

## 409-025-0100

### **Definitions**

The following definitions apply to OAR 409-025-0100 to 409-025-0190:

- (1) "Accident policy" means an insurance policy that provides benefits only for a loss due to accidental bodily injury.
- (2) "Allowed amount" means the actual amount of charges for healthcare services, equipment, or supplies that are covered expenses under the terms of an insurance policy or health benefits plan.
- (3) "APAC" means all payer all claims.
- (4) "Association" means any organization, including a labor union, that has an active existence for at least one year, that has a constitution and bylaws and that has been organized and is maintained in good faith primarily for purposes other than that of obtaining insurance.
- (5) "Attending provider" means the individual health care provider who delivered the health care services, equipment, or supplies specified on a health care claim.
- (6) "Authority" means the Oregon Health Authority.
- (7) "Billing provider" means the individual or entity that submits claims for health care services, equipment, or supplies delivered by an attending provider.
- (8) "Capitated services" means services rendered by a provider through a contract in which payments are based upon a fixed monthly dollar amount for each enrollee.
- (9) "Carrier" shall have the meaning given that term in ORS 743B.005.
- (10) "Certificate of authority" shall have the meaning given that term in ORS 731.072.
- (11) "Charges" means the actual dollar amount charged on the claim.
- (12) "Claim" means an encounter or request for payment under the terms of an insurance policy, health benefits plan, Medicare, or Medicaid.
- (13) "Coinsurance" means the percentage an enrollee pays toward the cost of a covered service.
- (14) "Control totals file" means a data set containing summary information on medical, pharmacy and dental claims, members, providers, and premiums used to validate the detailed files submitted.
- (15) "Coordinated Care Organization (CCO)" shall have the meaning given that term in ORS 414.025.
- (16) "Copayment" means the fixed dollar amount an enrollee pays to a health care provider at the time a covered service is provided or the full cost of a service when that is less than the fixed dollar amount.
- (17) "Data file" means electronic health information including medical claims files, enrollment files, medical provider files, pharmacy claims files, dental claims files, control totals files, subscriber-billed premiums files, payment arrangement files and any other related information specified in these rules.
- (18) "Data set" means a collection of individual data records, whether in electronic or manual files.
- (19) "Data vendor" means the entity under contract with the Authority to administer in whole or in part the all payer all claims database and related functions.

- (20) “DCBS” means the Oregon Department of Consumer and Business Services.
- (21) “Deductible” means the total dollar amount an enrollee pays toward the cost of covered services over an established period before the carrier or third-party administrator makes any payments under an insurance policy or health benefit plan.
- (22) “De-identified health information” means health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.
- (23) “Dental claims file” means a data set comprised of dental health care service level remittance information for all adjudicated claims for each billed service including but not limited to provider information, charge and payment information, and clinical diagnosis and procedure codes for an Oregon resident as defined in ORS 803.355 or a non-resident who is a member of a PEBB or OEGB group health insurance plan.
- (24) “Direct personal identifier” means information relating to an individual patient or enrollee that contains primary or obvious identifiers, including:
- (a) Names;
  - (b) Business names when that name would serve to identify a person;
  - (c) Postal address information other than town or city, state, and 5-digit zip code;
  - (d) Specific latitude and longitude or other geographic information that would be used to derive postal address;
  - (e) Telephone and fax numbers;
  - (f) Electronic mail addresses;
  - (g) Social security numbers;
  - (h) Vehicle identifiers and serial numbers, including license plate numbers;
  - (i) Medical record numbers;
  - (j) Health plan beneficiary numbers;
  - (k) Certificate and license numbers;
  - (L) Internet protocol (IP) addresses and uniform resource locators (URL) that identify a business that would serve to identify a person;
  - (m) Biometric identifiers, including finger and voice prints; and
  - (n) Personal photographic images.
- (25) “Disability policy” means an insurance policy that provides benefits for losses due to a covered illness or disability.
- (26) “Disclosure” means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.
- (27) “DRC” means Data Review Committee.
- (28) “Dual eligible special needs plan” means a special needs plan that enrolls beneficiaries entitled to both Medicare and Medicaid.
- (29) “Enrollment file” means a data set containing demographic information for each individual enrollee eligible for medical benefits for one or more days of coverage at any time during a calendar month for an Oregon resident as defined in ORS 803.355 or a non-Oregon resident who is a member of a PEBB or OEGB group health insurance plan.
- (30) “Eligible employee” shall have the meaning given that term in ORS 743B.005.

- (31) "Employee" shall have the meaning given that term in ORS 654.005.
- (32) "Employer" shall have the meaning given that term in ORS 654.005.
- (33) "Encrypted identifier" means a code or other means of identification to allow individual patients or enrollees to be tracked across data sets without revealing their identity.
- (34) "Encryption" means a method by which the true value of data has been disguised to prevent the identification of individual patients or enrollees and does not provide the means for recovering the true value of the data.
- (35) "Enrollee" means enrollee as defined in ORS 743B.005.
- (36) "ERISA" means the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001.
- (37) "Exemption" means a requested variance from a validation rule on data format or quality threshold.
- (38) "Extension" means a requested variance from the Data Submission schedule incorporated by reference under OAR 409-025-0120 and 409-025-0125.
- (39) "Facility" means a health care facility as defined in ORS 442.015.
- (40) "Genetic test" shall have the meaning given that term in ORS 192.531.
- (41) "Group health insurance" shall have the meaning given that term in ORS 731.098.
- (42) "Health benefit plan" shall have the meaning given that term in ORS 743B.005.
- (43) "Health care" shall have the meaning given that term in ORS 192.556.
- (44) "Health care operations" means certain administrative, financial, legal, and quality improvement activities that are necessary to run programs including, but not limited to, conducting quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, case management and care coordination, evaluating practitioner, provider, or health plan performance, and underwriting, enrollment, premium rating and other activities related to creation, renewal, or replacement of a health insurance contract.
- (45) "Health care provider" shall have the meaning given that term in ORS 192.556.
- (46) "Health information" shall have the meaning given that term in ORS 192.556.
- (47) "Health insurance exchange" shall have the meaning given that term in ORS 741.300.
- (48) "Healthcare Common Procedure Coding System (HCPCS)" means a medical code set, maintained by the United States Department of Health and Human Services, that identifies health care procedures, equipment, and supplies for claim submission purposes.
- (49) "HIPAA" means Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996, 42 USC 1320d, et seq. and the federal regulations adopted to implement the Act.
- (50) "Hospital indemnity policy" means an insurance policy that provides benefits only for covered hospital stays.
- (51) "Indirect personal identifier" means information relating to an individual patient or enrollees that a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods could apply to render such

information individually identifiable by using such information alone or in combination with other reasonably available information.

(52) "Individual", when used in a list of required lines of business, means individual health benefit plans.

(53) "Individually identifiable health information" shall have the meaning given that term in ORS 192.556.

(54) "Insurance" shall have the meaning given that term in ORS 731.102.

(55) "Labor union" means any organization which is constituted for the purpose, in whole or in part, of collective bargaining or dealing with employers concerning grievances, terms or conditions of employment or of other mutual aid or protection in connection with employees.

(56) "Large group" means health benefit plans for employers with more than 50 employees.

(57) "Long-term care insurance" shall have the meaning given that term in ORS 743.652.

(58) "Mandatory reporter" means any reporting entity defined as a mandatory reporter in OAR 409-025-0110.

(59) "Medicaid" means medical assistance provided under 42 U.S.C. section 1396a (section 1902 of the Social Security Act) or Children's Health Insurance Program (CHIP) medical assistance provided under 42 U.S.C section 1397aa-mm (section 2103 of the Social Security Act), as administered by the Division of Medical Assistance Programs.

(60) "Medicaid fee-for-service" (Medicaid FFS) means that portion of Medicaid where a health care provider is paid a fee for each covered health care service delivered to an eligible Medicaid patient.

(61) "Medical claims file" means a data set composed of health care service level remittance information for all adjudicated claims for each billed service including but not limited to provider information, charge and payment information, and clinical diagnosis and procedure codes for an Oregon resident as defined in ORS 803.355 or a non-Oregon resident who is a member of a PEBB or OEGB group health insurance plan.

(62) "Medicare" means coverage under Part A, Part B, Part C, or Part D of Title XVIII of the Social Security Act, 42 U.S.C. 135 et seq., as amended.

(63) "Non-claims based primary care expenditures" means resources given to a primary care provider or practice for services and are not otherwise in a fee-for-service arrangement.

(64) "OEGB" means the Oregon Educators Benefit Board.

(65) "Paid amount" means the actual dollar amount paid for claims.

(66) "Patient" means any person in the data set who is the subject of the activities of the claim performed by the health care provider.

(67) "Patient-Centered Primary Care Home" or "PCPCH" means a health care team or clinic as defined in ORS 414.655 that meets the standards pursuant to OAR 409-055-0040, and has been recognized through the process pursuant to OAR 409-055-0040.

(68) "Payment arrangement file" means a data set composed of total and primary care-related dollars disbursed, by payment arrangement and line of business.

- (69) "PEBB" means the Oregon Public Employees' Benefit Board.
- (70) "Person" shall have the meaning given that term in ORS 731.116.
- (71) "Pharmacy benefit manager (PBM)" means a person or entity that performs pharmacy benefit management, including a person or entity in a contractual or employment relationship with a person or entity performing pharmacy benefit management for a health benefits plan.
- (72) "Pharmacy claims file" means a data set containing service level remittance information from all adjudicated claims including, but not limited to provider information, charge and payment information, and national drug codes for an Oregon resident as defined in ORS 803.355 or a non-Oregon resident who is a member of a PEBB or OEGB group health insurance plan.
- (73) "Policy" shall have the meaning given that term in ORS 731.122.
- (74) "Prepaid amount" means the fee for the service equivalent that would have been paid for a specific service if the service had not been capitated.
- (75) "Premium" shall have the meaning given that term in ORS 743B.005.
- (76) "Primary care" means family medicine, general internal medicine, naturopathic medicine, obstetrics and gynecology, pediatrics or general psychiatry.
- (77) "Primary care provider" means:
- (a) A physician, naturopath, nurse practitioner, physician assistant or other health professional licensed or certified in this state, whose clinical practice is in the area of primary care.
  - (b) A health care team or clinic certified by the Authority as a PCPCH.
- (78) "Principal investigator (PI)" means the person in charge of a research project that makes use of limited data sets. The PI is the custodian of the data and shall comply with all state and federal restrictions, limitations, and conditions of use associated with the data release.
- (79) "Protected health information" shall have the meaning given that term in ORS 192.556.
- (80) "Provider file" means a data set containing information about health care providers providing health.
- (81) "Public health authority" means the Public Health Division of the Authority or local public health authority as defined in ORS 431A.005.
- (82) "Public health purposes" means the activities of a public health authority for preventing or controlling disease, injury, or disability including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, investigations, and interventions.
- (83) "Registered entity" means any person required to register with DCBS under ORS 744.714.
- (84) "Reporting entity" means:
- (a) An insurer as defined in ORS 731.106 or fraternal benefit society as defined in ORS 748.106 required to have a certificate of authority to transact health insurance business in Oregon;
  - (b) A health care service contractor as defined in ORS 750.005 that issues medical

insurance in Oregon;

(c) A third-party administrator required to obtain a license under ORS 744.702;

(d) A pharmacy benefit manager or fiscal intermediary, or other person that is by statute, contract, or agreement legally responsible for payment of a claim for a health care item or service;

(e) A coordinated care organization as defined in ORS 414.025; and

(f) An insurer providing coverage funded under Part A, Part B, or Part D of Title XVIII of the Social Security Act, subject to approval by the United States Department of Health and Human Services.

(85) "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

(86) "Self-insured plan" means any plan, program, contract, or any other arrangement under which one or more employers, unions, or other organizations provide health care services or benefits to their employees or members in this state, either directly or indirectly through a trust or third-party administrator.

(87) "Small employer health insurance" means health benefit plans for employers whose workforce consists of at least two but not more than 50 eligible employees.

(88) "Special Needs Plan" means a Medicare health benefit plan created by the Medicare Modernization Act that is specifically designed to provide targeted care to individuals with special needs.

(89) "Specific disease policy" means an insurance policy that provides benefits only for a loss due to a covered disease.

(90) "Strongly-encrypted" means an encryption method that uses a cryptographic key with many random keyboard characters.

(91) "Subscriber" means the individual responsible for payment of premiums or whose employment is the basis for eligibility for membership in a health benefit plan.

(92) "Subscriber-billed Premium File" means the data set that includes premium information at the subscriber level for medical, pharmacy and dental insurance.

(93) "Summarized data" means data aggregated by one or more categories.

Summarized data created from protected health information may not contain direct or indirect identifiers.

(94) "Third-party administrator (TPA)" means any person who directly or indirectly solicits or effects coverage of, underwrites, collects charges or premiums from, or adjusts or settles claims on, residents of Oregon or residents of another state from offices in Oregon, in connection with life insurance or health insurance coverage; or any person or entity who must otherwise be licensed under ORS 744.702.

(95) "Transact insurance" shall have the meaning given that term in ORS 731.146.

(96) "Trust" means a fund established by two or more employers in the same or related industry or by one or more labor unions or by one or more employers and one or more labor unions or by an association.

(97) "Vision policy" means a health benefits plan covering only vision health care.

(98) "Voluntary reporter" means any registered or reporting entity, other than a

mandatory reporter, that voluntarily elects to comply with the reporting requirements in OAR 409-025-0100 to 409-025-0170.

(100) "Waiver" means an approved variance from the types of files submitted under OAR409-025-0120 and 409-025-0125.

**Statutory/Other Authority:** ORS 443.373

**Statutes/Other Implemented:** ORS 443.373 & ORS 442.372

### 409-025-0110

#### **General Reporting Requirements**

(1) Determination of "mandatory reporter":

(a) For carriers and licensed third-party administrators, the Authority shall identify mandatory reporters using information collected by DCBS including, but not limited to, data from the Health Insurance Member Enrollment Report.

(A) The Authority shall aggregate the most recent four quarters of data.

(B) The Authority shall calculate the mean total lives for each carrier and licensed third-party administrator. Mean total lives shall be calculated by using the total covered lives in the following lines of business for each carrier and licensed third-party administrator:

(i) Large group;

(ii) Small group;

(iii) Individual market;

(iv) Medicare Advantage; and

(v) Self-insured.

(C) All carriers and licensed third-party administrators with calculated mean total lives of 5,000 or higher shall be mandatory reporters.

(b) All PBMs shall be mandatory reporters.

(c) All CCOs shall be mandatory reporters.

(d) All reporting entities with Dual Eligible Special Needs Plans in Oregon shall be mandatory reporters.

(e) All insurers providing coverage funded under Part D of Medicare shall be mandatory reporters.

(f) All insurers offering a health benefits plan in Oregon's health insurance exchange shall be mandatory reporters.

(g) All insurers providing group health insurance plans to PEBB and OEGB members shall be mandatory reporters.

(2) If an organization believes a determination by the Authority of its mandatory status to be in error, the organization must contact the Authority to contest the determination as described in the notice no later than 90 days prior to the first scheduled date of submission of production files.

(3) Any carrier or licensed third-party administrator who has been identified as a mandatory reporter and believes their entity has fewer than 5,000 mean total lives due to ERISA self-insured shall notify the Authority by filing a request for waiver under OAR

409-025-0140.

(4) An organization may elect to participate as a voluntary reporter by notifying the Authority in writing.

(5) Mandatory and voluntary reporters shall submit data files for all required lines of business. They may submit data files for the voluntary lines of business and may not submit data files for any excluded lines of business.

(a) Required lines of business include:

(A) Medicare Advantage Part C and Medicare Part D;

(B) Medicaid;

(C) Individual;

(D) Small employer health insurance;

(E) Large group;

(F) Associations and trusts;

(G) PEBB and OEBB group health insurance plans;

(H) Self-insured plans not subject to ERISA; and

(I) Dental insurance.

(b) Voluntary lines of business include self-insured plans subject to ERISA.

(c) Excluded lines of business include:

(A) Accident policy;

(B) Disability policy;

(C) Hospital indemnity policy;

(D) Long-term care insurance;

(E) Medicare supplemental insurance;

(F) Specific disease policy;

(G) Stop-loss plans;

(H) Student health policy;

(I) Supplemental insurance that pays deductibles, copays or coinsurance;

(J) Vision-only insurance; and

(K) Workers compensation.

(d) A mandatory reporter that contracts with another entity remains responsible for reporting all required lines of business. If the mandatory reporter elects to have the data reported by a contracted entity, the mandatory reporter shall notify the Authority and provide contact information for the contracted entity.

(6) Mandatory and voluntary reporters shall comply with data file layout, format, and coding requirements in OAR 409-025-0120.

(7) Mandatory and voluntary reporters shall comply with data submission requirements in OAR 409-025-0130.

(8) A mandatory reporter who plans to withhold data must submit a waiver of reporting in compliance with OAR 409-025-0140. If the mandatory reporter believes that the data are prohibited from disclosure under state or federal statutes, regulations or rules, then the waiver request must state the data prohibited from disclosure and the statute, regulation or rule that requires withholding the data.

(9) The Authority shall provide written notification by July 1 of each year to all

mandatory reporter's subject to the reporting requirements of OAR 409-025-0100 to 409-025-0150 for the following calendar year.

(10) New mandatory reporters submitting for the first time, or mandatory reporters that did not submit data in the previous year, shall submit test files before production files are due. The mandatory reporters shall submit test files no later than 60 days before the first scheduled date of submission of production files.

**Statutory/Other Authority:** ORS 442.466

**Statutes/Other Implemented:** ORS 442.464 & 442.466

### 409-025-0120

#### **Data File Layout, Format, and Coding Requirements**

(1) All mandatory reporters shall submit claims-based data for all claims where the subscriber's residence is in Oregon or the subscriber is enrolled in a plan for which the State of Oregon is the payer.

(2) Claims-based data files shall include:

- (a) Enrollment;
- (b) Medical claims;
- (c) Pharmacy claims;
- (d) Dental claims;
- (e) Provider;
- (f) Subscriber-billed premiums; and
- (g) Control totals files.

(3) Mandatory reporters must include plan-specific identifiers for members, subscribers, providers and contracts in required files. Mandatory reporters authorized by the Centers for Medicare and Medicaid Services or contracted through an insurer must provide the member's identifier for those organizations in addition to the mandatory reporters' member specific identifier. All identifiers must be:

- (a) Sufficient length to be unique within the mandatory reporters' solution;
- (b) Assigned to a single individual, entity or contract;
- (c) Consistent across all files for the submission; and
- (d) Persistent over time unless change in identifier is required due to change in coverage or contract.

(4) The enrollment file shall be submitted by all mandatory reporters except CCOs using the approved layout, format, and coding described in Appendix A, Enrollment.

(a) Mandatory reporters shall report race and ethnicity data as outlined in Appendix A, Enrollment. This layout aligns with the Office of Management and Budget's (OMB) Federal Register Notice of October 30, 1997 (62 FR 58782-58790).

(b) Mandatory reporters shall report primary language in accordance with ANSI/NISO guidance using the three-character string outlined in Codes for the Representation of Languages for Information Interchange.

(c) Race, ethnicity and primary language data shall be collected in a manner that aligns

with the following principles:

(A) To the greatest extent practicable, race, ethnicity, and preferred language shall be self-reported.

(i) Collectors of race, ethnicity and primary language data may not assume or judge ethnic and racial identity or preferred signed, written and spoken language, without asking the individual.

(ii) If an individual is unable to self-report and a family member, advocate, or authorized representative is unable to report on his or her behalf, the information shall be recorded as unknown.

(B) When an individual declines to identify race, ethnicity or preferred language, the information shall be reported as refused.

(5) The membership total and claims control files shall be submitted by all mandatory reporters except CCOs using the approved layout, format, and coding described in Appendix G, Membership Total and Claims Control.

(6) The subscriber-billed premium file shall be submitted by all mandatory reporters except CCOs using the approved layout, format, and coding described in Appendix F, Subscriber-Billed Premium.

(7) The provider file shall be submitted by all mandatory reporters other than PBMs and CCOs using the approved layout, format, and coding described in Appendix E, Provider.

(8) The medical claims file shall be submitted by all mandatory reporters other than PBMs, CCOs, and dental carriers using the approved layout, format, and coding described in Appendix B, Medical Claims.

(9) The pharmacy claims file shall be submitted by PBMs and carriers using the approved layout, format, and coding described in Appendix C, Pharmacy Claims.

(10) The dental claims file shall be submitted by all mandatory reporters other than PBMs and CCOs who provide dental coverage using the approved layout, format, and coding described in Appendix D, Dental Claims.

(11) All data elements are required unless specified as optional or situational within the file layout.

(12) All required data files shall be submitted as delimited ASCII files.

(13) Numeric data are positive integers unless otherwise specified.

(a) Negative values are allowed for quantities, charges, payment, co-payment, co-insurance, deductible, and prepaid amount.

(b) Negative values shall be preceded by a minus sign.

(14) All data files shall pass edit checks and validations implemented by the Authority or the Authority's data vendor.

(a) Data vendors may perform quality and edit checks on data file submissions. If data files do not pass data vendor edit checks or validation, mandatory reporters must make corrections and resubmit data. Mandatory reporters must submit corrected data that passes all quality and edit checks or receive an approved exemption within 14 calendar days of notification by the Authority or the Authority's data vendor of the error.

(b) Mandatory reporters must participate in efforts to validate and check the quality of

current and historic APAC data, as prescribed and requested by the Authority.

(A) The Authority may request from mandatory reporter's information from their internal records that is reasonably necessary to validate and check the quality of APAC data.

This information may include, but is not limited to, aggregated number of enrolled members, number of claims and claim lines, charges, allowed amounts, paid amounts, co-insurance, co-payments, premiums, number of visits to primary care, emergency department, inpatient, and other health care treatment settings, and number of prescriptions.

(B) Mandatory reporters shall provide the aggregated information within 30 days of the Authority's request.

(C) If the Authority finds errors through edit checks or validation, mandatory reporters must make corrections and resubmit data or receive an approved extension or exemption within 30 days or at the next regularly scheduled submission due date.

**Statutory/Other Authority:** ORS 442.466

**Statutes/Other Implemented:** ORS 442.464 & 442.466

New Version in effect 12/1/22

## 409-025-0125

### **Payment Arrangement Reporting: File Layout, Format, and Coding Requirements**

- (1) All mandatory reporters other than PBMs shall report payment arrangements for all contracts situated in Oregon. For contracts issued at the group level, the contract is considered situated where the contract is sold. For contracts that are issued at the individual level, the contract is considered situated where the individual resides.
- (2) All data files shall include:
  - (a) Payment arrangement file described in Appendix 1; and
  - (b) Payment arrangement control file described in Appendix 2.
- (3) The Payment arrangement file shall be submitted using the approved layout, format, and coding described in Appendix 1, Payment Arrangement File.
- (4) The Payment arrangement control file shall be submitted using the approved layout, format, and coding described in Appendix 2, Payment Arrangement Control File.
- (5) All data elements are required unless specified as optional or situational in the file layout.
- (6) All required data files shall be submitted as delimited ASCII files or the template provided by the Authority. Both Appendix 1 and Appendix 2 are required regardless of method used.
- (7) Numeric data are positive integers unless otherwise specified.
  - (a) Negative values are allowed for quantities, charges, payment, copayment, coinsurance, deductible, and prepaid amount.
  - (b) Negative values shall be preceded by a minus sign.
- (8) All data values shall pass edit checks and validations implemented by the Authority or the Authority's data vendor.
  - (a) Data vendor may perform quality and edit checks on data file submissions. If data files do not pass data vendor edit checks or validation, mandatory reporters must make corrections and resubmit data. Mandatory reporters must submit corrected data that passes all edit checks and validations or receive an approved exemption within 14 calendar days of notification by the Authority or the Authority's data vendor of the error.
  - (b) Mandatory reporters must participate in efforts to validate and check the quality of current and historic APAC data, as prescribed and requested by the Authority.
    - (A) The Authority may request from any mandatory reporter information from their internal records that is reasonably necessary to validate and check the quality of APAC data. This information may include, but is not limited to, aggregated number of enrolled members, number of claims and claim lines, charges, allowed amounts, paid amounts, coinsurance, copayments, premiums, number of visits to primary care, emergency department, inpatient, and other health care treatment settings, and number of prescriptions.
    - (B) Mandatory reporters shall provide the aggregated information within 30 days of the Authority's request or request an extension.
    - (C) If the Authority finds errors through edit checks or validation, mandatory reporters must make corrections and resubmit data or receive an approved extension or exemption within 30 days or at the next regularly scheduled submission due date.

(9) These submissions shall meet the requirement that all Coordinated Care Organizations report primary care services to the Oregon Health Authority each year through 2027 for the prior calendar year's data. The findings generated from these submissions will be presented to the legislature no later than February 1 of each year through 2028.

**Statutory/Other Authority:** ORS 442.373

**Statutes/Other Implemented:** ORS 442.373 & ORS 442.372

Rule Currently in Effect

#### 409-025-0130

##### **Data Submission Requirements**

- (1) Mandatory reporters shall submit data files as specified in the Data Submission Schedule. Voluntary reporters may consult with the Authority to submit healthcare claims data files on an alternative schedule.
- (2) Mandatory and voluntary reporters shall submit data files directly to the data vendor unless otherwise specified by the Authority. Each mandatory reporter is required to maintain an active user in the data vendor's reporting portal to receive communications on deadlines and submit files and resolve validation issues in a timely manner.
- (3) Mandatory and voluntary reporters shall transmit data files using one of the following approved processes:
  - (a) Secure file transfer protocol (SFTP) including separate strong encryption of data files prior to SFTP transmission; or
  - (b) Any process incorporating strong encryption that is approved in writing by both the Authority and the data vendor.

**Statutory/Other Authority:** ORS 442.466

**Statutes/Other Implemented:** ORS 442.464 & 442.466

#### 409-025-0140

##### **Waivers, Extensions and Exemptions**

- (1) The Authority may grant a waiver, deadline extension, or exemption to the reporting and validation requirements.
- (2) A mandatory reporter is required by law and rule to submit all required data files no later than the submission deadline and at sufficient quality to meet or exceed the published validation requirements. Mandatory reporters shall notify the Authority of their inability to meet any requirement within the timeline stated in rule or incorporated by reference.
- (3) A mandatory reporter may request a waiver of reporting requirements. The request shall be submitted 60 calendar days prior to the applicable reporting deadline using the APAC-1a form.
  - (a) Mandatory reporters may request a waiver of reporting for the following reasons:
    - (A) A mandatory reporter who is a carrier or a third party administrator and, either due to decrease in covered lives or covered lives excluded as reporting to the federal Department of Labor under the Employment Retirement Income Security Act (ERISA), has fewer than 5,000 covered lives in Oregon to report;
    - (B) A mandatory reporter does not bill subscribers for premiums (Appendix F only);
    - (C) A mandatory reporter has no contracts situated in Oregon for Appendices 1 and 2 under OAR 409-025-0125; or
    - (D) A mandatory reporter whose data is reported by another affiliated or contracted Oregon All Payer All Claims mandatory reporter if submitting files would create duplicate claims.

- (b) A mandatory reporter who intends to withhold data under OAR 409-025-0110(8) must request a waiver and receive approval prior to withholding data.
- (c) Mandatory reporters other than carriers and third party administrators may request a waiver of reporting based on the number of covered lives potentially reported. The Authority may approve a waiver if it determines the burden of reporting outweighs the value of the data in understanding services and costs in Oregon.
- (d) Waivers are required only for the file types identified for the mandatory reporter type under OAR 409-025-0120 and OAR 409-025-0125.
- (e) The Authority shall approve or deny the waiver request and provide written notification to the requestor within 14 calendar days of receipt of the request.
- (f) Waivers of reporting are approved for one calendar year and may cover partial reporting years. Waivers must be requested each year that the reason for waiver continues to be in effect.
- (4) A mandatory reporter may request a deadline extension for initial submission or correction of validation errors of required files. The request shall be submitted within the APAC vendor's reporting portal at least 14 calendar days prior to the applicable reporting deadline.
- (a) The mandatory reporter must explain why sufficient data or resources are not allocated to reporting to meet the published expectations for timing and data quality. The request must include the organization's plan to mitigate future incidents and whether the plan has been approved and resources allocated to accomplish the activity within the stated timeline.
- (b) The Authority shall approve or deny the extension request and provide notification to the requestor within seven (7) calendar days of receipt of the request.
- (c) Extensions are approved for one reporting period. Failure to submit acceptable files at the end of the extension may result in a civil penalty under OAR 409-025-0150.
- (5) A mandatory reporter may request an exemption for validation rules identified as 'Exemption' level. The request must be submitted through the APAC vendor's reporting portal and cannot be submitted in advance of validation failure.
- (a) Specific review of the failed validation results is required prior to requesting an exemption. Mandatory reporters must explain why the validation rule cannot be met and should not rely on receipt of poor-quality data as a reason for exemption. Requests that are not specific to the validation rule and data file submitted will be denied.
- (b) The Authority shall approve or deny the exemption request and provide notification to the requestor through the APAC vendor's reporting portal within seven (7) calendar days of receipt of the request.
- (c) Exemptions are approved for a single submission or up to one calendar year. Failure to submit acceptable files based on approved exemptions may result in a civil penalty under OAR 409-025-0150.
- (6) If the Authority denies the request, the requestor may appeal the denial by requesting a contested case hearing. The appeal must be filed within 30 business days of the denial. The appeal process is conducted pursuant to ORS Chapter 183 and the Attorney General's Uniform and Model rules of Procedure for the Office of

Administrative Hearings, OAR 137-003-0501 to 137-003-0700. The requestor shall have the burden to prove a compelling need for the waiver or exception.

**Statutory/Other Authority:** ORS 442.466

**Statutes/Other Implemented:** ORS 442.464 & 442.466

#### 409-025-0150

##### **Compliance and Enforcement**

- (1) Unless approved by a waiver or extension, failure to comply with general reporting requirements includes but is not limited to:
  - (a) Failure to submit data files for a required line of business; or
  - (b) Submitting health information for an excluded line of business.
- (2) Unless approved by a waiver or exemption, failure to comply with data file requirements includes but is not limited to:
  - (a) Submitting a data file in an unapproved layout;
  - (b) Submitting a data element in an unapproved format;
  - (c) Submitting a data element with unapproved coding;
  - (d) Failure to submit a required data element; or
  - (e) Failure to comply with validation and quality control efforts, including resubmitting or correcting data as requested by the Authority.
- (3) Unless approved by a waiver or extension, failure to comply with data submission requirements includes but is not limited to:
  - (a) Failure to maintain an active user in the data vendor reporting portal;
  - (b) Failure to submit test files as specified by the data vendor;
  - (c) Submitting data files later than five days after the submission due date as detailed in Data Submission Schedule;
  - (d) Rejection of a data file by the data vendor that is not resubmitted or corrected by the submitter within 14 calendar days from notification of error; or
  - (e) Transmitting data files using an unapproved process.
- (4) The Authority shall provide mandatory reporters written notification of each failure to comply prior to imposing a civil penalty under this rule. Mandatory reporters will have 30 calendar days to come into compliance.
- (5) The Authority may impose civil penalties against mandatory reporters for each failure to comply that is not resolved within 30 calendar days of written notification. If a mandatory reporter does not come into compliance within 30 days of written notification, penalties will be assessed starting from the date the mandatory reporter was notified of non-compliance. Pursuant to ORS 442.993, the Authority adopts the following schedule of civil penalties:
  - (a) Up to \$400.00 per day for violations of OAR 409-025-0150(1);
  - (b) Up to \$300.00 per day for violations of OAR 409-025-0150(2) or OAR 409-025-0140(2)(a); and
  - (c) Up to \$200.00 per day for violations of OAR 409-025-0150(3);
- (6) If a mandatory reporter was issued a final order imposing civil penalties within 24

months from the date the Authority issues a notice of intent to impose a civil penalty, the Authority may impose an additional \$100.00 per day for each of the category of violations listed in section (5) of this rule.

(7) If a mandatory reporter has made documented efforts to comply with these rules, the Authority may consider this a mitigating factor before imposing civil penalties against the mandatory reporter.

**Statutory/Other Authority:** ORS 442.466 & 442.993

**Statutes/Other Implemented:** ORS 442.464, 442.466 & 442.993

New Version in effect 12/1/22

## 409-025-0160

### **Data Access and Release**

- (1) The Authority shall comply with all relevant state and federal data privacy, security, and antitrust regulations, including The Health Insurance Portability and Accountability Act (HIPAA), when sharing APAC data.
- (2) The Authority may collect payment to recoup costs when APAC data requests are fulfilled.
- (3) The Authority shall provide a public use data set, which shall include de-identified health information, in compliance with applicable Authority policies and state and federal rules, regulations, and statutes.
  - (a) The Authority shall maintain a list of data elements that may be included in APAC public use data sets.
  - (b) Requestors seeking access to an APAC public use data set shall complete a Pre-Application for APAC Data Files (APAC-2) and submit full payment as follows:
    - (A) Actual cost with a maximum cost of \$500 per data year for Medical Claims;
    - (B) Actual cost with a maximum cost of \$500 per data year for Pharmacy Claims;
    - (C) Actual cost with a maximum cost of \$500 per data year for Dental Claims; and
    - (D) Enrollment file requested in conjunction with Medical, Pharmacy or Dental Claims will be provided without additional charge.
  - (c) The Authority may approve or deny the completed request and provide written notification to the requestor within 30 calendar days of receipt of the request.
  - (d) The Authority shall deny the completed request for reasons which include, but are not limited to:
    - (A) Requestor or any person who will have access to the data has previously violated a data use agreement with the Authority.
    - (B) The Authority finds that the specific details of the request do not sufficiently explain the proposed use.
    - (C) The Authority finds that the specific details of the request violate any state or federal rule, regulation, or statute.
    - (D) Full payment is not included with the application.
  - (e) If the Authority denies the Pre-Application for APAC Data Files (APAC-2):
    - (A) The Authority shall provide written notification stating the reason for the denial and process return of payment; and
    - (B) The requestor may appeal the denial by requesting a contested case hearing. The appeal must be filed within 30 business days of the denial. The appeal process is conducted pursuant to ORS chapter 183 and the Attorney General's Uniform and Model Rules of Procedure, OAR 137-003-0501 to 137-003-0700. The requestor shall have the burden to prove that the Authority unreasonably denied the application.
  - (f) The public use data sets may not be used to identify any individual, including but not limited to patients, physicians, and other health care providers. The requestor may not use outside information to attempt to ascertain the identity of individuals who are the subject of public use data sets.
- (4) The Authority shall provide limited data sets, in compliance with applicable Authority

policies and state and federal rules, regulations, and statutes. Limited data sets may include protected health information.

(a) The Authority shall maintain a list of data elements that may be included in APAC limited data sets if approved for a specific request.

(b) APAC limited data sets may be disclosed for purposes allowed by state and federal regulations, including research, public health, and health care operations.

(c) Requestors seeking access to APAC limited data sets shall complete the Application for APAC Data Files (APAC-3).

(d) Requestors must identify each data element requested and explain the use of the data element within the description of activity in the application. The Authority will determine which data elements will be released after review under HIPAA and other applicable laws, regulations, and rules.

(e) The Authority shall determine the hours required to complete the data request and inform the requestor of the cost of the resulting data set.

(5) The Authority shall provide data, in compliance with applicable Authority policies and state and federal rules, regulations and statutes, to Oregon state agencies and local public health authorities. Use is limited to activities required to meet the agency's duties as authorized by Oregon law.

(a) Agency-use data sets may include protected health information.

(b) Requestors seeking access to APAC agency data sets shall complete the Application for Agency Data Files and must explain use of each data element requested.

(c) Agency requests will be posted on the Data Review Committee for a minimum of two weeks to support transparency in data use.

(6) Requests for public use data set or limited data sets must be made using the form and manner prescribed by the Authority that is available on the agency's website. The form shall collect sufficient information to evaluate any request for APAC data.

(7) Requestors who receive a limited data set must maintain Institutional Review Board (IRB) approval, if required for the data use agreement, throughout the span of authorized use of the data and until the data is destroyed. Requestors must submit updated documentation authorizing continued activity prior to the expiration of the previous authorization.

(8) Requestors who receive a limited data set must submit an amendment to the Authority when there is a change in the proposed use of the data within the scope of the original data request.

(a) Requestors shall file such an amendment when any of the following is anticipated:

(A) A change in persons accessing the data;

(B) Additional data elements are requested;

(C) Additional years of data are requested;

(D) Any change in the use of the data including linking or the addition of research questions; or

(E) Any change in research protocol, regardless of approval by an IRB.

(b) Changes or additions to use that are outside of the scope of the original data request

will not be approved.

(c) Requestors may not implement any change related to access or use of data prior to receiving approval from the Authority.

(d) Changes in data elements, data use or research protocol must be reviewed by the Data Review Committee (DRC) described in OAR 409-025-0190. In addition, a recommendation by the DRC may be sought for additional years of data or new project staff for limited data sets the Authority determines to include vulnerable populations.

(e) The Authority shall review for completeness all applications and provide requestors written notification of completeness within 30 calendar days of receipt of the request. If the Authority determines that the application is incomplete, the requestor shall have 30 calendar days from notification of incompleteness to complete the application. Incomplete applications that are not completed shall be discarded without further notification to the requestor.

**Statutory/Other Authority:** ORS 442.373

**Statutes/Other Implemented:** ORS 442.373 & ORS 442.372

**409-025-0170**

**Public Disclosure**

The Authority and applicable contractors, shall perform data analyses and publish data and reports that serve the public's interest. This may include, but is not limited to:

- (1) Comparing healthcare cost and quality;
- (2) Assessing health care utilization;
- (3) Assessing the capacity and distribution of healthcare resources;
- (4) Assessing health care purchasing decisions;
- (5) Assessing the effectiveness of public health programs; or
- (6) Assessing disparities in health care delivery and outcomes.

**Statutory/Other Authority:** ORS 442.466

**Statutes/Other Implemented:** ORS 442.464 & 442.466

New Version in effect 12/1/22

#### 409-025-0180

##### **APAC Technical Advisory Group**

The Oregon Health Authority shall convene a technical advisory group to advise the Authority on submission specifications including but not limited to file layouts, the Data Submission Schedule, and any additional data submission requirements. The advisory group shall include but is not limited to representatives from:

- (1) Mandatory reporters;
- (2) Providers;
- (3) Researchers, and;
- (4) Other stakeholders and interested parties.

**Statutory/Other Authority:** ORS 413.042 & 442.466

**Statutes/Other Implemented:** ORS 442.464 & 442.466

#### 409-025-0190

##### **Data Review Committee**

(1) The Authority shall convene a Data Review Committee (DRC) to evaluate completed applications.

(2) The Authority may accept nominations for and make appointments to the DRC. The DRC shall include at least one mandatory reporter to serve in an advisory capacity.

(3) The DRC evaluation shall include, but is not limited to:

(a) Whether proposed purpose for accessing APAC data is allowable under Authority policies and state and federal rules, regulations, and statutes;

(b) Whether IRB documentation is required and, if submitted, is sufficient;

(c) Whether the proposed privacy and security protections are sufficient; and

(d) Whether additional clarification is needed to complete the review.

(4) The Authority shall publish a DRC meeting schedule on its website and post applications scheduled to be reviewed, which detail the proposed use of the data and detail the data elements requested to be released at least two weeks prior to the next DRC meeting. The Authority shall receive public comment on applications scheduled for review. The DRC will review and consider all public comments as part of the data request review process.

(5) Consideration of applications for limited data sets:

(a) The Authority shall schedule completed applications for review by the DRC on a first-come-first-served basis.

(b) The DRC shall recommend that The Authority approve or deny the application or defer action pending clarification from the requestor.

(c) The Authority shall accept or reject the DRC's recommendation and notify the requestor within 10 business days of the review.

(d) The Authority may deny a completed application for reasons which include, but are not limited to:

(A) Requestor or any person who will have access to the data has previously violated a

data use agreement with the Authority;

(B) Full payment is not included with the application;

(C) The proposed privacy and security protections are not sufficient;

(D) Information provided is not sufficient to approve the request; and

(E) Proposed purpose for accessing APAC data is not allowable under authority policies or state or federal rules, regulations, or statutes.

(e) If the DRC requests clarification, the requestor shall have 30 calendar days to provide the requested information to the Authority. After 30 calendar days, applications with incomplete requests for clarification shall be discarded without further notification to the requestor.

(f) Upon receipt of the requested clarification the Authority shall schedule re-evaluation with the DRC on a first-come-first-served basis.

(g) If a request is denied, a person may submit a written request for reconsideration that includes the basis upon which the person believes the request should have been granted. If the Authority receives a request for reconsideration, it will determine whether to grant reconsideration and approve the request or whether the denial stands. The Authority shall provide its decision in writing to the person requesting reconsideration.

**Statutory/Other Authority:** ORS 413.042 & 442.466

**Statutes/Other Implemented:** ORS 442.464 & 442.466