Patient Counseling

Martha Dye-Whealan, R.Ph., J.D.

OBRA-90’s role:
- The Omnibus Reconciliation Act of 1990 (OBRA-90) effectively imposed a counseling requirement on the states as a condition for Medicaid funding.
- Because the federal government cannot directly regulate professional practice, individual states had to determine how to impose this added responsibility on pharmacists.

OBRA-90 requirements
- "The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant..." 

Suggested topics for counseling under OBRA-90
- Name and description of medication
- Dosage form, dosage, route of administration, and duration of drug therapy
- Special directions and precautions for preparation, administration, and use by the patient
- Techniques for self-monitoring drug therapy

Suggested topics for counseling (cont’d)
- Action to be taken in the event of a missed dose
- Proper storage
- Prescription refill information

Suggested topics for counseling (cont’d), OBRA-90
- Common severe side effects; adverse effects; interactions and therapeutic contraindications that may be encountered, including ways to prevent them and actions that can be taken if they occur
  - Discuss both common side effects in terms of frequency, and severe side effects in terms of magnitude.
Patient counseling in Washington

- This regulation imposed a counseling requirement with every new prescription.

Patient counseling regulation-old

Pursuant to the old regulation, the pharmacist must:
- “Orally explain to the patient or the patient’s agent the directions for use and any additional information, in writing if necessary, for those prescriptions delivered inside the confines of the pharmacy;” or;
- “Explain by telephone or in writing for those prescriptions delivered outside the confines of the pharmacy”.

Patient counseling regulation--old

Requirements for refills:
- “In those instances where it is appropriate, when dispensing refill prescriptions, the pharmacist shall communicate with the patient or the patient’s agent, by the procedure outlined... [in the slide above], or the patient’s physician regarding adverse effects, over or under utilization, or drug interaction with respect to the use of medications”.

2000: WAC 246-869-220 overhauled

- Old regulation did not promote compliance in terms of quality or quantity of interactions with patients.
- Old regulation did not promote refill counseling.
- Old regulation was hard to enforce.

Issues addressed in committee:
- The need to provide adequate counseling on refills.
- The need to design counseling sessions to the individual patient: what does the patient need to know?
- The need to promote the appropriate therapeutic outcome: how can the pharmacist assure compliance?
- The burden to provide the appropriate environment for counseling needed to encompass employers as well as individual pharmacists.

Patient counseling regulation-new

Ultimately the committee drafted a regulation that promotes a professional standard rather than providing a checklist.
- Still WAC 246-869-220
- Purpose (as stated): “to educate the public in the use of drugs and devices dispensed upon a prescription”.

**Patient counseling regulation-new**

- “The pharmacist shall directly counsel the patient or patient’s agent on the use of drugs or devices”.
- “For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist”.

**Patient counseling regulation-new**

- “For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription”.

**Patient counseling regulation-new**

- Exception: medication is to be administered by a licensed health professional authorized to administer medications.

**Waiver of counseling**

- Patient can refuse counseling.
- Cannot force patient to waive counseling because it is inconvenient or difficult for pharmacist.
- Waiver is effective only if:
  - Patient makes informed decision
  - Patient is not pressured into waiver