug[2] interactions or drug-disease contraindications;
- Prescription refill information; and
- Action to be taken in the event of a missed dose.[3]

As a condition of participation and to receive continued Federal funding for State Medicaid programs, OBRA '90 and regulations adopted by CMS[4] require States to establish standards regarding implementation of patient counseling requirements. Although the original Federal requirements of OBRA '90 were intended to apply only to Medicaid beneficiaries, States established unique patient counseling regulations for both Medicaid and non-Medicaid beneficiaries. As a result, all patients are entitled to the benefits associated with patient counseling standards of care.



Counseling When the Patient Is Not Present

When prescriptions are delivered or mailed to patients, pharmacies are not exempt from the patient counseling provision of care. Pharmacies must establish a process to offer patient counseling services when a patient is not present. One method to ensure compliance is to provide printed drug information that includes pharmacy business hours as well as a toll-free telephone number for patients to speak with a pharmacist. Mail order pharmacies commonly use this method. Some States establish regulations specifically for mail order pharmacies, according to the National Health Law Program (NHeLP). It is common to require the pharmacy to provide information that includes a toll-free phone number on the prescription bottle or label as well as the pharmacy's business hours. In addition, States may have specific regulations that require a mail order pharmacy to be open a certain number of hours (and sometimes a certain number of days) per week in order to be compliant.[5]

Limited English Proficient Patient

Depending on local and regional demographics, pharmacies may interact with different degrees of non-English speaking patients. The largest numbers of limited English proficient (LEP) patients speaking Spanish, Chinese, Korean, Vietnamese, or Tagalog who spoke English "less than very well" lived in the States of New York, California, Texas, and Florida, according to the 2011 language mapper from the U.S. Census Bureau.[6] New York has passed a law that requires language services to LEP patients. Any pharmacy that is part of a group of eight or more pharmacies located within New York State and owned by the same corporate entity is required to provide, at no charge, LEP individuals with oral language translation services for medication labels, associated warning labels, and other written materials.[7] It is important to become familiar with the regulations in your State and establish a means to safely provide medications and counseling to LEP patients in your pharmacy to ensure compliance.

Provision of Written Information

Providing written information to a patient as a supplement to oral counseling ensures patient access to important medication information after he or she leaves the pharmacy. States may have laws that require the provision of written information to a patient under specific circumstances. Four States—New York,[8] California,[9] Texas,[10] and North Carolina[11]—have requirements for the provision of written materials in certain circumstances. More information on the implementation of these requirements, including translation of certain materials into other languages, is summarized in a 2010 study by the National Health Law Program.[12]

California has a number of written materials regulations. One of these regulations requires provision of an emergency contraception fact sheet when dispensing emergency contraception to any patient.[13] To accommodate the large number of LEP individuals in the State, PDF versions are available to pharmacies in 10 different languages through the California Board of Pharmacy website for patient distribution.[14] California also requires the provision of culturally sensitive patient information, which is printed in certain languages in order to participate in the State’s HIV treatment program (Cal. Health & Safety Code §125092).[15]

Oral Counseling Exclusions

Circumstances may exist when patient counseling is not required by a State or not desired by the patient. According to NHeLP, many States exempt pharmacists from patient counseling requirements when drugs are dispensed to patients as part of institutional care.[16] For example, patient counseling requirements may not apply when the medication is administered to the patient by a health care professional during an inpatient hospital admission, in a long-term care facility, or in another institutional setting. In addition, not every patient may want to be counseled on his or her medication therapy. OBRA '90 mandates that an “offer to counsel” must be made; however, pharmacists are not required to provide counseling to a patient (or patient’s caregiver) who refuses the offer.[17] Pharmacists, pharmacy interns, and pharmacy technicians should consult their State statutes to determine when oral counseling exclusions are applicable.

Comparison of State Requirements

According to the 2010 NHeLP Analysis of State Pharmacy Laws, 47 States, plus the District of Columbia, have enacted laws that require patient counseling or an offer to counsel.[18] All States except for Hawaii, Louisiana, and Vermont include provisions related to the requirement for patient counseling in their statutes.[19] Requirements for compliance in each State vary widely. Pharmacists, pharmacy interns, and pharmacy technicians should consult their State Medicaid agency and Board of Pharmacy to ensure that pharmacy personnel understand and are in compliance with State regulations. Table 1 compares common State requirements.

Table 1. State Compliance Requirements and Patient Counseling Documentation Requirements by State

State	Require oral counseling in certain situations or an “offer to counsel”	Documentation of “offer to counsel” required by State	Documentation of patient’s refusal for counseling	Counsel new prescriptions and refills	Process for counseling when patient is not in the pharmacy	Discuss with patient prior to generic substitution	Require distribution of written materials
Alabama	Y	Y	N	N	N	N	Y
Alaska	Y	N	N	N	Y	Y	N
Arizona	Y	Y	Y	N	Y	Y	Y
Arkansas	Y	N	N	N	Y	Y	N
California	Y	Y	N	N	Y	Y	Y
Colorado	Y	Y	Y	N	N	Y	Y
Connecticut	Y	Y	Y	Y	N	Y	N
Delaware	Y	Y	Y	N	Y	Y	Y
District of Columbia	Y	Y	Y	N	Y	N	Y
Florida	Y	Y	N	Y	Y	Y	Y
Georgia	Y	N	N	Y	Y	N	N
Hawaii	N	Y	N	N	N	Y	Y
Idaho	Y	Y	N	Y	N	N	N
Illinois	Y	Y	Y	Y	N	N	N
Indiana	Y	Y	N	Y	Y	N	Y
Iowa	Y	Y	Y	N	N	N	N
Kansas	Y	Y	N	N	N	Y	N
Kentucky	Y	Y	Y	N	N	N	Y
Louisiana	N	N	N	N	N	N	N
Maine	Y	Y	Y	N	Y	Y	Y
Maryland	Y	N	N	N	N	Y	Y
Massachusetts	Y	Y	Y	N	Y	N	N
Michigan	Y	Y	N	N	Y	Y	N
Minnesota	Y	Y	N	N	Y	Y	Y
Mississippi	Y	Y	N	Y	Y	Y	N
Missouri	Y	N	N	Y	Y	N	Y
Montana	Y	Y	Y	N	N	N	N
Nebraska	Y	Y	Y	Y	N	Y	N
Nevada	Y	Y	N	N	Y	Y	Y
New Hampshire	Y	Y	N	N	Y	Y	Y
New Jersey	Y	Y	Y	N	Y	N	N
New Mexico	Y	Y	N	N	Y	N	Y
New York	Y	Y	Y	N	Y	Y	Y
North Carolina	Y	Y	N	N	Y	N	N

Table 1. State Compliance Requirements and Patient Counseling Documentation Requirements by State (cont.)

State	Require oral counseling in certain situations or an “offer to counsel”	Documen- tation of “offer to counsel” required by State	Documen- tation of patient’s refusal for counseling	Counsel new prescriptions and refills	Process for counseling when patient is not in the pharmacy	Discuss with patient prior to generic substitution	Require distribution of written materials
North Dakota	Y	N	N	Y	Y	Y	Y
Ohio	Y	Y	Y	Y	Y	N	N
Oklahoma	Y	Y	N	N	Y	N	N
Oregon	Y	N	Y	N	Y	Y	N
Pennsylvania	Y	Y	Y	N	Y	Y	Y
Rhode Island	Y	Y	Y	N	N	Y	N
South Carolina	Y	Y	N	N	N	Y	N
South Dakota	Y	N	Y	N	Y	N	Y
Tennessee	Y	Y	N	N	Y	N	N
Texas	Y	Y	Y	N	Y	Y	Y
Utah	Y	Y	Y	N	Y	Y	N
Vermont	N	Y	Y	Y	N	N	N
Virginia	Y	Y	Y	N	Y	Y	Y
Washington	Y	N	N	Y	Y	N	Y
West Virginia	Y	Y	Y	N	N	Y	N
Wisconsin	Y	N	N	Y	Y	N	N
Wyoming	Y	Y	Y	N	N	N	N
Total number of States with requirement	48	40	25	14	33	28	24

Documentation Requirements

Documenting that patient counseling was offered and indicating whether it was accepted or declined is critical to ensuring compliance with State statutes. There is currently no Federal requirement for documentation, and compliance requirements vary by State. The patient (or patient caregiver) may simply mark a “yes” or “no” checkbox when the prescription is picked up to satisfy the documentation requirement in most instances.

Key Points

Pharmacists, pharmacy interns, and pharmacy technicians should consider the following aspects of patient counseling to ensure compliance:

- Understand the patient counseling components of OBRA '90;
- Be familiar with State patient counseling regulations;
- Establish a process to ensure compliance when the patient is not present in the pharmacy;
- Understand when oral counseling is not required;
- Provide written materials to supplement oral counseling;
- Establish processes to accommodate LEP individuals; and
- Comply with State documentation requirements for acceptance or refusal of the counseling offer.

Conclusion

The provision of quality patient counseling requires much more than having effective communication skills. It entails understanding the patient counseling requirements as outlined in OBRA '90 as well as complying with State-specific regulations. In addition, there need to be processes in place for provision of counseling when the patient is not present or when the patient is non-English speaking, as well as for the provision of written materials to supplement oral counseling. Finally, establishing a process to document the acceptance or refusal of the counseling offer is critical. If there is no documentation that patient counseling was offered, there is no proof to demonstrate compliance.

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November 2014



November 2014