Chapter 6. Patient Information: Collection, Use, Quality Assurance, and Confidentiality

1. Informational responsibilities of pharmacists. In general, pharmacists have six major responsibilities regarding patient information, under both federal and state laws and regulations.

   a. They must maintain patient records for every patient which will aid them in documenting the distribution of drugs and devices to the patients and in providing pharmaceutical care services to their patients.

   b. They must use these records to review therapy prior to dispensing; this is known as Prospective Drug Use Review (P-DUR).

   c. They must act to correct any problems that are discovered as a result of this review.

   d. They must provide information to their patients necessary to insure appropriate use of their medications and promote the attainment of desired therapeutic outcomes.

   e. They must assure the confidentiality of protected health information (PHI) under their control.

   f. They must use information concerning patient outcomes and adverse events to continuously improve the quality of their patient care.

   Table 6-1-f summarizes the legal sources for these requirements:

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>State Law or Regulation</th>
<th>Federal Law or Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintain patient records</td>
<td>RCW 18.64.245, 69.41.042; WAC 246-875-020</td>
<td>Omnibus Budget Reconciliation Act of 1990 (OBRA-90)</td>
</tr>
<tr>
<td>Conduct P-DUR</td>
<td>WAC 246-875-040</td>
<td>OBRA-90</td>
</tr>
<tr>
<td>Act on P-DUR findings</td>
<td>WAC 246-875-040; WA case law (McKee v American Home Products, 782 P2d 1045, 1989)</td>
<td>OBRA-90</td>
</tr>
<tr>
<td>Provide information to patients</td>
<td>WAC 246-869-220</td>
<td>OBRA-90</td>
</tr>
<tr>
<td>Assure confidentiality of PHI</td>
<td>RCW 70.02; RCW 18.64.245; 69.41.044, 69.41.055; WAC 246-875-070(2)</td>
<td>Health Information Portability and Accountability Act of 1996 (HIPAA)</td>
</tr>
<tr>
<td>Engage in Quality Improvement Activities</td>
<td>RCW 43.70.510; WAC 246-50-001 thru 990; JCAHO standards</td>
<td>Patient Safety and Quality Improvement Act of 2005 (PSQIA)</td>
</tr>
</tbody>
</table>

Table 6-1-f. Sources of Patient Information Collection, Use, Quality Assurance and Confidentiality Requirements
2. **Maintaining Patient Records.**
   a. **Historical development of the patient records requirement.** The requirement to maintain a record of all prescriptions dispensed has been in WA law since at least 1939. However, maintenance of individual prescription records for each patient was not a standard of practice nationally well into the 1980s. The first state to actually require pharmacists to maintain patient profiles was New Jersey, whose administrative rule was sustained by the New Jersey Supreme Court in 1973. The Washington Board, at about the same time, adopted a regulation requiring the pharmacist to maintain such records as would enable him or her to “attempt” to detect drug-drug interactions, multiple prescribing of similar drug classes by different physicians, and the like. The Board adopted more specific regulations setting forth the requirements of patient records systems in 1984. Among the changes in practice needed to bring about patient record systems were the following, which were reflected in the 1984 regulations:
      i. Allowing refill information to be recorded on the patient record, rather than on the back of hardcopy of the prescription.
      ii. Allowing (prior to computerization) pharmacists to refill prescriptions without going back to the original prescription each time, if the patient record contained a correct copy of the original.
      iii. Recognition that a system of records could be used to meet needs for patient information as well as records of distribution of drugs. This included understanding that in some facilities, the patient’s chart or medical records could be used as part of a system accessible to the pharmacist to fulfill the needs of a patient medication record system.
   b. **Washington’s regulations require every pharmacy and other place where dispensing of drugs takes place to maintain a “patient medical record system.”** It must assure the pharmacist the means to retrieve all new and refill prescription information relevant to patients of the pharmacy. (WAC 246-875-001)
      i. **Individual records required.** The regulation does not explicitly require that an individual record is maintained for each patient. However, the same chapter (WAC 246-875-070) sets forth a requirement that information in the patient medication record which identifies the patient shall be deemed confidential. Thus, the Board has held for many years that a “family medication record” cannot be maintained, because it creates a record that, when shared

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with any patient in the record, reveals protected information about other patients.

ii. **Minimum required information.** The regulation sets forth minimum information that must be maintained in the patient medication record. It specifies this slightly differently depending upon whether a manual or computer system is used for ambulatory patients. The requirements for an automated system are specified in WAC 246-875-020. The manual system requirements are set forth in WAC 246-875-030. The requirements are the same for institutional patients whether a manual or automated system is used, and are repeated for each section.

### Table 6-2-b. Required Elements in Patient Medication Record Systems in WA

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Required by WA Regulation</strong></td>
<td>WAC 246-875-020(1)</td>
<td>WAC 246-875-030(1)</td>
<td>WAC 246-875-020(2)</td>
<td>WAC 246-875-030(2)</td>
</tr>
<tr>
<td>Patients full name</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient’s address</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unique Patient Identifier</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient location</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient status (on leave, discharged, etc.)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serial number of Rx</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of dispensing</td>
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<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ID of dispenser</td>
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<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug dispensed (name, strength, dosage form, quantity)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug name, dose, route, form, quantity when appropriate</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Refill instructions</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start and stop dates and time when appropriate</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Prescriber (name, address, DEA number if required)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>--------------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>Required by WA Regulation</strong></td>
<td>WAC 246-875-020(1)</td>
<td>WAC 246-875-030(1)</td>
<td>WAC 246-875-020(2)</td>
<td>WAC 246-875-030(2)</td>
</tr>
<tr>
<td>Complete directions for use (&quot;as directed&quot; not allowed)</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient allergies, idiosyncrasies, or chronic condition</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>which may relate to drug utilization. If no allergy data,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>indicate &quot;none&quot; or &quot;NKA&quot;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authorization for non-CRC use</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special status (on hold, dc'd, self-administration, etc.)</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Any cautionary alerts to be placed on labeling</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Required by OBRA-90 (see below)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient’s age or DOB</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient’s gender</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient’s telephone number</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Pharmacist’s comments regarding therapy</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

As seen from the above table, it is assumed that refill instructions in a manual system may be maintained on the original prescription, but they may be maintained in the manual system/card itself. Likewise, although information on use of non-CRCs does not need to be on the manual patient medication record, it may be, or it may be maintained in a separate file or on the original prescription. Note that OBRA-90 also requires outpatient pharmacies to maintain the patient’s age or date of birth, the patient’s gender, and telephone number in medication record systems. Some believe that the WA regulation does require gender as a “chronic condition” that may relate to drug utilization; in any case, recording age and gender can be considered a
standard of practice, or at least a practical necessity in an age of third party payers. OBRA-90 also requires “pharmacist’s comments relevant to an individual’s therapy.”

c. Omnibus Budget Reconciliation Act of 1990 (OBRA-90) Patient Record Requirements

i. The sections of OBRA-90 that relate to Medicaid prescription drug programs were enacted by Congress primarily to take advantage of certain pharmaceutical care services that were expected to result in more appropriate utilization of outpatient prescription drugs by Medicaid patients, and that, in turn was expected to produce savings in the federal government’s share of the cost of these drugs. The Act mandated that federal and state Medicaid programs perform or require the following activities:

1. Establish a system of mandatory rebates from manufacturers of prescription drugs purchased for use by Medicaid recipients.

2. Fund demonstration projects among one or more states to establish the value of
   a. On-line Prospective Drug Use Review (OPDUR). These systems involve use of centralized computer systems to screen for patient drug related problems prior to authorization of payment for a proposed claim. A project was conducted in Iowa. These systems are commonly used in all states and by almost all third-party payors and pharmaceutical benefits managers (PBMs).
   b. Payment for pharmacist’s cognitive services. This project was funded and conducted in Washington. Overall, it showed that in the mid-1990s, for an average payment of around $5, each cognitive service provided by participating pharmacists saved approximately $13.

3. Mandate states to conduct Retrospective Drug Use Review, whereby overall utilization of various drugs or classes of drugs is reviewed by the Medicaid agency to determine population-based approaches to improving drug use.

4. Require pharmacists in community pharmacies to conduct Prospective Drug Use Review prior to filling prescriptions for Medicaid recipients

5. Require pharmacists to offer counseling to Medicaid recipients.
ii. The patient record requirements arose because without an adequate patient medication record, pharmacists cannot conduct prospective drug use review. OBRA-90 calls these records “Patient Drug Use Histories,” and requires that the pharmacist make a “reasonable effort to obtain” the following information for each patient:

1. Name, address, phone, age/DOB, and gender of each patient
2. Significant disease states that the patient has that may affect drug therapy
3. Known allergies or drug reactions
4. A list of all drugs and devices previously used by the patient (from ANY source, not just the dispensing pharmacy)
5. Pharmacist comments relevant to an individual’s therapy.

iii. States were required to modify their own regulations as they related to Medicaid patients to comply with OBRA-90. Washington had both patient record system and patient counseling requirements in place that applied to ALL patients well before OBRA-90, so the federal government deemed our state to be in substantial compliance without further rule changes.

1. Pharmacies that provide services to Medicaid patients agree to abide by OBRA-90 as part of their contract with the Department of Social and Health Services, which is Washington’s Medicaid agency. Technically, these pharmacies do not need to maintain OBRA-90-only data elements for all patients, since the Board has not amended its regulations, but they do need to maintain them for Medicaid patients. Obviously, they must perform a review of the record and provide counseling to ALL patients in Washington.

d. May the patient refuse to provide certain information? Those elements that are only required by OBRA-90 are subject to the “reasonable effort” qualification of OBRA-90, so it seems that a patient may decline to provide them, which would include age/DOB, gender, and telephone number. Washington’s rule is not so qualified, however, it is clear that a pharmacist can’t collect information that is inapplicable or unavailable from a given patient. If a pharmacist requests that the patient inform him or her of other medications he or she is taking, and the patient omits some drugs, the pharmacist will only be held responsible for knowing what the patient revealed.
e. **Data Security.**

i. Washington’s pharmacy regulations require that information in patient records be maintained for a minimum of two years, and that security codes must be imposed in automated systems to prevent unauthorized modification of data. (WAC 246-875-0070)

ii. Each pharmacy must have an auxiliary record system for use when the automated system is inoperative due to system interruption, with provisions for prompt entry of information into the system – within two working days – after the system is again functioning. (WAC 246-875-050)

iii. Pharmacies are also subject to the requirements of Washington’s Health Care Information Act, RCW 70.02, which specifies in RCW 70.02.150 that:

> A health care provider shall effect reasonable safeguards for the security of all health care information it maintains. Reasonable safeguards shall include affirmative action to delete outdated and incorrect facsimile transmission or other telephone transmittal numbers from computer, facsimile, or other data bases. When health care information is transmitted electronically to a recipient who is not regularly transmitted health care information from the health care provider, the health care provider shall verify that the number is accurate prior to transmission.

iv. **New federal rules governing security** of patient information have been promulgated under authority of the Health Information Portability and Accountability Act of 1996 (HIPAA). The final rule was published in the *Federal Register on February 23, 2003* (68 FR 8334) and took effect for most pharmacies on April 21, 2005.

1. The “Security Standards” are related to HIPAA’s “Privacy Rule”, which is discussed below. The Privacy Rule establishes how a pharmacy may use and disclose protected health information (PHI), whereas the **Security Standards require pharmacies to provide basic safeguards** that will “protect electronic PHI from unauthorized access, alteration, deletion, and transmission.” Much of the summary in this section is based on Bell’s presentation to the NACDS Foundation HIPAA Security Conference, available on the Internet.²

a. The standards apply to electronic PHI only, or PHI that is maintained or transmitted using electronic media. These systems include
   1. Computers and computer networks;
   2. Optical and magnetic storage;
   3. Telephone voice response and “faxback” systems; and
   4. The Internet
   5. Information transmitted via telephone is NOT included in these standards.

b. It is the purpose of the standards to protect the integrity, confidentiality, and availability of electronic PHI
   1. Integrity – the data has not been altered or destroyed in an unauthorized manner
   2. Confidentiality – data or PHI is not disclosed to unauthorized persons or processes
   3. Availability – data is accessible on demand by an authorized requestor

c. The standards allow for each entity to develop approaches appropriate to their own systems, scope of operations, and capabilities
   1. This does mean that each entity needs to assess its own system, size, and capabilities, and identify specific risks applicable to its systems as it develops its safeguards

2. They require each covered entity (eg, pharmacy) to establish the following Organizational Practices:
   a. Establishment of information security officer
   b. Establishing security policies
   c. Providing for education and training for each employee in security practices
   d. Sanctions for violation of policies

3. They require that each covered entity have in place Technical Practices and Procedures that encompass the following elements:
   a. Individual authentication of users of health information systems
   b. Access controls
   c. Audit trails
   d. Physical security and disaster recovery
   e. Protection of remote access points
f. Protection of external electronic communications
g. Software discipline
h. System assessment

4. The federal rule sets forth “Implementation Specifications” that describe how the entity is to undertake to fulfill the standard in specific areas. These specifications may be “addressable” or “required.”

a. Addressable standards -- The entity needs to assess whether an addressable specification is reasonable and appropriate for its situation, and
   1. Implement the specification if it is reasonable and appropriate, or
   2. If the specification is not reasonable and appropriate to the entity’s situation,
      1. Document in its plan why the specification is inappropriate and
      2. Implement an equivalent alternative measure if appropriate.

b. Required standards -- The entity must implement the specification as written in the rules. For example, according to Bell, all pharmacies must adhere to the “Security Management Process” specified in the rules.

5. Ultimately, each pharmacy will need to take advantage of resources provided by various professional organizations, such as the National Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), or their state pharmacy association, all of whom provide access to implementation manuals or guides. Larger pharmacy firms may well have in-house expertise, but smaller firms may need to work with their system vendors or other experts to help develop their implementation plan.

6. The major impact of the security standards on individual practicing pharmacists will likely be
   a. the implementation of more stringent authentication processes, such as requiring re-logging on to the terminal after a minimum timeout and use of positive ID requirements, such as thumb print, retinal scan, or key card access to terminals;
b. creation of a hierarchy of system users, such that, for example, Pharmacy Assistants will not be able to access prescription entry or editing functions of the computer system;

c. Pharmacists and pharmacy department managers will be more responsible for overseeing security issues and knowing how to report and respond to security incidents

3. Use of Patient Information in Providing Pharmaceutical Care: Reviewing the information and taking action if problems are found

a. **Minimum Procedures for Use of Patient Information.**
   Washington pharmacy regulations have required prospective drug use review since at least 1984. WAC 246-875-040 sets forth the “Minimum procedures for utilization of a patient medication record system:"

   i. On receipt of a prescription or drug order, a dispenser must
      1. **Examine the patient’s medication record,** visually or via an automated data processing system to determine the possibility of
         a. A clinically significant drug interaction;
         b. A clinically significant drug reaction;
         c. A clinically significant therapeutic duplication;
         or
         d. Improper utilization of the drug
      2. **Consult with the prescriber** if needed
   ii. **Orders modified in the system** must carry in the audit trail the unique identifier of the person who modified the order.
   iii. **Any change in drug name, dose, route, dose form or directions** which occurs after an initial dose has been given must
      1. result in a new order entered into the system and the old order discontinued; or
      2. accurately document changes in the system in such a manner that the original record or its audit trail is not destroyed.

b. Note that Washington’s rule
   i. **Does NOT distinguish between new and refill requests.**
      1. Although it requires the review “on receipt of” an order, which might imply only when the order is first received, it also requires that the review must consider improper utilization of the drug, which involves looking at the patient’s history of use as revealed by prior dispensing of the drug; thus, one should consider the receipt of an order to include the patient’s request for a refill of that order

6-10
ii. Requires the dispenser to examine the medication record each time (for new and refill requests) an order or prescription is processed
   1. This involves “interpretation of the data in a patient medication record system” which is a professional responsibility that cannot be delegated to ancillary personnel (WAC 246-863-095(e)).
   2. This is part of the “verification” defined in WAC 246-901-010(10). “Verification’ means the pharmacist has … examined the patient’s drug profile …”

iii. Requires evaluation of the patient’s “utilization of the drug” – this includes early and late refills or other evidence that the drug is not being utilized properly
iv. Uses the phrase “prescription or drug order” so that this rule covers inpatient and ambulatory care settings.

c. The Supreme Court of Washington has concluded that a “pharmacist has a duty to take corrective measures when confronted with a prescription containing an obvious or known error, such as an obviously lethal dosage, inadequacies in the instructions, known contraindications, or incompatible prescriptions.”

d. OBRA-90’s prospective drug use review rules closely parallel Washington’s regulation.
   i. They require that all prescriptions are “screened against the patient’s drug use history” to identify
      1. Therapeutic duplication
      2. Drug-disease contraindications
      3. Drug-drug interactions (including interactions with OTC drugs)
      4. Incorrect dosage or duration of treatment
      5. Drug allergies
      6. Clinical abuse or misuse
   ii. They specify that the review be manual and/or computer-assisted, and may take advantage of “on-line” PDUR
   iii. OBRA-90 rules impose at least three additional requirements on pharmacists beyond those that are imposed by Washington regulation
      1. They explicitly require the PDUR to consider interactions with OTC drugs the patient is taking
      2. They are based on the assumption that the patient’s drug use history is current and contains information concerning all the drugs that the patient is taking, whether or not they have been dispensed by the pharmacy conducting the review

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3. They anticipate that pharmacists will record their observations concerning therapy and the decisions they have made in the patient record.

e. The pharmacist is not required to contact the prescriber in every case where a potential problem is identified. WAC 246-875-040 only requires contacting the prescriber “if needed.” However, it is clear that the pharmacist must “take corrective measures” when problems are discovered. A couple of obvious possibilities include

   i. Consulting with the patient to gain more information that helps resolve the problem.

      1. Example: a prescription is written for Tylenol with Codeine 30 mg tablets, with directions to “Take 1-2 tabs q4-6h pm infection.” This suggests a possible error in the product that is specified, or at least “inadequacies in the directions.” However, the pharmacist notes that the patient also has a prescription for an antibiotic, which is also labeled “for infection.” She asks the patient what the physician told her the Tylenol with Codeine was for, and the patient responds, “The pain of my sinus infection.” This clarifies the order, and the pharmacist may resolve the problem by augmenting the directions to read, “Take 1 or 2 tablets every 4 to 6 hours if needed for pain of sinus infection.”

   ii. Exercising his or her judgment and subsequently informing the prescriber of the decision.

      1. Example: a prescription is received for a 3-year old for 30 Amoxicillin 250 mg capsules, to be taken q8h. The dose is appropriate for the child’s weight, but the child cannot swallow capsules. The prescriber is not immediately available for consultation. The pharmacist discusses with the mother the choice of liquid or chewables, which the child can ingest, and they agree on the use of chewables. This is not technically allowed by the generic substitution rules, but it is arguably a form of “secundum artem” that effectively solves the problem. This will allow the resolution of the problem promptly and get the mother and sick child on their way. The pharmacist can notify the prescriber of the decision, which will normally be acknowledged without any problems.
Providing Information to Patients

a. **Washington was the first state in the US to require all pharmacists to provide patient consultation.** The original rule (WAC 360-16-250), promulgated in 1973, specified that “With each new prescription dispensed after January 1, 1974, the pharmacist, in addition to labeling the prescription in accordance with preexisting requirements, must orally explain to the patient or the patient’s agent the directions for use and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation shall be by telephone or in writing. PROVIDED, that this shall not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications, or to those prescriptions for patients who are to be discharged from a hospital or institution.”

i. This regulation, although it set a national precedent, was limited to requiring information on new prescriptions only. In addition, in its actual application, pharmacists tended to limit their “counseling” to fairly superficial issues. Also, the Board has, over the years, been disappointed with the extent of compliance with this requirement by pharmacists.

b. In 2001, the Board promulgated a **revised patient counseling regulation, WAC 246-869-220,** which sets forth its purpose as “educate the public in the use of drugs and devices dispensed upon a prescription.”

i. **The pharmacist shall directly counsel the patient or the patient’s agent on the use of drugs or devices.**

ii. **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.

iii. For each patient, **the pharmacist shall determine the amount of counseling that is reasonable and necessary** under the circumstance

1. to promote safe and effective administration of the medication, and
2. to facilitate an appropriate therapeutic outcome for that patient from the prescription.

iv. **This rule applies to all prescriptions except where a medication is to be administered by a licensed health professional** authorized to administer medications.

c. Note that the current WAC 246-869-220 **differs from the old rule** in several significant ways

i. It is **not limited to new prescriptions** only
ii. It requires an offer to counsel, not just written information, on drugs dispensed outside of the pharmacy

iii. It requires the pharmacist to evaluate what is needed to promote safe and effective use of the drug and facilitate an appropriate therapeutic outcome and to tailor the counseling to the specific patient

iv. It no longer specifically exempts hospital or institutional discharge medications from its requirements
d. OBRA-90 requires that pharmacists
i. Make an “offer to counsel” Medicaid patients; and
ii. If the offer is accepted, OBRA-90 sets forth the following “significant items” that the pharmacist should be prepared to discuss with patients:
   1. Name and description of the medication
   2. Dosage form, dose, route, and duration of therapy
   3. Special directions for preparation, administration, or use by the patient
   4. Common severe side effects, adverse effects, interactions, or contraindications that the patient can detect and deal with
   5. Self-monitoring techniques
   6. Storage and refill information
   7. What to do if a dose is missed

iii. Pharmacists may allow the patient to refuse to be counseled. “Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual … or caregiver of such individual refuses such consultation.” (42 USC § 1396r-8(g)(2)(A)(ii)(II)) Nor does OBRA-90 require that refusal be documented, although some states have placed such a requirement in their rules.
e. Currently, there is no requirement in Washington that counseling must be documented or that refusal to be counseled must be documented. Given the continued concern by the Board that pharmacists are not as fully compliant with these rules as they should be, the Board at its October, 2004, meeting voted to establish a stakeholders group to advise the Board on a rule to require documentation of counseling.

   i. Voluntary Sign in Pharmacy. After much deliberation, the Board decided not to proceed with further rule making, but in January 2006 developed a notice to patients that could be voluntarily placed in the pharmacy. The figure below is similar to the one developed by the Board; the original is available on the Board website.⁴

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f. Legal impact of OBRA-90
   i. States have implemented OBRA-90 patient counseling requirements in different ways. Some allow an offer to counsel to be made by other than the pharmacist; some, like Washington, simply require counseling and make no provision for an “offer.” (Washington requires an “offer” only when the drug is delivered outside the pharmacy.) In a few states, these rules apply only to Medicaid patients, but most states chose to apply the requirements to all patients.
   ii. OBRA-90 rules, however, do establish an objective standard for the structure needed to support patient counseling and prospective drug use review (i.e., patient drug use histories, on-line or pharmacy-based computer systems)
   iii. OBRA-90 rules also establish an objective standard for the process of patient counseling and prospective drug use review.
   iv. Finally, OBRA-90 rules establish an objective standard for the content of patient counseling
   v. In a state with a rule like Washington’s, OBRA-90 rules provide evidence of a minimum, objective standard of how the pharmacist should have implemented patient counseling in his or her practice.
   vi. To the extent that pharmacists can document their compliance with OBRA-90 standards, they are providing evidence of proper professional practice.
Improving use and availability of patient care data – the Health Information Portability and Accountability Act of 1996 (HIPAA) – provisions to improve use and availability of patient care data. Passed by Congress with three major goals:

i. Portability
   1. Improve the ability of employees to take insurance coverage with them when they change jobs
   2. These portability provisions add to those that are generally known as “COBRA” provisions
      a. COBRA (Consolidated Omnibus Budget Reconciliation Act of 1986) provided that employees who leave one employer may keep their health care benefits in force for up to 18 months by paying premiums
      b. A problem arose with the ability of COBRA beneficiaries to convert their old coverage to new coverage with a new employer, since the new employer’s plan would often not cover “preexisting conditions.”
      c. HIPAA establishes that the maximum time period during which a new employer’s plan can refuse coverage for preexisting conditions is 12 months, after which these conditions must be covered, unless the condition is not covered for any employee

ii. Accountability
   1. Integrity of health care information
   2. Confidentiality of health care information
   3. Availability of health care information

iii. Administrative Simplification. The Act recognized considerable health care costs in the US associated with administrative complexity – some estimates are that over 20% of the health care dollar is spent on claims processing costs. Thus HIPAA dealt with “Administrative Simplification” involving electronic transmission of health care data among providers and payers. It established five major areas of new federal regulation:
   1. Transaction standards – creating a common set of standards for sharing claims among providers and payers
      a. For pharmacies, the regulations have adopted the NCPDP 5.1 standards
         1. Developed by the National Council on Prescription Drug Programs
2. All pharmacy computer systems were required to be compliant with NCPDP 5.1 by October 2003

3. All Medicare claims must be submitted electronically (no longer able to submit paper claims to Medicare)

2. **Standard identifiers** – establishing a single set of identifiers for health care providers
   a. Rules (45 CFR 162.402-414) established a National Provider System which assigns a unique National Provider Identifier (NPI) to each health care provider and covered entity.
      1. 10-digit number, which for some uses will be expressed in conjunction with an international prefix of 80840 (80 = health care, 840 = United States)
   b. The NPI replaces all other provider identifiers (CHAMPUS, UPIN, Blue Cross/Blue Shield, etc.)
   c. The NPI is assigned for the provider’s lifetime
      1. Address, name, and other changes will be made on-line, and must be made within 30 days.
   d. Each individual provider – including pharmacists – is eligible to receive an NPI
   e. Effective date was May 23, 2005, after which all pharmacists are able to apply for an NPI.
      1. The application is online, through the National Plan & Provider Enumeration System (NPPES) website.  
      2. All health care providers who are covered entities under HIPAA must obtain an NPI no later than May 23, 2007, or whenever they first become a covered entity, whichever is later.
   f. No charge to individuals to apply
   g. Pharmacists will need to know NPI of the prescriber to submit prescription claims
   h. Will allow systems to track contributions and productivity of individual pharmacists

3. **Code sets for data elements** – establishing a common data set to simplify communications among providers and payers

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5 [https://nppes.cms.hhs.gov/NPPES/Welcome.do](https://nppes.cms.hhs.gov/NPPES/Welcome.do)
4. **Security Standards** – providing for integrity and security of health care information (see discussion above)

5. **Electronic signatures** – allowing for a paperless health care information system

iv. **Covered Entities** – with regards to the accountability requirements, HIPAA applies to all entities that
   1. Render care to individuals
   2. Collect and maintain Protected Health Information (PHI)
   3. Exchange electronic records
   4. Virtually all pharmacies fit these requirements and are “covered entities”

6. **Assuring the confidentiality of patient information**

   a. HIPAA has been the center of recent national attention regarding protection of the privacy of patient information. However, **Washington has required confidentiality of patient records in pharmacy regulations at least since the inception of mandatory patient records, and the Washington Legislature passed a comprehensive Health Care Information Act in 1994 (RCW 70.02), prior to HIPAA.** Other state rules affecting privacy of medical records include the AIDS Omnibus Act of 1988 (RCW 70.24) and various statutes and regulations regarding mental health (RCW 71.05.390). Federal laws (PL 104-193 § 407) also govern confidentiality in substance abuse treatment programs. The privacy rules of each state are important for practitioners to understand, since HIPAA does not preempt any state or other federal privacy rules which are more stringent than the HIPAA requirements. Thus, in each state, what is actually required will be a combination of federal and state rules.

   b. The **HIPAA Privacy Rule is encoded at 45 CFR 160 and 45 CFR 164.** It’s principal features are:
      i. **Protected Health Information (PHI)** is that which
         1. Relates to a health condition (past, present, or future); and
         2. Identifies the patient (45 CFR 164.501)
      ii. **Covered entities may use PHI for TPHCO:**
         1. Treatment;
         2. Payment; or
         3. Health care operations
      iii. **Consent from the patient is not required to use information for TPHCO**
      iv. **All other disclosures or dissemination of PHI requires consent**
v. **Use of PHI for marketing, research, and other non TPHCO functions requires permission**
   1. Data may be shared for marketing or research if it is “de-identified”

vi. **Stricter provisions of any state law** must be followed

vii. **Business associates** must assure compliance with the rules
   1. Business associates include firms who perform payment or health care operations functions on the entity’s behalf

viii. **Consent from minors is subject to state law**

ix. **Each patient must be provided with a Notice of Privacy Practices (NOPP)** at first point of contact; receipt of the NOPP must be documented

c. **Use of PHI for Treatment.** Pharmacies may use PHI to provide treatment to patients. The NOPP of the pharmacy must include a description of how it will use PHI for treatment, which would typically include the following activities:
   i. Processing prescriptions and dispensing drugs
   ii. Maintaining and reviewing patient profiles
   iii. Consulting with prescribers relative to the patient’s care
   iv. Providing emergency information necessary for the patient’s care
   v. Consulting with the patient or caregiver regarding the patient’s medications
   vi. Transferring refill information to or from other pharmacies

d. **Use of PHI for Payment.** Typical pharmacy activities involving payment would include:
   i. Determining eligibility or coverage
   ii. Preauthorization of prescriptions and on-line prospective drug use review
   iii. Billing 3rd party payers, justifying charges
   iv. Collecting payment from the patient, or collecting past-due charge accounts
   v. Providing certain information to consumer reporting agencies
   vi. Transmitting credit card charges
   vii. Refunding charges or payments

e. **Use of PHI for Health Care Operations.** Typical pharmacy HCO activities would include:
   i. Quality assurance within the pharmacy
   ii. Quality assurance activities with external organizations
   iii. Contacting providers or patients with information on treatment alternatives and related functions that do not include treatment
   iv. Medical review, legal services, auditing, and fraud and abuse detection
v. Employee training and development
vi. Complying with regulatory agencies and complying with other provisions of HIPAA
vii. Inventory control and planning

f. Notice of Privacy Practices
   i. Advises patients that you will use their PHI for TPHCO
      1. Spells out what that means for your pharmacy
   ii. Advises patients of their rights
   iii. Advises patients that you do need written permission to release PHI for non-TPHCO purposes
   iv. Identifies the pharmacy’s Privacy Officer and how to contact that person
   v. Describes business associate relationships
   vi. Describes applicable state laws and regulations
   vii. Describes how you will notify of changes
      1. Most pharmacies will take advantage of the option to notify of changes to the NOPP by posting them in the pharmacy
   viii. Requires patient to acknowledge receipt of the NOPP
      1. May use a signature log
      2. Should place an indication in the computer record that notice was provided
   ix. The title of the notice must be printed exactly as stated in the regulation:
      1. “This Notice Describes How Medical Information About You May Be Used And Disclosed And How You Can Get Access To This Information”
   x. The pharmacy must post a notice announcing the availability of this information
   xi. Must provide a copy of the NOPP to any person who requests it
   xii. Must track changes to the NOPP


g. Patients have a right to see a copy of their record
   i. Patient may see records, and may request changes in the record to correct any errors
1. **The pharmacy must respond to the request in a timely manner.** This is treated differently under Washington law than under HIPAA, so the shorter time limits apply in Washington.

<table>
<thead>
<tr>
<th>Type of Request</th>
<th>Limits under HIPAA</th>
<th>Limits under Washington law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to records</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time for Initial Response</td>
<td>If information is available on site</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td>If information is off-site</td>
<td>60 days</td>
</tr>
<tr>
<td>One time extension</td>
<td>30 days (total of 60 or 90 days)</td>
<td>6 days (total of 21 days)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corrections to Records</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial response</td>
<td>60 days</td>
<td>10 days</td>
</tr>
<tr>
<td>One time extension</td>
<td>30 days (total of 90 days)</td>
<td>11 days (total of 21 days)</td>
</tr>
</tbody>
</table>

ii. **When a patient requests copies of his or her records,** the pharmacy must either deliver the copies within the time limit for an initial response, or provide the patient with an explanation that it will take additional time to provide the records; the pharmacy then can take advantage of a one-time extension as specified in the law. In Washington, the maximum time is 21 days, including the extension, and the initial response must be made within 15 days. Washington law, unlike HIPAA, does not distinguish between on-site and off-site records.

iii. **When a patient requests changes to his or her records,** the pharmacy must respond within 10 days in Washington, which may include a notice that additional time is needed, which will provide an extra 11 days in which to
   1. Amend the record as requested by the patient; or
   2. Deny the request to amend the record.
      a. If the pharmacy denies the requested change, the patient may provide a statement to be inserted into the record.

iv. **HIPAA and Washington law allow providers to charge a reasonable fee for searching and copying records.** (If there is a fee to be charged, it should probably be set forth in the NOPP.) Washington law sets forth maximum amounts that can be charged in WAC 246-08-200:
1. Copying charges
   a. 1st 30 pages, not more than $0.91 per page.
   b. Beyond 30 pages, not more than $0.69 per page
2. Other charges
   a. Up to a $21 clerical fee for searching and handling records
   b. If the provider personally edits confidential information, may charge his or her usual and customary fee for a basic office visit. (Pharmacists may be able to establish a UAC office visit fee based on charges for disease management services, such as diabetic counseling, etc.)
3. These fees are updated each biennium; the current fees are approved through June 30, 2007.

h. Patients may request an accounting of disclosures. The patient may request that the provider provide a listing of all disclosures of PHI made during the six years prior to the request.
   i. The provider is not required to account for disclosures
      1. Made directly to the patient
      2. Made to carry out TPHCO
      3. Made pursuant to an authorization granted by the patient
      4. Made to persons involved in the patient’s care
      5. Made prior to April 14, 2003 (the effective date of the HIPAA privacy rule)
   ii. The provider may not charge for the first accounting provided to the patient within any 12-month period; a reasonable cost-based fee may be charged for additional requests within 12 months.
   iii. Some disclosures made to law enforcement agencies or as a result of a court order may not be subject to the accounting. The pharmacist should consult legal counsel in these cases, since the rules are complex and involve both state and federal restrictions.

i. The patient may request that communication of PHI to the patient be restricted to confidential channels, such as:
   i. A particular address
   ii. A particular telephone number
   iii. A particular electronic address
   If they choose one of these options, they must acknowledge that this may restrict communications with family members or caregivers.

j. Washington’s rules are more stringent than HIPAA in the following ways, and must be followed
i. **Time limits to respond to requests** to see or amend records

ii. **Consent by certain minors** (see below)

iii. **Consent by patients with STDs or HIV for certain otherwise permitted disclosures** (eg, oral communications with family member)

iv. **HIPAA allows reports to the military concerning military personnel; Washington law does not**

v. **Abuse of a vulnerable adult or child MUST be reported**

k. Washington law – in ways that are consistent with HIPAA – allows **disclosure without the patient’s consent under the following circumstances** (RCW 70.02.050):

   i. To a person who is reasonably believed to be providing health care to the patient

   ii. To a provider who has previously treated the patient, if necessary for the patient’s care, UNLESS the patient has previously instructed the pharmacist not to disclose to that provider

   iii. To any person if it is reasonably believed to be needed to avoid or minimize imminent danger to the health or safety of the patient or another individual (this is allowed but not required)

   iv. Oral disclosures, if made to immediate family members or other person with whom the patient is known to have a close relationship, in accordance with good medical or professional practice, UNLESS the patient has instructed the provider in writing not to make the disclosure

   v. To a provider who is successor in interest to the provider maintaining the information (eg, on the sale of the pharmacy).

   vi. Additional conditions are listed in RCW 70.02.050

l. **Board of Pharmacy rule is obsolete.** WAC 246-875-070(2) specifies that information in the patient medication record is confidential, and restricts its disclosure more stringently than the HCIA. This rule was promulgated in 1992, prior to the adoption of RCW 70.02.050; to the extent that it conflicts with the RCW, it is probably not enforceable.

m. **Age of consent.** As with most other legal issues, persons who are 18 years of age or older a considered adults and must consent to medical treatment for themselves; they control the disclosure of PHI as it pertains to them, and have a right to see their medical records.

   i. A key issue deals with whether parents or minors have control of PHI for the minor. HIPAA defers to state rules on this issue. **Generally, parents or legal guardians have control over health care decisions for minors. Important exceptions include:**
1. **Emancipated minors.** Minors over age 16 may petition the court to become emancipated, and if successful may consent to health care services. (RCW 13.64.060)

2. **Minors married to a person who is not a minor.** (RCW 26.28.020)

3. **Minors who may have come in contact with an STD and are 14 years of age or older** may consent to treatment. (RCW 70.24.110)

4. **Minors seeking contraceptive or pregnancy termination services at any age** may consent to treatment. (State v. Koome, 84 Wn.2d 901; 530 P.2d 260, 1975)

5. **Minors 13 years of age or older may consent to inpatient** (RCW 71.34.500) or **outpatient** (RCW 71.34.530) **mental health treatment.**

6. **Minors 13 years of age or older may consent to outpatient treatment for chemical dependency.** (RCW 70.96A.095)

   ii. **Power to consent to disclosure of PHI is vested in the minor for any information relating to treatment for which the minor was allowed to consent.** (RCW 70.02.130). Thus, the pharmacist should presume that the minor can control disclosure of treatment with contraceptives, psychotropics, or drugs used for STDs or pregnancy. Treatment for other conditions could be disclosed with permission of the parent or guardian, but the safest approach is to consult the minor prior to disclosure if any part of the PHI is related to matters over which the minor has control.

   iii. **Washington law specifically protects health care providers from liability when they disclose PHI for a minor (other than when the minor has control of the record) based on permission of either parent or any legal guardian,** as long as the parent or guardian represents to the health care provider that they are authorized to give consent. (RCW 70.02.130) This protects the health care provider from disputes when parents are divorced or separated.
n.  **Compliance with Notice of Privacy Practice rules.** A survey of published NOPPs from 16 Washington chains and 7 independent pharmacies found that the majority of pharmacies failed to accurately list the more stringent requirements of Washington law.\(^6\) We assume this is because they adopted NOPPs from one of the national organizations’ manuals. The results are summarized in the following table:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Chains (n=16)</th>
<th></th>
<th></th>
<th>Independents (n=7)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Correct</td>
<td>Wrong</td>
<td>No Mention</td>
<td>Correct</td>
<td>Wrong</td>
<td>No Mention</td>
</tr>
<tr>
<td>Mental health</td>
<td>1</td>
<td>15</td>
<td></td>
<td>7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STDs/HIV</td>
<td>5</td>
<td>11</td>
<td>2</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minor’s consent</td>
<td>3</td>
<td>3</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Abuse or neglect</td>
<td>9</td>
<td></td>
<td>7</td>
<td></td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Military reporting</td>
<td>1</td>
<td>8</td>
<td>7</td>
<td></td>
<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

7.  **Quality Assurance Activities**
   
   a.  **IOM Report.** The 1999 publication of *To Err is Human* by the Institute of Medicine generated significant national attention concerning medical errors, of which medication errors constitute a significant segment.

   b.  **Required CQI Programs.** In general, hospitals are now required by state law and/or JCAHO accreditation requirements to have a continuous quality improvement process in place by which quality-related events (QREs) are reported, investigated, tracked, and efforts made to improve the system of care so as to reduce the incidence and impact of these events. Washington’s law requiring all hospitals to maintain a Coordinated Quality Improvement Program (CQIP) is RCW 70.41.200 et seq.

   c.  **Required Reporting of Adverse Events.** The Washington Medical Malpractice Act of 2006 (2006 c 8 § 106) requires medical facilities to notify the Department of Health of adverse events using an online reporting system.

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i. **Adverse events** are those events found on the list of serious reportable events adopted by the National Quality Forum in 2002.7

ii. **The report shall identify the facility**, but not any healthcare professionals, employees, or patients involved.

iii. **A root cause analysis** shall be conducted and included as part of the report.

d. **Hospital Notification of Unintended Outcomes.** Effective January 1, 2006, Washington hospitals shall have in place policies to assure that, when appropriate, information about unanticipated outcomes is provided to patients or their families or any surrogate decision makers. (RCW 70.41.380)

e. **Community pharmacies are not generally required to implement quality improvement activities at present**, but a clear national trend is emerging. As of 2005, four states, California, Florida, Massachusetts, and Texas, have implemented requirements for pharmacies in all settings to have in place a quality assurance or quality improvement program.

f. **Most states have now enacted legislation to encourage continuous quality improvement programs**, including Washington. Under Washington law, entities other than hospitals (for whom CQIPs are required) wishing voluntarily to develop CQIPs may apply to the Department of Health to be recognized, in accordance with RCW 40.73.510. The DOH CQIP website provides information needed to develop CQIPs ([http://www.doh.wa.gov/CQIP/default.htm](http://www.doh.wa.gov/CQIP/default.htm)). Regulations governing CQIPs are contained in **RCW 246-50**. Eligible entities may be developed by

   i. Professional societies or organizations
   
   ii. Health care service contractors
   
   iii. Health maintenance organizations
   
   iv. Health carriers
   
   v. Health care institutions and medical facilities, other than hospitals
   
   vi. Provider groups of ten or more. This may take many forms, as long as its members are practitioners regulated under the state’s laws for health professionals (Title 18)
   
   1. A group might consist of providers sharing treatment modalities and perspectives.
   
   2. A community of providers which cross-disciplinary lines.
   
   3. Solo practitioners may form a group to create a Coordinated Quality Improvement Program.

g. **A list of approved CQIPs in Washington** is available on the DOH website at [http://www.doh.wa.gov/CQIP/Approved.htm](http://www.doh.wa.gov/CQIP/Approved.htm). The

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Northwest Medication Safety Council is an approved CQIP that was established to deal primarily with the quality of pharmacy care.

h. The goal of the CQIP or similar organization is to provide structures and processes that:
   i. Measure, retrospectively and prospectively, key characteristics of services such as effectiveness, accuracy, timeliness and cost.
   ii. Review categories of services and methods of service delivery to improve health care outcomes.
   iii. Ensure information gathered for the program is reviewed and used to revise health care policies and procedures.

i. Coordinated quality improvement programs approved by the states are provided discovery limitations. Once approved by Department of Health, information and documents specifically created for, collected, and maintained by an approved program are exempt from discovery during lawsuits in most cases.

j. To assure the same protection to quality improvement programs that transcend state lines, Congress enacted the Patient Safety and Quality Improvement Act of 2005. The information used in these programs is defined in the Act as “Patient Safety Work Product” (PSWP), and as with most of the state laws, is protected from being discovered or used in civil lawsuits, administrative hearings, and most criminal proceedings.
   i. These protections are found in Washington law in RCW 4.24.250. In addition to protecting quality review or provider review information from discovery, it immunizes providers who in good faith file charges or provide evidence to review bodies concerning incompetence or gross negligence of other members of their profession.

k. To qualify as PSWP, the protected information must be gathered for patient safety purposes, kept separate from other health care information collected by the provider, and communicated to a Patient Safety Organization (PSO) that is registered with the Department of Health and Human Services (through the Agency for Healthcare Research and Quality – AHRQ).

l. In general, state and federal laws prohibit unauthorized disclosure of PSWP that contains the identity of any provider (including individual practitioners as well as provider entities). This identifiable PSWP may only be used for patient safety activities. In a way, these laws protect the identity of practitioners in the same way as HIPAA protects the privacy of patients.

m. The federal law specifically protects employees of a provider from retaliation for reporting errors, either to the provider or to a PSO.

n. Increasingly, pharmacists will need to understand the operation of patient safety programs, including patient safety
tools such as Root Cause Analysis and Failure Mode Analysis. The California Pharmacy Jurisprudence Exam specifically includes questions related to quality improvement, RCA, and FMA.

i. More in-depth instruction concerning patient safety and quality improvement is covered at WSU in PharP 591 – Patient Safety and Medication Error Prevention.

1/9/07