FY26

Trinity Health PACE Integrity and Compliance Program Description

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Mission

We, Trinity Health, serve together in the spirit of the Gospel as a compassionate and transforming healing presence within our communities

Core Values

Reverence
We honor the sacredness and dignity of every person

Commitment to Those Experiencing Poverty
We stand with and serve those who are experiencing poverty, especially the most vulnerable.

Safety
We embrace a culture that prevents harm and nurtures a healing, safe environment for all.

Justice
We foster right relationships to promote the common good, including sustainability of Earth

Stewardship
We honor our heritage and hold ourselves accountable for the human, financial and natural resources entrusted to our care

Integrity
We are faithful to who we say we are

Our Vision

As a mission-driven innovative health organization, we will become the national leader in improving the health of our communities and each person we serve. We will be your most trusted health partner for life.

Introduction

This document describes the Trinity Health PACE (TH PACE) National Health Ministry compliance program referred to as the "Integrity and Compliance Program" (ICP). The ICP is one demonstration of TH PACE's commitment to ensuring its operations are conducted in a manner consistent with its Mission and Core Values, with the highest standards of ethical and professional behavior, and in compliance with all applicable laws and regulations that apply to our national health ministry.

The terms "integrity" and "compliance" are purposefully referenced in the name of the program. Integrity is a Trinity Health Core Value – "we are faithful to who we say we are". Trinity Health PACE is committed to ethical behavior and actions consistent with Trinity Health's Mission and Core Values. Compliance generally means acting in accordance with the requirements of law, regulations, policies and standards. The TH PACE ICP requires compliance with all laws and regulations that apply to our health ministry's operations as a ***minimum*** expectation. The ICP also requires all who work in TH PACE to also consider the impact, consistency and alignment of their actions and decisions with Trinity Health's Mission and Core Values

As stated by the Centers for Medicare and Medicaid Services (CMS), the Programs of All-Inclusive Care for the Elderly (PACE) provides comprehensive medical and social services to certain frail, community-dwelling elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. An interdisciplinary team of health professionals provides PACE participants with coordinated care. For most participants, the comprehensive service package enables them to remain in the community rather than receive care in a nursing home. Financing for the program is capped, which allows providers to deliver all services participants need rather than only those reimbursable under Medicare and Medicaid fee-for-service plans. PACE is a program under Medicare, and states can elect to provide PACE services to Medicaid beneficiaries as an optional Medicaid benefit. The PACE program becomes the sole source of Medicaid and Medicare benefits for PACE participants.

The CMS requirements for the PACE program are found in 42 CFR Part 460 and in Medicare Part D regulations.

The TH PACE ICP has four primary goals:

1. Promote standards of ethical behavior and conduct by all who work within TH PACE, including colleagues, volunteers, medical staff, and suppliers
2. Foster an organizational culture that promotes compliance with laws, regulations and professional standards
3. Educate and train all who work within TH PACE concerning the organization's commitment to acting with integrity, being honest, and following all laws and regulations that apply to TH PACE operations
4. Establish systems to continuously monitor TH PACE operations and to identify and correct any violations or deficiencies in a timely and appropriate manner

Purpose and Scope

The TH PACE ICP is designed and operated to fully meet requirements for an effective corporate compliance program for participants in federal and state health care programs as established by the United States Sentencing Commission and adopted by the Department of Health and Human Services – Office of Inspector General (DHHS – OIG), the Centers for Medicare and Medicaid Services (CMS), the Department of Justice ("DOJ"), and other health care industry regulators.

TH PACE ICP addresses each of the elements of an effective corporate compliance program as displayed below:

The TH PACE ICP applies to all organizations in which TH PACE:

- Is the sole member or owner
- Maintains a majority investment or ownership interest (e.g. 51%) or otherwise controlling interest
- Is responsible for overall management of the operations of the organization by contract or otherwise, and
- First Tier, Downstream and Related Entities

The TH PACE ICP applies to all colleagues, volunteers, agents and other persons employed directly by or providing services under the direction of TH PACE.

The ICP also extends to TH PACE's relationships with members of the independent medical staff of Trinity Health hospitals, suppliers, contractors, and other business partners and affiliated organizations, including organizations in which Trinity Health maintains a minority or non-controlling investment or ownership interest. TH PACE management and colleagues are expected to use their best efforts to promote the principles of the ICP in all TH PACE business relationships with external parties.

Leadership and Oversight

Effective compliance programs must designate a compliance officer with responsibility for the implementation and operation of the compliance program. Regulators note that designating a compliance officer with sufficient authority is critical to the success of the program. The compliance officer must have direct access to the governing body and to the chief executive officer.

Service Area 4 Vice President and Chief Integrity and Compliance Officer

Trinity Health system-wide Integrity & Compliance Program includes four service areas. Service Area 4 encompasses Trinity Health's National Health Ministries including among others TH PACE, Mission Health Ministries, and System Services Functions. It is led by Service Area 4 Vice President and Chief Integrity and Compliance Officer (Service Area 4 ICO). The Service Area 4 ICO leads the ICP across the National Health Ministry of TH PACE and is responsible for ensuring the ICP is effectively implemented and operated, consistent with Trinity Health (TH) and TH PACE integrity and compliance policies. The TH Continuing Care President/CEO, with input and concurrence of Trinity Health's System Chief Compliance Officer (CCO), appoints the Service Area 4 ICO. The Service Area 4 ICO is an employee of Trinity Health and has dual accountability to both the TH PACE CEO and to the TH System CCO as it relates to the ICP, including goal setting and performance assessment. Due to regulator concerns with potential conflicts of interest, the Service Area 4 ICO may not serve as TH PACE's General Counsel or functionally report to the General Counsel.

The Service Area 4 ICO has direct access to the governing board overseeing TH PACE, TH Continuing Care CEO, and TH PACE COO.

The roles and responsibilities of Service Area 4 ICO, as they pertain to TH PACE ICP, include, but are not limited to:

- Accountability for the selection, evaluation, and overall success of the functional TH PACE compliance team;
- Supporting TH PACE efforts to comply with functional area priorities;
- Organization-wide focal point for establishing functional strategies and governance over compliance-related financials and staffing;
- Accountability for communication between TH System Services functional areas, TH PACE and its leaders;
- Ensuring regular reporting to TH PACE COO, leadership team, and governance on the operations of the ICP;
- Ensuring proper compliance oversight of TH PACE Integrity & Compliance Council;
- Supporting training of TH PACE colleagues and the board on the Code of Conduct and the ICP;
- Maintenance of policies and procedures supporting the Integrity & Compliance Program at TH PACE;
- Coordination of compliance risk assessments in partnership with the TH System Integrity & Compliance Center of Expertise and with the input of TH PACE leadership;

- Investigations of matters reported via the Trinity Health Integrity & Compliance Line reporting system or reported directly to TH PACE compliance team in coordination with TH PACE and System resources as appropriate;
- Assisting TH PACE's response to regulatory audits and investigations in partnership with TH System and TH PACE legal counsel and management as appropriate;
- Supporting sanctions/eligibility screening processes for TH PACE colleagues and suppliers;
- Integration of the ICP with TH PACE performance management and disciplinary processes in coordination with Human Resources;
- Coordination of TH PACE privacy program with the TH Privacy Center of Expertise; and
- Administration of Trinity Health conflicts of interest policies for boards and senior executives.

The Service Area 4 ICO may be supported by additional colleague resources at both the Trinity Health system-wide and TH PACE system office level and at local TH PACE organizations (POs) to perform the roles and responsibilities listed above.

To promote consistency in Trinity Health's system-wide Integrity & Compliance Program and to achieve economies of scale, TH PACE ICP is supported by systems, tools, and other resources provided by Trinity Health System Office. These may include, among others, compliance administrative tools (e.g., Riskonnect), training and education programs, communication materials, hotline reporting system, compliance policies and procedures, and resources to assist with research, responding to audits and investigations, and internal auditing.

Privacy
Trinity Health maintains a system-wide privacy program to meet the requirements of the Health Insurance Portability and Accountability Act ("HIPAA"), its implementing regulations, and other applicable federal and state privacy laws and regulations. Trinity Health privacy program is led by a Vice President, System Privacy Official who works with the Trinity Health Chief Information Security Officer to ensure Trinity Health has established a privacy and security program that addresses HIPAA and other applicable privacy and security requirements and is consistent with leading industry standards. The System Privacy Official has appointed a Privacy Officer for Service Area 4, including TH PACE, who is responsible for leadership of the Trinity Health privacy program across TH PACE and its POs in accordance with Trinity Health policies and at the direction of the System Privacy Official.

TH PACE Integrity and Compliance Council (ICC)

The TH PACE ICC shall be composed of the following positions:

Service Area 4 ICO (Chair)
TH PACE VP Finance
TH PACE CHRO
TH PACE National Director, Quality Improvement and Compliance
TH PACE Manager Compliance & Risk (Facilitator)
TH PACE Manager of Medicare Part D Compliance
TH PACE Director Coding and Documentation
Service Area 4 Integrity & Compliance Manager
Trinity Health IAS Representative

Representatives from the Trinity Health PACE Organizations (POs) local Quality & Compliance team

Each local TH PACE PO shall have in place a structure for an Integrity and Compliance Sub-Committee for reporting, auditing and monitoring purposes, and for ensuring compliance with any State specific regulations. This may vary based on size and structure of the PO and may be coordinated with their overall Quality Improvement program structure, and may incorporate review meetings with Pharmacy Benefit Manager (PBM) team, or meetings with CMS/SAA Account Managers as appropriate.

Duties of the ICC

The ICC shall assist the Service Area 4 ICO in ensuring the ICP is effectively implemented and operated within TH PACE, including, but not limited to:

- Evaluating and discussing CMS PACE regulations, Medicare Part D and other applicable regulations to ensure compliance, recommending specific risk areas that the ICP should address;
- Assessing existing policies and procedures that address these risk areas for possible incorporation into the ICP;
- Collaborating with appropriate departments to develop standards of conduct and policies and procedures to promote adherence to the ICP;
- Recommending and monitoring, in conjunction with the relevant operating units, the development of internal systems and controls to carry out standards, policies, and procedures as part of their daily operations;
- Determining the appropriate strategy/approach to promote adherence to the ICP and the reporting of potential violations;
- Monitoring internal and external audits;
- Reporting and discussing any local compliance activities, local monitoring activities, concerns or violations with the intent of creating a culture of collaborative risk mitigation across TH PACE and its POs.

Senior Management

The Continuing Care CEO, TH PACE COO, and other senior management recognize the importance of and are fully engaged in the ICP. The Continuing Care CEO, TH PACE COO, and senior management responsibilities for the ICP include, but are not limited to, the following:

- Reviewing reports from the Service Area 4 ICO regarding areas of risk facing the organization, the strategies being implemented to address those areas of risk, and the results of those strategies;
- Being advised of all governmental compliance enforcement activity at TH PACE, including Notices of Non-Compliance, Warning Letters, more formal sanctions, and formal enforcement activities;
- Ensuring the Service Area 4 ICO is integrated into the organization and is given the credibility, authority, and resources necessary to operate a robust and effective ICP.

Governance Oversight

The TH Continuing Care Board of Directors (the Board) shall oversee the development, implementation, operation, and effectiveness of the TH PACE ICP. The Board's responsibilities for the ICP include, but are not limited to:

- Being knowledgeable about the structure, content and operations of the TH PACE ICP and exercising reasonable oversight over the implementation and effectiveness of the ICP.
- Reviewing annual reports from the Service Area 4 ICO and/or the ICC regarding the operation of the TH PACE ICP, including but not limited to, reports of audits performed on the Program's effectiveness; reports of potential violations or other compliance concerns; reports about compliance investigations and correction of problems identified, including governmental compliance enforcement activity such as Notices of Non-Compliance, Warning Letters and/or sanctions that are more formal.

Subsidiary boards shall contribute to the oversight of the pertinent local TH PACE PO ICP.

Code of Conduct/Policies and Procedures

The creation and communication of a code of conduct is a requirement for effective compliance programs. Regulators emphasize that the code of conduct serves in a similar fashion as a "constitution," outlining the organization's commitment to ethical behavior and compliance with laws and regulations. Adherence to the code of conduct should be a condition of continued employment or eligibility to conduct business with the organization. The code of conduct must be provided to or be accessible to all employees, suppliers, agents, and contractors.

Trinity Health has created a system-wide Code of Conduct describing behavior and actions expected of all who work in our health ministry. The Code of Conduct emphasizes Trinity Health's commitment to integrity, to following all laws, regulations and professional standards that apply to TH and to operating in a manner consistent with TH's Mission and Core Values.

The TH PACE Code of Conduct is customized to include the contact information of the Service Area 4 ICO.

The Code of Conduct is made available electronically to all colleagues upon hire. Colleagues are required to attend an orientation session on the Code of Conduct and the ICP within their first 30 days of employment. Colleagues acknowledge receipt of the Code of Conduct through a Workday acknowledgement. The Code of Conduct is also publicly available on Trinity Health website and on Trinity Health and TH PACE intranet (OneSource) sites. In addition to the Code of Conduct, additional supplements have been created for the following:

- A Code of Conduct Supplement for Medical Staff for use with independent medical staffs. The Supplement for Medical Staff describes those areas in the Code of Conduct that particularly apply to medical staff members and is provided to physicians or other credentialed providers at the time of credentialing and re-credentialing.
- A Supplier Code of Conduct communicates the minimum standards by which all Trinity Health suppliers are expected to conduct themselves when providing goods or services to Trinity Health. The Supplier Code of Conduct is located on the Trinity Health Supplier Portal and is incorporated by reference as a requirement for conducting business with Trinity Health in all contracting and procurement activities.
- A Code of Conduct Supplement for Research providing additional guidance to colleagues and others engaged in the performance of clinical research, including research involving human subjects.

In addition to the Code of Conduct, Trinity Health has established policies and procedures supporting the operation of the ICP and addressing key compliance risk areas, including revenue cycle operations, conflicts of interest, financial relationships with physicians, employment practices, and the privacy and security of patient and other confidential information. All system policies and procedures are accessible to colleagues via the Trinity Health *OneSource* site. Compliance policies applicable to suppliers are communicated in the Supplier Code of Conduct.

TH PACE has an established set of policies and procedures specific to Medicare Part D program compliance, along with additional policies and procedures addressing significant regulatory requirements and local areas of risk.

Record retention rules dictate that TH PACE and all POs will maintain, for a period of at least ten (10) years, books, records, documents, and other evidence of accounting procedures.

In order to implement the Code of Conduct, individual departments are responsible for developing and distributing to colleagues all policies and procedures relating to federal and/or state laws and regulations that have an impact upon their activities. The Service Area 4 ICO, in conjunction with the ICC, shall ensure that the appropriate departments develop policies and procedures that address special risk areas identified by the OIG or gleaned from other sources (such as internal audit results) from time to time. Targeted training and educational programs will accompany distribution of new/revised policies and procedures as appropriate.

Effective Lines of Communication

Effective compliance programs must have systems that provide employees and others the opportunity to report issues and concerns, including potential violations of laws and regulations, on an anonymous basis without fear of retaliation or harassment. The reporting system must be publicized regularly to employees and matters reported must be investigated in a timely manner by qualified personnel, with actions taken, as appropriate, based on the investigation results.

Open Communications

TH PACE promotes an environment that encourages all colleagues to seek answers to questions and to report issues and concerns. TH PACE colleagues have a right and a duty to report any activity they believe may violate applicable laws, regulations, professional standards of practice, or the Code of Conduct. Colleagues may request guidance from the Integrity and Compliance department, their immediate supervisor, a higher-level manager or seek help through other areas, such as human resources, or by filing a report in a patient safety incident reporting system (e.g., Midas).

Colleagues may also file reports using the Trinity Health Integrity & Compliance Line. The Integrity & Compliance Line is a system-wide colleague line managed by Ethico, LLC, a third-party hotline operator on behalf of Trinity Health. The Integrity & Compliance Line is operated 24/7/365. Individuals may file reports by either telephone or directly online. Individuals may choose to remain anonymous. Regardless of the manner in which a report is filed, every effort is made to maintain, within the limits of the law, the confidentiality of information reported and the identity of individuals who file reports. Individuals are provided a case identification number to call back and obtain a status report or resolution of their issue.

Trinity Health licenses Riskonnect, a cloud-based, integrated risk management platform, to support Integrity & Compliance Program Line activities. Riskonnect is integrated with Trinity Health's third-party hotline operator. All Integrity & Compliance Line reports received in Riskonnect are initially reviewed by the Compliance Center of Expertise and then assigned for investigation, either by individuals at TH PACE or a System Office or Shared Services function (e.g., Colleague and Labor Relations). Final reports documenting the results of investigations are reviewed and approved by the Compliance Center of Expertise management prior to closing of the reports in Riskonnect.

The availability and purpose of the Integrity & Compliance Line is regularly communicated to colleagues through new hire and annual training programs, the Code of Conduct, posters, electronic message boards, the Trinity Health OneSource intranet site, and e-newsletters. The availability of the Integrity & Compliance Line is also communicated to external parties in the Supplier Code of Conduct and the Trinity Health internet site.

Usage of the Integrity & Compliance Line is regularly benchmarked against national hotline statistics to measure colleague awareness, understanding and comfort in using the hotline reporting system, and other performance indicators.

Non-Retaliation Policy

Trinity Health policy strictly prohibits retaliation, retribution or harassment against individuals reporting issues or concerns in good faith. Acts of retaliation are subject to discipline, up to and including termination of employment or termination of business relationships with TH PACE. This policy is communicated in the Code

of Conduct and related supplements, and to colleagues as part of new hire and annual colleague training programs.

Third-party contractors and their employees are expected to report actual or suspected wrongdoing to the Service Area 4 ICO. The Service Area 4 ICO, with assistance from the ICC, shall ensure that appropriate contractors and their employees are made aware of the Integrity and Compliance Line and of the obligation to report actual or suspected wrongdoing.

The Service Area 4 ICO shall make regular reports to the ICC on the Integrity and Compliance reporting system, including the number of calls received and the status and disposition of any resulting investigations.

The Service Area 4 ICO shall also document all compliance questions raised other than through the Integrity and Compliance Line, including the nature of the question raised and how it was answered/resolved.

The Service Area 4 ICO in coordination with the TH Integrity & Audit Services (IAS), TH PACE legal counsel, and with the support of the appropriate TH PACE colleagues will work with the Executive Directors of each TH PACE Organization to voluntarily self-disclose any areas of non-compliance with the PACE regulations; this will be conducted during meetings with the appropriate CMS Account Manager.

The Service Area 4 ICO, in partnership with the IAS, TH PACE legal counsel, and with the support of the appropriate TH PACE colleagues, also ensures that any potential/actual instances of fraud are reported to the appropriate Medicare Drug Integrity Contractor (NBI MEDIC) and/or CMS, when determined that such a report is appropriate.

Response and Prevention

Eligibility Screening

Federal and state regulators require health care organizations to screen employees, physicians, suppliers, and contractors as part of an effective compliance program. Health care providers are prohibited from billing Medicare, Medicaid, and other federal and state health care programs for services ordered or provided by individuals or companies excluded from participation in these programs. TH PACE is prohibited from paying for services provided by excluded providers. Federal and state regulators can levy significant fines and penalties and take other enforcement actions against organizations found in violation of eligibility screening requirements.

Trinity Health contracts with Sterling Infosystems, Inc., to perform pre-employment background checks and sanctions screening of all new colleagues prior to hire. Screening for medical staff applicants is performed at time of initial credentialing and re-credentialing by Trinity Health's Central Verification Office (CVO). Suppliers are screened by Supply Chain Management as part of initial supplier vetting and procurement processes. HealthTrust, Trinity Health's group purchasing organization, also performs eligibility screening for suppliers contracted through its programs.

Monthly exclusion/preclusion screening of TH PACE colleagues and contracted providers is performed by TH Integrity and Compliance staff using Streamline Verify ™ with follow up and resolution of any potential matches conducted in collaboration with local PO resources.

Regulatory Communications
HHS-OIG, CMS and its contractors, and other government agencies regularly issue bulletins, transmittals and other information on new and changing regulatory requirements to the health care industry. We consider it important to ensure that TH PACE is proactive in preparing and responding to regulatory requirements. Revenue Excellence and Integrity & Compliance have established a system for the review and timely communication of CMS regulatory bulletins and transmittals impacting revenue cycle operations to approximately 1,400 individuals in key subject matter areas within Trinity Health. Other functional areas such as Legal, Performance Excellence, Integrated Clinical Services, Medical Groups, Payer Strategies and Product Development, and Human Resources continuously monitor regulatory pronouncements for changes impacting our operations and communicate changes to their key stakeholders in Trinity Health. Additionally, TH PACE Risk and Compliance staff routinely monitor communications from HHS-OIG, CMS and its contractors or other government agencies for changes in laws and regulations impacting TH PACE operations. Regular communication summaries are distributed to all TH PO's, in addition to immediate distribution of transmittals with more urgent timelines or deadlines.

Updates are provided at meetings such as ICC and PACE Strategic Operations Council (PSOC).

Response to Investigations and Corrective Actions

Trinity Health has established policies for responding to potential compliance issues, including government audits and investigations, and corrective actions, including repayments to federal and state health care programs and, as necessary, Medicare Advantage Organizations. The Code of Conduct and Trinity Health policies require all Trinity Health colleagues to cooperate with any government investigation and to never, under any circumstances, destroy or alter documents requested as part of a government investigation. Policies have also been established for the retention of records, including electronic records, in connection with legal and regulatory investigations.

The Service Area 4 ICO works closely with the IAS, the local PO leadership team, and TH PACE Director of Quality Improvement & Compliance in responding to all routine regulatory audits and any non-routine audits or investigations. Other TH PACE leadership and Trinity Health resources, such as the legal department, support the response as needed.

Corrective actions are reviewed and overseen through collaboration between local PO leadership and the TH PACE leadership team.

Tracking of all audit finding and corrective actions occurs at TH PACE system office with the purpose of developing proactive, system-wide corrective actions to mitigate the potential of future non-compliance.

Enforcing Standards

Compliance programs are required to have policies addressing disciplinary actions that address an employee's failure to comply with the organization's code of conduct and violations of laws and regulations. Regulators

have emphasized the need for such policies to be widely publicized and consistently enforced across all levels of the organization.

Trinity Health has established policies addressing disciplinary actions to be taken for violations of the Code of Conduct, including laws and regulations, up to and including termination of employment, suspension of medical staff privileges, or termination of business relationships with external parties, as applicable. These policies are incorporated into human resources policies and procedures, medical staff bylaws, and supply chain management policies. Disciplinary actions are determined according to the nature of the violation, case-specific considerations and the individual's work performance history. Integrity & Compliance leadership works closely with Human Resources Colleague and Labor Relations to ensure disciplinary guidelines are applied on a consistent basis across the system for Code of Conduct violations.

Risk Assessment, Monitoring and Auditing

The Federal Sentencing Guidelines were amended in 2004 to add performance of periodic risk assessments as part of an effective compliance program. Organizations must periodically assess the risk that violations of laws or regulations may occur based on the nature of the organization's business and its prior history. Regulators expect organizations to continuously adapt their compliance programs based upon compliance risks identified in the industry and to perform regular auditing and monitoring of areas identified as high-risk for potential non-compliance with laws and regulations.

Trinity Health's IAS Department regularly seeks input from System Shared Services and Ministry leaders, including TH PACE, to assess compliance risks and support development of work plans. These assessments consider current health care industry compliance risks and areas of audit and enforcement activity as reported by HHS-OIG, CMS, DOJ, the Internal Revenue Service, and other regulators.

The IAS Department performs regular internal audits throughout the system, with a significant portion of IAS' annual Work Plan focusing on compliance with legal and regulatory requirements.

IAS prepares work plans in response to the risk assessments for review by the Integrity & Audit Committee of the Trinity Health Board of Directors. The work plan is continuously updated in response to issues identified or changes in the regulatory environment. Updates on the status and results of the work plan are reported to the Integrity & Audit Committee on a quarterly basis.

In addition, TH PACE facilitates an annual risk assessment that is completed with input from the leadership team at each TH PACE PO. The risk assessment includes categories that cover compliance with PACE regulations, Medicare Part D plan regulations, emergency preparedness, coding and documentation, and privacy. Resources used in developing this risk assessment include but are not limited to:

- The HHS Office of Inspector General (HHS-OIG) Annual Work Plan;
- Current CMS PACE Part D Application;
- PACE Audit Guide ;
- Current CMS MA-PD Readiness Checklist;
- Previous Part D audits by CMS or its contractors;
- Relevant guidance/information provided through the Health Plan Management System (HPMS);
- Recent guidance from CMS, the HHS-OIG and/or other relevant authorities;
- Recent amendments or additions to the Part D regulations and/or Chapter 9 of the Medicare Prescription Drug Benefit Manual.

The results of this assessment guide local PO's in development of their annual work plans; it also guides TH PACE in identifying system-wide vulnerabilities and opportunities to refine or develop standard operational improvements.

Monitoring of available reports and data is utilized to assist in identifying areas of risk or vulnerability; these include but are not limited to: Acumen patient safety/PDE analysis reports; pharmacy benefit manager benchmarking reports; key performance indicators.

TH PACE Risk and Compliance staff will conduct internal audits from time to time, based on identified areas of vulnerability on the annual risk assessment, or from trends identified in CMS PACE audits. TH PACE engages

external consultants to perform audits of specific areas; this includes a proactive approach to auditing coding and documentation.

In addition to data analysis, the Service Area 4 ICO and local PO Quality/Compliance colleagues may conduct on-site visits with contracted providers and FDRs, such as pharmacies or Pharmacy Benefit Manager (PBM).

The Service Area 4 ICO or designee presents a report at least annually to the ICC, the Continuing Care CEO and the Board of Directors. This includes a review of the effectiveness of the Integrity and Compliance Program.
More frequent reports are made when circumstances warrant.

Education and Training

Training and education are required elements of an effective compliance program. Regulators require that all employees receive training on the organization's compliance program, its commitment to high ethical standards, and compliance with laws and regulations at time of hire and regularly thereafter. Employees whose job responsibilities require knowledge and understanding of specific federal and state health care program laws and regulations are expected to receive additional training specific to their job responsibilities.

All new TH PACE colleagues are required to attend an orientation program on the Code of Conduct and the Integrity & Compliance Program within 30 days of their start date. Orientation training materials are standard for use with all Trinity Health colleagues. Key messages addressed in the training include:

- The role and purpose of the Integrity & Compliance Program;
- The Code of Conduct and key areas that apply to a colleague's work responsibilities at Trinity Health;
- Resources available for reporting issues and concerns, including the identity and role of the Integrity & Compliance Officer and the Integrity Line reporting system;
- The responsibility of all colleagues to follow the Code of Conduct and to report issues and concerns, including potential violations of laws and regulations;
- The federal False Claims Act and similar state laws, including the rights of individuals under such laws.

In addition to new hire orientation, all colleagues are required to complete annual training on the ICP. TH has created an annual training program available on TH's system-wide learning management system. The training program is refreshed annually. Trinity Health has adopted a process for the escalation of incomplete training assignments, including corrective action up to termination of employment.

Industry regulators expect employees with job responsibilities involving federal and state health care programs to receive ongoing compliance training pertinent to their responsibilities in the organization, particularly when laws and regulations affecting such programs change. The responsibility for ensuring colleagues receive appropriate training specific to their job responsibilities rests with the colleagues' direct supervisor as well as leadership of the department or function. Trinity Health licenses the rights to compliance training and education programs developed by third-party developers. These programs are available through TH's system-wide learning management system and address current legal and regulatory issues, new or changing coverage, coding, and billing requirements, and other time sensitive compliance topics. Trinity Health has also created internally developed compliance education and training courses made available to colleagues.

Education regarding compliance is provided to the Board and subsidiary boards as part of orientation for new board members and on at least an annual basis.

Contracted providers (first tier, downstream and related entities) are included in educational activities as applicable or are requested to provide annual attestation that education regarding fraud, waste and abuse (FWA)/compliance was completed.

Record retention rules require that training records are maintained for 10 years.

Fraud, Waste, Abuse (FWA) and False Claims

There are many Federal and state laws designed to protect government health care programs, such as Medicare and Medicaid, and other third-party payers and consumers that pay for health care services. These laws generally prohibit:

- Submitting inaccurate or misleading claims for services provided;
- Submitting claims for services not provided;
- Submitting claims that do not meet payer requirements (e.g., coverage for services);
- Making false statements or representations to obtain payment for services or to gain participation in a health care program;
- Offering or paying money, goods, or anything of value in return for the referral of patients to a health care provider;
- Offering or giving something of value to patients to encourage them to use or purchase health care services.

The federal False Claims Act and similar state laws prohibit conduct such as submitting fabricated data to CMS or other government agencies, prescribing a particular drug for which there is no medical necessity, falsifying data in the Risk Adjustment Processing Data System (RAPS) or other system in order to induce a higher reimbursement or capitation rate, and submitting data to CMS showing actual costs incurred for purposes of the reinsurance or other subsidy, when in fact such costs were not incurred.

As an integral part of the overall ICP TH PACE is committed to detecting, correcting, and preventing fraud, waste, and abuse in the administration of its Medicare Part D Prescription Drug Plan (PCP).

TH PACE PO's do not utilize a formulary.

Monitoring and/or auditing extends to all areas of TH PACE operations vulnerable to FWA, including:

- Operations of contracted providers, First Tier, Downstream, and Related Entities (FDR), pharmacies and pharmacy benefit manager;
- Claims processing;
- Pricing, rebates, and other price concessions;
- Marketing and enrollment violations;
- Agent/broker misrepresentations;
- Selective marketing;
- Enrollment/disenrollment noncompliance;
- Credentialing;
- Quality assessment;
- Appeals and grievance procedures
- Transition policy;
- Protected classes policy;
- Utilization management;
- CMS payments;
- Utilization patterns of PACE Participants to ensure that Participants, or Participants' family members, are not improperly using or obtaining prescription drugs;

- Prescription Data Event (PDE) data reports for any significant outliers, disproportionate utilization of controlled substances and use of prescription medications for excessive periods of time (e.g. multiple refills for drugs commonly prescribed for short-term pain).

TH PACE and/or contracted auditing and monitoring partners (such as Milliman or Pharmastar) periodically monitor:

- PDE information;
- Cost data;
- Diagnoses information reported through RAPS;
- Deletion records;
- Data on direct and indirect remuneration;
- Enrollment and disenrollment data;
- Submission of claims under the appropriate reimbursement program (e.g., Medicare Part B claims versus Medicare Part D claims);
- All other information required to be reported, including information about generic drug utilization, overpayments, pharmaceutical manufacturer rebates, discounts and other price concessions, and long-term care rebates.

Reports available from Pharmacy vendor are also reviewed periodically to track and monitor prescribing patterns to guard against FWA on the part of prescribers.

If an FDR submits data on behalf of TH PACE, TH PACE will periodically review such entity's compliance policies, procedures, and other internal controls to ensure that it maintains sufficient mechanisms for monitoring compliance and mitigating risks of FWA.

Quarterly meetings occur between Pharmacy Benefit Manager and TH PACE senior leadership and Service Area 4 ICO (or designee) to review data trends and compliance by TH PACE PO's in responding to appropriate report reviews.

All colleagues who work at Trinity Health are required to act with honesty and integrity in all their business activities and to follow all laws, regulations and other requirements of Medicare, Medicaid and third-party payers, as applicable. These expectations are communicated to individuals through the Code of Conduct and through annual training and communications activities.

Conflict of Interest (COI)

Key employees and Board members complete an annual questionnaire relating to conflicts of interest. This questionnaire requires disclosure of all actual or potential COIs. The Service Area 4 ICO will review the COI questionnaire information annually to determine whether any conflicts of interest exist. When a conflict is identified, an appropriate course of action is determined, including the exclusion of the affected individual from any involvement in particular matters.

All colleagues are required to report any potential COI to their manager and/or in Workday.

Conclusion

The Integrity and Compliance Program is a demonstration of TH PACE's commitment to ensuring its operations are conducted with integrity and in a manner consistent with its Mission and Values, with the highest standards of ethical and professional behavior, and in full compliance with all laws and regulations that apply to our health care ministry.

This document provides a summary description of the TH PACE ICP. The ICP is continually evaluated in consideration of changes in TH PACE operations as well as changes in health care laws, regulations, and business ethics practices.

The ICP is modified from time to time, as necessary, to respond to such changes.