5557 FAQs & Definitions

These Questions and Answers are intended to present information that has been acquired as part of the discovery process and provides necessary context for the Policy Directives and Operational Expectations documents.

What are the definitions of terms commonly used in these documents?

1) Provider - a licensed healthcare professional.   AKA - practitioner, healthcare professional

2) Pharmacist - a specific type of provider that meets the Washington State licensing requirements.

3) Medical services - services covered under a patient's medical benefit

4) Provider network - the group of participating providers and facilities providing medical services to a particular health plan or line of business (individual, small, or large group)

What is the legislation that set the stage for the current project?

Senate Bill 5557 was signed into law May 11, 2015. The new law requires that pharmacists be included within the provider networks of Washington State licensed insured large group, small group, individual, and family plans. (RCW 48.43.005 (26)) The law calls for these health plans to reimburse pharmacists for care provided that is within their scope of practice. These reimbursement requirements may not apply to Federal plans such as Medicare, Tricare, Taft-Hartley, AND other State plans, e.g. PEBB/Uniform Medical plans, Washington State Medicaid and related plans, commercial self-insured plans, etc. They also may not apply to health plan sponsored programs, such as the Medication Therapy Management (MTM) program sponsored by Medicare, that are targeted at managing the care of specific populations. MTM programs may have patient eligibility requirements and only be offered through specific network of providers, defined by the health plan.

Note: the law sets two different implementation dates.

• For plans that are issued or renewed on or after January 1, 2016, this law applies to pharmacists that are employed or contracted by facilities in which health plans delegate credentialing.

• For plans that are issued or renewed on or after January 1, 2017, this law applies to all pharmacists.

Does this legislation apply to services that are covered under a patient's medical benefit and pharmacy-drug benefit?

Health plans offer two types of coverage, medical benefit coverage and pharmacy (drug) benefit coverage. This legislation only applies to services covered under a patient's medical benefit, i.e. services which may also be performed by a qualified physician, ARNP, PA, etc., as appropriate to their scope of practice and licensure. For services that

are covered under patient's pharmacy-drug benefit, billing and reimbursement policies and procedures will not be impacted.

What is a pharmacist's scope of practice in Washington State?

Per RCW 18.64.011 (23) http://app.leg.wa.gov/RCW/default.aspx?cite=18.64.011 and related WACS

1. Interpreting prescription orders
2. Compounding, dispensing, labeling, administering, and distributing of drugs and devices

3. Monitoring of drug therapy and use (WAC 246-863-110)

    a. Collecting and reviewing patient drug use histories;

    b. Measuring and reviewing routine patient vital signs including, but not limited to, pulse, temperature, blood pressure, and respiration; and

    c. Ordering and evaluating the results of laboratory tests relating to drug therapy including, but not limited to, blood chemistries and cell counts, drug levels in blood, urine, tissue or other body fluids, and culture and sensitivity tests when performed in accordance with policies and procedures or protocols applicable to the practice setting, which have been developed by the pharmacist and prescribing practitioners and which include appropriate mechanisms for reporting to the prescriber monitoring activities and results.

4. The initiating or modifying of drug therapy and use in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs (WAC 246-863-100)

5. Participating in drug utilization reviews and drug product selection

6. Proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof

7. Providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the use of drugs and devices

What training and education do pharmacists receive to obtain their pharmacy degree?

In order to be eligible to become a licensed pharmacist in the state of Washington, licensure applicants must have completed their Pharmacy degree from the Accreditation

Council for Pharmacy Education (ACPE) accredited pharmacy program. While many pharmacists are practicing as Registered Pharmacists, the Doctor of Pharmacy degree has been the standard degree for ACPE accreditation since 2003.

The ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education. The ACPE standards outline the required didactic and experiential curriculums for accredited pharmacy programs. The most current standards are available at: https://acpe-accredit.org/pdf/Standards2016FINAL.pdf.

Though the training of pharmacists is highly focused on the pharmacology, chemistry, and therapeutic applications of medications to promote a strong understanding of medication safety and efficacy, considerable attention in pharmacy curricula (both didactic and experiential) is devoted to the development of core ability in communication education, leadership, and inter-professional teamwork.

Post degree, many pharmacists obtain additional training in one or two year accredited residency programs and/or certification programs noted in the FAQ below. Many health system and community retail pharmacies also have training and competency programs built in to their organizational staff development to ensure quality and consistency.

What are the Washington State licensure requirements for pharmacists?

Per RCW 18.64; WAC 246-861 and WAC 246-863
http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/Pharmacist/LicenseRequirements

Education:
    Pharmacy Degree from an Accreditation Council for Pharmacy Education (ACPE) accredited pharmacy program

Examinations:
- North American Pharmacy Licensure Examination
- Multi-state Jurisprudence Examination

Training:
- 1,500 hours of experiential training
- 7 hours of HIV training

Renewal:
    15 hours of continuing education requirements annually

What are the currently recognized certifications a pharmacist can have?

The Council on Credentialing in Pharmacy has developed and maintains a list of Pharmacist Certifications (http://www.pharmacycredentialing.org/Files/CertificationPrograms.pdf). Certifications continue to evolve, so the list is not complete, but it is fairly comprehensive of the majority of certifications for pharmacists.

Currently there are no certifications available for many areas of pharmacy practice, e.g. reproductive health.

Are Pharmacists primary care providers or specialty care providers? Are there implications for patient co-pay?

For each of their benefit plans, the health plan (in alignment with CMS and/or national mandates, e.g. ACA) will determine if a type of provider is to be designated as a primary care provider or a specialty care provider. For the limited number of health plan products where a patient co-pay differential exists, that determination will establish whether the patient will have a primary care co-pay or a specialty care co-pay when visiting a provider of that type.

Explanatory Note:

1. When making a "visit" to a provider the patient may have a co-pay, the amount of which is determined by whether the provider visited is Primary care or Specialty Care.

2. The co-pay is related to the visit regardless of the number and type of services delivered during the visit.

3. The co-pay for an Emergency Room visit or a Hospital Admission visit is set regardless of the number and types of providers that will deliver services over the course of that ER or hospital visit.

Some pharmacists have offered the following perspective on their role in primary care and request that health plans consider it when making their determination.

- Many pharmacist-provided services should be regarded as primary care services, based on specific examples from ACA provisions, as well as common medical usage of what constitutes primary care services. The pharmacist is a member of the primary care team, providing primary care services.

- The ACA contemplates that a pharmacist is part of a primary care team, and the sorts of services provided by a pharmacist (medication management, medication reconciliation, preventive care services, medication education and counseling) are those provided within the scope of primary care. Common usage in medical

practice includes these areas as part of a primary care practice. Additionally, the ACA includes examples of pharmacists acting as part of the primary care medical team which are consistent with the ACA policy objective of incenting lower cost providers to provide high quality care at the top of their licensure.

- However, in some patient care situations, certain pharmacist provided services may be considered specialty services when working in collaboration with other specialty providers.

What is a Collaborative Drug Therapy Agreement (CDTA)?

WAC 246-863-100   http://app.leg.wa.gov/WAC/default.aspx?cite=246-863-100

A CDTA is a signed agreement between one or more providers with prescriptive authority and one or more licensed pharmacists. It is required in those situations when the pharmacist will exercise prescriptive authority in his or her practice (see RCW 18.64.011(23), WAC 246-863-100) by initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs. This document is filed with the Pharmacy Quality Assurance Commission (PQAC). CDTAs are applicable in all care delivery environments, hospital, clinics, and community pharmacies.

Per WAC 246-863-100, these agreements between prescriber(s) and pharmacist(s) shall include:

1. A statement identifying the practitioner authorized to prescribe and the pharmacist(s) who are party to the agreement. The practitioner authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' current practice.

2. A time period not to exceed 2 years during which the written guideline or protocol will be in effect.

3. A statement of the type of prescriptive authority decisions which the pharmacist(s) is (are) authorized to make, which includes:

   a. A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case.

   b. A general statement of the procedures, decision criteria, or plan the pharmacist(s) is (are) to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved.

4. A statement of the activities pharmacist(s) is (are) to follow in the course of exercising prescriptive authority, including documentation of decisions made, and a plan for communication or feedback to the authorizing practitioner concerning

specific decisions made. Documentation may occur on the prescription record, patient drug profile, patient medical chart, or in a separate logbook.

Are the CDTAs reviewed by the Department of Health?

http://www.doh.wa.gov/portals/1/Documents/Pubs/690212.pdf,

The Pharmacy Quality Assurance Commission (PQAC), reviews the agreement to ensure:

1. The agreement includes a signed statement delegating prescriptive authority to named pharmacist(s).

2. The agreement lists, by name and license number, all of the pharmacists that are party to the agreement and includes a signature by each pharmacist named in the agreement to verify acceptance of delegation.

3. The agreement designates a time frame for the agreement, not to exceed two years.

4. The delegating prescriber(s) signed the agreement.

5. The agreement specifies which patients are eligible to receive services under the agreement. It can narrowly define the patient population, e.g. patient eligibility per assessment criteria, specific age range, or only patients of the physician who signed the CDTA. Or, if designated in the agreement, it could apply broadly to any patient meeting eligibility per assessment criteria for certain situations as determined by the prescriber such as immunizations, tobacco cessation, or Take Home Naloxone

6. Delegated prescribing activities are specified (disease, drugs, categories) in the agreement.

7. Whether or not the agreement includes controlled substances.

8. The agreement includes a plan for prescriber feedback and quality assurance.

9. The agreement includes a plan or guideline for making prescribing decisions.

10. The agreement includes procedures for documenting prescribing decisions.

11. The agreement includes copies of any/all forms to be used in association with the agreement.

12. The agreement includes a description of any training the pharmacist must complete to include specialized training required for immunizations. Though not required, the CDTA may contain requirements pertaining to Board Certifications/advanced trainings

Upon filing of the CDTA with the PQAC, each pharmacist will be assigned a unique CDTA identifier.

Employers may facilitate the filing and management of a CDTA on behalf of a

pharmacist(s) and prescriber however;
- A CDTA is an agreement between a pharmacist and a prescriber.
- It is not an agreement between a corporation or an employer and a prescriber.
- Employers may not restrict or impose limitations on communication between the pharmacist(s) and the authorizing prescriber.

When a CDTA is facilitated by an employer:
- The employer may coordinate the QA program or systems that support WAC 246-863-100 (2) (d) used to provide the authorizing prescriber with documentation of decisions, communication and feedback.
- An employer through policy may limit the implementation of a pharmacist's CDTA within the employer's setting.

A CDTA will be continually updated to reflect all current pharmacist(s) covered by the agreement. This includes both additions and deletions of pharmacist(s). A change in the authorizing prescriber will require a new CDTA be filed.

When multiple prescribers have signed the CDTA:

- A change in one or more of the authorizing prescribers does not require a new CDTA as long as at least one of the other authorizing prescribers is continuing to authorize the prescription authority delegated in the CDTA.

- A new CDTA shall be required if there is a change in scope of the delegation, whether by amendment from the authorizing prescriber or by removal of an authorizing prescriber who had delegated specific (qualified or limited) prescription authority and no other authorizing prescriber on the CDTA is delegating the specific prescription authority to the pharmacist(s) in the CDTA.

- A new pharmacist may be added to the agreement during the two-year period the agreement is on file by submitting to the PQAC a document signed by the authorizing prescriber and the pharmacist and a copy of the CDTA previously filed

- The addition or deletion of a pharmacist(s) does not extend the PQAC's assigned expiration date.

When is a CDTA necessary?

Under current (2015) Washington State prescribing laws, if a pharmacist will be prescribing medications in the course of their patient care services, such as for chronic disease management (adjusting blood pressure medications or anticoagulation), or initiating new therapies (Take home naloxone, immunizations), then a CDTA would be necessary to delegate prescribing authority to the pharmacist.

For more information on how CDTAs are regulated, see WAC 246-863-100

http://app.leg.wa.gov/WAC/default.aspx?cite=246-863-100 and
http://doh.wa.gov/portals/1/Documents/Pubs?690212.pdf

How many CDTAs are there and how are they same/different?

As of September 2015,

CDTA Statistics – approximately 10,000
- Each pharmacist covered under a CDTA counts as 1 CDTA.
- 6,500 allow pharmacists to prescribe immunizations
- 3,500 allow pharmacists to prescribe (initiate or modify) prescriptions in other areas of care provision.
  - 2,450 for Integrated Delivery System Pharmacists[*1]
  - 1,050 for Community Clinical Pharmacists[*2]

Definitions used by Washington State Department of Health

[*1]Pharmacists in hospital-based practice setting or clinic setting that provide medical services requiring a CDTA

[*2]Pharmacists in a community pharmacy setting that provide medical services requiring a CDTA

1) Immunization Agreement CDTA (6,500)

   Establishes procedures for pharmacists to determine which vaccinations are necessary for a patient, assess for contraindications, document prescription and administration, and manage side effects. Also may list required trainings or certifications, referral, necessary communication plan with prescriber, prescriber review, and which patients and which immunizations are included, even if these CDTA requirements are not required by state law.

2) Integrated Delivery System CDTA (2,450)

   Medical director often establishes procedures/protocols, in partnership with the Health System's or hospital's Pharmacy and Therapeutics Committee – may be inclusive of multiple protocols requiring multiple CDTAs

3) Community Clinical Pharmacy CDTA (1,050)
   - Pharmacist forms agreement with local prescriber for a symptom specific protocol.
   - Best practice is to notify the patient's diagnosing provider, if one exists, when they receive treatment consistent with that protocol. This notification must be consistent with patient consent privacy practices.

What are Credentialing and Privileging and how do they apply?

Credentials include, but may not be limited to, Academics/Examination, Licensure, Internships/Residencies, Experience, Certifications, and Advanced Training that demonstrate qualification to provide a set of services.

Credentialing is the process used by health plans and provider organizations to gather and verify a defined set of provider credentials. Direct credentialing is when a health plan or provider organization gathers and verifies the defined set of provider's credentials, and this process can require multiple months. Delegated credentialing is when a health plan has approved a provider organization's process for defining, gathering and verifying a provider's required set of credentials.

Privileging is the process used by provider organizations to determine which providers can provide which services within their organization and which credentials are required to provide those services. These providers may be employees of the organization or contracted by the organization. As part of this process, the credentials required of a provider, e.g. PA, ARNP, Pharmacist, *may vary* based on the specific services that a provider of that type delivers in the course of their work. In other words, organizations may gather and verify different credentials of providers of a given type depending upon the services that the specific provider can/will deliver. The determination of which credentials are required for which services is made using evidence-based standards that are reviewed by the organization's medical staff and which is an integral part of the quality assurance review process.

The application of credentialing and privileging depends upon the type of organization.

- <u>Health plans</u> ONLY credential providers, i.e. they do not privilege providers. For health plans, the defined set of credentials gathered and verified for a provider, e.g. PA, ARNP, Pharmacist, to deliver services to that health plan's members ***do not vary*** based on the specific services that a provider of that type delivers in the course of their work.

- <u>Provider organizations</u> may credential only, or may credential AND privilege their providers. Examples of these organizations include but are not limited to hospitals, ambulatory surgery centers, and medical clinics. For provider organizations that privilege their providers, the defined set of credentials gathered and verified for a provider, e.g. PA, ARNP, Pharmacist, ***may vary*** based on the specific services that a provider of that type delivers in the course of their work. When a provider organization performs 'delegated credentialing' on behalf of a health plan, the health plan approves the credentialing process already in place, which takes into account the health plan's defined set of credentials as well as additional training and certification standards established within the provider organization. In other words, the credentials required by the provider organization must meet, and can exceed, the set of credentials required by the health plan.

- <u>Organizations that are both a provider organization AND a health plan</u>, i.e. provide

patient care and take on financial risk for providing care, may credential only, or may credential AND privilege their providers. Examples of these organizations include but are not limited to Accountable Care Organizations (ACO), Health Maintenance Organizations (HMO), and Managed Care Organizations (MCO). Similar to provider organizations, for these provider-health plan organizations the defined set of credentials gathered and verified for a provider, e.g. PA, ARNP, Pharmacist, *may vary* based on the specific services that a provider of that type delivers in the course of their work. These organizations have a baseline set of credentials that apply to all providers of a given type AND they may have additional training and certification standards depending upon the services that the provider delivers.

What are the different places of service in which a Pharmacist may practice?

Pharmacists practice in a variety of 'places of service', e.g. pharmacy, inpatient hospital, home, nursing facility, independent clinic, etc. For the purposes of billing, the place of service designated on the claim form must corresponded to a CMS defined place of service (https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html.)

Reimbursement of a service may vary depending upon the place of service, as defined in the link above. Reimbursement rates may or may not vary between organizations that are the "same place-of-service" depending upon the contract between the health plan and that organization.

Is a diagnosis required to bill for services?

In accordance with industry practice standards, a diagnosis must be documented in the patient's record along with the need for treatment. In addition, a valid ICD10 coded diagnosis must be submitted on the claim form.

If the reason for the services **IS NOT** related to illness or injury, e.g. preventative care, smoking cessation, immunization, etc., the appropriate ICD10 Z-series diagnosis codes can be selected by the pharmacist and used on the claim form. Coding guidelines for ICD10-CM Diagnosis codes, "*ICD10 CM Official Guidelines for Coding and Reporting FY 2016"* can be found on the CMS ICD10 Website (https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2016-ICD-10-CM-Guidelines.pdf). Chapter 21 of these guidelines discusses how to use the Z series diagnosis codes. These codes MUST be billed to the highest level of specified digits (4, 5, 6 or 7 required digits) in order to be considered a "valid code". Associated with many of the codes in the Z-series are those codes that state either "with abnormal findings" or "without abnormal findings". If a Z-code is used that states "with abnormal findings", a

second code is needed in order to identify the abnormal findings.   An additional code is not needed when no abnormal findings are found.

If the reason for the service **IS** related to illness or injury, e.g.. diabetes mellitus, hypertension, lipid management, etc. the appropriate ICD10 code from the diagnosis range A00-Y99 must be used on the claim form.   This diagnosis must be obtained from a provider with diagnosing authority within their scope of practice, either via a shared patient record (integrated delivery system) or via a referral or CDTA (community clinical pharmacy).

What CPT/HCPCS Codes do pharmacists anticipate billing?   How will they be reimbursed?

The following types of codes are likely to be used when billing for medical services. Note: this is not an exhaustive list, other codes may be billed.

CPT / HCPCS Code Types
E&M Codes
MTM Codes
Medication/Vaccination Codes
Lab Test Codes
Diabetes Mellitus Self Management Code
Potential Harm Reduction

- *E&M Codes:* Evaluation and Management Services describe provider-patient encounters that vary based on complexity of care, level of service etc., regardless of whether these services are provided in the provider's office, hospital, or in the patient's home. These codes can cover a variety of services including Complex Chronic Care Coordination, Alcohol and Substance Abuse, Preventive Medicine Counseling, etc. Code assignment should be based on documentation present in the medical record.

- *MTM Codes:* Medication Therapy Management Services describe face-to-face patient assessment and intervention by a provider. These services, initiated by request of a physician, are designed to optimize response to medication or to manage treatment related medication interactions or complications. Uses of these codes are NOT intended for services associated with routine dispensing.

- *Medication/Vaccination Codes*: Vaccines and other drugs administered by a pharmacist.   **Note:** Use of these codes and medical billing is not appropriate for administration/dispensing that is covered under a patient's pharmacy-drug benefit

- *Lab Test Codes:* Lab testing pursuant to drug therapy management or assessment of adverse effects.

- *Diabetes Mellitus (DM) Self-management education*: This may include Blood Glucose (BG) meter training, use of meter in overall DM management, counseling, etc. It would not take the place of the typical counseling/set-up requirement for BG meters and would likely require fairly significant documentation.

- *Potential Harm Reduction:* This includes individual and group class billing (such as Tobacco cessation)

Note: *Telemedicine***:** Healthcare services rendered via telecommunications delivery whether synchronous/asynchronous communication, telephone assessment and management, or online/internet communications. Coverage of this category is dependent on a member's benefits and how the health plan has defined what services will be accepted as "telehealth services".

Medical services provided need to be coded and billed per established industry coding and billing guidelines such as those outlined below. The code used for a service on a claim form and the documentation in the patient's record in support of that code must be consistent with industry standards as outlined below.

Reimbursement processes for medical services will be consistent with those in place for all other providers. Health plans will offer no instruction in how coding should be done or which codes should be used. Health plan systems will accept and adjudicate all valid codes in accordance with the patient's benefits.

Services covered under the patient's pharmacy benefit-drug benefit will continue to be billed and reimbursed per the terms of the health plan contract, subject to current WACs.

What are documentation and coding standards for medical services?

These standards, which are followed by all providers that bill for medical services, are outlined in industry coding and billing guidelines such as those published by:

- American Medical Association's Current Procedural Terminology (CPT) codebook available online through vendors like
  - AMA Store: https://commerce.ama-assn.org/store/
  - OPTUM products: https://www.optumcoding.com/

- International Classification of Diseases 10th revision (ICD10 CM), codebook available online through vendors like
  - AMA Store: https://commerce.ama-assn.org/store/
  - OPTUM products: https://www.optumcoding.com/

- Centers for Disease Control and Prevention
  ICD10-CM: http://www.cdc.gov/nchs/icd/icd10cm.htm

- Centers for Medicare and Medicaid Services (CMS)
  ICD10-CM: https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html

- Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Level II codes and codebook available online through vendors like
  - AMA Store: https://commerce.ama-assn.org/store/
  - OPTUM products: https://www.optumcoding.com/
  - HCPCS General Information:
     https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html

- National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services. Manual and overview of NCCI billing and edits: https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html?redirect=/NationalCorrectCodInitEd/

What claim forms are used for the billing of medical services?

Medical services provided in a facility, e.g. hospital, emergency department, ambulatory surgery center, etc. are typically billed on the UB04 – CMS1450 claim form and submitted electronically using the X12 837I transaction
Ex. https://www.ibx.com/pdfs/providers/npi/ub04_form.pdf

Medical services provided in a non-facility location, e.g. community pharmacy, physician's office, etc. are typically billed on the CMS1500 claim form and submitted electronically using the X12 837P transaction.
Ex. http://www.bcbsil.com/PDF/complete_cms_1500.pdf

Will Pharmacist bill directly or as "incident to"?

Depending upon the place of service and the relationship between pharmacist and physician, pharmacist provided services can be billed by the pharmacist (using the pharmacist's National Provider Identifier - NPI) or can be billed as "incident to" by the physician (using the physician's NPI). Industry standard guidelines, such as those provided by CMS, should be followed when billing as "incident to". (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0441.pdf).

Similar to other providers billing "incident to" services, reimbursement rates are likely to vary depending upon who bills the service, per the terms of the health plan contracts.