Inter Valley Health Plan	Dept: Corporate Compliance Committee
POLICIES AND PROCEDURES	Effective Date: May 24, 2016 Policy No: P402
Subject: Compliance – Element VI – Routine Auditing & Monitoring -Risk Assessment, Work Plan & Audit Schedule	Revised: 3/30/2017, 3/1/2018, 5-1-2019; May 2021, Sept 2021 Page No: Page **1** of **9**

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POLICY

Inter Valley Health Plan (Plan) follows the Centers for Medicare & Medicaid Services (CMS) requirements contained in the Medicare Compliance Program Guidelines as well as Parts 422 and 423 of Title 42 of the Code of Federal Regulations (CFR). Note for purposes of this policy and procedure, the term "Medicare programs" includes the Medicare Advantage ("MA"), Part D Prescription Drug ("Part D") business. Inter Valley Health Plan has established protocols to ensure 1) compliance risks are identified and investigated, and 2) effective monitoring and auditing of its internal business units as well as first-tier, downstream, and related entities (FDRs) responsible for administering the Medicare program. This area of compliance is completed through the Plan's IVHP Work Plan; Risk Assessment and Auditing & Monitoring Schedule.

To ensure processes are in place to:

- Conduct a formal baseline assessment of the Plan's compliance risk areas
- Rank the risks to determine which risk areas have the greatest impact
- Prioritize the monitoring and auditing strategy accordingly,
- and Conduct monitoring and auditing to test and confirm compliance with MA and Part D regulations, sub-regulatory guidance, contractual arrangements, and applicable State and federal laws

DEFINITIONS:

Audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures. Annual audits are established via Plan Audit Schedule to track annual FDR Audits. Audit schedules may be impacted and require changes due to ongoing risk assessment; regulatory changes; monitoring and auditing findings.

Data Analysis is a tool for identifying coverage and payment errors, and other indicators of potential FWA and noncompliance.

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Deemed Provider or Supplier means a provider or supplier that has been accredited by a national accreditation program (approved by CMS) as demonstrating compliance with certain conditions.

External Audit means an audit of the sponsor or its FDRs conducted by outside auditors, not employed by or affiliated with, and independent of, the sponsor.

First Tier/Downstream/Related Entity: FDR means First Tier, Downstream or Related Entity. First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program. (See, 42 C.F.R. § 423.501).

Formulary means the entire list of Part D drugs covered by a Part D plan and all associated requirements outlined in Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 6.

Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347.

FWA means fraud, waste and abuse.

Internal Audit means an audit of the sponsor or its FDRs conducted by auditors who are employed by or affiliated with the sponsor

Monitoring Activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

OIG is the Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.

Pharmacy Benefit Manager (PBM) is an entity that provides pharmacy benefit management services, which may include contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs. Some sponsors perform these functions in-house and do not use an outside entity as their PBM. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies. A PBM is often a first-tier entity for the provision of Part D benefits.

PDP means Prescription Drug Plan.

Risk Assessment: a formal baseline assessment of the Plan's major compliance and FWA risk areas, such as through a risk assessment. The sponsor's assessment must take into account all Medicare business operational areas. Each operational area must be assessed for the types and levels of risks the area presents to the Medicare program and to the sponsor. Factors that sponsors may consider in determining the risks associated with each area include, but are not limited to:

- Size of department;
- Complexity of work;
- Amount of training that has taken place;
- Past compliance issues; and
- Budget.

Areas of particular concern for Medicare Parts C and D sponsors include, but are not limited to, marketing and enrollment violations, agent/broker misrepresentation, selective marketing, enrollment/disenrollment noncompliance, credentialing, quality assessment, appeals and grievance procedures, benefit/formulary administration, transition policy, protected classes policy, utilization management, accuracy of claims processing, detection of potentially fraudulent claims, and FDR oversight and monitoring.

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Risks identified by the risk assessment must be ranked to determine which risk areas will have the greatest impact on the sponsor, and the sponsor must prioritize the monitoring and auditing strategy accordingly. Risks change and evolve with changes in the law, regulations, CMS requirements and operational matters. Therefore, there must be ongoing review of potential risks of noncompliance and FWA and a periodic reevaluation of the accuracy of the sponsor's baseline assessments. Risk areas identified through CMS audits and oversight, as well as through the sponsor's own monitoring, audits and investigations are priority risks. The results of the risk assessment inform the development of the monitoring and audit work plan

Waste is the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

Work Plan Once the risk assessment has been completed, a monitoring and auditing work plan must be developed. The compliance officer may coordinate with each department to develop a monitoring and auditing work plan based upon the results of the risk assessment. The work plan may include: • The audits to be performed;

- Audit schedules, including start and end dates
- Announced or unannounced audits;
- Audit methodology;
- Necessary resources;
- Types of Audit: desk or onsite;
- Person(s) responsible;
- Final audit report due date to compliance officer; and
- Follow up activities from findings. Sponsors must include in their work plans a process for responding to all monitoring and auditing results and for conducting follow-up reviews of areas found to be non-compliant to determine if the implemented corrective actions have fully addressed the underlying problems.

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Corrective action and follow-up should be led or overseen by the compliance officer and assisted, if desired, by the compliance department staff, and include actions such as reporting findings to CMS or to the NBI MEDICs, if necessary.

I. **PROCEDURE CORPORATE COMPLIANCE COMMITTEE & COMPLIANCE OFFICER**

Risk Assessment:

- On an annual basis, the Compliance department and Corporate Compliance Committee perform a baseline assessment of major compliance and fraud, waste, or abuse (FWA) risk areas related to Medicare Advantage and Part D for functions performed by plan staff in operational areas and functions performed by FDRs.

- Identified risks are ranked in order to determine which risk areas will have the greatest impact to the Plan; including: ODAG/CDAG, FDR oversight, Formulary Administration, Network Management, Financial Solvency, and any other risks identified internally, externally, and by CMS/OIG. ALL FDRs identified as “core” or “shared-risk” FDRs on the IVHP FDR Tracking and Risk Assessment Listing are audited at least annually.

IVHP Work Plan:

- On an annual basis, the Compliance department and Corporate Compliance Committee implement a Work Plan that encompasses all the risk areas applicable to the organization and its FDRs as noted internally, externally, and by CMS/OIG. The Work Plan also incorporates any annual Medicare Program Changes, information and implementation from the annual Advanced Notices I & II, a Risk Assessment of the Organization based on the overall work plan and input from functional areas, board members, etc.
- Areas noted in best practice memos, pharmacy risk assessments, major compliance and fraud, waste, or abuse (FWA) risk areas related to Medicare Advantage and Part D area also included.
- Identified risks are ranked, in order to determine which risk areas will have the greatest impact to the Plan (low, medium, high).

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- The baseline risk assessment is reviewed on a periodic basis throughout the year and updated as deemed appropriate.
- This information is used to create the audit schedule annually.

Auditing and Monitoring Schedule:

- The Compliance department along with the Corporate Compliance Committee uses the results of the risk assessment to develop the annual schedule and lists the auditing and monitoring activities to be conducted by Functional Area and performed from an internal monitoring and auditing perspective and by the Compliance Department acting as the governmental auditor and not part of ongoing operations within the organization.
- The audit activities included in the schedule are designed to test and confirm compliance with the MA and Part D regulations, sub-regulatory guidance, contractual arrangements, and applicable State and Federal laws, as well as associated internal policies and procedures.
- Auditing and monitoring activities are designed to test and confirm operational components that are not specifically tied to MA, Part D regulatory requirements are not included in the audit schedule.
    - Where applicable, the Audit Schedule includes activities designed to test areas previously found non-compliant to determine if the implemented corrective actions have fully addressed the underlying problem.

- The audit schedule includes the following elements for each activity listed;
- The f functional area, auditor or external audit firm responsible for conducting the activity;
    - The component, function, Unit, or first tier entity that will be audited or monitored;
    - A brief description the responsibilities the component;
    - FDR audit schedules for delegated FDRs are created by the Delegation Oversight Committee who reports information to the Corporate Compliance Committee.

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- The Compliance Officer and Corporate Compliance Committee provide reports into the Board Compliance Committee who reports to the Board of Directors.
- Those areas audited by the DOC are: PBM CDAG/Formulary Administration, PBM and FDR Claims, UM/QM PBM, FDR, Denial/Authorizations and all ancillary first tier, Credentialing FDRs and ancillary; and Compliance Oversight ALL FDRs. Multiple methods are used to monitor and audit FDRs including on-site audits, desk reviews, and monitoring of self-audit reports.
- CDAG and ODAG audits for selected FDRs based on risk assessment
- The date the activity is scheduled to be initiated, started, or reopened; audit information includes; but not necessarily limited to:
    - The frequency of the activity (ad-hoc, daily, monthly, etc.); A brief description of what the auditing or monitoring activity will be focused on
    - The audit methodology (i.e., process, outcome, data vs sample review, targeted vs random, etc.); Which individuals and/or committees receive reports of the results; and when
        - Auditing and monitoring methodology - ventures to utilized targeted auditing when applicable.
        - The Plan also utilizes industry standard benchmarks an CMS-defined benchmarks for auditing.
        - Internal Monitoring efforts utilize CMS Compliance Program Effectiveness Program Audit Universes
          When applicable, plan utilizes targeted or stratified sampling methods driven by data mining and complaint monitoring are utilized
    - The Compliance Officer ensures an annual audit is scheduled and conducted of the effectiveness of the Medicare compliance program.
        - The audit is conducted by an external auditor or trained staff.
        - The results of the compliance program effectiveness audit are reviewed with the Corporate Compliance Committee to implement any corrective action findings;

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- Any fraud or significant non-compliance issues uncovered via monitoring or auditing are reported through the governance structure and to CMS Regional Account Manager.
    - If appropriate, reported to NBI MEDIC (within 30 days) and or local law enforcement
    - Compliance Officer works with Compliance Committee to address findings of non-compliance that would require and outside SIU entity to be involved. Compliance Officer work with CCC and senior management to identify SIU qualified to investigate.
    - Audit results, corrective action plans, SIU investigations for all audits internal and external are reported to the Board Compliance Committee, and the Board of Directors.
    - Reporting Results of Auditing and Monitoring Activities are reported through the governance structure of the organization:

II. COMPLIANCE OFFICER PROCESS:

- Reviews internal operational reports, dashboards, metrics, and/or scorecards received from functional areas to ensure compliance with CMS requirements;
- Reviewed quarterly at Corporate Compliance Committee with senior executives
- Where operational dashboards, metrics, and/or scorecards do not exist or are not adequate, the Compliance department works with the applicable functional area to ensure these are developed;
- Conducts ad-hoc or routine auditing or monitoring activities in situations where internal operational reports, dashboards, metrics, and/or scorecards are not available or to validate self-monitoring results reported by functional areas;
- Uses applicable laws, regulations, and CMS guidance as well as associated internal policies and procedures when developing auditing and monitoring methodology and utilizes CMS methodology when known and/or applicable.

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- Reviews new and revised policies and procedures with the Corporate Compliance Committee assistance and approval;
- Submits a Corrective Action Request to the functional area when deficiencies are identified;
- Tracks Corrective Action Plan updates provided by the functional business
- Oversees validation activities to determine if corrective action has addressed the issue

References: Chapter 9 and Chapter 21 Element: Auditing and Monitoring and FDR Oversight