

# Cooperative Advantage D-SNP

*Administered By:*



## Compliance Program

2024

*Administered By:*

Group Health Cooperative of Eau Claire  
2503 North Hillcrest Parkway | Altoona, WI 54720  
715.552.4300 or 888.203.7770  
[group-health.com/cooperative-advantage](http://group-health.com/cooperative-advantage)

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## Summary

### Compliance Program

Group Health Cooperative of Eau Claire (the Cooperative) has established practices and procedures which ensure that the conditions of providing services under the Medicare Advantage and Part D programs are in compliance with applicable Federal and State laws. This document along with the Cooperative's Compliance policies and procedures, collectively comprise the Compliance Program. This program is intended to prevent, detect, and correct non-compliant operational practices and improper and/or unethical conduct impacting the Cooperative.

The Cooperative is committed to conducting its business with the highest level of integrity and in accordance with all applicable Federal and State laws, regulations and standards. It is the policy of the Cooperative to ensure that any unlawful behavior is identified, reported, and corrected as soon as it is identified.

With respect to Medicare, two Federal agencies have issued guidance regarding compliance programs: the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG).

The compliance program requirements for Federal Health programs which include Medicare Advantage plan sponsors are contained in 42 C.F.R. sections 422.503(b)(4)(vi) and 423.504(b)(4)(vi). The CMS regulations require that Medicare compliance programs include: (1) Written policies, procedures and standards of conduct articulating the Cooperative's commitment to comply with all applicable Federal and State laws and regulations, (2) The designation of a compliance officer and compliance committee accountable to executive leadership, (3) Effective compliance training and education, (4) Effective lines of communication between the compliance officer and employees, contractors, agents, directors, and members of the compliance committee, (5) Enforcement of standards through documented disciplinary guidelines, (6) Procedures for internal monitoring and auditing, (7) Procedures for confirming that prompt responses are made to detected offenses and that corrective action initiatives are developed, as appropriate, with respect to State and Federal contracts with, (8) A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse.

The Cooperative Advantage D-SNP Compliance Program is intended to meet all Federal and State guidelines related to Fraud, Waste and Abuse and privacy issues related to HIPAA.

## Ethical Business Conduct

All employees are expected to follow elements of the Compliance Program, the associated policies and procedures and the Standards of Conduct. The Cooperative also expects that management and staff will report any non-compliant activity to the Cooperative's Compliance Officer. This individual will work with the Cooperative's Corporate Compliance Committee and report to the CEO and General Manager of the Cooperative.

Since laws and regulations are constantly implemented and modified, it is imperative that this Compliance Program be reviewed and modified on a regular basis. The Cooperative's Corporate Compliance Committee will review the Compliance Program no less than annually to ensure that it adheres to any new or modified laws and regulations. The Compliance Program will also be approved on an annual basis by the Cooperative's Board of Directors.

## Definitions

**Abuse** includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between "fraud" and "abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

**Act** refers to the Social Security Act.

**Appeal (Part C Plan):** Any of the procedures that deal with the review of adverse organization determinations on the health care services an enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service as defined in 42 C.F.R. § 422.566(b). These procedures include reconsideration by the MA Plan and, if necessary, an independent review entity, hearings before Administrative Law Judges (ALJs), review by the Medicare Appeals Council (MAC), and judicial review.

**Appeal (Part D Plan):** Any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in 42 C.F.R. §423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity (IRE), Administrative Law

Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews

**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.

**Centers for Medicare & Medicaid Services (CMS):** A federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid. In addition to these programs, CMS has other responsibilities, including the administrative simplification standards from the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

**Contractor:** A contractor is any entity or individual that directly contracts with CMS to provide items or services, or perform tasks related to the Part D Program. Therefore, types of contractors include Part D Sponsors and Medicare Prescription Drug Integrity Contractors (MEDICs).

**Corrective Action Plan (CAP):** A formal document outlining the Cooperative or provider compliance deficiencies and establishing the Cooperative's actions to institute changes aimed at correcting the deficiencies along with timeframes in which to do so, and the responsible parties for making the changes.

**Cost Plan** is a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) with a cost-reimbursement contract under section 1876(h) of the Act (See 42 C.F.R. §417.1, §423.4). Cost Plan sponsors may contract to offer prescription drug benefits under the Part D program. (See, 42 C.F.R. §423.4.

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

**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.

**Delegation** (^Delegated'): The legal assignment to others of the authority for particular functions, tasks, and decisions on the original party's behalf. The original party remains liable for compliance with any and all rules and requirements pertaining to the delegated functions.

**DHHS** is the Department of Health and Human Services. CMS is the agency within DHHS that administers the Medicare program.

**DOJ** is the Department of Justice.

**Downstream Entity** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangements between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See, 42 C.F.R. §, 423.501).

**Employee(s)** refers to those persons employed by the sponsor or a First Tier, Downstream or Related Entity (FDR) who provide health or administrative services for an enrollee.

**Enrollee** means a Medicare beneficiary who is enrolled in a sponsor's Medicare Part C or Part D plan.

**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.

**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 programs (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.

**Governing Body** means that group of individuals at the highest level of governance of the sponsor, such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control the sponsor in the best interest of the organization and its enrollees. As used in this document, governing body does not include C-level management such as the Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, etc., unless persons in those management positions also serve as directors or trustees or otherwise at the highest level of governance of the sponsor.

**GSA** means General Services Administration.

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

**Medicare** is the health insurance program for the following:

- People 65 or older,
- People under 65 with certain disabilities, or
- People of any age with End-Stage Renal Disease (ESRD) (permanent kidney failure requiring dialysis or a kidney transplant)

**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.

**NBI MEDIC** means National Benefit Integrity Medicare Drug Integrity Contractor (MEDIC), an organization that CMS has contracted with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program. The NBI MEDIC's primary role is to identify potential FWA in Medicare Parts C and D.

**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.

**Related Entity** means any entity that is related to an MAO or Part D sponsor by common ownership or control and (1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation; (2) Furnishes services to Medicare enrollees under an oral or written agreement; or (3) Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period. (See, 42 C.F.R. §423.501).

**Special Investigations Unit (SIU)** is an internal investigation unit responsible for conducting investigations of potential FWA.

**Sponsor** refers to the entities described in the Introduction to these guidelines.

**TrOOP (True Out of Pocket) Costs** are costs that an enrollee must incur on Part D covered drugs to reach catastrophic coverage. (These incurred costs are defined in regulation at §423.100 and Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 5, section 30). In general, payments counting toward TrOOP include payments by enrollee, family member or friend, Qualified State Pharmacy Assistance Program (SPAP), Medicare's Extra Help (low income subsidy), a charity, manufacturers participating in the Medicare coverage gap discount program, Indian Health Service, AIDS Drug Assistance Programs, or a personal health savings vehicle (flexible spending account, health savings account, medical savings account). Payments that do NOT count toward TrOOP include Part D premiums and coverage by other insurances, group health plans, government programs (non-SPAP), workers' compensation, Part D plans' supplemental or enhanced benefits, or other third parties, drugs purchased outside the United States, and over-the counter drugs and vitamins.

**Vendor:** Any entity or individual who contracts with the Cooperative to provide merchandise or other non-essential services outside of the Cooperative's core operating functions, i.e., suppliers of office equipment and material or real estate brokers in connection with office space. These persons and entities have entered into administrative contracts that do not relate to core operating functions.

**Waste:** 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.

## **Section I: Compliance Program Structure and Oversight**

The Cooperative's Board of Directors has delegated the monitoring of compliance activities to the Compliance Officer. The Compliance Officer is responsible for the day-to-day operations of the Compliance Department. The Board of Directors is responsible for approving the Compliance Program. The Corporate Compliance Committee includes members of the executive leadership team.

The Board of Directors will review the Compliance Program annually which will be completed and monitored by the Corporate Compliance Committee. Operational reports will be developed quarterly and shared with the Board of Directors and Corporate Compliance Committee. These reports will summarize the overall compliance activity and any changes that are recommended to improve compliance.

Privacy issues related to Cooperative Advantage D-SNP are managed by the Compliance Officer and reported to the Corporate Compliance Committee. The Compliance Officer



and Corporate Compliance Committee will work to ensure that the Cooperative Advantage D-SNP Compliance Program meets the standards and expectations of the privacy office.

The Cooperative's Compliance Officer reports directly to the CEO & General Manager of the Cooperative and is responsible for implementing processes, delegating as appropriate, and providing oversight of the following:

1. Overseeing and monitoring the implementation of the Compliance Program and reporting to the CEO & General Manager and the Board of Directors summarizing the Corporate Compliance Committee's efforts to ensure adherence to the Compliance Program. A quarterly report summarizing the activities of the Corporate Compliance Committee is also reported to the Board of Directors.
2. Acting as the liaison between the Cooperative and OIG for fraud and abuse issues;
3. Maintaining compliance policies and ensuring regular policy review;
4. Managing hotline inquiries pertaining to the Cooperative, in accordance with the specific processes outlined in the hotline protocols, and ensuring that anyone working on such investigations understand and follow the hotline protocols;
5. Conducting investigations of compliance violations within the Cooperative in partnership with human resources adhering to company policies;
6. Handling of the Cooperative's government investigations, including but not limited to the OIG;
7. Ensuring timely completion of risk assessments and related activities;
8. Directing corrective action plans resulting from compliance reviews, risk assessments, etc., and coordinating any necessary policy or procedure changes, repayments, etc.
9. Working closely with Human Resources when compliance violations occur to ensure consistent disciplinary standards are being met, in accordance with the corporate guidance;
10. Providing education to the Cooperative's Board and executive leadership groups on compliance-related initiatives and emerging issues;
11. Identifying key stakeholders and subject-matter experts within the Cooperative to provide input or assistance for various compliance projects;

12. Cooperative Compliance Committee meetings no less than quarterly;
13. Ensuring that delegated entities, first tier, downstream entities and independent contractors who furnish services to Cooperative Advantage D-SNP members are informed of the Cooperative's standards of business conduct with respect to privacy, fraud, waste and abuse, among other topics;
14. Coordinating with the departments responsible for ensuring that the OIG LEIE and GSA SAM sanction listings have been checked and acted upon, as necessary for all team members, providers and vendors related to the Cooperative;
15. Report to the Cooperative's CEO & General Manager any inquiries concerning improper billing practices or reports of non-compliance.

At least quarterly, a written report on compliance activities shall be presented to the Corporate Compliance Committee. The report shall identify areas where corrective actions are needed and shall be used by the Compliance Officer and management to correct problems and prevent them from recurring. Subsequent reviews will be performed to ensure that corrective actions have been implemented and are successful.

The Cooperative's Compliance Officer shall have the authority to review all documents and other information relevant to compliance activities, including, but not limited to, member records, billing records, records concerning the marketing efforts of the Cooperative and the Cooperative's arrangements with other parties, including Team Members, professionals on staff, relevant independent contractors, suppliers, providers, agents, and supplemental staffing entities. The Compliance Officer shall have the authority to consult with legal counsel when necessary.

The Corporate Compliance Committee will meet no less than quarterly and its functions shall include:

1. Reviewing and monitor the effectiveness of the Compliance Program;
2. Analyzing the regulatory environment, the legal requirements with which the Cooperative must comply and specific risk areas;
3. Assessing existing policies and procedures that address these areas for possible incorporation into the Compliance Program;
4. Developing standards of business conduct and policies and procedures to promote compliance;

5. Recommending and monitoring the development of internal systems and controls to implement the Cooperative's standards and policies and procedures as a part of its daily operations;
6. Determining the appropriate strategy/approach to promote compliance and detect potential violations;
7. Developing a system to solicit, evaluate and respond to complaints and problems; and
8. Monitoring internal, State and CMS audits for the purpose of identifying troublesome issues and deficient areas experienced by the Cooperative and implementing and approving corrective and preventive action.

## **Section II: Code of Conduct and Compliance Policies and Procedures**

The cornerstone of the Compliance Program is the Code of Conduct which outlines the Cooperative's expectations for employee conduct. Employees are provided the Code of Conduct upon hire, and annually thereafter. The Code of Conduct has been written for all Cooperative employees and entities. The Code of Conduct sets the expectation that any and all Cooperative employees and entities will conduct themselves in a manner that demonstrates the highest level of integrity and business ethics possible. The Code of Conduct also reviews the mission and values of the Cooperative and states the expectation that all Cooperative entities and employees will adhere to federal, state, and local laws, regulations and standards when conducting business. In order to articulate the Cooperative's compliance and ethical standards and its commitment to comply with all applicable Federal and State laws and regulations, the Cooperative has established written policies, procedures, and a Code of Conduct. These policies describe compliance expectations and describe how to report, investigate and resolve issues.

The Compliance Program leads the effort to ensure that appropriate compliance policies are in place to further clarify the goals outlined in the Code. The policies and procedures are reviewed at least annually and on an as-needed basis based on State and Federal regulatory changes.

The Compliance Officer, or designee, will ensure that all employees and agents are informed of applicable policy requirements and that this education is documented and retained in accordance with applicable record retention standards. Education for employees also includes those general compliance policies which addressed topics of non-retaliation, fraud, waste and abuse prevention, conflicts of interest, and privacy.

Copies of all policies can be found on the Cooperative's SharePoint site. All Compliance policies and procedures are reviewed annually and approved by the Director of Compliance or Executive Director of Compliance.

### **Section III: Communication Strategy**

The Compliance Department has developed ways to ensure that staff and first tier, downstream, and related entities understand and implement regulatory requirements appropriately and completely. Communication activities also include a personal understanding and commitment to reporting non-compliant activities and behaviors. The Compliance Department has developed various ways for staff to receive and report information and concerns.

#### **Reporting Compliance Concerns**

In order to have an effective Compliance Program, employees, providers/ subcontractors, and beneficiaries must be aware of the process for reporting potential non-compliant activities. In addition, they must understand that they will not be retaliated against if they report such activities. It is the policy of the Cooperative that retaliation is not acceptable by any employee or level of management within the Cooperative. This policy is clearly outlined in the Cooperative's Compliance Concern Communication policy, which is received by every employee.

Employees are instructed that the Director of Compliance, Executive Director of Compliance, or Executive Director of Human Resources are available to receive any anonymous issues on a confidential basis. A Compliance Hotline and a dedicated fax and e-mail address are available to team members, beneficiaries, providers, business associates, first-tier and downstream entities, and any individual/entity to report incidents regarding legal/regulatory compliance issues, violations of the company policy, or the Code of Conduct. The contact information is listed below:

**Telephone:**

English speaking USA and Canada: (877) 472-2110 (not available from Mexico)

Spanish speaking North America: (800) 216-1288 (from Mexico user must dial 001-800-216-288)

**E-mail:** [reports@lighthouse-services.com](mailto:reports@lighthouse-services.com)

**Website:** <http://www.lighthouse-services.com/group-health>

**Fax:** (215) 689-3885

Employees are also encouraged to contact their immediate supervisor when non-

compliant activity is suspected. This report should be made immediately upon identifying the issue. The supervisor will report this information to the Director of Compliance, Executive Director of Compliance, or Executive Director of Human Resources for further investigation and reporting to the Cooperative's Corporate Compliance Committee. If the employee feels as though their immediate supervisor did not adequately address the complaint, the employee may go directly to the Director of Compliance, Executive Director of Compliance, or Executive Director of Human Resources via phone or e-mail.

Calls or issues reported to the Compliance department are logged in a spreadsheet and investigated by the Compliance Department. Calls or issues reported through the anonymous Compliance hotline are logged into a database and investigated by the Director of Compliance, Executive Director of Compliance, and Executive Director of Human Resources. No disciplinary action will be taken against individuals making reports. Every effort will be made to keep reports confidential. The process for reporting suspected violations to the Compliance hotline will be a part of the education and/or orientation for all employees. Failure to report known violations, failure to detect violations due to negligence or reckless conduct and making false reports shall be grounds for disciplinary action, up to and including termination.

Providers, delegated entities, and beneficiaries are instructed on how to report compliance issues and suspected fraud through various communication channels including but not limited to website, manuals, and member communications.

Beneficiaries are encouraged to call the Compliance Hotline if they have identified potential non-compliant activity. If beneficiaries do not receive a satisfactory response they also have access to the Compliance Officer through the hotline. Beneficiaries have the right to also contact the OIG Complaint Hotline related to suspected fraud, waste, or abuse.

Providers are encouraged to call the Executive Director of Compliance directly to report suspected fraud, waste, or abuse. Any concerns reported by providers, delegated entities and beneficiaries will be kept confidential and investigated in a timely manner.

Every effort will be made to keep reports confidential. The Cooperative's non-retaliation policy also pertains to reports received from providers, subcontractors, and beneficiaries. This policy is communicated along with reporting instructions.

The Compliance Department maintains a log of beneficiary discrimination allegations reported to the Compliance Department or the Cooperative's Civil Rights Coordinator... Allegations of discrimination based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, mental condition, sexual orientation, claims experience, medical history, evidence of insurability (including conditions arising out of acts of domestic violence, disability, genetic information, or source of payment are addressed). Allegations of beneficiary discrimination are reviewed by the Compliance Officer, or a

designee, and the Civil Rights Coordinator. Criteria used to determine the substantiation of discrimination include, but are not limited to, the specificity of the allegation; the behavior displayed that led to the allegation; and, the provider's history relative to the number of previous and/or current discrimination allegations. Allegations that are substantiated will be referred to a Medical Director for peer review action, the Credentialing Committee, and to regulatory bodies as contractually required.

## **General Compliance Communication**

### *Employee Communication*

Staff may receive information pertaining to compliance directly through:

1. CEO Communication
2. Compliance SharePoint Site-Compliance Department posts policies and procedures as well as monthly education topics offering an opportunity for the Cooperative staff to enhance their knowledge.
3. Electronic Mail – Compliance Department may periodically send e-mail communication to staff reminding them how to report issues, identifying useful resources, providing updates on changes to regulatory guidance, and offering updates to internal compliance policies and processes.

### *Management Communication*

The Cooperative uses communication strategies to distribute new regulatory guidance and communicate areas of concern or non-compliance.

- (1) All Product Regulatory Change/Update Alerts – The Compliance Department, through the Regulatory Risk Assessment Committee, is responsible for tracking, assessing, and analyzing the impact of new laws, regulatory guidance, and standards on current policies and procedures. Compliance will work with the functional areas to communicate the changes. A database of all new guidance will be managed by compliance. Business owners/responsible parties will be identified for each change. The Compliance Officer or designee will work with the functional areas to develop action plans, update policies and procedures, and in some cases develop new processes that meet the guidelines.

- (2) Compliance Reported Issues – Compliance will maintain an issues log that will track and monitor issues to resolution. This report will also be used to communicate to ensure that issues are visible to leadership at all levels.
- (3) Non-Compliance – The Cooperative will respond timely to all identified areas of non-compliance, including but not limited to, CMS and State notices and letters. When an issue of non-compliance is identified, either internally or via a regulatory agency warning letter, Compliance will work with the affected area to investigate, develop corrective action, and design strategies to ensure that the occurrence no longer persists and never happens again.

#### **Section IV: Education and Training**

The Cooperative requires that all employees attend specific training upon hire and on an annual basis. The training emphasizes the Cooperative's commitment to making compliance with Federal and State requirements a top priority for all employees and delegated entities.

All employees, Board of Directors, and first tier, downstream, and related entities, are required to review the Code of Conduct, Medicare Parts C and D General Compliance, and Combating Medicare Parts C and D Fraud, Waste, and Abuse trainings.

#### **Standards of Conduct**

Education and training are critical elements of the Compliance Program. All employees are required to complete training regarding key compliance and IT policies and review of the Standards of Conduct within the Employee Handbook each year. Employees shall receive such training when they are first hired and on a periodic basis (at least annually) thereafter. Completion of such training is a condition of continued employment.

#### **Medicare Parts C and D General Compliance and Combating Medicare Parts C and D Fraud, Waste, and Abuse Training**

General Compliance and Fraud, Waste, and Abuse training focuses on adherence to the provisions of the Compliance Program, including training requirements.

Such training shall emphasize the Cooperative's commitment to compliance with federal and state statutes, regulations, program requirements, internal policies and ethics. It shall highlight the elements of the Compliance Program, including how to report suspected violations, summarize the fraud and abuse laws, and review requirements.

The Cooperative's Compliance Officer and the Cooperative's Executive Leadership team are responsible for ensuring that all Cooperative employees complete this training on an annual basis. If additional training related to fraud, waste, and abuse is required, the Cooperative's Compliance Officer, or designee, will develop relevant materials.

In addition to training associated with the performance of certain job functions, First tier, downstream, and related entities are also required to complete Medicare Parts C and D General Compliance Training and Combating Medicare Parts C and D Fraud, Waste, and Abuse Training.

## **Section V: Enforcement**

- A. **Investigations.** Once an allegation of non-compliant activity is reported to the Compliance Officer or discovered during routine or random reports and audits, an investigation into the allegation will be initiated promptly. The allegation will be documented in a spreadsheet. The Compliance Officer will gather all relevant documentation and findings.

If the Compliance Officer determines that a violation has occurred, the matter will be shared with the Cooperative's Corporate Compliance Committee. The Compliance Officer shall conduct a more detailed investigation which may include, but is not limited to, the following:

1. Interviews with individuals who have knowledge of the facts alleged;
2. A review of documents;
3. Legal research and contact with governmental agencies for the purpose of clarification.
4. A record shall be kept of all reports of possible misconduct that indicates the nature of any investigation and its results in a database, in accordance with the Cooperative's protocols.
5. Any reports to an outside agency shall only be made as directed by the Compliance Officer and CEO in conjunction with legal counsel pursuant to the Cooperative's existing policies. The information will be shared with the appropriate State and Federal agencies in accordance with regulations and the Cooperative's compliance policies and procedures.

If it is determined that an employee has been engaged in a non-compliant activity, the appropriate Cooperative personnel policies and procedures regarding



such violations will be followed. The employee's supervisor and Executive Director of Human Resources will document any disciplinary action in the employee's personnel file.

If a provider or subcontractor has committed a non-compliant activity or has demonstrated misconduct related to payment or delivery of service/items (under the contract), the Cooperative has the legal right to terminate the contract immediately. The process for determining if this course of action will be taken, as described above, a timely, comprehensive investigation will commence. Once misconduct has been identified the Cooperative's business unit, provider or subcontractor will be asked to submit a corrective action plan which could include repayment of overpayments or disciplinary action. This will be determined in coordination with the Compliance Officer and the Corporate Compliance Committee.

If a member is involved in non-compliant activity or it is strongly suspected that the member is involved in non-compliant activity, the Cooperative does not have the authority to disenroll the member without explicit consent from appropriate State and Federal regulators.

All employees and delegated entities are expected to cooperate with any and all investigations relating to non-compliant activity. The investigations can be conducted by the Compliance Officer and/or designee. If appropriate, employees will be notified of governmental investigations in which they may be required to provide assistance.

- B. **Corrective Actions & Regulatory Reporting:** Once evidence confirms that a non-compliant activity has occurred, a corrective action plan will be developed to resolve the occurrence and then to prevent the activity in the future. At this time, the Compliance Officer and the CEO will determine if the issue needs to be self-reported to the CMS regional office and/or the State regulatory agency with all pertinent and appropriate information about the issue and its planned resolution. The Compliance Officer, with guidance from the State and/or Federal agency, will develop a written corrective action plan within the requested timeframe. The corrective action plan will include documenting internal controls and policies and procedures that will be put into place to correct the issue and prevent it from occurring again. The corrective action plan will also include recommendations for disciplinary action and sanctions, as appropriate. The Corporate Compliance Committee will be responsible for reviewing and approving the corrective action plan as necessary.

Cooperative employees and agents who violate relevant laws and regulations established by governmental agencies, and/or policies as established may be subject to disciplinary action in accordance with Human Resource policies and procedures. Violations of the Cooperative's policies could result in termination of

employment or other contractual arrangements. The Cooperative may also report such violations to applicable regulatory or licensing authorities, which may result in loss of licensure, fines, exclusion from federally funded programs, and/or imprisonment, as determined by the governing enforcement agency.

## **Section VI: Auditing, Monitoring and Risk Assessments**

Activities associated with monitoring and auditing are identified through a combination of activities: risk assessments, Corporate Compliance Committee discussions, and internal and external reporting.

### **Risk Assessment**

The Cooperative's Compliance Officer will work with the Corporate Compliance Committee to identify areas of focus for monitoring and auditing potential non-compliant activity. The focus on identifying operational risk areas to be monitored and audited are determined by:

- Size of department;
- Complexity of work;
- Amount of training that has taken place;
- Past compliance issues; and
- Impact on member experience.

Areas of particular concern may 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,
- FDR oversight and monitoring.

The Corporate Compliance Committee will receive the outcomes from the Compliance Risk Assessment that will be performed annually. The risk tool will be used to assess the current status of each operational area. The weighted values will be used to determine if processes should be deemed as high or low risk. High-risk processes will be a part of the regular monitoring activities.

### **Monitoring and Auditing**

The Compliance Officer, or delegate, in conjunction with the Corporate Compliance Committee, will develop a monitoring and auditing work plan based on the risk assessment results. Monitoring and Auditing work plans are used to detect potential areas of risk and/or non-compliant activity. 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

In addition to the operational areas, the Cooperative regularly monitors its provider network for individuals that should be excluded from participating in a federal health care program. The Cooperative's Credentialing Committee is responsible for identifying any contracted providers that may be on the excluded HHS/OIG Cumulative Sanctions List and the GSA Excluded Parties List System. The procedure for monitoring these lists can be found in the Cooperative's Policies and Procedures. The Compliance Department also checks the HHS/OIG Cumulative Sanctions List and the GSA Excluded Parties List System prior to employing or contracting with anyone who may provide services directly or indirectly to beneficiaries within a federal health care program. If the Cooperative learns that any prospective or current employee or contractor has been proposed for exclusion or excluded, the Cooperative will remove he/she from work that involves a federal health insurance program until it has been confirmed that he/she is no longer subject to exclusion.

Audits for each identified risk area will be conducted throughout the year. The Compliance Officer will coordinate with internal audit staff and, in some cases, with assistance from an outside vendor. Audit methodologies are based on regulatory requirements and standards. Once the review is completed, the audit team will meet with the Compliance Officer, or designee, to discuss results and reach a decision concerning any follow-up corrective action. The Compliance Officer, or designee, will provide reports to the Corporate Compliance Committee. If issues that are deemed fraud, waste, or abuse are identified during an audit, the information will be referred to the Special Investigations Unit (SIU) for additional investigation.

## **Section VII: First Tier, Downstream and Related Oversight**

The Cooperative may delegate the authority and responsibility to carry out program/plan activities that are otherwise performed by the Cooperative to first tier, downstream, or related entities (FDRs). The Cooperative retains accountability for services provided by FDRs. Further, the Cooperative maintains compliance with applicable State and Federal requirements.

To ensure the terms and conditions of its contractual obligations to CMS and other governmental entities are adhered to, the Cooperative will conduct a pre-contractual evaluation and annual audit of FDRs. The Cooperative monitors FDR performance on an ongoing basis. The Cooperative will implement corrective action and revoke delegation of duties if it determines that an FDR is unable or unwilling to carry out its responsibilities.

An annual risk assessment will be completed to aid in identifying high risk FDRs. High risk FDRs are those that are continually non-compliant or those that are determined high risk based on: scope of work performed; past compliance issues; and impact on member experience. FDRs determined to be high risk may be subjected to a more frequent monitoring and auditing schedule. This risk assessment process will be managed by the Compliance Department and presented to the Corporate Compliance Committee for review and discussion.

The Compliance Department determines the process for monitoring delegated FDRs. In addition, the department creates the annual audit calendar in order to validate compliance with contractual standards and regulatory requirements.

The Cooperative's operational areas and departments implement the FDR and Delegation Oversight at an operational level. The departments are responsible for the following:

- Manages the day-to-day FDR relationship.
- Identifies negative trends or vulnerabilities.
- Monitors FDR compliance according to the Program and associated tools and processes.
- Monitors operational performance.
- Day-to-day management of issues and actions; escalated as required.
- Assists with implementation and monitoring of corrective action plans. Manages FDR operational communications or training.
- Reports performance to the Compliance Department.
- Assists the Compliance Department in identifying risk as part of the annual risk assessment.

### **Initial Evaluation**

Prior to executing a contract or delegation agreement with a potential FDR, requests for an initial evaluation will be forwarded to Compliance by the department executing the contract or delegation agreement. The IT Security Risk Assessment Committee (ISRAC) will conduct an initial evaluation to determine the ability of the potential FDR to assume responsibility for delegated activities and to maintain the Cooperative's standards, applicable State, CMS, and accreditation requirements.

The following will be assessed in the initial evaluation:

- The entities' ability to perform the required tasks. The Compliance Officer will verify that the FDR meets both contractual and regulatory requirements.
- Policies and procedures specific to the delegated function(s).
- Operational capacity to perform the delegated function(s).
- Resources (administrative and financial) sufficient and qualified to perform the required function(s).

- Exclusion of the FDR from participating in the federal health program (excluded parties lists):
  - General Services Administration – Excluded Parties List System (EPLS)
  - Office of Inspector General – List of Excluded Individuals/Entities (LEIE)

If the FDR is not in full compliance with delegated standards, the FDR's action plan and timeline to achieve full compliance is reviewed. The oversight process may be modified for accredited/certified FDRs as applicable. The need for an on-site visit and/or file audit is at the sole discretion of the Cooperative. The Cooperative determines the frequency and format of contact with the FDR to verify compliance with established, revised, or new state, CMS, and accreditation requirements. The FDR is required to comply with the Cooperative's reporting requirements.

Results of the initial evaluation are presented to the Compliance Department and subsequently the ISRAC for review and/or approval. To accommodate business needs, ad hoc meetings or electronic review and/or approval may substitute for routinely scheduled meetings.

The delegation agreement specifies the delegated activities, responsibilities of the parties, reporting frequency, the process for evaluation, and remedies available to the Cooperative. The Cooperative determines who will directly monitor the downstream or related entity's compliance with requirements.

Once delegation is approved and a contract is executed, the FDR must submit data as contractually required.

In identified risk areas, additional reporting may be required from the FDR. The FDR may be obligated to submit a report summarizing activities completed during the quarter, identifying barriers to improvement and the effectiveness of any improvement plans. These reports will be reported to the Corporate Compliance Committee.

The Cooperative conducts a comprehensive review of the FDR's ability to provide delegated services in accordance with contractual standards and applicable state, CMS, and accreditation requirements. High risk FDRs, as determined by the annual risk assessment and/or continued non-compliance, will obtain priority status on the annual audit calendar. In conjunction with policies and procedures, the Cooperative will not limit its audit calendar to high risk FDRs.

If the Cooperative has reason to believe the FDR's ability to perform a delegated function is compromised, a discretionary audit may be performed. The results of these audits will be reported to the Corporate Compliance Committee. The Compliance Department may also recommend discretionary audits upon evaluation of non-compliant trends or reported incidents.

### **Annual Risk Assessment**

The Compliance Department will conduct an annual comprehensive risk assessment to determine the FDR's vulnerabilities and high-risk areas. A look-back period is determined which includes any corrective actions; service level performance; reported detected offenses; or complaints and appeals from the previous year. Any FDR deemed high risk or vulnerable is presented to the Corporate Compliance Committee for suggested audit.

### **Corrective Action**

A corrective action plan is developed for the delegated entity by the Compliance Department in instances where non-compliance is identified. Each corrective action plan is presented to the Corporate Compliance Committee for review and approval. Supplementary, discretionary audits and additional reporting may be required until compliance is achieved.

At any time the Cooperative may require remediation by an FDR for failure to fulfill contractual obligations including development and implementation of a corrective action plan. Failure to cooperate with the Cooperative in any manner may result in termination of the agreement (revocation) and return of delegated activities to the Cooperative.

### **Training**

The Cooperative will make training materials available to FDRs; however, it is expected that FDRs institute their own training program intended to communicate the compliance characteristics related to the FDR and their contractually delegated area(s). Training materials will be reviewed by the Cooperative during the audit process.

The Cooperative will distribute an annual attestation to FDRs. The completed, returned attestation confirms compliance with new hire and annual training and education requirements to include General Compliance and Fraud, Waste, and Abuse.

FDR training documentation will be requested and evaluated as part of the annual audit process. Material for review may include, but not be limited to, training presentations; sign-in sheets; test scores; trainer proficiencies; new hire orientation packets; employee list (including date of hire and date of previous training).

## **Section VIII: Fraud, Waste and Abuse Prevention and Detection**

### **Training**

Fraud, Waste and Abuse training is provided to all staff. This training assists with helping staff identify claims that would constitute fraudulent activities. Every Cooperative employee is required to report any situation that he or she believes is unethical and/or illegal if it involves another employee or anyone acting on behalf of the Cooperative. An employee's failure to report regulatory violations or false claims of which the employee is aware can lead to discipline. Any potential issue should be reported to the supervisor, through the normal chain of command. If a person does not feel comfortable reporting this matter to their supervisor or if they are concerned that the matter is not being handled appropriately, they may call the Cooperative's compliance hotline. Employees can also email the Compliance Officer.

### **Analysis and Identification of Risk Areas**

The Cooperative has a Special Investigative Unit Committee (SIU) responsible for reviewing, evaluating, mitigating, and monitoring the Cooperative's efforts to identify fraud, waste, and abuse. Routine review of claims data will be conducted in order to identify outliers in billing and utilization and identify the population of providers and pharmacies that will be audited.

Referrals for potential fraudulent cases will not only come from claims data but can also originate from many sources internally and externally. Beneficiaries, providers, employees, law enforcement and regulatory agencies, and others are able to contact the plan via phone and e-mail if they suspect that a provider is engaged in inappropriate practices. Medical claims are pended if they meet certain criteria that warrant research and/or a double check for validity. Payments for pharmacy claims will also be pended or denied if needed – based on criteria focused on the types of drugs (for example narcotics), provider patterns, and challenges previously reported pertaining to certain pharmacies.

The Cooperative along with the PBM will perform data analysis on behalf of the Cooperative in order to identify potential issues of fraud, waste or abuse. New cases identified are entered into the database and a report is generated and submitted to the Cooperative's SIU Committee.



## **Investigations and Research**

After the reports are generated identifying the high-risk providers, they are sent to the Compliance Officer or delegate, for the SIU. The SIU will determine if further investigation commences from that point generating results and follow-up plans that are discussed with the Corporate Compliance Committee. If the investigation finds that providers are in fact engaging in improper activities, the Compliance Officer reports the issue to the CEO, the State and the OIG as required.

## **Section VIV: Compliance Program Evaluation**

In order to ensure the effectiveness of the Compliance Program, the Cooperative will conduct an annual self-assessment. The assessment will evaluate the plan against the OIG seven elements of an effective Compliance Program. The following areas will be reviewed.

<b>Review Element</b>	<b>Sample Evaluation Questions</b>
Policies and Procedures	<ul style="list-style-type: none"> <li>• Are policies and procedures specific and detailed in describing the mechanisms by which compliance objectives will be achieved?</li> <li>• Is there proactive oversight of FDRs to ensure they are adhering to the Cooperative's Code of Conduct and the policies and procedures?</li> </ul>
Compliance Officer and Corporate Compliance Committee	<ul style="list-style-type: none"> <li>• Does the responsible compliance position report to the CEO?</li> <li>• Does the responsible compliance position have a regular pre-scheduled meeting with the governing board to report on activities of the compliance program (either directly or through a report delivered by the CEO)?</li> </ul>
Training and Education of Employees and First Tier, Downstream and Related Entities	<ul style="list-style-type: none"> <li>• Is there evidence of a compliance training program which includes the Cooperative's Code of Conduct; expectations of the compliance program; and how the compliance program operates?</li> <li>• Are new employees, board members and affiliates trained in compliance so that they could identify circumstances of fraud, waste and abuse?</li> </ul>

Effective Lines of Communication	<ul style="list-style-type: none"> <li>• Are there accessible mechanism(s) for the governing board, management, employees and others associated with all programs to communicate compliance related concerns to the responsible compliance position?</li> <li>• Do the accessible mechanisms include methods for anonymous or confidential communication?</li> </ul>
Well Publicized Disciplinary Guidelines	<ul style="list-style-type: none"> <li>• Do disciplinary policies set out expectations for reporting compliance issues and for assisting in their resolution?</li> <li>• Do disciplinary policies outline sanctions for failing to report suspected problems; participating in non-compliant behavior; or encouraging, directing, facilitating or permitting non-compliant behavior?</li> </ul>
Internal Monitoring and Auditing	<ul style="list-style-type: none"> <li>• Does a system exist within the functional area to routinely conduct self-evaluation of risk areas, including internal audits and as appropriate external audits?</li> <li>• Does the functional area routinely evaluate potential or actual non-compliance as a result of its self-assessments and audits?</li> </ul>
Prompt Responses to Detected Offenses	<ul style="list-style-type: none"> <li>• Does a process exist within the Compliance Program for responding to compliance issues as they are raised?</li> <li>• Does a process exist within the Compliance Program for investigating potential compliance issues?</li> </ul>