

# 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 to offer patient counseling to Medicaid patients. Pharmacists will understand that laws established by each State may differ and will recognize the importance of complying 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 following 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

Federal lawmakers enacted Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to ensure fiscally responsible spending of Federal funding while ensuring safe and effective therapeutic outcomes for Medicaid patients. OBRA '90 includes three key drug utilization review components that affect pharmacy practice: 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 he or she accepts the offer to counsel, 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 interactions or drug-disease contraindications;
- Prescription refill information; and
- Action to take in the event of a missed dose.[2]

OBRA '90 and regulations adopted by Centers for Medicare & Medicaid Services (CMS)[3] require States to establish standards regarding implementation of patient counseling requirements to participate in and to receive continued Federal funding for State Medicaid programs. 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. For links to State Boards of Pharmacy and their rules and regulations regarding patient counseling, refer to <http://www.nabp.net/boards-of-pharmacy> on the National Association of Boards of Pharmacy website.

## Counseling When the Patient Is Not Present

When pharmacies deliver or mail prescriptions to patients, they are not exempt from the patient counseling provision of care. Pharmacies should 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. 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 to be compliant.

## 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.[4] 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.[5] 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.

## Providing Written Information

Providing written information to a patient as a supplement to oral counseling ensures patient access to important medication information after they leave the pharmacy. States may have laws that require pharmacies to provide written information to a patient under specific circumstances. Several States have requirements or an option for providing 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.[6]

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.[7] To accommodate the large number of LEP individuals in the State, PDF versions are available to pharmacies in seven different languages through the California Board of Pharmacy website for patient distribution.[8] California also requires

the provision of culturally sensitive patient information, which is printed in certain languages, to participate in the State’s HIV treatment program (Cal. Health & Safety Code Section 125092).[9]

## Oral Counseling Exclusions

Circumstances may exist when a State does not require patient counseling or the patient does not desire it. States may exempt pharmacists from patient counseling requirements when drugs are dispensed to patients as part of institutional care.[10] For example, patient counseling requirements may not apply when a health care professional administers the medication to the patient during an inpatient hospital admission, in a long-term care facility, or in another institutional setting. In addition, not every patient may want counseling on his or her medication therapy. OBRA ’90 mandates that pharmacists make an “offer to counsel;” however, pharmacists are not required to provide counseling to a patient (or patient’s caregiver) who refuses the offer.[11] Pharmacists, pharmacy interns, and pharmacy technicians should consult their State statutes to determine when oral counseling exclusions are applicable.

## Comparison of State Requirements

All States require pharmacists to counsel or at least offer to counsel Medicaid patients.[12] Other requirements for counseling compliance in each State vary widely depending on the payer; new or refill prescription; face-to-face, written, or telephonic interaction; or mail-order or in-store delivery. Rules for documenting patient counseling or refusal to accept counseling vary widely as well. Pharmacists, pharmacy interns, and pharmacy technicians should consult their State Medicaid agency and Board of Pharmacy to ensure that pharmacy personnel understand and are complying with State regulations. For a comprehensive overview and comparison of the finer points of State pharmacy law, refer to the National Association of Boards of Pharmacy’s (NABP’s) Survey of Pharmacy Law, updated annually and available for a fee from <https://www.nabp.net/publications/survey-of-pharmacy-law/> on the Internet.

## Documentation Requirements

Documenting that patient counseling was offered and indicating whether it was accepted or declined is critical to ensuring compliance with State statutes. Social Security Act Section 1927(g)(2)(A), amended by the Deficit Reduction Act of 2005, says pharmacists are not required to provide documentation of an offer to counsel or of the refusal of the patient to accept counseling, but many States require such documentation anyway.[13] 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.

## Resources

American Pharmacists Association. <http://www.pharmacist.com>

American Society of Health-System Pharmacists Guidelines on Pharmacist-Conducted Patient Education and Counseling. <http://www.ashp.org/DocLibrary/BestPractices/OrgGdlPtEduc.aspx>

National Association of Boards of Pharmacy. <http://nabp.net>

## Conclusion

Providing 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 needs to be processes for providing 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 with documentation requirements.

To see the electronic version of this booklet and the other products included in the “Drug Diversion” Toolkit, visit the Medicaid Program Integrity Education page at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html> on the CMS website.

Follow us on Twitter  [#MedicaidIntegrity](https://twitter.com/MedicaidIntegrity)

## References

- 1 Omnibus Budget Reconciliation Act of 1990. Pub. L. 101-508, § 4401, 104 Stat. 143. Retrieved January 12, 2016, from [https://www.ssa.gov/OP\\_Home/comp2/F101-508.html](https://www.ssa.gov/OP_Home/comp2/F101-508.html)
- 2 Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(g). Retrieved January 12, 2016, from <http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/pdf/USCODE-2008-title42-chap7-subchapXIX-sec1396r-8.pdf>
- 3 Prospective Drug Review, 42 C.F.R. § 456.705. Retrieved January 12, 2016, from [http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=40186ffdc8d94276897981632b944bc0&n=pt42.4.456&r=PART&ty=HTML#se42.4.456\\_1705](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=40186ffdc8d94276897981632b944bc0&n=pt42.4.456&r=PART&ty=HTML#se42.4.456_1705)
- 4 United States Census Bureau. U.S. Department of Commerce. 2011 Language Mapper. Retrieved January 12, 2016, from [http://www.census.gov/hhes/socdemo/language/data/language\\_map.html](http://www.census.gov/hhes/socdemo/language/data/language_map.html)
- 5 N.Y. Comp. Codes R. & Regs. tit. 8, § 63.11 (2014). Retrieved January 12, 2016, from [https://govt.westlaw.com/nycrr/Document/Ib6ca32d5cea011e282c80000845b8d3e?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/nycrr/Document/Ib6ca32d5cea011e282c80000845b8d3e?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))
- 6 National Health Law Program. (2010, February). Analysis of State Pharmacy Laws: Impact of Pharmacy Laws on the Provision of Language Services (p. 14). Retrieved January 12, 2016, from <http://www.aacp.org/resources/education/documents/pharmacylawbooklet%20final.pdf>
- 7 Cal. Code Regs. tit. 16, § 1746. Retrieved January 12, 2016, from [https://govt.westlaw.com/calregs/Document/IE328F2D0941211E29091E6B951DDF6CE?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/IE328F2D0941211E29091E6B951DDF6CE?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))
- 8 State of California. Department of Consumer Affairs. Board of Pharmacy. Consumers. Emergency Contraception. Retrieved January 12, 2016, from [http://pharmacy.ca.gov/consumers/emergency\\_cont](http://pharmacy.ca.gov/consumers/emergency_cont)
- 9 Cal. Health & Safety Code § 125092. Retrieved January 12, 2016, from <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=125001-126000&file=125050-125119.5>
- 10 Drug Use Review Program. 42 C.F.R. § 456.703(b), (c). Retrieved January 12, 2016, from [http://www.ecfr.gov/cgi-bin/text-idx?SID=6550376a840cc4495b16f1fa802ebbac&mc=true&node=se42.4.456\\_1703&rgn=div8](http://www.ecfr.gov/cgi-bin/text-idx?SID=6550376a840cc4495b16f1fa802ebbac&mc=true&node=se42.4.456_1703&rgn=div8)
- 11 Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(g). Retrieved January 12, 2016, from <http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/html/USCODE-2008-title42-chap7-subchapXIX-sec1396r-8.htm>
- 12 National Association of Boards of Pharmacy. (2011). 2012 Survey of Pharmacy Law (pp. 78–80). Retrieved January 12, 2016, from <https://pharmacy.uc.edu/admin/documents/2012%20Survey%20of%20Pharmacy%20Law.pdf>
- 13 Social Security Act § 1927(g)(2)(A). Retrieved January 12, 2016, from [https://www.ssa.gov/OP\\_Home/ssact/title19/1927.htm](https://www.ssa.gov/OP_Home/ssact/title19/1927.htm)

## Disclaimer

This booklet was current at the time it was published or uploaded onto the web. Medicaid and Medicare policies change frequently so links to the source documents have been provided within the document for your reference.

This booklet was prepared as a service to the public and is not intended to grant rights or impose obligations. This booklet may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. Use of this material is voluntary. Inclusion of a link does not constitute CMS endorsement of the material. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

February 2016



February 2016