PURPOSE:
The purpose of this document is to implement the relevant provisions of 42 C.F.R. §§ 422.503(b)(4)(vi), and 423.504(b)(4)(vi), Chapter 9 of the PDBM, and Chapter 21 of the MMCM, which requires Part C and Part D sponsors to have an effective compliance program, including the implementation and operation of an effective system for routine monitoring and auditing, identifying compliance and Fraud, Waste and Abuse (“FWA”) risks with prompt responses, as necessary, in order to protect the Medicare program.

POLICY:
Devoted Health will comply with all applicable federal and state laws and regulations regarding the establishment of its Medicare Compliance Plan and Work Plan(s). Devoted Health has established and maintains a process to audit and/or monitor its Medicare functions, including those performed by First Tier, Downstream and Related Entities, (“FDRs”), for compliance with Medicare regulatory and sub-regulatory guidance, compliance with contractual terms, compliance with applicable federal and state laws, and adherence to internal policies and procedures in order to identify potential or actual compliance and/or FWA risks. Devoted Health complies with the prompt response requirements when such risks are ascertained. In addition, Devoted Health assesses the overall effectiveness of the Medicare Compliance Program on a periodic basis. Desk reference guides or other information and policies may be in place to define further procedural actions of each of the processes described in this policy.

In addition to the Medicare Compliance activities within this policy, the Special Investigation Unit (“SIU”) and other Business functions may conduct risk assessments and subsequently develop audit plans. These areas maintain their own policies and procedures associated with these processes. Medicare Compliance collaborates with these areas to leverage internal resources and enhance multi-disciplinary collaboration and visibility.
PROCESS:

I. Medicare Compliance may coordinate with other areas while conducting annual baseline risk assessments relating to Medicare compliance and FWA risk areas. Each business area is assessed and consideration may be given to size of the department, complexity of work, potential compliance issues, degree of regulatory change, initial auditing and monitoring results, and areas of interest by regulators or other external parties. These assessments are designed to review, rank risk through normative and empirical modeling, and prioritize the key regulatory risks for all Medicare business operations into a range of Risk Priority categories. The top Risk Priority scores are used for driving the development of the annual Medicare Compliance audit plan. The MCO is integral to this process, and the results of the risk assessment are reviewed with the MCC.

Inclusive in the Work Plans are the completion of First Tier Risk Assessments. The assessment includes all First Tier entities servicing Devoted Health Medicare contracts. First Tier entities may be scored as First Tier Types. First Tier entities are scored individually. The highest risk entities are the priority for the development of a list of targeted First Tier entities to be evaluated during the calendar year as part of the Work Plan. Other considerations during the stratified First Tier selection for inclusion in the Work Plan include, but are not limited to, any recommendations received, initial audit failures.

II. Annual Medicare Compliance Plan
   A. Development - Using the results of the risk assessment, the MCO, with participation of the Medicare Compliance staff, will develop an annual Work Plan to define the schedule of the monitoring and auditing activities of the prioritized risk areas. The Work Plan defines the auditing and monitoring activities for the relevant calendar year such as the objective, frequency, and schedule, etc. Auditing and monitoring activities are assigned based on knowledge and expertise of the reviewers, as well as resource availability and timing needs.
   B. Work Plan - The work plan will define the process for responding to audit and/or monitoring results and conducting follow up reviews of areas found to be non-compliant to determine if the implemented CAs have fully addressed the problems. The Work Plan also contains the annual First Tier Risk Assessment which defines the number of First Tier entities strategically selected for review and how they were selected. The stratified selection of First Tiers from the highest risk entities in the First Tier risk assessment are listed in the Work Plan. Targeted Downstream and/or Related entities may also be added to the Work Plan. Medicare Compliance collaborates with business partners for completion of these audits. A designated Medicare Compliance audit tool is used for these reviews and includes Compliance Program components such as the completion of the initial 90 day FWA training, monthly employee screening against the sanction and debarment lists, First Tier oversight of their Downstream entities, etc. Devoted Health maintains a comprehensive approach to oversee Devoted Health’s FDRs which also includes “Relationship Managers” who are business partners that are responsible for the FDR and specialized oversight units/practices. The associated business areas of these processes maintain their own policies and procedures.
   C. Execution of the Work Plan - The Medicare Compliance staff have access to company personnel, documents, legal counsel, operational units, and FDRs as needed to support the Work Plan activities. The audits in the Work Plan are led or overseen by Devoted Health Medicare Compliance to ensure
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compliance with Medicare regulations and other applicable requirements. The audit methodology and scope will include appropriate methods for selecting facilities, pharmacies, providers, claims, appeals and other areas for audit, as applicable; determining appropriate sample sizes. Audits will typically be an assessment of compliance with Devoted Health’s internal process and procedures and federal regulations. Where there is specific operational, clinical and/or compliance-related expertise that is required, the audit lead will solicit the assistance of other operational and clinical staff to assist in the review (example medical denials). The audit lead is independent of the area/function being audited, allowing for an unbiased audit opinion. The Work Plan is dynamic and may need to be modified as higher risks/priorities arise, however, any changes made to it must be approved by the MCO.

D. Tracking & Reporting Results - Work Plan progress, including its subset FDR audits and monitoring events, will be tracked by the MCO. The results of all Work Plan activities are regularly reported to the MCO, along with the status and effectiveness of any CAs. Work Plan activities are subject to specific standards. For example, the results of the Work Plan audits shall be reflected in standard audit reports that meet CMS requirements and include key stakeholders during distribution. The MCO or designee(s) provide updates on Work Plan, including any approved changes, to the MCC, and when appropriate to any of the following: the Devoted Health Chief Executive Officer, Devoted Health’s Senior Leadership, and Devoted Health’s BOD or subset. These reports may be in the form of an oral report, written report and/or dashboard view.

III. Audit of the Devoted Health Medicare Compliance Program
Devoted Health’s Medicare Compliance Program and Medicare Compliance functions and activities can be audited by a third party and by CMS. Results of the compliance program audits are shared with the MCO, the MCC members of senior leadership and the Devoted Health CEO and BOD. Any identified deficiencies result in corrective actions for issue resolution.

IV. OIG/SAM Exclusion and Debarment Screenings
Various business areas within Devoted Health (e.g., Compliance, Human Resources, Credentialing, Broker Services, etc.) conduct OIG SAM sanction and debarment screenings. These areas maintain their own policies and procedures related to these processes. Any potential matches are investigated with appropriate actions taken. In addition, Devoted Health’s Medicare contracts with First Tier entities require that they perform the same pre-hire/contracting and monthly verifications against the same lists for all of their employees and downstream entities that support Devoted Health’s Medicare business. Attestations, audits or other methods of verification may be implemented within the business to evaluate their compliance. Otherwise, compliance is assessed for the applicable First Tier entities that are selected for the annual Work Plan. In the event that a First Tier entity is unable to evidence compliance with this requirement, Corrective Actions will be taken in accordance with contractual provisions.

V. Devoted Health’s Special Investigation Unit (SIU)
Devoted Health’s SIU is responsible for the identification of potential FWA, timely initiation of investigations, and, where potential FWA is identified, reporting such to the monthly CPE universe, to the NBI MEDIC and/or law enforcement as warranted. Medicare Compliance supports reporting of concerns to the SIU. Medicare Compliance and Corporate Devoted policies identify the various methods available for reporting of FWA
Concerns to Medicare Compliance and the SIU. In addition, Medicare Compliance personnel and the MCO are accessible to the SIU personnel on an ongoing basis. The SIU interacts frequently with Medicare Compliance and presents routinely to the MCC regarding case file trends, emerging schemes, and case metrics. The SIU maintains a Devoted Health, Health Care Anti-Fraud Plan and Special Investigations Unit Policies and Procedures.

A. Responding to CMS-Issued Fraud Alerts - On occasion, CMS will issue Fraud Alerts via their HPMS notification System. Upon receipt of the Alert, Devoted Health Medicare Compliance will add the notification to the Alert distribution system, and distribute to all impacted parties for processing.

B. SIU maintains case files for a period of ten (10) years in accordance with Devoted Health’s record retention policy and procedure. At the launch of each investigation, the SIU reviews case history to determine whether prior complaints were made, and the nature of any prior complaints. Completion of this activity may result in either a case re-opening or new case assignment.

VI. Corrective Actions
Corrective Action Plans (CAPS) to address non-compliance or suspected FWA are developed and implemented on a case-by-case basis. The MCO or his/her designee oversees all CAPS for each issue. CAPS are designed to correct the underlying problem leading to the issue of non-compliance to prevent future instances of or continued non-compliance of the nature identified in the issue, and will include timeframes for specific achievements.

A. CAP Implementation
   a) General Compliance and Ethics issues: In accordance with Devoted Health’s Code of Conduct, and related Workplace Policies, CAPS may include (i) employee discipline (e.g., coaching, written warnings, suspension and other actions up to and including employee termination), (ii) new and/or revised policies/procedures/workflows, and (iii) employee training.
   b) Potential FWA issues are referred to CMS or to the NBI MEDIC by the MCO, his/her designee, the SIU or another Devoted Health party, as necessary.
   c) CAPS may include overpayment recovery, payment suspension, Prescription Drug Event correction/deletion, and other actions up to and including provider termination.
   d) Issues of non-compliance require remediation and any CAPS are reviewed by Devoted Health Medicare Compliance to determine the reasonableness of the plan of action to address compliance deficiencies. In addition, Devoted Health Medicare Compliance tracks the completion of the CAP to resolution.

B. Devoted Health’s Compliance Procedures:
   a) CAPS are added to the Medicare Compliance issue tracking database.
   b) Status meetings between the MCO and/or a Medicare Compliance designee and the Business Owner(s) may occur to ensure progress on the CAP.
   c) CAPS must address the root causes of any deficiency to correct the underlying problem and prevent future recurrences. These may include interim and long term solutions.
   d) Upon completion of CAP implementation, Medicare Compliance will validate the effectiveness of the CAPs such as through testing results, schedule a follow-up review, or develop and implement ongoing monitoring activities.
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e) Medicare Compliance maintains and/or has access to documentation of all deficiencies and CAPs taken.

f) Routine reporting of the status/progress of CAPs are provided to the MCO and other governing bodies (eg. MCC) and when appropriate to any of the following: the Devoted Health Chief Executive Officer for Medicare, Devoted Health Senior Leadership, and Devoted Health’s Board of Directors or subset. These reports may be in the form of an oral report, written report and/or dashboard view.

VII. Procedures for Self-Reporting Potential FWA and Significant Non Compliance

In the event that potential FWA is identified through daily activities, monthly reporting to the CPE universes (including at the FDR level, CVS Health), Devoted Health promptly refers the issue to the NBI MEDIC, in accordance with the guidance defined by the NBI MEDIC. In the event of an instance of significant non-compliance, Devoted Health’s MCO or his/her designee will report such incident to CMS as soon as possible after discovery, in accordance with relevant regulatory requirements and guidance.

In certain situations, Devoted Health engages CMS in order to report proactively key information (e.g., upcoming provider terminations, changes to FDR contracts for key functions, etc.). PBM changes are reported to Devoted Health’s CMS Account Manager at least 60 calendar days prior to the effective date of the new contract or the date the new PBM would begin providing services to beneficiaries, whichever is earlier. In instances of a contract change occurring within less than 60 days, Devoted Health must notify within 5 days of signing the new contract. Other FDR changes are evaluated by the MCO for similar proactive reporting using the same timeframe as referenced in this section.

VII. Auditing by CMS or its Designee

In accordance with Devoted Health’s contracts with CMS, Devoted Health provides access to any regulatory agency or auditor acting on behalf of the federal government to conduct a desk review, an on-site audit or other activities. In addition, Devoted Health’s contracts with First Tiers include provisions ensuring the external entity adheres to the same requirements. Responses to requests for information or information requested by the NBI MEDIC will be responded to within the timeframe required. In the event that additional time is needed, Devoted Health will communicate such needs directly with the requester.

REGULATORY REFERENCES:
42 CFR 422.503 and 42 CFR 423.504
100-18 Medicare Prescription Drug Benefit Manual (Chapter 9 and Chapter 5)
100-16 Medicare Managed Care Manual (Chapter 21)
REFERENCED DOCUMENTATION:
N/A

ACRONYMS & DEFINITIONS:
BOD – Board of Directors
CA – Corrective Action(s)
CAP - Corrective Action Plan
CMS - Centers for Medicare & Medicaid Services
CTM – Complaints Tracking Module
FDR - First Tier, Downstream, and Related entities
FWA – Fraud, Waste, and Abuse
HPMS – Health Plan Management System
MA – Medicare Advantage
MCC – Medicare Compliance Committee
MCO - Medicare Compliance Officer
MMCM - Medicare Managed Care Manual
NBI MEDIC - National Benefit Integrity Medicare Drug Integrity Contractor
OIG – U.S. Department of Health & Human Services’ Office of Inspector General
PBM – Pharmacy Benefit Manager
PDBM - Prescription Drug Benefit Manual
SAM - General Services Administration’s System for Award Management
SIU – Special Investigations Unit

REVIEW:

<table>
<thead>
<tr>
<th>Accountable for Policy Maintenance</th>
<th>Kiley Cernansky</th>
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<td>Accountable for Implementation</td>
<td>Shannon O’Kane</td>
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Review and Revision History:

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<th>Date</th>
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<td>01.01.2020</td>
<td>1.1</td>
<td>Annual Review and Update of the Policy (Shannon O’Kane)</td>
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<tr>
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<td>02.05.2021</td>
<td>1.2</td>
<td>Added Referenced Documentation Section (Kiley Cernansky)</td>
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<tr>
<td>01.20.2022</td>
<td>1.3</td>
<td>Added auditing of exclusion screening (Sandy DeLehman)</td>
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