

Patient Counseling and provision of drug information – Class A - 291.33(c)

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist **shall communicate** to the patient or the patient's agent, information about the prescription drug or device which **in the exercise of the pharmacist's professional judgment** the pharmacist **deems significant**, such as the following:

- (i) the name and description of the drug or device;
- (ii) dosage form, dosage, route of administration, and duration of drug therapy;
- (iii) special directions and precautions for preparation, administration, and use by the patient;
- (iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (v) techniques for self-monitoring of drug therapy;
- (vi) proper storage;
- (vii) refill information; and
- (viii) action to be taken in the event of a missed dose.

(B) Such communication **shall** be:

- (i) **provided with each new prescription drug order;**

From Definitions:

(29) **New prescription drug order**--A prescription drug order that:

(A) has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year;

(B) is **transferred** from another pharmacy; and/or

(C) is a discharge prescription drug order. (Note: furlough prescription drug orders are not considered new prescription drug orders.)

(ii) provided for any prescription drug order dispensed by the pharmacy on **the request** of the patient or patient's agent;

(iii) **communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;**

(iv) documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

- (I) on the original hard-copy prescription, provided the counseling pharmacist clearly records his or her initials on the prescription for the purpose of identifying who provided the counseling;
- (II) in the pharmacy's data processing system;
- (III) in an electronic logbook; or
- (IV) in a hard-copy log; and

(v) **reinforced** with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information.

- (I) Written information must be in plain language designed for the patient and printed in an easily readable font size comparable to but no smaller than ten-point Times Roman.
- (II) When a compounded preparation is dispensed, information shall be provided for the major active ingredient(s), if available.
- (III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:
 - (-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;
 - (-b-) the pharmacist documents the fact that no written information was provided; and
 - (-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.
- (IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel **may not ask questions** of a patient or patient's agent which are **intended to screen and/or limit interaction** with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist **shall document such refusal** for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable.

- (i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section.
- (ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.
- (iii) A Class A pharmacy shall make available for use by the public a current or updated patient prescription drug information reference text or leaflets designed for the patient.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order **is delivered to the patient or his or her agent at the patient's residence or other designated location**, the following is applicable.

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription **in writing**.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and if applicable, toll-free telephone number of the pharmacy **and the statement**: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(v) The pharmacy shall use a delivery system which is designed to assure that the drugs are delivered to the appropriate patient.

(G) Except as specified in subparagraph (B) of this paragraph, in the best interest of the public health and to optimize drug therapy, **upon delivery of a refill prescription**, a pharmacist **shall ensure** that the patient or patient's agent is offered information about the refilled prescription. Either a pharmacist **or other pharmacy personnel** shall inform the patient or patient's agent that a pharmacist is available to discuss the patient's prescription and provide information.

(H) A pharmacy shall post a sign no smaller than 8.5 inches by 11 inches in clear public view at all locations in the pharmacy where a patient may pick up prescriptions. The sign shall contain the following statement in a font that is easily readable: "Do you have questions about your prescription? Ask the pharmacist." Such notification shall be in both English and Spanish.

(I) The provisions of this paragraph **do not apply** to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

Discussion – Comments and Questions

There is general agreement that quality appropriate drug counseling “can” be beneficial to patients and their caregivers.

The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) required states to establish standards governing patient counseling, in particular that Pharmacists **must offer** to discuss the unique drug therapy regimen of each Medicaid recipient when filling prescriptions for them and that in the discussion, include matters that **are significant in the professional judgment** of the pharmacist.

- Texas Pharmacy Rules language allows for the pharmacist to exercise professional judgment and what information they deem to be significant
- Primary difference is that Texas **mandates** the communication

Texas rules addresses and mandates medication communication is a number of ways:

- Mandates **oral** counseling and documentation of individual counseling or patient refusal for new prescription drug orders
- “reinforce” counseling with written information
- Requires public posting of signage that contains wording “Do you have questions about your prescription? Ask pharmacist”
- On delivery of “refill prescriptions” at the pharmacy to offer information about the medication by pharmacy personnel informing that a pharmacist is available to discuss the prescription
- Delivery of prescription outside of the pharmacy, written information plus contact information for a pharmacist

The large number of “requirements” stated above tends to create additional confusion at the pharmacy, especially since many pharmacies have to rely on “people” processes to ensure compliance. Even pharmacies with additional technological tools struggle.

The above rules at 291.33(c) under Class A pharmacies are applicable whenever delivery of a prescription to a patient occurs at the licensed facility, including discharge orders in Class C facilities. However, mandated oral counseling and documentation is not required for Class E pharmacies, only written and contact information is required. The same is true if a Class A pharmacy delivers to patient residence or place of work.

Concern: Current mandated counseling rules historically have not worked and are not working as intended today with compliance varying greatly from location to location. Patient acceptance and response varies greatly.

Challenge: What is the best approach to create meaningful counseling/medication communication between the patient and the pharmacist and that works in the least intrusive manner possible that is acceptable to patients and pharmacists?

Comments:

- More people refuse counseling than accept counseling
- Pharmacy community generally views rules as punitive in nature
- Pharmacists are driven to comply by fear of license being disciplined more than affecting a positive patient outcome
- Patients/agents are barriers to provision of counseling
- 40-50% of prescriptions are picked up by agents (friends, relatives, caregivers, etc)
- Hard to regulate quality
- Professional judgment is prominent in rules – should we allow pharmacist to exercise professional judgment in counseling and move away from prescriptive regulations –
- In practice, customer push back is common and strict enforcement of rule creates unintentionally, tension between pharmacist and patients.

Questions:

- Why is our approach to counseling not working?
- Why are pharmacists not compliant with the rules?
- Are patients impacted positively or negatively by our current rules?
- Would an offer to counseling negatively impact patients?
- What is in the patient's best interest and workable?
- Do we trust pharmacists to exercise sound professional judgment in determining when counseling should occur?
- Do pharmacists understand the "new" order requirement?
- What does the refusal rate look like?
- What do pharmacists tell us about this mandated activity?
- Is there anything that we can do to ensure compliance to mandated counseling?
- Are we overwhelming patients with too much information? How do we ensure we are providing meaningful information that is understandable?
- Do pharmacists actually understand what constitutes counseling?
- How do pharmacists "fit" in counseling with their other mandated activities?
- Oral counseling versus adequate written information – should there be an option?

Comments on New Order Definition

- ..."transferred from another pharmacy"
 - If pharmacies are under common ownership sharing a common database or an agreement is in place, it appears counseling is required even though the prescription has been filled within the last twelve months and the transfer is done electronically and not "orally" or by fax. OR is this meant only for external transfers.

- Discharge prescription order
 - Is the intent to be applicable to a Class C pharmacy or if patient brings in a prescription order written on a hospital blank to a Class A pharmacy, must the pharmacy counsel simply because it is a discharge prescription even if the medication is currently active on the patient prescription profile?
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Staff Materials

1. Recap of other state BOP counseling rules
- 2.

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

2014

ORGANIZATIONAL LAW

LICENSING LAW

DRUG LAW

CENSUS DATA



Survey of Pharmacy Law

Including all 50 states, DC, Guam, and Puerto Rico

23. Patient Counseling Requirements

State	Is Patient Counseling Required for:				Must Patient Counseling be Performed Personally, Face-to-Face, by the Pharmacist?	Are Patient Profiles Mandated?
	Medicaid Patients?	All Other Patients?	New Prescriptions?	Refill Prescriptions?		
Alabama	Yes Z	Yes Z	Yes Z	A	Yes Z	Yes
Alaska	Yes	Yes	Yes	No	Yes C	No
Arizona	Yes	Yes	Yes	Yes D	Yes	Yes
Arkansas	Yes	Yes	Yes	E	Yes B	Yes
California	Yes	Yes	Yes	No E	No I	Yes
Colorado	Yes	No	No	No	No	No
Connecticut	Yes	No	Yes G	No	Yes C, G	Yes
Delaware	Yes H	Yes H	Yes H	No	Yes C	Yes
District of Columbia	Yes	Yes	Yes	No AA	Yes L	Yes
Florida	H	H	H	H	Yes I	Yes
Georgia	Yes	Yes	Yes	No	Yes C	Yes
Guam	Yes	Yes	Yes	No	Yes	No
Hawaii	Yes J	No	J	J	Yes	Yes
Idaho	Yes	Yes	No BB	No	Yes Y	Yes
Illinois	H	H	H	H	Yes I, M	Yes
Indiana	H	H	H	H	Yes A, L, O	Yes
Iowa	Yes	Yes	Yes	No	No N	Yes
Kansas	Yes	Yes	Yes	No E	Yes B	Yes
Kentucky	Yes	Yes	Yes	No	Yes B	Yes
Louisiana	Yes	Yes	Yes M	Yes M	Yes B, M	Yes A
Maine	Yes	Yes	Yes	H	Yes	Yes
Maryland	Yes	No	Yes	No	No	No
Massachusetts	H	H	H	E	Yes I	Yes
Michigan	Yes	Yes	Yes	E	Yes O	Yes A
Minnesota	Yes	Yes	Yes	Yes E	Yes	Yes
Mississippi	Yes	Yes A	Yes A	Yes A	Yes B	Yes
Missouri	Yes	Yes	Yes	Yes	Yes P	Yes
Montana	Yes	Yes	Yes	E	Yes K	Yes
Nebraska	Yes H	Yes H	Yes H	Yes H	No	Yes
Nevada	Yes	Yes	Yes	E	Yes I, K	Yes
New Hampshire	Yes	Yes	Yes	No	Yes B	Yes
New Jersey	Yes	Yes	Yes	No	Yes K	Yes
New Mexico	Yes	Yes	Yes	Yes X	Yes K	Yes
New York	Yes	Yes	Yes W	Yes W	Yes A, K	Yes
North Carolina	Yes	Yes	Yes L	E	Yes	Yes
North Dakota	Yes	Yes	Yes	Yes	Yes	Yes
Ohio	Yes H	Yes H	Yes H	Yes H	Yes I, L	Yes
Oklahoma	Yes A	Yes A	E	E	Yes	Yes
Oregon	Yes	Yes	Yes	Yes Q	Yes B	Yes
Pennsylvania	Yes	Yes	Yes	No	Yes A	Yes
Puerto Rico	Yes	Yes	Yes	Yes	Yes	U
Rhode Island	Yes H	Yes H	Yes H	No	Yes K, L	Yes
South Carolina	Yes R	No H	No H	No	No B	Yes
South Dakota	Yes	Yes	Yes	No	Yes B, N	Yes
Tennessee	Yes	Yes	Yes	Yes H	Yes	Yes
Texas V	Yes	Yes	Yes	Yes S	Yes S	Yes
Utah	Yes	Yes CC	Yes CC	Yes CC	Yes I	Yes
Vermont	Yes H, P	Yes H, P	Yes H, P	Yes H, P	Yes O	Yes
Virginia	Yes	Yes	Yes	E	Yes B	Yes T
Washington	Yes	Yes	Yes	E	Yes B	Yes
West Virginia	H	H	H	E	Yes M	Yes
Wisconsin	Yes	Yes	Yes	Yes	Yes F	Yes
Wyoming	H	H	H	No	Yes B	Yes

Colored text denotes change from 2013 edition.

LEGEND

- A — When applicable/appropriate. (AL – Only when appropriate in judgment of a registered pharmacist.)
- B — Face-to-face if prescription is delivered to the patient within the pharmacy; otherwise, by telephone or in writing. Required for all new prescriptions and as appropriate for refills. (KY – Required for all original prescriptions and as appropriate for refills. LA and SC – Face-to-face when possible, otherwise by alternative method.)
- C — Whenever practicable. (AK – When not possible, pharmacist must make reasonable effort to counsel by telephone, two-way radio, or in writing.)
- D — With different directions, dose, or dosage form.
- E — The pharmacist can use professional judgment in deciding whether or not to counsel.
- F — Although face-to-face counseling is not required, the pharmacist must personally counsel the patient.
- G — For Medicaid patients.
- H — Only an offer to counsel is required. (SC – On new medication.)
- I — Face-to-face if prescription is delivered to the patient or patient's agent within the pharmacy; otherwise, a written offer to counsel with toll-free telephone access to a pharmacist must be made. (CA – For prescriptions dispensed out-of-state.)
- J — Omnibus Budget Reconciliation Act requirements under the jurisdiction of the Department of Human Services, Health Care Authorization Branch.
- K — In person, whenever practicable, or by telephone. (MT – Shall include appropriate elements of patient counseling. NM – If the patient or agent is not present when the prescription is dispensed, including but not limited to a prescription that was shipped by mail, the pharmacist shall ensure that the patient receives written notice of his or her right to consultation and a telephone number to obtain oral consultation from a pharmacist. Required for all new and refill prescriptions. NV – May also be in writing if the patient or caregiver is not present at the pharmacy. NY – If the patient or agent is not present when the prescription is dispensed; toll-free number required.)
- L — The offer to counsel may be delegated by the pharmacist to non-licensed personnel. The actual counseling must be performed by the pharmacist or pharmacist intern/extern. (IN – May be delegated to other pharmacy personnel. DC – The consultation shall be face to face, whenever practicable, or by telephone. The consultation shall be reinforced with the provision of written information, which may include information leaflets, pictogram labels, or video programs.)
- M — Unless pharmacist deems counseling inappropriate or unnecessary, in which case it may be written, by telephone, or as considered appropriate.
- N — If oral counseling is deemed not practicable, alternate forms of patient information may be used, which also advise patient or caregiver that pharmacist is available for consultation at pharmacy, via toll-free telephone number or collect call. Combination of oral and alternative forms of counseling is encouraged. (IA – The mere offer to counsel is not sufficient.)
- O — In person to patient or patient's caregiver; if communication barrier prohibits oral communication, then providing printed material. (IN – May counsel patient's representatives.)
- P — The offer to counsel may be delegated by the pharmacist to technical personnel. The actual counseling must be performed by the pharmacist or pharmacist extern (only under supervision of a pharmacist).
- Q — Counseling on refill prescriptions shall be such as a reasonable and prudent pharmacist would provide including but not limited to changes in strength or directions. A pharmacist may provide counseling in a form other than oral counseling when, in their professional judgement, a form of counseling other than oral counseling would be more effective. For a discharge prescription from a hospital, the pharmacist must ensure that patient receives appropriate counseling.
- R — Health and Human Services Finance Commission Regulation.

Legend continued on page 83

NABPLAW Online Search Terms

Patient Counseling Requirements

(type as indicated below)

- ◆ advise patient
- ◆ inform patient
- ◆ patient counseling requirements
- ◆ patient profile
- ◆ prescription counsel
- ◆ refill counsel

LEGEND — cont.

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|---|---|
| S — Face-to-face if prescription is delivered to the patient within the pharmacy; otherwise in writing. Required for all new prescriptions, pharmacist or agent must make an offer to counsel on all prescription refills and in the professional judgment of the pharmacist for all other refills. | X — Offer to counsel on a refill may be made by a registered technician. |
| T — Not specifically called “patient profile.” | Y — When possible or appropriate. |
| U — Not specifically addressed in Pharmacy Act or regulations. | Z — An offer to counsel is mandatory. The offer must be face-to-face unless in the professional judgement of the pharmacist face-to-face counseling is inappropriate or unnecessary and in that situation, the offer to counsel may be in writing, by telephone, or in any other manner deemed appropriate by the pharmacist. |
| V — Pharmacy must post a sign informing patients that a pharmacist is available to answer questions about prescription medications. | AA — Once yearly on maintenance medications. See DCMR 22 1919.1(c). |
| W — A pharmacist or intern must counsel on all new prescriptions or when a regimen is changed. Anyone under the direction of a pharmacist may make an offer to counsel on refills. | BB — New medications only. |
| | CC — Offer to counsel required on all new prescriptions, once yearly on maintenance medication. |